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RESERVATIONS: 1–800–688–9889

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WHEN: April 23, 1996 at 9:00 am
WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street, NW., Washington, DC (3 blocks north of Union Station Metro)
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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM–118; Special Conditions No. 25–ANM–112]

Special Conditions: Israel Aircraft Industries (IAI), Model Galaxy, High-Intensity Radiated Fields

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Israel Aircraft Industries (IAI) Model Galaxy airplane. The new airplane will utilize new avionics/electronic systems, such as electronic displays and electronic engine controls, that perform critical functions. The applicable regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high-intensity radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

EFFECTIVE DATE: May 3, 1996.

FOR FURTHER INFORMATION CONTACT: Timothy Dulin, FAA, Standardization Branch, ANM–113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (206) 227–2141; facsimile (206) 227–1149.

SUPPLEMENTARY INFORMATION:

Background

On July 29, 1992, Israel Aircraft Industries (IAI), Ben Gurion International Airport, Tel Aviv 70100, Israel, applied for a new type certificate in the transport airplane category for the Model Galaxy airplane. On April 19, 1995, IAI applied for an extension of the original application and selected June 21, 1994, as the new reference date of application. The Model Galaxy is a derivative of the IAI Model 1125 Westwind Astra and is designed to be a long-range, high-speed airplane with a swept low wing and two aft-fuselage-mounted Pratt & Whitney Canada (PWC) 306A engines. The Model Galaxy will have a maximum takeoff weight of 33,450 pounds, a conventional empennage, a crew of two, and will be operated as an executive/corporate or commuter airplane with a maximum seating capacity of 19 passengers.

Type Certification Basis

Under the provisions of § 21.17, IAI must show, except as provided in § 25.2, that the Model Galaxy meets the applicable provisions of part 25, effective February 1, 1965, as amended by Amendments 25–1 through 25–82. In addition, the proposed certification basis for the Model Galaxy includes part 34, effective September 10, 1990, including all amendments in effect at the time of certification; and part 36, effective December 1, 1969, including all amendments in effect at the time of certification. No exemptions are anticipated. These special conditions form an additional part of the type certification basis. In addition, the certification basis may include other special conditions that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25, as amended) do not contain adequate or appropriate safety standards for the Model Galaxy because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR after public notice, as required by §§ 11.28 and 11.29, and become part of the type certification basis in accordance with § 21.17(a)(2).

In addition to the applicable airworthiness regulations and special conditions, the Model Galaxy must comply with the fuel vent and exhaust emission requirements of part 34 and the noise certification requirements of part 36, and the FAA must issue a finding of regulatory adequacy pursuant to § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for the model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

The Model Galaxy airplane incorporates new avionic/electronic systems, such as electronic displays and electronic engine controls, that perform critical functions. These systems may be vulnerable to high-intensity radiated fields external to airplane.

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems for HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the applicable regulations, special conditions are needed for the IAI Galaxy to require that electrical and electronic systems which perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF

protection special condition is shown with either paragraphs 1 or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–100 KHz ..	50	50
100 KHz–500 KHz	60	60
500 KHz–2 MHz	70	70
2 MHz–30 MHz	200	200
30 MHz–100 MHz .	30	30
100 MHz–200 MHz	150	33
200 MHz–400 MHz	70	70
400 MHz–700 MHz	4,020	935
700 MHz–1 GHz ...	1,700	170
1 GHz–2 GHz	5,000	990
2 GHz–4 GHz	6,680	840
4 GHz–6 GHz	6,850	310
6 GHz–8 GHz	3,600	670
8 GHz–12 GHz	3,500	1,270
12 GHz–18 GHz ...	3,500	360
18 GHz–40 GHz ...	2,100	750

As discussed above, these special conditions are applicable to the IAI Model Galaxy. Should IAI apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well, under the provisions of § 21.101(a)(1).

Discussion of Comments

Notice of proposed special conditions No. SC–95–6–NM for the IAI Model Galaxy airplanes was published in the Federal Register on October 30, 1995 (60 FR 55221). No comments were received, and the special conditions are adopted as proposed.

Conclusion

This action affects certain design features only on the IAI Galaxy airplane. It is not a rule of general applicability and affects only the manufacturer who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and record keeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the IAI Model Galaxy airplanes.

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high-intensity radiated fields.

2. For the purpose of these special conditions, the following definition applies:

Critical Functions. Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on March 25, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate Aircraft Certification Service, ANM–100.

[FR Doc. 96–8036 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 39

[Docket No. 94–NM–140–AD; Amendment 39–9558; AD 96–07–09]

Airworthiness Directives; Boeing Model 747–400, 757, and 767 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to Boeing Model 747–400, 757, and 767 series airplanes, that requires a revision to the Airplane Flight Manual that advises flight crews to monitor the engine indication and crew alerting system (EICAS) for ''status'' level messages pertaining to impending engine fuel filter bypass. This amendment also requires the installation of upgraded EICAS computers that provide ''advisory'' level messages to indicate such bypass conditions. This amendment is prompted by a finding that EICAS computers currently installed on these airplanes do not provide an appropriate indication to the flight crew of an impending engine fuel filter bypass condition. The actions specified by this AD are intended to ensure that the flight crew is appropriately aware of conditions involving a severely contaminated airplane fuel system and the associated increased potential for engine power loss.

EFFECTIVE DATE: May 3, 1996.

ADDRESSES: Information related to this action may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket No. 94–NM–140–AD, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: G. Michael Collins, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (206) 227–2689; fax (206) 227–1181.

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 Boeing Model 747–400, 757, and 767 series airplanes was published in the Federal Register on May 24, 1995 (60 FR 27446). That action proposed to require a revision to the FAA-approved Airplane Flight Manual (AFM) that would advise flight crews to monitor the engine indication and crew alerting system (EICAS) for ''status'' level messages pertaining to impending engine fuel filter bypass. That action also proposed to require the installation of upgraded EICAS computers that provide ''advisory'' level messages to indicate such bypass conditions.

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

Support for the Proposal

One commenter supports the proposed rule.

Request To Withdraw the Proposal: Addressed Unsafe Condition Is Extremely Remote

One commenter requests that the FAA define ''unsafe condition'' as required by part 39 (''Airworthiness directives'') of the Federal Aviation Regulations (FAR) (14 CFR 39), and discern whether a condition is unsafe if its occurrence is ''extremely remote.'' This commenter points out that data previously presented to the FAA demonstrate that the risk of solid particulate contaminated fuel in excess of that already addressed during engine certification is ''less than 1×10^8 [sic],'' making such contamination an ''extremely remote [sic]'' event. This

commenter asserts that, if the risk of gross fuel contamination is considered extremely remote, then it does not matter that the flight crew be made aware of such contamination, since the possibility that gross contamination will occur does not warrant that a status level message on the EICAS system be active. Since part 25.1305(c)(6) (''Powerplant instruments'') of the FAR requires only that a fuel filter bypass warning be installed, the present indication system satisfies the certification standards.

This commenter states that if the occurrence of an event is ''extremely remote'' or less, then the demonstration of an unsafe condition required by part 39 has not been achieved for this AD action. Any FAA determination on what is unsafe should not extend beyond the type certification requirements. This commenter considers that the FAA's adoption of risk assessment methodology is critical to place the relative risks addressed in the proposed AD to proper perspective.

The FAA does not concur with the commenter. According to section 39.1 of the FAR (14 CFR 39.1), the issuance of an AD is based on the finding that an unsafe condition exists or is likely to develop in aircraft of a particular type design. That section of the FAR does not specify that an unsafe condition is considered unsafe, or a condition is ''likely to develop,'' only if it meets a specific reliability standard, such as suggested by the commenter. Further, the criteria of the probability of an occurrence being ''extremely remote (improbable),'' as described in section 25.1309 (''Equipment, systems, and installations'') of the FAR (14 CFR 25.1309), is on the order of 1×10^{-9}. Thus, it is a condition that is not expected to result in any occurrences during the life of the affected fleet. The FAA points out, however, that there have been several recent incidents of fuel contamination on transport category airplanes that caused the blockage of one or more engine fuel filters. Because of the awareness provided to the flight crew by the cockpit indication of the impending filter bypass, the flight crew was able to land the airplanes safely at the nearest airport. These recent events demonstrate that (1) the risk of the addressed unsafe condition is much greater than ''extremely remote;'' and (2) the impending fuel filter bypass message will provide the flight crew with timely indication and awareness before any engine's fuel filter is clogged to the point that the contaminated fuel bypasses the filter and causes operational problems with the engine(s).

Further, as explained in detail in the preamble to the proposal, relevant service data has led the FAA to determine that the current use of a ''status'' level message to indicate an impending engine fuel filter bypass creates an unsafe condition, since such messages do not provide information to the flight crew at an appropriate level of awareness to enable them to take immediate action to correct the condition. Using a ''status'' level message to indicate an impending engine fuel filter bypass condition could result in the flight crew being unaware of a severely contaminated airplane fuel system and the associated increased potential for engine power loss. It is this condition that the FAA considers to be unsafe for, if it is not corrected, it could result in the airplane landing with reduced engine power, or the total loss of engine power before the airplane is able to reach a suitable landing site.

Request To Withdraw the Proposal: No Documented Occurrences of the Unsafe Condition

Several commenters contend that there have been no documented in-service events to justify the proposed AD. These commenters state that historical jet transport safety records disclose that no accident has occurred that was related to solid particulate contaminated fuel from the period of 1959 through 1993, which involved over 230 million aircraft flights. These commenters point out that, although there have been numerous occurrences of annunciation to the flight crew of impending fuel filter bypass, none of the affected fleet has ever experienced loss of thrust or interruption of power subsequent to a fuel filter bypass indication. In fact, the opposite situation has occurred several times: engine power was lost due to contaminated fuel, but there was no indication of an impending fuel filter bypass annunciated to the crew. The manufacturer also describes 7 events that occurred on the affected fleet where permanent loss of thrust greater than one propulsion system occurred; although 5 of these events were a result of water contamination and the other 2 were associated with contamination of the engine vane and bleed control system on a specific engine type, none of the 7 events were annunciated to the flight crew by an impending fuel filter bypass indication. These commenters assert that lack of substantiation for the FAA's position that an unsafe condition exists is reason to withdraw the proposal.

The FAA does not concur. Although there have been no reported cases of loss of thrust or interruption of power subsequent to a fuel filter bypass indication, the potential for this unsafe condition exists as long as the potential for contaminated fuel exists. This AD action addresses that potential unsafe condition.

As stated earlier, there have been several recent incidents of fuel contamination on transport category airplanes that caused the blockage of one or more engine fuel filters. The flight crews of the incident airplanes were made aware of this condition by the cockpit indication of the impending filter bypass and, in each case, were able to land the airplanes safely. These recent events demonstrate that the impending fuel filter bypass message should provide the flight crew with timely indication and awareness before any engine's fuel filter is clogged to the point that the contaminated fuel bypasses the filter and causes operational problems with the engine(s). The FAA maintains that early recognition of an impending fuel filter bypass will reduce the potential hazards associated with subsequent power loss and engine shutdowns.

Request To Withdraw the Proposal: Maintenance Practices Should Be Followed Properly

Several commenters indicate that the unsafe condition could be better addressed by improving maintenance practices relevant to the fuel system, rather than by requiring the proposed EICAS upgrade. These commenters state that ''gross contamination'' of the fuel to the levels discussed in the notice can only result from long-term negligence and disregard of standard servicing and maintenance practices. These commenters contend that appropriate maintenance programs relative to airplane fuel systems are required by the FAR: namely, parts 121.135(b)(18) (''Maintenance manual requirements—contents'') and 121.1369(b) (''Manual requirements'') [14 CFR 121.135(b)(18) and 21.1369(b)]. To meet the requirements of these regulations, maintenance programs must entail controls and refueling procedures, including sampling prior to fueling, to ensure that fueling processes will be safe and clean. Therefore, if maintenance programs are followed correctly, there is ample assurance that the possibility of contamination of the fuel system will be prevented. Finally, these commenters point out that ensuring that proper aircraft fuel servicing and storage methods are followed would be far more economical to operators than installing the proposed EICAS modification.

The FAA does not concur. Service experience has demonstrated that, despite regulations that mandate the proper maintenance of fuel systems, fuel contamination in airplane fuel systems continues to occur. In fact, subsequent to the issuance of the notice, the FAA was advised of three recent incidents of fuel system contamination on transport category airplanes. In these incidents, the engine fuel filter bypass indication system alerted the flight crew that impending fuel filter bypass conditions were present on one or more engines:

1. The first of these incidents occurred during the climb phase of flight. At that time, the crew elected to return to the departure airport. During the approach to that airport, the other engine's fuel filter bypass annunciation light illuminated.

2. The second incident occurred three hours after the airplane had departed the airport. At that time, the fuel filter bypass annunciation light illuminated on one engine. Following this indication, and during the airplane's descent to the destination airport, the other engine's fuel filter bypass annunciation light illuminated.

3. In the third incident, at approximately four hours into the flight, a fuel filter bypass alert occurred on each of the airplane's three engines.

Investigation into all three of these events revealed that apparently the contamination of the airplanes' fuel systems was the result of malfunctions of the fuel hydrant system installed at a particular airport where these airplanes took on fuel.

By citing these recent incidents, which demonstrate the need for flight crew awareness of impending engine fuel filter bypass, the FAA emphasizes that it is likely events of fuel system contamination will occur in the future, despite the industry's efforts to maintain a ''clean'' fuel supply.

Fuel contamination can affect the operation of all engines on an airplane. Section 25.1305(c)(6) of the FAR [14 CFR 25.1305(c)(6)] requires an indication to alert the flight crew that an engine's fuel filter is contaminated before the filter is clogged to the point that the fuel bypasses the filter(s) and allows the contamination to pass to the engine(s). A separate indication is required for each engine's fuel filter. The purpose of these requirements is to provide the flight crew with an indication that the fuel is contaminated before the contamination causes flameout or operational anomalies of one engine or multiple engines. This indication of impending engine fuel filter bypass provides the flight crew with important information when they still have an opportunity to consider action such as diverting to an alternative airport.

Request To Withdraw the Proposal: Distraction of Flight Crew by Alert Messages

Several commenters contend that the proposed ''interim'' action requiring the flight crew to check the EICAS status page, and the proposed final action of modifying the EICAS computer to display the fuel filter bypass message as an ''advisory'' level message, will result in the confusion and distraction of the flight crew. These commenters point out that flight crews are trained to check the ''status'' message display before engine start; therefore, checking the ''status'' message display during flight contradicts their basic operational practices and likely will cause them confusion. Additionally, the flight crew could be distracted by other ''status'' level messages that may occur during a flight.

Another commenter indicates that the reliability of the sensor switch for the fuel filter bypass indication is rated at 1×10^{-4}. From this reliability standpoint, it is obvious that ''nuisance warnings'' (that is, indications of a fuel filter bypass condition when one does not actually exist) will occur more frequently than will an actual gross fuel contamination event (which has a 1×10^{-8} probability). In light of this, the commenter considers that the proposed rule should address the safety concerns that will be created by the flight crew's response to what may amount to ''nuisance'' messages. This commenter and several others believe that safety will be reduced when flight crews are tasked to respond to such false indications by (1) making unnecessary flight diversions, (2) landing at airports that they are not familiar with; and (3) shutting down engines needlessly.

The FAA does not concur with the commenters' suggestion that the requirements of this AD will result in unnecessary distractions or confusion of the flight crew.

''Status'' level messages do not provide immediate crew awareness; the only sign given to the crew regarding ''status'' level information is the appearance of the word ''STATUS'' on the EICAS screen. Under ordinary circumstances, in order to find out the nature of a ''status'' level message, the flight crew has to take action to review the status. Such a review normally is done when practical, based on the activity level in the flight deck; in general, it is not done during flight.

''Advisory'' level messages, on the other hand, are brought to the flight crew's attention by the appearance of the complete message on the EICAS screen (e.g., the message ''R ENG FUEL FILT'' appears on the existing EICAS screen of Model 767 series airplanes that are powered by Pratt & Whitney JT9D engines). No additional action must be taken by the flight crew in order to find out the nature of ''advisory'' alerts.

For the reasons discussed in detail in the proposal, the FAA finds that an ''advisory'' level message is the appropriate level for alerting the flight crew to an impending fuel filter bypass condition. The requirement of this AD for the flight crew to respond to EICAS ''status'' level indications relative to an engine fuel filter bypass message (by first checking the status page) is consistent with the level of response required for an ''advisory'' level message. In support of the FAA's position on this issue, two operators commented that their crews are already trained to check the status page whenever the status cue appears.

The FAA also does not concur with the commenters' suggestion that the display of the fuel filter bypass message as an ''advisory'' level message will cause a reduction in safety. On the contrary, an ''advisory'' level message appears on the upper EICAS display, providing the flight crew with an immediate awareness of the impending bypass condition, without the need to look up any status page to obtain the relevant information necessary for reaction.

With regard to the possibility that flight crews would divert to an alternative airport because of false indications of impending fuel filter bypass, the FAA considers that, if false indications are occurring frequently, then the reliability of the indication system should be improved. However, other than the reliability level presented by the commenter, no other data has been presented to the FAA to indicate that the indication system is not reliable. In fact, one operator commented that, because the fuel filter bypass system on its fleet has a good reliability record, the proposed rule would not have an operational impact on the affected fleet.

The FAA does acknowledge the commenters' concern, however, that flight crews could divert to alternate airports because of an increased awareness of other status level messages that may be displayed. To address this, the FAA has revised paragraphs (a) and (b) of the final rule to include the following sentence in the text that is to be added to the Airplane Flight Manual (as interim action):

''If other status level messages are displayed, the flight crew may deal with them in accordance with the appropriate operator procedure.''

Request To Withdraw the Proposal: Current Level of Message Indication Is Adequate

Several commenters assert that the proposed rule is not necessary because the current flight crew indication system is adequate. The flight crew is made aware of fuel filter problems via the ''status'' message system of the EICAS, which they must check prior to dispatch of the airplane. The current ''status'' level message gives adequate indication to the flight crew of an impending fuel filter bypass; from this message, the flight crew can determine what action is required prior to dispatch. Further, these commenters point out that the Master Minimum Equipment List (MMEL) does not permit dispatch with an ''engine fuel filter'' message indicated.

The FAA does not concur with these commenters. The original design and operational philosophy of the EICAS on the affected airplanes is that ''status'' level messages are to be reviewed by the flight crew only prior to dispatch of the airplane. The FAA now considers that this is not adequate for two reasons:

1. It does not meet the need for immediate crew awareness of an impending fuel filter bypass during flight. The crew would not be alerted to the fact that an engine fuel filter had became blocked during a flight until the operation of one or more engines was affected. This could result in the flameout of one or all engines.

2. The operational requirements under part 121 of the FAR permit more than one flight under one ''airplane dispatch.'' This could result in operating an airplane for several flights without checking for ''status'' level messages. In such cases, a message indicating an impending fuel filter bypass could go unnoticed by the fight crew for several flights.

Request To Withdraw the Proposal: Unsafe Condition Is Actually Water in the Fuel

Two commenters state that the principal source of fuel contamination in the affected airplanes is from water in the fuel and the consequent formation of ice particles across the fuel filter due to the sub-zero temperatures that occur during flight. These commenters contend that there are either procedures or systems already in place that effectively control this and thereby eliminate any associated unsafe condition.

These commenters believe that the original reason for providing flight crews with immediate indication of an impending engine fuel filter bypass was to prompt them to activate the fuel heating system. Some of the aircraft that would be affected by the proposed AD incorporate a manual fuel heat system designed to increase the temperature of the fuel upstream of the fuel filter to avoid blockage of the filter due to ice accumulation. The fuel heat system servo valve is activated by an electrical switch; and the fuel filter system contains a differential pressure switch that sends a signal to lights on the flight deck that indicate an impending fuel filter bypass condition. The flight crew procedure for responding to this illumination of the light is to activate the fuel heat system. These procedures are to ensure that fuel heat is applied to the engine fuel system to eliminate any blockage due to icing. Other aircraft affected by the proposed AD have continuous fuel heating, which requires no flight crew action or immediate indication. In light of this, the commenters consider that no AD action is necessary.

The FAA does not concur. The original intent of indicating an impending fuel filter bypass condition was to indicate clogging of the fuel filter due to fuel contamination, not merely ice formation. While it is true that the FAA has accepted the inclusion of a procedure in the AFM for certain airplanes to prompt the flight crew to activate the fuel heating system when the fuel filter bypass indication is annunciated, this was not the original, nor only, intent for the indication. [This has been confirmed by a review of the docket file for the amendment to part 25 that established FAR 25.1305(c).]

Request To Withdraw the Proposal: ''Gross Contamination'' Is an Undefined Concern

Several commenters request that the FAA define ''gross contamination'' of fuel and determine its physical and chemical properties. These commenters state that gross contamination has not been defined and documentation of it has not been provided to substantiate its existence. They consider it unrealistic and inappropriate for the FAA to mandate protection against a condition that has not been technically defined. One of these commenters points to the description offered by the FAA in the preamble to the proposal and states that fuel system contamination of the particulate size and concentration described by the FAA would likely cause damage and/or blockage to other fuel system components and reduce fuel flow without ever causing an impending fuel filter bypass indication.

Other commenters argue that section 33.67 (''Airworthiness standards—Fuel system'') of the FAR (14 CFR 33.67) allows for continued operation of the aircraft with the maximum contamination rate (specified in the FAR) for a period of time that exceeds the typical maximum flight leg of the aircraft before the fuel filter bypass valve opens. Based on this current certification design standard, the commenters consider that the capacity of the filters currently installed on the affected airplane is sufficient to allow the airplane to continue to the destination airport following an impending bypass indication.

The FAA responds to these comments by pointing out that part 25.997 (''Fuel filter or strainer'') specifies that fuel filters must:

''* * * Have the capacity (with respect to operating limitations established for the engine) to ensure that engine fuel system functioning is not impaired, with the fuel contaminated to a degree (with respect to particle size and density) that is greater than that established for the engine in part 33 [of the FAR].

''Gross contamination'' is defined in the context of this AD action to include levels of fuel contamination that are greater than those established for the engine in part 33 of the FAR. Examples of such contamination that actually have been found in service include microbial growth, sealant, lint, metal particles, fuel tank cleaning chemicals, paper towels, rags, and liquid fertilizer. There also have been data indicating the existence of other contaminants in the fuel system that, although unidentified, were severe enough to cause engine power loss. The numerous reports of in-service incidents associated with gross fuel contamination demonstrate that, despite the many industry standards intended to maintain cleanliness of the airplane fuel supply, contamination of airplane fuel systems will likely occur in the future. In anticipation of this likelihood, the FAA considers that an immediate indication of impending engine fuel filter bypass will provide the flight crew with the appropriate information required to take action before contamination of the fuel system becomes a source of engine operational problems.

Requests To Change the AFM Revision Requirement

One commenter requests that the proposed AFM revision be changed to allow the flight crew the option of continuing the flight to the original destination, without diverting, if the

''ENG FUEL FILT'' message illuminates during flight and no other engine parameter fluctuations (i.e., low fuel flow, low fuel pressure, rotor speed deterioration, etc.) are evident. The commenter considers this change in the wording to be necessary in order to decrease the possibility of confusion on the part of the flight crew should a nuisance message occur (that is, the message actually is false) and the flight crew risks diverting to an unfamiliar airport.

The FAA does not agree that a change to the AFM revision is necessary. As worded in the AD, the text of the AFM revision does not instruct the flight crew to land at the nearest airport. The AFM revision provides information to the flight crew to indicate that, if more than one engine's fuel filter message is displayed, the airplane fuel system may be contaminated and erratic engine operation or engine flame out may occur. This addresses the possibility of a false indication on one engine fuel filter. The wording of the AFM revision addresses only the situation where there are engine fuel filter messages for more than one engine's fuel filter, and it leaves the decision on any flight crew action, including diverting to an alternative airport, up to the flight crew.

One operator requests that paragraphs (a) and (b) of the proposal be revised to include the AFM revision regarding ''advisory'' level messages that is currently contained in proposed paragraph (d)(2); and that proposed paragraph (d)(2) subsequently be deleted. Proposed paragraphs (a) and (b) would require an AFM revision relative to status level messages. Paragraph (d)(2) then would require that, concurrent with the installation of the upgraded EICAS, operators are to remove the AFM revision required by paragraphs (a) and (b), and to insert a new AFM revision pertaining to advisory level messages. This operator has an AFM assigned to each aircraft in its fleet, and believes that it would be nearly impossible to ensure that the [(paragraph (d)(2)] AFM revision gets incorporated concurrently with the installation of the upgraded EICAS computer, since the upgrade could occur at any time on the flight line. This operator requests that the proposed AD be revised so that only one AFM revision would be necessary.

The FAA does not concur. The FAA considers that incorporating both of the proposed AFM revisions at the same time in the same location in the AFM could cause undue confusion for the flight crew. For example, on an airplane having the upgraded EICAS computer, if an ''advisory'' level ENG FUEL FILT message appeared on the EICAS display during flight, and then later the status cue appeared, the flight crew would look for a ''status'' level ENG FUEL FILT message on the EICAS status page. No ''status'' level message would be displayed because the EICAS computer had been updated to display that message only as an ''advisory'' level message. This could lead the flight crew to distrust the ''advisory'' level message because of the absence of a ''status'' level message. However, if the upgrade of the EICAS computer were eventually developed so that it can be accomplished using a method that incorporates both the ''status'' level message and the ''advisory'' level message in the modified computer, and if either level message can be selected after the computer is installed (i.e., pin selectable), then operators could modify their entire fleet and change the message level and AFM wording across their fleet at the same time. This capability depends on the method that is finally developed by the manufacturer to incorporate the upgrade of the EICAS computers. The FAA acknowledges that there may be other situations and other methods that could be used to achieve the intent of this portion of the AD. For these cases, paragraph (e) of the final rule provides operators the opportunity to request the use of alternative methods of compliance.

Requests To Extend the Compliance Time for Modification

Several commenters request that paragraph (d) of the proposed rule be revised to extend the compliance time for the modification from the proposed 4 years to as much as 6 years. These commenters state that it will take approximately 2 years for Boeing and the EICAS computer manufacturer to define, develop, and release the modified software necessary to accomplish the change in message level. Some commenters point out that certain older model EICAS computers will also require additional hardware modifications before the required modification can be installed. One operator is concerned that the modification for the Model 757 will not be available until after the modifications for the Model 747–400 and 767 are released.

These commenters state that, once the modification is available, they will require a minimum of an additional 18 months to modify all of the affected airplanes in their fleets. Further, the proposed compliance time will likely require that the modification be installed during special shop visits, instead of during regularly scheduled maintenance. This would impose an undue financial burden on operators, and disproportionate manpower constraints on maintenance facilities.

The FAA does not concur with the commenters' request. In developing an appropriate compliance time, the FAA considered not only the safety implications, but the time necessary for design of an acceptable modification, and normal maintenance schedules for timely accomplishment of the modification. In light of all of these items, as well as discussions with the manufacturer, the FAA finds that 4 years provides an acceptable level of safety, and provides sufficient time to produce the modification as well as install it on the affected fleet during regular maintenance intervals. However, paragraph (e) of the final rule does provide affected operators the opportunity to apply for an adjustment of the compliance time if data are presented to justify such an adjustment.

Request To Delete the Requirement for Modification

One commenter concurs with the proposed ''interim'' requirement to revise the AFM to advise the flight crew to respond to the ''status'' level messages. However, this commenter requests that the proposed requirement for the modification (upgrade) of the EICAS computer be deleted because an acceptable modification has not yet been designed and made available. The commenter suggests that the FAA postpone action on that specific requirement until the modification is developed and an adequate cost analysis of it can be made.

The FAA does not concur that delaying this AD is warranted. The FAA maintains that sufficient technology and data exist to enable the manufacturer(s) to devise, and operators to install, the EICAS upgrade within the compliance time provided by the AD. Further, the FAA has determined that an EICAS upgrade (and accompanying AFM revision) to provide ''advisory'' level messages of an impending engine fuel filter bypass condition is the most effective way to positively address the unsafe condition that is the subject of this AD. The FAA considers that long-term continued operational safety will be better assured by this design change rather than by only implementing the ''interim'' action of revising the AFM to advise the flight crew to respond to the ''status'' level messages.

Request To Allow Dispatch With an Inoperative EICAS

Several commenters request that the proposed AD be revised to include a

provision to allow dispatch of the airplane with an inoperative EICAS computer. These commenters point out that the MMEL for the affected airplanes currently allows dispatch with one EICAS computer removed or inoperative for one calendar day. An inoperative or removed EICAS computer would preclude the display of status messages during that time, which would be contrary to the requirements of the proposed AD. These commenters are concerned that dispatch capability under the MMEL will be reduced or restricted as a result of the proposed AD, and this would have an extensive operational impact on affected operators. The commenters believe that the risk of a gross fuel contamination event is so low that the current MMEL dispatch relief should be continued even though an ''ENG FUEL FILT'' status message is not available.

The FAA does not concur with the commenters' request. The use of the status message as a method of providing the flight crew with indication of an impending fuel filter bypass precludes dispatch with an inoperative EICAS computer. Dispatching an airplane configured so that the flight crew does not have the ability to check the ''ENG FUEL FILT'' status display messages only exacerbates the unsafe condition addressed by this AD. In order to ensure and maintain the ability of the flight crew to check these messages during flight, the status display must be operational. After the EICAS computers have been modified to provide ''advisory'' level messages to the flight crew to indicate an impending fuel filter bypass condition, dispatch with an inoperative EICAS computer will again be permitted under the existing MMEL.

Request for Additional Cost Impact Information

Several commenters consider that the cost impact information provided by the FAA in the preamble to the notice is inadequate:

1. Certain of these commenters state that preliminary estimates from industry indicate that the cost to upgrade the EICAS computers could be between $18 and $25 million for the affected fleet. One of these commenters requests that the adoption of the final rule be postponed to permit operators to obtain additional costs data from the manufacturer.

2. Another commenter states that the cost analysis presented in the proposal assumes that all operators will upgrade the EICAS computers to provide for global positioning system (GPS) navigation, and this will reduce the cost to accomplish the modification to change the ''engine fuel filter'' message to an advisory level. The commenter contends that all operators may not incorporate GPS or other EICAS upgrades within the compliance time proposed, and the cost to an operator who elects only to change the level of the engine fuel filter message could be as much as $100,000 per airplane.

3. One commenter states that the proposed requirement to upgrade the EICAS computer could include additional incidental costs, such as rewiring and the installation of cockpit annunciator lights. All of this could cost $10,000 per airplane, in addition to the EICAS upgrade.

4. Another commenter states that, if the upgraded EICAS computers are not interchangeable with the non-upgraded computers, the increased cost to maintain a supply of spare EICAS computers of both configurations should be included in the cost impact of the AD.

5. One commenter requests that, prior to issuing a final rule, the FAA perform a full cost-benefit analysis of it in accordance with Executive Order 12866, and that the results of the analysis be presented in a supplemental notice of this proposed rulemaking.

The FAA acknowledges these commenters' concerns about the cost impact of this AD action.

As for the cost of the upgraded EICAS computers, the FAA has attempted to obtain definitive data to verify what the actual cost of the ultimate modification will be, but it has been unable to do so. The FAA invited commenters to provide such information, but received what can only be called ''best guesses'' and no verifiable cost estimates. Comments are more likely to be persuasive to the extent that they provide specific and detailed information regarding actual costs. When commenters submit simple generalizations about the costs, there is little that the FAA can consider.

The FAA did attempt to estimate the cost of the EICAS upgrade required by this AD by reviewing the average costs of similar types of previous modifications of EICAS computers (and other avionics components) installed on transport category airplanes. The labor and parts costs for other individual EICAS modifications have proven to be quite variable, ranging from 1 to 20 work hours for labor and as much as $46,000 for parts. Because of these variables and because the manufacturers have not completed development of the EICAS upgrade, the FAA's attempt to determine a realistic cost estimate has been somewhat futile. The FAA is continuing to work with the appropriate manufacturers to establish verifiable costs of labor and parts associated with the upgrade specifically required by this AD.

Despite the costs associated with the individual EICAS upgrade required by this AD, the FAA does expect most operators to accomplish this upgrade at the same time that they accomplish other upgrades to the EICAS systems on the affected airplanes. The FAA bases this expectation on discussions it has held with the pertinent manufacturers and a review of the history of EICAS upgrades. These have led the FAA to be confident that the cost of modifying the EICAS computers in accordance with the requirements of this AD will be shared with other upgrades to the EICAS computers that are planned to be developed and made available during the 4-year compliance time of this AD. For example, as indicated in the proposal, the addition of GPS navigation capability is one modification that is known to require modification of the EICAS computers, and this modification likely will be introduced into the entire fleet of airplanes affected by the this AD within the 4-year compliance time.

In fact, the 4-year compliance time was established specifically in consideration of allowing sufficient time for operators to incorporate the EICAS upgrade required by this AD at the same time they incorporate other upgrades to EICAS that will be available. The intent of this was to enable operators to reduce the costs of fleet downtime, labor, and parts. This is not to imply that the EICAS upgrade required by this AD *must* be incorporated together with any other change to the EICAS. Rather, it means that cost-conscious operators have the opportunity of accomplishing several other modifications of the EICAS concurrently with the upgrade required by this AD, and thereby reduce their affected fleet's downtime, labor costs, and parts costs.

As for additional incidental costs that would be associated with the requirements of this AD, the FAA recognizes that, in accomplishing the requirements of any AD, operators may incur ''incidental'' costs in addition to the ''direct'' costs of the specific action required by the AD. However, the cost analysis in AD rulemaking actions typically does not include incidental costs. Because incidental costs may vary significantly from operator to operator, they are almost impossible to calculate.

As for the interchangeability of the upgraded EICAS computer with the existing computers, the FAA notes that incorporation of previous modifications of this type into the EICAS system has always provided for interchangeability with earlier upgrades. The FAA expects

that the manufacturer of the EICAS computer will design the modification for the message level change to maintain interchangeability of units.

As for the request that the FAA conduct a ''full cost-benefit analysis'' of the proposed AD in accordance with Executive Order 12866, the FAA points out that it is not required to do a such an analysis for each AD. In fact, AD's were explicitly exempted from the Office of Management and Budget (OMB) coordination process described in Section 6 of that Executive Order. Looking at the reasoning behind this, it is important first to realize that, as a matter of law, in order to be airworthy, an aircraft must conform to its type design and be in a condition for safe operation. The type design is approved only after the FAA makes a determination that it complies with all applicable airworthiness requirements. In adopting and maintaining those requirements, the FAA has already made the determination that they establish a level of safety that is ''cost-beneficial.'' Second, it is important to understand that, when the FAA later makes a finding of an unsafe condition in an aircraft and issues an AD, it means that the original cost-beneficial level of safety established for that aircraft is no longer being achieved, and that the required AD actions are necessary in order to restore that level of safety. Because the original level of safety has already been determined to be cost-beneficial, and because the AD does not add an additional regulatory requirement that increases the level of safety *beyond* what has been established by the type design, a full cost-benefit analysis for each AD would be considered redundant and would be unnecessary.

In general, because AD's require specific actions to address specific unsafe conditions, they appear to impose costs that would not otherwise be borne by operators. However, because of the general obligation of operators to maintain and operate aircraft in an airworthy condition, this appearance is deceptive. Attributing those costs solely to the issuance of this AD is unrealistic because, in the interest of maintaining and operating safe aircraft, prudent operators would accomplish the required actions even if they were not required to do so by the AD. In any case, the FAA has determined that direct and incidental costs are still outweighed by the safety benefits of the AD.

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 change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 1,378 Model 747–400, 757, and 767 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 588 airplanes of U.S. registry will be affected by this proposed AD.

The initial revision to the AFM will take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of this action on U.S. operators is estimated to be $35,280, or $60 per airplane.

The FAA currently has no specific cost estimates associated with the installation of upgraded EICAS computers, since the upgrade has not been developed yet. The FAA has been advised, however, that the manufacturer is planning other changes to these EICAS computers that are necessary to provide for GPS navigation capability and other enhanced features. The compliance time of four years for the EICAS installation requirements of this AD will allow a portion of the EICAS computers installed on airplanes affected by this AD to have the required EICAS message upgrade made concurrently with those other planned EICAS changes, thereby reducing the costs and scheduling impact of such changes on operators.

The revision to the AFM that will be required subsequent to the installation of the upgraded EICAS computers will take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of this action on U.S. operators is estimated to be $35,280, or $60 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, 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:

96–07–09 Boeing: Amendment 39–9558. Docket 94–NM–140–AD.

Applicability: All Model 747–400, 757, and 767 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 (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if 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 flight crew is appropriately aware of conditions involving

a severely contaminated airplane fuel system and the associated increased potential for engine power loss, accomplish the following:

(a) For all Model 747–400 series airplanes: Within 60 days after the effective date of this AD, revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following statement. This may be accomplished by inserting a copy of this AD in the AFM.

''Respond to the EICAS STATUS CUE by checking for the following status level messages(s):

ENG 1 FUEL FILT
ENG 2 FUEL FILT
ENG 3 FUEL FILT
ENG 4 FUEL FILT

If more than one of these impending fuel filter bypass messages is displayed, airplane fuel system contamination may be present, which can result in erratic engine operation and engine flameout.

If other status level messages are displayed, the flight crew may deal with them in accordance with the appropriate operator procedure.''

(b) For all Model 757 series airplanes, and Model 767 series airplanes powered by General Electric CF6–80A and CF6–80C2 engines, Pratt & Whitney PW 4000 engines, and Rolls-Royce RB211–524 engines: Within 60 days after the effective date of this AD, revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following statement. This may be accomplished by inserting a copy of this AD in the AFM.

''Respond to the EICAS STATUS CUE by checking for the following status level messages(s):––

R ENG FUEL FILT ––
L ENG FUEL FILT

If more than one of these impending fuel filter bypass messages is displayed, airplane fuel system contamination may be present, which can result in erratic engine operation and engine flameout.

If other status level messages are displayed, the flight crew may deal with them in accordance with the appropriate operator procedure.'' –

(c) For Model 767 series airplanes powered by Pratt & Whitney JT9D engines: Within 60 days after the effective date of this AD, revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following statement. This may be accomplished by inserting a copy of this AD in the AFM.

''If both of the following EICAS advisory level messages for impending fuel filter bypass are displayed, and engine fuel icing is not suspected (based on the fuel temperature being too high or because engine fuel heat has been selected ''on''), airplane fuel system contamination may be present, which can result in erratic engine operation and engine flameout:––

R ENG FUEL FILT ––
L ENG FUEL FILT''–

(d) For all Model 747–400 series airplanes; all Model 757 series airplanes; and Model 767 series airplanes powered by General Electric CF6–80A and CF6–80C2 engines, Pratt & Whitney PW 4000 engines, and Rolls-Royce RB211–524 engines: Accomplish the requirements of paragraph (d)(1) and (d)(2) of this AD: –

(1) Within 4 years after the effective date of this AD, install an upgraded engine indication and crew alerting system (EICAS) computer that will provide ''advisory'' level messages to the flight crew to indicate an impending engine fuel filter bypass condition for each engine. The installation shall be accomplished in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. –

(2) Concurrent with the installation required by paragraph (d)(1) of this AD, remove the AFM revisions required by paragraphs (a) and (b) of this AD, and revise the Limitations Section of the AFM to advise the flight crew that impending engine fuel filter bypass advisory level messages for multiple engines may indicate contamination of the airplane fuel system, which can result in erratic engine operation and engine flameout. The revision to the Limitations Section must be approved by the Manager, Seattle ACO, FAA, Transport Airplane Directorate. –

(e) 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, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Operations 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.

(f) 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. –

(g) This amendment becomes effective on May 3, 1996.

Issued in Renton, Washington, on March 27, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–7959 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–13–P

Federal Highway Administration

23 CFR Part 230

[FHWA Docket No. 82–19]

RIN 2125–AB15

Equal Employment Opportunity on Federal and Federal-Aid Construction Contracts (Including Supportive Services); Report Requirements

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule; technical amendments.

SUMMARY: This document amends the current regulation on recordkeeping and reporting requirements for on-the-job training on Federal-aid construction contracts which require contractors to submit Form FHWA–1409, Federal-Aid Highway Construction Contractor's Semi-Annual Training Report, and State highway agencies to complete and submit Form FHWA–1410, Federal-Aid Highway Construction Semi-Annual Training Report. This amendment eliminates these reporting requirements in order to reduce the administrative burden on contractors as well as States. Additionally, the Office of Management and Budget approval for these forms under the Paperwork Reduction Act has lapsed, and as a matter of common industry practice, compliance by construction contractors and States is not required.

EFFECTIVE DATE: May 3, 1996.

FOR FURTHER INFORMATION CONTACT: Linda J. Brown, Chief, Policy and Program Development Division, Office of Civil Rights, 202–366–0471, or Will Baccus, Office of Chief Counsel, 202–366–1396, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: On November 22, 1982, the FHWA published an NPRM in the Federal Register (47 FR 52470). The rulemaking sought comments on the elimination of unnecessary and burdensome recordkeeping requirements being imposed on State highway agencies and construction contractors. The data and information received during the comment period and analysis initiated by the FHWA indicate that elimination of the reporting requirement regarding on- the-job training on Federal-aid construction contracts (23 CFR 230.121(d)(1) and (2)) would not adversely impact other areas of the equal opportunity program as these reports are not used for any related purpose e.g., contract compliance determination or compilation of any report on the status of civil rights programs.

Twenty-nine comments were submitted to the docket. State transportation agencies, contractors, contractors associations, unions, and other interested parties that commented to the docket overwhelmingly supported the elimination of these recordkeeping and reporting requirements. Also, current industry practice reflect the views of the commenters regarding the

elimination of these recordkeeping and reporting requirements.

The FHWA agrees with the commenters since FHWA's goal is to avoid imposing undue administrative burdens on the State highway agencies and contractors while carrying out its equal opportunity program responsibilities. The FHWA believes that amendment would have a positive economic impact on contractors and State highway agencies as well as the FHWA itself.

Additionally, the FHWA has convened an implementation team on civil rights regulations. The team consists of representatives from FHWA's headquarters and field offices, whose goal is to review, streamline, and simplify civil rights regulations and to integrate civil rights requirements with other program requirements. As a result of the team effort, an NPRM will be published in 1996 to solicit comments on the proposed revisions to the civil rights regulations.

Rulemaking Analyses and Notices

The NPRM upon which this final action is in part based was published in 1982. The FHWA believes that further notice and opportunity to comment are not necessary because the comments received support elimination of these recordkeeping requirements, the common practice now is not to require compliance with these requirements, and removal of these requirements is consistent with the requirements of the Paperwork Reduction Act and the President's Regulatory Reinvention Initiative to reduce regulatory burdens.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of the Department of Transportation's regulatory policies and procedures. This rulemaking would result in the elimination of FHWA regulations requiring contractors and State highway agencies to submit semi-annual reports regarding on-the-job training. This rulemaking eliminating these regulations will lessen an economic burden imposed on these entities by these recordkeeping and reporting requirements, but it will not cause any significant changes to the amount of funding available to the State highway agencies. Thus, it is anticipated that the economic impact of this rulemaking will be minimal. In addition, it will not create a serious inconsistency with any other agency's action or materially alter the budgetary impact of any entitlement, grants, user fees, or loan programs; nor will elimination of these regulations raise any novel legal or policy issues. Therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this rule on small entities. Repeal of the recordkeeping and reporting requirements that are the subject of this rulemaking will eliminate an administrative burden currently being imposed on State highway agencies and construction contractors. Some of these contractors most likely qualify as ''small entities'' as defined in section 601 of the Regulatory Flexibility Act. However, we believe that the lessening of the administrative burden that will result from this rulemaking will not result in a significant economic impact on these small entities. Thus, the FHWA hereby certifies that this regulatory action will not have significant economic impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this rule will not have sufficient federalism implications to warrant the preparation of a federalism assessment. Elimination of these recordkeeping and reporting requirements will not preempt any State law or State regulation. No additional costs or burdens would be imposed on the States as a result of this action, and the States' ability to discharge traditional State governmental functions would not be affected by this rulemaking.

Executive Order 12374 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation of Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. In fact, this rulemaking eliminates two information collection requirements.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

Lists of Subjects in 23 CFR Part 230

Equal employment opportunity, Grant programs— transportation, Highways and roads, Minority businesses, Reporting and recordkeeping requirements.

Issued on: March 25, 1996.

Rodney E. Slater,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA amends title 23, Code of Federal Regulations, part 230 as set forth below.

PART 230—EXTERNAL PROGRAMS

1. The authority citation for part 230 is combined at the part level and revised to read as follows and all other authority citations which appear throughout part 230 are removed:

Authority: 23 U.S.C. 101, 140, and 315; 42 U.S.C. 2000d et seq.; 49 CFR 1.48 and 60–1.

§ 230.121 [Amended]

2. In § 230.121, paragraph (d) is removed and reserved.

Appendices E and F to Subpart A [Removed and reserved]

3. In part 230, subpart A, Appendices E and F are removed and reserved.

[FR Doc. 96–8159 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 3500

[Docket No. FR–3780–N–06]

RIN 2502–AG40

Office of the Assistant Secretary for Housing-Federal Housing Commissioner; Mortgage Broker Fee Disclosure Rule: Notice of Next Meetings of Negotiated Rulemaking Advisory Committee

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice of committee meeting.

SUMMARY: The Department has established a Negotiated Rulemaking Advisory Committee to address certain issues concerning indirect payments to mortgage brokers and certain other mortgage originators (retail lenders) and volume-based compensation. This notice announces the time and place for the next meeting of the committee, which is open to the public.

DATES: The next meeting of the committee will be on April 8–9, 1996. On Monday, April 8, the meeting will start at 9:00 a.m. and will end at 5:00 p.m., and on Tuesday, April 9, the meeting will start at 9:00 a.m. and run until approximately 3:30 p.m. An additional meeting has been scheduled for May 20–21, 1996, in Washington, D.C.

ADDRESSES: The next meeting of the committee will be held in the Headquarters of the National Association of Home Builders, 15th and ''M'' Streets, N.W., Washington, D.C. 20005 (Auditorium 1; for more information, please direct inquiries to the contact listed under the heading ''For Further Information Contact,'' below). For information on the location in Washington, D.C., of the May 20–21, 1996, meeting, please direct inquiries to the contact listed under the heading **FOR FURTHER INFORMATION CONTACT**, below. These meetings are open to the public, with limited seating available on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: David R. Williamson, Director, RESPA Enforcement Unit, Department of Housing and Urban Development, Room 5241, 451 Seventh Street, S.W., Washington, D.C. 20410–0500; telephone (202) 708–4560 (this is not a toll-free number); e-mail through Internet at david____r.____williamson@hud.gov (use underscore characters). Persons who are hearing- or speech-impaired may access the above phone number by calling the Federal Information Relay Service at 1–800–877–TDDY (1–800–877–8339).

SUPPLEMENTARY INFORMATION: On December 8, 1995 (60 FR 63008), HUD published a notice announcing the establishment and first meeting of the Negotiated Rulemaking Advisory Committee on Mortgage Broker Disclosures, to discuss and negotiate a proposed rule on the treatment under RESPA, including disclosure requirements, of indirect payments to retail lenders and of volume-based compensation to mortgage brokers. In a notice published on February 20, 1996 (61 FR 6334), the Department announced it would publish notice of changes in the schedule of subsequent meetings as far in advance of the meetings as possible. Because the location of the next meeting of the committee has been changed, the Department is publishing this notice.

Therefore, the next meeting of the committee will be on April 8–9, 1996, and will be held in the Headquarters of the National Association of Home Builders, 15th and ''M'' Streets, N.W., Washington, D.C. 20005. In addition, the committee has agreed to meet on May 20–21, 1996, in Washington, D.C. For more information of the location of these meetings, please direct inquiries to the contact listed under the heading **FOR FURTHER INFORMATION CONTACT**, above. These meetings are open to the public, with limited seating available on a first-come, first-served basis.

Authority: 42 U.S.C. 1437g, 3535(d).

Dated: March 27, 1996.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 96–8129 Filed 3–29–96; 12:57 pm]

BILLING CODE 4210–27–P

DEPARTMENT OF INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AC26

Oregon Caves National Monument, Admission to Caves

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: The National Park Service (NPS) is publishing this final rule to remove an existing regulation that prohibits children under the age of six years from entering Oregon Caves at Oregon Caves National Monument. Elimination of this regulation will allow children to enter the Caves, regardless of age. The existing age restriction is not necessary to provide safe and quality interpretive tours in the Caves. The effect of this removal is to establish a more equitable criteria for allowing children access to the caves.

EFFECTIVE DATE: This final rule becomes effective on May 3, 1996.

FOR FURTHER INFORMATION CONTACT: Craig W. Ackerman, Superintendent, Oregon Caves National Monument. Telephone 503–592–2100.

SUPPLEMENTARY INFORMATION:

Background

This final regulation addresses a specific management problem involving access to the only public tour route in Oregon Caves. The present restriction found at 36 CFR 7.49, states that ''Children under the age of 6 are not permitted to enter the caves.'' A search of historical records has failed to find any extensive discussion of or justification for this particular age limit. No other Park Service cave, open for public tours, has a similar regulatory restriction for general tours.

Employees who give the cave tours or sell tickets for the tours generally make the determination as to whether a child wanting to enter the caves is under six years of age. Since most parents do not carry documentation of the age of a child, verification of age is usually not possible. Some parents become upset when their children are denied access to the Caves. The age limit restriction has been the most common visitor complaint to both park and concession employees over the last few decades. Denying access to children who can physically and safely travel through the Caves contradicts one of the management objectives of Oregon Caves National Monument's General Management Plan, which is to ''Provide quality interpretive service that increases the visitors' knowledge, appreciation and enjoyment of the resources at Oregon Caves.''

There appears to be little justification for using six years of age in determining who enters the Caves. The width of tread, number and rise of steps, the length of the tour, and the height of railings better determine whether visitors can safely negotiate the cave tour. Renovation of the entire trail system, which is being designed with children in mind, is currently in the planning stage. This revision would greatly reduce visitor conflicts by instituting safety restrictions that are fair and equitable. Sufficient

discretionary authority can be found at 36 CFR 1.5 (Closures and public use limits) and at 36 CFR 1.7(b) (Park compendium) to safely regulate access to the Caves.

On March 14, 1995, the NPS published the proposed regulation that would delete this special regulation (60 FR 13662). Public comment was invited. The comment period closed on May 15, 1995. No comments were received during the comment period.

Drafting Information

The primary authors of this final rule are Craig W. Ackerman, Area Manager of Oregon Caves National Monument and Dennis Burnett, Washington Office of Ranger Activities, National Park Service.

Paperwork Reduction Act

This final rule does not contain collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

Compliance with Other Laws

This rule was not subject to Office of Management and Budget review under Executive Order 12866. The Department of the Interior determined that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*). The economic effects of this rulemaking are local in nature and negligible in scope.

The NPS has determined that this final rule will not have a significant effect on the quality of the human environment, health and safety because it is not expected to:

(a) Increase public use to the extent of compromising the nature and character of the area or causing physical damage to it;

(b) Introduce non-compatible uses which might compromise the nature and characteristics of the area, or cause physical damage to it;

(c) Conflict with adjacent ownerships or land uses; or

(d) Cause a nuisance to adjacent owners or occupants. Based upon this determination, this regulation is categorically excluded from the procedural requirements of the National Environmental Policy Act (NEPA) by Departmental regulations in 516 DM 6, (49 FR 21438). As such, neither an Environmental Assessment (EA) nor an Environmental Impact Statement (EIS) has been prepared.

List of Subjects in 36 CFR Part 7

National parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, 36 CFR Chapter I, is amended as follows:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

1. The authority citation for part 7 continues to read as follows:

Authority: 16 U.S.C. 1, 3, 9a, 460(q), 462(k); Sec. 7.96 also issued under D.C. Code 8–137 (1981) and D.C. Code 40–721 (1981).

§ 7.49 [Removed]

2. Section 7.49 is removed.

Dated: March 14, 1996.

George T. Frampton, Jr.,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 96–7978 Filed 4–2–96; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 223

RIN 0596–AB58

Disposal of National Forest System Timber; Modification of Timber Sale Contracts in Extraordinary Conditions

AGENCY: Forest Service, USDA.

ACTION: Interim final rule; request for public comment.

SUMMARY: This interim rule revises the existing regulations regarding noncompetitive sale of timber based on the Secretary of Agriculture's determination that extraordinary conditions exist. The intended effect is to allow forest officers, without advertisement, to make modifications to timber sales awarded or released pursuant to section 2001(k) of the 1995 Rescissions Act, which result in the substitution of timber from outside the sale area specified in the contract for timber within the timber sale contract area. Good cause exists to adopt this interim final rule without prior notice and comment; however, public comment is invited and will be considered before adoption of a final rule.

DATES: This rule is effective April 3, 1996. Comments must be received by May 20, 1996.

ADDRESSES: Send written comments to: Chief (2400), Forest Service, USDA, P.O. Box 96090, Washington, DC 20090–6090.

The public may inspect comments received on this rule in the Office of the Director, Timber Management Staff, Forest Service, USDA, 201 14th Street, SW., Washington, DC 20250. Parties wishing to view comments are requested to call ahead ((202) 205–0893) to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Bob Lynn, Timber Management Staff (202) 205–1787; Jay McWhirter, Natural Resources Division, Office of the General Counsel (202) 690–0329.

SUPPLEMENTARY INFORMATION:

Applicable Contract Law

The rules at 36 CFR Part 223 govern the sale of National Forest System timber. Sections 223.80 and 223.100 address the requirements for advertisement and for award of timber sale contracts respectively. Title 16 U.S.C. 472a(d) requires the Secretary of Agriculture to advertise all sales of forest products unless the value of the sale is less than $10,000, or the Secretary determines that extraordinary conditions exist, as defined by regulation. Current regulations at 36 CFR 223.80 require advertisement of a sale for 30 days when its value is greater than $10,000. The Secretary has not previously promulgated rules to implement section 472a(d)'s authority to dispose of timber without advertisement when extraordinary conditions exist.

The advertising requirement of 16 U.S.C. 472a(d) also limits modifications to contracts involving the addition or substitution of timber outside a contract's sale area. Since only the timber within the contract's sale area was subject to competitive bidding, any timber located outside the contract's sale area would theoretically be available for sale to other interested purchasers; thus the current rules do not permit contract modifications that add or substitute timber outside a contract's sale area for timber under contract within the sale area. Moreover, the General Accounting Office has held that substitution of timber outside a contract's sale area for timber within the contract area violated the agency's authority to sell timber. B–177602 (1973). The Agriculture Board of Contract Appeals has decided similarly in several cases. See *Appeal of Summit Contractors*, AGBCA No. 81–252–1, AGBCA No. 83–312–1 (Jan. 8, 1986), and *Appeal of Jay Rucker*, AGBCA No. 79–211A CDA (June 11, 1980). In addition, in a recent case involving the Bureau of Land Management, the Court of Federal Claims stated that modifications to existing timber sales must conform with agency status and regulations regarding disposal of timber. *Croman Corporation* v. *United States*, 31 Fed. Cl. 741, 746–47 (August 16, 1994).

The 1995 Rescissions Act

On July 27, 1995, President Clinton signed into law the 1995 Rescissions Act (Pub. L. 104–19, 109 Stat. 246). Section 2001(k) of the 1995 Rescissions Act directed the release of timber sales subject to section 318 of the Fiscal Year 1990 Interior and Related Agencies Appropriations Act (Pub. L. 101–121, 103 Stat. 745). Section 318 has been the subject of extensive litigation, including a Supreme Court decision ultimately affirming the constitutionality of the law in *Robertson* v. *Seattle Audubon Society*, 503 U.S.C. 429 (1992). Some section 318 timber sales were affected by litigation over compliance with various terms of section 318, such as the requirement to minimize fragmentation of ecologically-significant old growth. See *Seattle Audubon Society* v. *Robertson*, Civ. No. 89–160 (W.D. Wash.).

Many section 318 sales did not go forward as a result of concerns about significant impacts to species listed under the Endangered Species Act (ESA). In June 1990, after enactment of section 318, the United States Fish and Wildlife Service (FWS) listed the northern spotted owl as a threatened species under the ESA (55 FR 26189; June 26, 1990). Because of the listing of the northern spotted owl as a threatened species, a number of Forest Service section 318 sales were ''modified, eliminated or held in abeyance.'' See *Gifford Pinchot Alliance* v. *Butruille*, 742 F. Supp. 1077, 1080.

On September 28, 1992, the FWS listed the marbled murrelet as a threatened species (57 FR 45328; Oct. 1, 1992). As a result of the listing, the Forest Service reinitiated consultation with the FWS under section 7(a)(2) of the Endangered Species Act, 16 U.S.C. 1536(a)(2), regarding the effects of murrelets of continuing to harvest section 318 sales that had already been awarded. In June 1995, the FWS concluded that further logging of a number of the Forest Service section 318 sales would likely jeopardize the continued existence of the marbled murrelet. As a result, these section 318 sales were suspended pending further field survey work.

Some section 318 sales were also affected when the National Marine Fisheries Service proposed listing several anadromous fish species in the region as threatened or endangered. These species include the Umpqua River cutthroat trout (59 FR 35089; July 8, 1994), and the coho salmon (60 FR 38011; July 25, 1995). As stated in these listings, the decline of these species is due in part to past timber harvest practices.

The 1995 Rescissions Act contained a provision directed at these section 318 sales that were still suspended. Section 2001(k) of the Act states:

> Notwithstanding any other provision of law, within 45 days after the date of the enactment of this Act, the Secretary concerned shall act to award, release, and permit to be completed in fiscal years 1995 and 1996, with no change in originally advertised terms, volumes, and bid prices, all timber sale contracts offered or awarded before that date in any unit of the National Forest System or district of the Bureau of Land Management subject to section 318 of Public Law 101–121 (103 Stat. 745). The return of the bid bond of the higher bidder shall not alter the responsibility of the Secretary concerned to comply with this paragraph.

Currently the Department is in litigation involving the implementation of section 2001 of the 1995 Rescissions Act. On September 13, 1995, the district court in *NFRC* v. *Glickman* No. 95–6244–HO (D. Or.), held that section 2001(k) applies to timber sales previously offered or awarded in all national forests in Washington and Oregon and BLM districts in western Oregon up to July 27, 1995. On October 17, 1995, the district court entered an order which ''compelled and directed'' the Secretary of Agriculture and the Secretary of the Interior, ''to award, release and permit to be completed in fiscal years 1995 and 1996, with no change in originally advertised terms, volumes, and bid prices, all timber sale contracts offered or awarded between October 1, 1990 and July 27, 1995, in any national forest in Oregon and Washington or BLM district in western Oregon, except for sale units in which a threatened or endangered bird species is known to be nesting.'' The government has appealed the district court's ruling (*NFRC* v. *Glickman*, 9th Cir. No. 95–36042), and is awaiting a decision.

After the district court's September 13, 1995, ruling, and its October 17, 1995, injunction, the Forest Service proceeded to release timber sales to previously identified high bidders. In one category of sales, however, the high bidders were either unwilling, unable, or unqualified to take advantage of the renewed offer of the timber sale. In another category of sales, courts had previously issued injunctions preventing the award of the sales, or the Forest Service had rejected bids, suspended, or terminated sales as a result of earlier litigation. For both categories, the Forest Service decided not to pursue the award or release of timber sales, and was challenged in district court in the *NFRC* v. *Glickman* case. In a decision dated January 10, 1996 (amended to address typographical errors on January 17, 1996), the district court enjoined the Secretary of Agriculture to award, release and permit to be completed immediately, all timber sales that were subject to section 2001(k). The January 10, 1996, injunction included sales where the Forest Service had rejected bids, suspended, or terminated sales as a result of earlier litigation, and those sales where the high bidders were unwilling, unable, or unqualified to be awarded sales.

In section 2001(k)(2) of the 1995 Rescissions Act, Congress created a limited exception from the general release requirements imposed by section 2001(k)(1). Under section 2001(k)(2), ''No sale unit shall be released or completed under this subsection if any threatened or endangered bird species is known to be nesting within the acreage that is the subject of the sale unit.'' Section 2001(k)(3) requires the Secretary of Agriculture and the Secretary of the Interior to provide an equal volume of alternative timber ''of like kind and value'' for timber sales withheld under 2001(k)(2)'s ''known to be nesting'' provision. On August 23, 1995, the Department of Agriculture and the Department of the Interior issued a joint letter of direction implementing section 2001(k)(2). The agencies concluded that, based on the scientific analysis used in a protocol developed by the Pacific Seabird Group, the protocol's criteria should be utilized in evaluating whether marbled murrelets are ''known to be nesting'' in timber sales that are subject to section 2001(k).

On September 1, 1995, a lawsuit was filed challenging the government's implementation of section 2001(k)(2). *Scott Timber Co.* v. *Glickman*, Civ. No. 95–6267–HO (D. Or.). The district court consolidated the Scott Timber case with *NFRC* v. *Glickman*, Civ. No. 95–6244–HO. On January 19, 1996, the district court issued a decision rejecting the government's interpretation of section 2001(k)(2) and use of the Pacific Seabird Group Protocol criteria to determine whether marbled murrelets are ''known to be nesting.'' The court stated:

> The language and legislative history of section 2001(k)(2) suggest that Congress intended to allow the agencies some leeway to determine what types of physical evidence observed within sale unit boundaries are sufficient to establish a ''known'' nesting site within the sale unit. Thus an agency may rely on the visual or auditory observation of a murrelet located sub-canopy within sale unit boundaries engaging in behavior that the

agency determines is sufficiently indicative of nesting to establish a ''known'' nesting site within that sale unit.

The District court then enjoined the Secretary of Agriculture to release sales that had previously been suspended if the sales did not satisfy the criteria set forth in the court's January 19, 1996, order. At a hearing held on January 25, 1996, the district court granted a 60-day stay of the injunction. The stay expires on March 25, 1996, and timber purchasers have opposed continuation of the stay order on the bases that they should be entitled to begin harvesting and any continuation may preclude them from completing timber sales due to the expiration of section 2001(k)(1) on September 30, 1996. The government has appealed both the January 10 and January 19, 1996, rulings of the district court; oral argument on the appeal is scheduled for the week of May 6, 1996.

Extraordinary Conditions

The Secretary of Agriculture is under October 17, 1995, January 10, 1996, and January 19, 1996, injunctions by the district court in *NFRC* v. *Glickman* to release sales that the Forest Service had previously suspended, withdrawn, or canceled. While the United States has taken appeals from the district court rulings underlying these injunctions, some sales have already been released, and others may be released in the future to comply with the district court injunctions.

Timber sales that have been released, or that may be released were planned and prepared under standards that pre-dated the Record of Decision for amendments to Forest Service and Bureau of Land Management planning documents within the range of the northern spotted owl, dated April 13, 1994 (hereinafter referred to as Northwest Forest Plan). The release and harvest of some of these sales may cause real harm to natural resources, including fish and wildlife resources. However, the opportunity exists to negotiate mutual modifications to these sales that will minimize environmental harm and bring them more in compliance with the Northwest Forest Plan's standards and guidelines. However, the mutual modifications likely to be needed for these sales would require the Forest Service to substitute timber from outside of the existing sale areas. Faced with these extraordinary conditions, unless the agency can immediately implement the authority provided in 16 U.S.C. 472a(d) to dispose of timber without advertisement, the opportunity to carry out section 2001(k) with a minimum of environmental harm through modifications to timber sale contracts will be lost.

Good Cause Exemption

Based on the foregoing extraordinary conditions, the Department finds that there exists good cause to promulgate this rule on an expedited basis. Because of district court injunctions in *NFRC* v. *Glickman* which require the Forest Service to take immediate action to award and release these timber sales, the Forest Service has a compelling need to make modifications to contracts which have been or will be awarded or released pursuant to section 2001(k) of the 1995 Rescissions Act. Without modification, sales will be awarded or released which contain provisions that pre-date the implementation of the timber sale standards and guidelines of the Northwest Forest Plan. Given the duty to comply with the district court's injunction, and the urgent need to modify timber sales to avoid environmental harm that would occur if these timber sales are completed without modification, the Department finds that notice and comment are impracticable prior to the issuance of this rule, and thus, that good cause exists to adopt this interim final rule.

Moreover, the Department finds that it would be contrary to the public interest, under these circumstances, to fail to act immediately to address the need for modification of these timber contracts. First, this rule will have a limited application. It will apply only to those sales that have been or will be released pursuant to section 2001(k) of the 1995 Rescissions Act. To date, the Forest Service has identified approximately 100 timber sales subject to section 2001(k). Second, without authority to make contract modifications that include timber outside the sale area, the Forest Service cannot provide a reasonable alternative to imminent harvest of environmentally harmful timber sales. It is the opinion of the Department, based on communications with timber contract holders, that failure to expeditiously provide alternatives to the timber sales released by section 2001(k) will lead to the immediate harvest of released sales. Such environmental harm, which may restrict options for future timber harvests, may occur within the time otherwise required for notice and public participation by E.O. 12866. Finally, section 2001(h) of the 1995 Rescissions Act does not require the Secretary of Agriculture to adhere to the requirements of 5 U.S.C. 553 in implementing the 1995 Rescissions Act. To the extent that this rule is in furtherance of the duties imposed by the Rescissions Act, normal rulemaking procedures would not apply.

Intended Effects

This interim final rule redesignates the existing text in 36 CFR 223.85 as paragraph (a) and adds a new paragraph (b) to define ''extraordinary conditions'' to allow forest officers, without advertisement, to make modifications to timber sales awarded or released pursuant to section 2001(k) of Public Law 104–19 (109 Stat. 246), which result in the substitution of timber from outside the sale area specified in the contract for timber within the sale area. It should be noted, however, that this rule change does not compel a timber purchaser to accept a timber sale modification offered under the interim final rule. The rule authorizes the Forest Service to propose modifications and to enter into discussions with purchasers on such modifications, but, as with all mutual transactions, purchasers are not obligated to accept any proposed modifications.

Regulatory Impact

This rule has been reviewed under USDA procedures and Executive Order 12866 on Regulatory Planning and Review. While it has been determined that this is not an economically significant rule, this rule has been determined to be significant because this rule implements a statutory authority for noncompetitive modification of timber sale contracts. Heretofore, there have been no rules on this subject. Given the wide interest in the timber sales and the statutory direction that gives rise to the extraordinary conditions which are the subject of this rulemaking, this rule has been reviewed by the Office of Management and Budget prior to publication.

Moreover, this rule has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) and it has been determined that this action will not have a significant economic impact on a substantial number of small entities as defined by that act.

Environmental Impact

This rulemaking action falls within a category of actions excluded from documentation in an Environmental Impact Statement or an Environmental Assessment. Section 31.1b of Forest Service Handbook 1909.15 (57 FR 43180, September 18, 1992) excludes from documentation in an environmental assessment or impact statement ''rules, regulations, or policies to establish Service-wide administrative

procedures, program processes, or instructions.'' The agency's assessment is that this rule falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an environmental assessment or environmental impact statement for this rule.

Controlling Paperwork Burdens on the Public

This rule does not require any recordkeeping or reporting requirements or other information collection requirements as defined in 5 CFR 1320 not already approved for use and, therefore, imposes no additional paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) and implementing regulations at 5 CFR 1320 do not apply.

List of Subjects in 36 CFR Part 223

Exports, Government contracts, National forest, Reporting and recordkeeping requirements, Timber sales.

Therefore, for the reasons set forth in the preamble, it is proposed to amend part 223 of title 36 of the Code of Federal Regulations as follows:

PART 223—SALE AND DISPOSAL OF NATIONAL FOREST SYSTEM TIMBER

1. The authority citation for part 223 continues to read as follows:

Authority: 90 Stat. 2958, 16 U.S.C. 472a; 98 Stat. 2213, 16 U.S.C. 618, unless otherwise noted.

Subpart B—Timber Sale Contracts

2. Section 223.85 is revised to read as follows:

§ 223.85 Noncompetitive sale of timber.

(a) Forest officers may sell, within their authorization, without further advertisement, at not less than appraised value, any timber previously advertised for competitive bids but not sold because of lack of bids and any timber on uncut areas included in a contract which has been terminated by abandonment, cancellation, contract period expiration, or otherwise if such timber would have been cut under the contract. This authority shall not be utilized if there is evidence of competitive interest in the product.

(b) Extraordinary conditions, as provided for in 16 U.S.C. 472(d), are defined to include the potential harm to natural resources, including fish and wildlife, and related circumstances arising as a result of the award or release of timber sale contracts pursuant to section 2001(k) of Public Law 104–19 (109 Stat. 246). Notwithstanding the provisions of paragraph (a) or any other regulation in this part, for timber sale contracts that have been or will be awarded or released pursuant to section 2001(k) of Public Law 104–19 (109 Stat. 246), the Secretary of Agriculture may allow forest officers to, without advertisement, modify those timber sale contracts by substituting timber from outside the sale area specified in the contract for timber within the timber sale contract area.

Dated: March 28, 1996.

Dan Glickman,

Secretary of Agriculture.

[FR Doc. 96–8095 Filed 4–2–96; 8:45 am]

BILLING CODE 3410–11–M

36 CFR Part 292

RIN 0596–AB39

Smith River National Recreation Area

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule implements Section 8(d) of the Smith River National Recreation Area Act of 1990 and sets forth the procedures by which the Forest Service will regulate mineral operations on National Forest System lands within the Smith River National Recreation Area. This rule supplements existing Forest Service regulations and is intended to ensure that mineral operations are conducted in a manner consistent with the purposes for which the Smith River National Recreational Area was established.

EFFECTIVE DATE: This rule is effective April 3, 1996.

FOR FURTHER INFORMATION CONTACT: Sam Hotchkiss, Minerals and Geology Management Staff, (202) 205–1535.

SUPPLEMENTARY INFORMATION:

Background

The Smith River National Recreation Area (SRNRA) was established by the Smith River National Recreation Area Act of 1990 (the Act) (16 U.S.C. 460bbb *et seq.*). The purpose of the Act is to ensure, ''. . . the preservation, protection, enhancement, and interpretation for present and future generations of the Smith River watershed's outstanding wild and scenic rivers, ecological diversity, and recreation opportunities while providing for the wise use and sustained productivity of its natural resources. . . .''

In order to meet the purposes of the Act, Congress directed the Secretary to manage the SRNRA to provide for a broad range of recreational uses and to improve fisheries and water quality. The Act prohibits mining, subject to valid existing rights and limits extraction of mineral materials to situations where the material extracted is used for construction and maintenance of roads and other facilities within the SRNRA and in certain areas specifically excluded from the SRNRA by the Act.

The SRNRA consists of approximately 300,000 acres of National Forest System lands in the Six Rivers National Forest in northern California. The Act divides the SRNRA into eight distinct management areas and specifies a management emphasis for each. One of these eight areas is the Siskiyou Wilderness, most of which was designated by Congress in 1984. The Gasquet-Orleans Corridor was added to the Siskiyou Wilderness by the Act in 1990. The Act specifies that the Siskiyou Wilderness is to continue to be managed pursuant to the provisions of the Wilderness Act.

The Act also designates the Smith River, the Middle Fork of the Smith River, the North Fork of the Smith River, the Siskiyou Fork of the Smith River, and the South Fork of the Smith River as components of the National Wild and Scenic Rivers System and stipulates that they be managed in accordance with the Act and the Wild and Scenic Rivers Act. In the event of a conflict between the provisions of these two statutes, the Act specifies that provisions of the most restrictive statute apply. Finally, the Act expressly excludes four areas that lie within the boundary of the SRNRA from compliance with provisions of the Act.

Mining and prospecting for minerals have been an important part of the history of the Smith River area since the 1850's. Historically, mining operations within the Smith River area have been small-scale placer gold exploration and recovery operations within the bed and banks of the Smith River and its main tributaries. Panning, sluicing, and dredging operations occur predominantly during the summer months. In recent years, large, low-grade, nickel-cobalt resources in the uplands of the Smith River watershed have attracted the attention of prospectors. In 1990, there were approximately 5,000 mining claims covering about 30,000 acres of National Forest System lands within the SRNRA. By 1995, however, there were only approximately 320 mining claims covering about 8,000 acres of National Forest System lands in the SRNRA that met current Bureau of Land Management filing requirements. In

contrast to the large number of claims, actual operations were conducted on only three claims under approved plans of operations in 1995. In addition, there are outstanding mineral rights within the SRNRA.

In Section 8 of the Act, Congress addressed the extent to which mineral operations would be authorized within the SRNRA. Section 8(a) of the Act withdrew as of the effective date of the Act, all federal lands in the SRNRA from the operation of the mining, mineral leasing, and geothermal leasing laws subject to valid existing rights. Section 8(b) precludes the issuance of patents for locations and claims made prior to the establishment of the SRNRA. Section 8(c) of the Act prohibits all mineral operations within the SRNRA except where valid existing rights are established. Section 8(c) also prohibits the extraction of mineral materials such as stone, sand, and gravel, except if used in the construction and maintenance of roads and other facilities within the SRNRA and the excluded areas. Finally, under Section 8(d) the Secretary is to promulgate supplementary regulations to promote and protect the purposes for which the SRNRA was designated.

On or about November 8, 1994, the largest claimholder in the SRNRA filed suit against the Department of Agriculture in United States District Court for the Northern District of California alleging violations of the Act. *California Nickel Corporation* v. *Epsy*, No. C94–3904 DLJ (N.D. Cal.). Specifically, the suit alleged that the Department was in violation of the Act by not promulgating regulations for mineral operations in the SRNRA as required under Section 8(d). The Forest Service did not dispute that Section 8(d) of the Act required the promulgation of supplementary regulations for the SRNRA and had, in fact, made some preliminary progress in developing a regulation prior to the initiation of this litigation. The case is still pending and the agency anticipates its dismissal shortly after the publication of the final rule.

On June 23, 1995, the Forest Service published a proposed rule for notice and comment in the Federal Register which contained supplementary regulations for mineral activities on National Forest System lands in the SRNRA pursuant to Section 8(d) of the Act (60 FR 32633). Seven letters expressing a variety of viewpoints were received during the 60-day comment period which expired on August 22, 1995. These letters were from a mining company, several individual prospectors, an environmental organization, a local resident, and another interested party. All comments received are available for review in the Office of the Director, Minerals and Geology Management Staff, Auditors Building, 4th Floor, 201 14th Street, SW., Washington, DC, during regular business hours (8 a.m. to 5 p.m.) Monday through Friday. The Department appreciates the time and energy the reviewers invested in preparing these letters and articulating their views on concerns with the proposed rule.

Analysis of Public Comment

Comments on the proposed rule dealt with general issues such as terminology, noncommercial recreational mineral collecting, civil rights, property rights, and constitutional protections related to such rights. In addition, there were several issues raised in the comments that dealt with specific provisions of the proposed rule. A summary of the comments and the Department's responses to them follows.

General Comments

1. *Omission of the word ''resources'' as used in the Act from the Supplementary Information.* One reviewer noted that the supplementary information provided in the proposed rule omitted the word ''resources'' from the section of the Act in which Congress articulated the purpose for which the SRNRA was established. The reviewer believed the omission was significant because it was not clear that a companion goal of preservation, protection, enhancement, and interpretation of the SRNRA is to provide for the wise use and sustained productivity of the SRNRA's natural resources.

Response: The stated purpose of the Act did include the word ''resources'' as this reviewer noted. The omission of this word from the preamble of the proposed rule was inadvertent, and the complete excerpt from Section 4 of the Act, including the word ''resources,'' has been set forth in the preceding ''Background'' section of this final rule.

2. *Disparity between proposed rule and Six Rivers LRMP on the number of current mining claims in the SRNRA.* One reviewer noted that the supplementary information section of the proposed rule stated that approximately 5,000 mining claims currently existed in the SRNRA, but that the June 1995 Final Environmental Impact Statement (FEIS) for the Six Rivers National Forest Land and Resource Management Plan (LRMP) identified only 300 current mining claims. The reviewer requested clarification as to which of these figures is accurate.

Response: The information in the FEIS for the Six Rivers National Forest LRMP is correct. As of November 23, 1995, approximately 300 mining claims in the SRNRA met Bureau of Land Management filing requirements. This is a significant reduction from the approximately 5,000 mining claims that existed in the SRNRA in 1990 and this reduction was not reflected in the preamble to the proposed rule. However, it has been corrected in the ''Background'' section of this final rulemaking.

3. *Lack of any new substantive standards in addition to those in the current Forest Service mineral regulations.* One reviewer observed that the proposed rule set forth no additional substantive standards for environmental protection beyond those set forth in 36 CFR part 228, subpart A, and requested that if additional substantive standards are subsequently added, they be articulated with greater clarity.

Response: The Department eschews attempts to characterize the standards in the proposed rule as ''substantive'' or ''procedural'' because such labels are fraught with subjectivity, and no useful purpose will be served by specifying whether the standards in the proposed rule are substantive or procedural.

4. *Characterization of nickel-cobalt resources as ''low grade.''* One reviewer objected to the characterization of the nickle-cobalt resources in the uplands of the Smith River watershed as ''low-grade'' to the extend that this characterization suggests that the resources are either insignificant or unworthy of development and requested that the characterization ''low-grade'' be deleted from the preamble.

Response: ''Low grade'' is a phrase commonly used within the mining industry to describe situations where the anticipated percentage of elements in a given area is less than the percentage of the same elements currently being mined elsewhere. This is an apt description of the nickel-cobalt resources in the SRNRA. In fact, the corporation holding most of the claims in the portion of SRNRA where the nickel-cobalt resources are located has previously acknowledged that the grade of the nickel-cobalt resources in the SRNRA is less than the grade of nickel-cobalt resources being mined in other parts of the world.

5. *Need for supplementary regulations for mineral operations to protect SRNRA.* One reviewer stated that there is no need for additional regulations of mineral operations in the SRNRA since the existing regulations governing these

activities provide ample protection to the SRNRA and its resources.

Response: The issue of whether additional regulation of mineral operations is necessary in the SRNRA was conclusively determined by Congress in Section 8(d) of the Act. This provision specifically states that ''the Secretary [of Agriculture] is authorized and directed to issue supplementary regulations to promote and protect the purposes for which the [SRNRA] is designated.'' It is not within the discretion of the Department to evaluate whether such regulations are necessary; the Act obligates the Department to issue them.

6. *Duplication of current mining law and Bureau of Land Management and California Fish and Game Department regulations.* One reviewer felt that the proposed rule is duplicative of current mining law and BLM and California Department of Fish and Game regulations. Although the reviewer made no specific recommendation based on this observation, the agency has construed it as a suggestion that the supplementary regulations for mineral operations in the SRNRA are unnecessary.

Response: As noted in the previous response, it is not within the Department's prerogative to determine whether supplementary regulations for mineral operations in the SRNRA are necessary if Congress specifically directs the agency to promulgate them. Furthermore, although the reviewer failed to identify which laws or BLM or California Department of Fish and Game regulations were duplicative of the proposed rule, the Department does not believe that such duplication exists.

7. *Applicability of rule to all uses in the SRNRA, not just mineral operations.* One reviewer noted that the provisions of the Act directing the Forest Service to promulgate regulations were not limited to mining. Therefore, the reviewer concludes that the agency should have expanded the subject matter of the proposed rule to address all uses occurring in the SRNRA.

Response: The reviewer correctly notes that Section 8(d) of the Act makes no specific reference to mineral operations in the SRNRA as the subject of the supplementary regulations. However, Section 8 is entitled ''Minerals'' and subsections (a), (b), and (c) all involve the administration of minerals and mining activities in the SRNRA. It is, therefore, reasonable for the agency to infer that the specific subject matter of the regulations required by Section 8(d) of the Act involves mineral operations in the SRNRA.

This inference is supported by the Act's legislative history. Early versions of the legislation to establish an SRNRA contained an outright prohibition on all mining activities in the SRNRA. Due to concerns associated with the cost entailed by a blanket prohibition, the legislation was subsequently amended as it moved through the legislative process, to prohibit only those mining activities in the SRNRA where valid existing rights had not been established as of the date of enactment of the Act. Where valid existing rights had been established, the legislation authorized the continuation of mineral development activities, provided that these activities would be subject to supplementary regulations designed to ensure the protection of the resource values for which the SRNRA was designated. One of the principal sponsors of the SRNRA legislation explained:

> With regard to mining, the amendments would give explicit recognition to the rights associated with valid existing claims, and direct the Secretary to issue supplementary regulations designed to 'promote and protect' the purposes for which the recreation area is created. Although I remain concerned about the potential for destructive mining, I am hopeful that the supplemental regulations will address these concerns. * * * 136 Cong. Rec. H13045, 13046 (Oct. 26, 1990) (Statement of Rep. Bosco).

Since limiting the scope of this rule to mineral operations in the SRNRA is fully consistent with the Act and its associated legislative history, the Department declines to expand the scope of this rule to address other activities occurring within the SRNRA.

8. *Improper withdrawal procedures after enactment of the Act.* One reviewer felt that certain procedures for the withdrawal of federal lands from the operation of federal mining laws were not complied with in the SRNRA following the enactment of the Act. According to this reviewer, in order to legally withdraw an area, the Bureau of Mines must evaluate existing mining claims and estimate the mineral value of the area. Claim holders who disagree with the findings of the Bureau of Mines should be allowed to appeal these findings and conduct their own discovery on appeal. This reviewer concluded that claim holders in the SRNRA should be allowed to perform additional discovery before submitting their plans of operation and proof of discovery, since this withdrawal procedure was not followed.

Response: Section 8 of the Act expressly withdrew all federal lands within the SRNRA from the operation of the mining law subject to valid existing rights. Therefore, no additional procedures must be followed by any federal agency to effectuate this withdrawal.

9. *Limiting operations to 5 months per year.* One reviewer contends that the proposed rule unreasonably restricts operations in the SRNRA to not more than five months a year and thus prevents operators from making a living.

Response: There was no provision in the proposed rule which imposed a limit on the maximum number of months during which mineral operations could be conducted in the SRNRA, nor is there such a provision in the final rule.

10. *Exorbitant bonding.* One reviewer contended that the requirement for a plan of operations includes exorbitant bonding which would effectively eliminate the prudent operator/claimant from mining.

Response: There was no provision in the proposed rule which established a bonding requirement. The only applicable bonding provisions for mineral operations in the SRNRA are those already set forth in the agency's general mining regulations at 36 CFR 228.13, which of course, do apply to mining operations in the SRNRA.

11. *Exemption of ''recreational mining''.* Three reviewers noted that the proposed rule did not distinguish between individuals who engage in mineral development activities for recreational reasons as opposed to those who engage in such activities for business purposes. These reviewers objected to any attempt to prohibit or regulate ''recreational'' mineral development activities in the SRNRA based upon, among other things, the history of this type of activity in the SRNRA and the value in preserving and interpreting it, the Act's recognition of a broad range of recreation uses in the SRNRA, representations made by government officials during deliberations of SRNRA legislation that such ''recreational'' activities would be unaffected by the passage of the Act, and the fact that permission has been granted for similar activities on the Rogue River National Recreation Area.

Response: The reviewers correctly observed that the proposed rule did not distinguish between mineral development activities engaged in for pleasure as opposed to mineral development activities engaged in for profit. The reason the proposed rule did not make such a distinction is, simply stated, that the applicable law does not allow for it. Under the United States mining laws, federal land is either open to mineral entry or it is withdrawn from such entry. Therefore, once an area like

the SRNRA is withdrawn from the operation of the mining laws subject to valid existing rights, the Department has no authority to allow for the continuation of mineral development activities, unless the Forest Service can verify that valid existing rights have been established. This applies even if the individual is mining for personal enjoyment rather than financial gain and even if the impact on the lands and resources of the SRNRA is minimal.

With respect to the reviewers' observations in support of a continuation of ''recreational'' mineral collecting activities in the SRNRA, the following should be noted. First, the historical significance of ''recreational'' mineral activities in the SRNRA cannot controvert the mining laws of the United States or the Act's express prohibitions against mining. Second, if government officials made representations that legislation to designate the SRNRA would not effect this activity, such statements cannot controvert the unambiguous prohibitions in the Act. If Congress intended to create an exception for the SRNRA for noncommercial mineral collecting activities, it could have included such a provision in the Act. Third, Section 2 of the Act lists wilderness, water sports, fishing, hunting, camping, and sightseeing as examples of specific recreational pursuits that already occur in the SRNRA and for which the area was designated. While it is not exhaustive, the list in Section 2 of the Act is instructive in its omission of mining, sluicing, and panning from the other, more traditional types of recreational activities. Fourth and finally, there is no Rouge River National Recreation Area. There is, however, a Rouge Wild and Scenic River that was designated in 1968 and is administered under the Wild and Scenic Rivers Act. A withdrawal provision similar to Section 8 of the Act is contained in Section 9(a)(iii) of the Wild and Scenic Rivers Act and applies only to those federal lands within segments of the Rogue River Wild and Scenic River classified as ''wild.'' Federal lands within segments of the Rogue River Wild and Scenic River classified as ''scenic'' or ''recreational'' are not subject to this provision of the Wild and Scenic Rivers Act and hence it may be permissible to engage in this type of activity in these areas.

In summary, the only mineral development activities that may occur in the SRNRA are those for which valid existing rights have been established or have been authorized by a mineral materials contract or permit. Neither the subjective intent of the individual nor the impact of the activity may be used to justify mineral development activities, in the absence of valid existing rights or a mineral materials contract or permit.

12. *Length of the proposed rule.* One reviewer stated that the length of the proposed regulations, 30 pages—twice the length of the 15-page Act, was excessive.

Response: The proposed rule as printed in the Federal Register was only seven pages long, and of those seven pages, only three contained proposed regulatory text; the balance was background and explanatory materials. The agency does not consider the length of this regulation to be excessive.

13. *Allowing patenting of claims.* One reviewer contended that there is no bona fide reason to preclude the issuance of patents in the SRNRA in light of the existing regulations which adequately protect the area.

Response: The proposed rule did not deal with the issuance of patents. That matter was definitively resolved in Sections 8(a) and (b) of the Act which withdrew the SRNRA from patenting under the mining laws and prohibited patenting under the mining laws for locations and claims made before the date of enactment of the Act. This rule cannot authorize the issuance of patents in contravention of the Act.

14. *Prohibitions of all mining activities on ''high ground''.* One reviewer stated that the proposed rule would accommodate only ''water mining'' in the SRNRA and would prohibit ''high ground mining'' everywhere else. This reviewer further stated that such a prohibition would affectively confiscate 94% of the area currently available to this reviewer for mining operations.

Response: There was no mention of ''water mining'' or ''high ground mining'' classifications in the proposed rule and hence there was no prohibition against such activities per se. The only prohibition against mineral operations addressed in the Act is when the operator is unable to establish valid existing rights as of the date of enactment of the Act. This prohibition was merely reiterated in the proposed rule and is retained in the final rule.

15. *Recognition of an existing large-scale mining operation as an appropriate activity within the SRNRA.* One reviewer, the largest claimholder in the SRNRA, stated that the proposed rule should recognize its large-scale mining operation as an appropriate activity within the SRNRA.

Response: Although it is unclear what the reviewer meant by recognition as an ''appropriate activity,'' it would be entirely arbitrary for the Forest Service to single out the mining operations of one company for special treatment of any kind. There is nothing in the Act to suggest that Congress intended the Forest Service to evaluate mining operations in the SRNRA differently depending on the party who may hold the valid existing rights. As noted above, the SRNRA was established for the purpose of ''ensuring the preservation, protection, enhancement, and interpretation for present and future generations of the Smith River watershed's outstanding wild and scenic rivers, ecological diversity, and recreation opportunities while providing for the wise use and sustained productivity of its natural resources.''

These supplementary regulations are intended to ensure that all mining operations in the SRNRA, not just some of them, are carried out in conformance with the Act and in such a way as to preserve, protect, and enhance the values for which the SRNRA was designated.

16. *Applicability of California's Surface Mining and Reclamation Act to mining on SRNRA lands.* One reviewer recommended that the rule should specifically make reference to the applicability of California's Surface Mining and Reclamation Act (SMARA) to federal lands in the SRNRA based on a 1992 Memorandum of Understanding (1992 MOU) executed by and between the State of California, the Department of the Interior, and the Department of Agriculture. This reviewer also suggested that the rule should specify that the Forest Service would assume financial and administrative responsibility for the implementation of SMARA if the County of Del Norte fails to properly discharge its duties under this statute.

Response: It is unnecessary to include a provision in this rule which singles out the applicability of the California Act to mining operations in the SRNRA. The rule already provides that mineral operations in the SRNRA are subject to all applicable laws, regulations, policies, and procedures governing these activities on National Forest System Lands. The 1992 MOU is merely one of the ''policies and procedures'' currently governing the administration of mining operations in the SRNRA. Consequently, it is unnecessary to include a separate provision in this rule which includes a specific reference to the California Act.

The agency also declines to include a provision in the rule under which it would assume the administrative and financial obligations of Del Norte

County, if the county is unable to carry out its responsibilities under the State surface mining statute. Such a commitment of Forest Service staff and financial resources without assurance of Federal funds for such purposes would be in violation of the Anti-Deficiency Act, 31 U.S.C. 1341. This Act prohibits federal agencies from ''mak[ing] or authoriz[ing] an expenditure or obligation exceeding an amount available in an appropriation or fund for the expenditure or obligation.''

17. *Civil Rights Impact Analysis.* One reviewer felt that the agency was required by Chapter 30 of Forest Service Handbook 1709.11 to complete a Civil Rights Impact Analysis, since he believes that this is a major action involving quite a number of concerned citizens.

Response: Pursuant to Departmental Regulation (DR 4300–4) a Civil Rights Impact Analysis is required only for major policy actions when the consequences of those actions ''will negatively and disproportionately affect minorities''. This rulemaking is determined not to have an adverse or disproportionate effect on minorities.

18. *Compliance with NEPA in developing the regulations.* One reviewer felt that the agency failed to comply with the National Environmental Policy Act (NEPA) and should have prepared an environmental impact statement (EIS) to verify the need for the proposed regulation.

Response: Environmental impact statements are prepared where there may be significant effects resulting from the proposed action. Service-wide procedural regulations will not cause significant environmental effects and generally can be categorically excluded from documentation in an EIS or environmental assessment except where there are extraordinary circumstances (Forest Service NEPA procedures at FSH 1909.15, Ch. 30, 57 FR 43180 (Sept. 18, 1992)). After further consideration, the Forest Service has determined that the geographically specific nature of the Smith River NRA regulations cannot be considered applicable Service-wide and thus are not subject to a categorical exclusion. Accordingly, an Environmental Assessment and Finding of No Significant Impact have been prepared on this final rule.

19. *Intent to harass miners and deter mining operations in the SRNRA.* One reviewer asserted that the agency would use the rule to harass miners and deter mining by burdening claimants with unnecessary and expensive procedures and that this is the real intent of the rule, rather than environmental protection.

Response: The Forest Service respects every individual's right to his or her opinion, but it categorically rejects any assertion that the purpose of this rule is to harass miners or deter legitimate mining operations where operators have established valid existing rights. As stated at the outset, the purpose of this rule is to develop standards for mining operations in the SRNRA that will ensure that the fishery, scenic, and other values for which the area was designated will be protected and enhanced in perpetuity.

20. *Taking of private property without just compensation.* One reviewer disagreed with the statement in the proposed rule that the proposed rule does not have a takings implication. Another reviewer contended that the withdrawal of federal lands from the operation of the mining laws effected a taking.

Response: The Fifth Amendment states in part ''. . . nor shall private property be taken for public use without just compensation.'' Executive Order 12630 requires the agency to evaluate proposed agency actions to determine whether it presents the risk of a taking. The proposed rule explained that the Forest Service had concluded that the promulgation of this regulation did not present a takings risk.

One reviewer disputed the Forest Service's conclusion and, in essence, contended that the mere promulgation of this rule has taken his property without compensation and thus affected a taking. The Supreme Court has held that in order for the promulgation of a regulation to effect a taking, the property owner must demonstrate that the regulation on its face, rather than as applied, prevents the economically viable use of a compensable property interest. In this instance, the rule itself does not preclude economically viable use of mining claims in the SRNRA where valid existing rights have been established. Rather, it merely requires the operator to conform his operations to certain standards. None of these standards, individually or collectively, would deprive an operator of the economically viable use of his or her valid existing rights.

The other reviewer is incorrect in his assertion that the mere withdrawal of federal lands in the SRNRA from the operation of the mining laws effected a taking. Because the withdrawal language in the Act specifically stated that it was subject to valid existing rights, no taking of private property interests was effected by this measure. The withdrawal merely reflected Congress' decision to prohibit the use of National Forest System lands in the SRNRA for mining purposes. In other words, except where an operator can establish valid existing rights, mining is no longer one of the uses for which the National Forest System lands in the SRNRA will be managed. Congress' authority to prescribe the management of federal lands is derived from the Property Clause of the United States Constitution, Art. IV, Section 3, cl. 2, which vests in it the power to ''dispose of and make all needful rules and regulations respecting the territory or other property belonging to the United States.'' The Property Clause has been construed expansively. The Supreme Court has on more than one occasion stated that ''. . . the power over the public land thus entrusted to Congress [under the Property Clause] is without limitations.''

In this case, the withdrawal of federal land in the SRNRA from the operation of the mining laws subject to valid existing rights is merely an example of Congress exercising its authority under the Property Clause to prescribe how the federal land in the SRNRA will be administered. This provision cannot effect a taking because no private property interests were impacted by the withdrawal.

Specific Comments on Proposed Subpart G of 36 CFR Part 292

The following is a discussion of comments that were received pertaining to specific sections of the proposed rule and the resulting changes that have been made in the final rule. The final rule contains only two minor changes from the text of the proposed rule. The first is a modification of the date in the definition of ''valid existing rights'' to reflect the different dates that the Smith Wild and Scenic River, the Siskiyou Wilderness, and the SRNRA were established. Because federal lands within these three areas were withdrawn from the operation of the mining and mineral leasing laws at different times, the dates by which valid existing rights must be established are different. The second change corrects an improper citation to 36 CFR 228.5(a) in § 292.63(d). Both of these changes are addressed in more detail in the section-by-section analysis that follows.

No comments were received on § 292.60—Purpose and Scope, § 292.65—Operating Plan Requirements, § 292.66—Operating Plan Acceptance, and § 292.67—Mineral Material Operations. Consequently, the final rule adopts the text of these sections as proposed, and they are not discussed further in this analysis.

Section 292.61. Definitions

The proposed rule defined certain terms that are either not defined in 36 CFR part 228, subpart A, or have special meaning as used in this rule.

Comment: The ''operating plan'' definition is erroneously applied. One reviewer contended that the definition of ''operating plan'' was erroneously confined to the exercise of outstanding mineral rights.

Response: The term ''operating plan,'' as defined in this section is used only in those portions of the rule dealing with outstanding mineral rights (§§ 292.65 and 292.66 and portions of § 292.68). The term ''plan of operations'' is used only in those portions of the rule dealing with operations on claims where valid existing rights have been established (§§ 292.62, 292.63, and 292.64 and portions of § 292.68). These two terms were purposely used in the proposed rule to differentiate operations on mining claims with valid existing rights from operations on lands with outstanding mineral rights. Moreover, the use of the terms ''operating plan'' and ''plan of operations'' in the proposed rule is consistent with the terminology in the agency's mining regulations at 36 CFR part 228, subpart A, and in the agency's directive system. Accordingly, no changes have been made in the final rule in response to this comment.

Comment: The Forest Service is without authority to alter the General Mining Laws in defining valid existing rights. One reviewer agreed with the definition of valid existing rights to the extent that it merely requires that the claimant have had a valid mining claim pursuant to the General Mining Laws as of the date of passage of the Act and has not abandoned it or otherwise failed to make appropriate filings and pay the annual maintenance fees. The reviewer objected, however, to other aspects of the definition which the reviewer alleged would alter the General Mining Laws. In particular, the reviewer contended that paragraph (4) of the definition of ''valid existing rights'' in the proposed rule which required continuity of the valuable mineral deposit even after the date of withdrawal is impermissible under the General Mining Laws.

This reviewer recommended that the definition of ''valid existing rights'' be revised and confined to the ''technical aspects'' of maintaining a claim's validity following the withdrawal of the SRNRA. This reviewer felt that the definition should not include within its scope any evaluation of the claim with respect to discovery of a valuable mineral as of the date of determination of valid existing rights.

Response: As an initial matter, it should be noted that there is no definition of ''valid existing rights'' in the General Mining Laws. The definition of ''valid existing rights'' (to the extent one exists), is largely the product of judicial and administrative interpretations of the General Mining Laws. The definition of ''valid existing rights'' in this rule is fully consistent with the General Mining Laws, relevant case law, and administrative interpretations. These authorities have long held that in order to establish valid existing rights, a mining claim must include the discovery and location of a valuable mineral deposit at the time of a withdrawal. In addition, these authorities have also held that in order to retain valid existing rights, an operator must comply with certain filing requirements, pay nominal fees, and the mineral deposit must remain valuable. The exhaustion of a mineral deposit or loss of its marketability may lead to a finding that the operator no longer possesses valid existing rights. Since the Act withdraws all federal lands from the operation of the general mining laws subject to valid existing rights, it is not within the agency's discretion to authorize mineral operations within the SRNRA if the operator can no longer prove that he or she possesses valid existing rights.

Comment: The date by which valid existing rights must be established for claims in the Siskiyou Wilderness and wild segments of the Smith Wild and Scenic Rivers is different from the date by which valid existing rights must be established for claims in the rest of the SRNRA.

Response: The proposed rule's definition of ''valid existing rights'' required operators to establish a valid mining claim in the SRNRA as of November 16, 1990. This is the date on which (1) The Act became law and (2) the federal land within the SRNRA was withdrawn from the operation of the mining and mineral leasing laws. The respondent is correct that this date is not accurate when applied to claims in wild segments of the Smith Wild and Scenic River and the Siskiyou Wilderness.

In considering this comment, the Department recognized that the proposed rule failed to take into account that some of the federal land within the SRNRA was withdrawn from the operation of the mining and mineral leasing laws prior to the enactment of the Act and that the establishment of valid existing rights varies depending on the date that the land was withdrawn. Both the Smith Wild and Scenic River (including the Middle Fork, North Fork, and South Fork and tributaries thereto) and the Siskiyou Wilderness are located within the SRNRA, but their designations predate the designation of the SRNRA. The Smith Wild and Scenic River was designated on January 19, 1981 and the Siskiyou Wilderness was designated on September 28, 1984. At the time of these designations, federal lands within wild segments of the Smith Wild and Scenic River and the Siskiyou Wilderness were withdrawn from the operation of the mining and mineral leasing laws. Consequently, in order to establish valid existing rights in wild segments of the Smith Wild and Scenic River or the Siskiyou Wilderness, the operator must demonstrate that there was a valid claim at the time of the designation of these areas, not at the time of the designation of the SRNRA.

One final point of clarification regarding the Siskiyou Wilderness is necessary. Though originally established on September 28, 1984, the Act added the Gasquet-Orleans Corridor to the Siskiyou Wilderness on November 16, 1990. Consequently, in order to determine whether valid existing rights have been established within the Gasquet-Orleans Corridor of the Siskiyou Wilderness, the operative date remains November 16, 1990.

In the final rule, the definition has been modified to reflect that the dates by which valid existing rights must be established for claims in the SRNRA will vary depending on where the claim is located. For claims on wild segments of the Smith Wild and Scenic River, valid existing rights must be established as of January 19, 1981. For claims in the Siskiyou Wilderness (minus the Gasquet-Orleans Corridor addition), valid existing rights must be established as of September 28, 1984. Finally, for claims in the rest of the SRNRA including, but not limited to, ''scenic'' and ''recreational'' segments of the Smith Wild and Scenic River and the Gasquet-Orleans Corridor addition to the Siskiyou Wilderness, the final rule makes clear that valid existing rights must be established as of November 16, 1990.

Section 292.62, Plan of Operations Supplementary Requirements

The proposed rule specified when a plan of operations is required for activities within the SRNRA and included suction dredge operations. Paragraph (b) of this proposed section would require as part of the plan of operations information necessary to evaluate the operator's claim of valid

existing rights and information necessary to evaluate the impacts of the proposed mining operation on SRNRA resources and determine the appropriate standards to mitigate and reclaim the affected areas.

Comment: Additional regulations and plans of operations should not be required for suction dredging. One reviewer contends that subsurface suction dredging should not be subject to these regulations or require the preparation of a plan of operations, as the activity is already well regulated and even benefits the SRNRA.

Response: Locatable mineral operations on National Forest System lands are primarily governed by the current locatable mineral regulations at 36 CFR part 228, subpart A. For the 1995 operating season, two plans of operations for suction dredging in the SRNRA were received, and both were approved. In the past, suction dredging operations in the SRNRA have been authorized by plans of operations, notices of intent, and, occasionally, without any written authorization at all. As noted previously, in establishing the SRNRA, Congress specified that all mineral operations, including suction dredging, are prohibited subject to valid existing rights. Further, even in those instances where an operator establishes valid dredging rights, the mineral operations would still be subject to regulation to ensure that the values for which the SRNRA was established were protected and enhanced.

By requiring a plan of operations for suction dredging activities, the Forest Service can accomplish two objectives. First, the Forest Service can verify that the operator engaging in the suction dredging operations possesses valid existing rights. Second, the Forest Service can ensure that the impacts of the suction dredging operations are minimized to the extent practicable in order to protect and preserve the values for which the SRNRA was established. The Department believes that in order to protect the unique fishery and other resource values of the SRNRA, careful and considered evaluation of all suction dredging activities is necessary. The best mechanism by which such evaluation can occur is through a plan of operations. Therefore, no changes were made in the final rule to exempt suction dredging activities from the purview of the plan of operations requirements.

Section 292.63, Plan of Operations Approval

Upon the submission of a plan of operations in accordance with § 292.62, this section of the proposed rule first directed the authorized officer to review it to determine whether the operator has established valid existing rights. If valid existing rights have not been established or if the plan of operations contains insufficient information in this regard, the proposed rule directed the authorized officer to notify the operator and request further information to assist in the determination. If valid existing rights are established, the proposed rule directed the authorized officer to so notify the operator and commence reviewing the operational aspects of the proposed mineral development activity in accordance with 36 CFR 228.5. If these requirements are met, this provision would authorize the approval of the plan of operations for a term not to exceed five years. The proposed rule also authorized the modification of approved plans of operations to take into account resource impacts or mineral development activities that were not contemplated in the original plan.

Comment: Requiring claim holders to prove their claims may deprive individuals of property rights guaranteed under the 1872 Mining Law. One reviewer asserted that the proposed rule's requirement that a claim holder prove that a valuable mineral is present in sufficient quantity gives the Forest Service too much discretion and could lead to the elimination of individual property rights guaranteed in the Mining Law of 1872.

Response: In order to establish valid existing rights under the General Mining Law of 1872, a claimant must: (1) discover a valuable deposit of a locatable mineral on lands open to the operation of the mining laws; (2) locate a claim on the valuable deposit; (3) monument the claim as required by state law; (4) do annual assessment work or pay holding fees; and (5) file various documents with the Bureau of Land Management. Furthermore, once established, the claimant has a continuing obligation to maintain the claim and discovery of a valuable mineral deposit in order to preserve its valid existing rights status.

The system devised under the 1872 Mining Law for establishing valid existing rights only applies if the federal land is open to mineral entry. When Congress enacts legislation that withdraws federal land from the operation of the mining laws, the valid existing rights that have been established as of the date of withdrawal in accordance with the above are generally protected providing that the mineral deposit remains valuable. However, if valid existing rights have not been established by this time, they may not be established thereafter.

Federal land in the SRNRA has been withdrawn from the operation of the mining laws on three separate occasions. The first occurred on January 19, 1981 when the Smith Wild and Scenic River was designated. The second occurred on September 28, 1984, when the Siskiyou Wilderness was designated. The third occurred on November 16, 1990, when the SRNRA was established.

The provision of the proposed rule at issue here simply requires that a claimant submit information which will enable the Forest Service to verify whether valid existing rights were established prior to the date of the withdrawal of federal land and, if so, whether claimant has maintained the claim and discovery of a valuable mineral deposit. In those instances where valid existing rights have been established, the Forest Service will authorize the associated development activities in accordance with these and other applicable regulations. At present, the agency would contemplate acquiring an operator's valid existing rights only if the proposed mineral development activities could not be conducted without unacceptable impacts to fishery and other resources for which the SRNRA was established.

It should be noted, that if valid existing rights have not been established an accordance with federal law, the Forest Service is legally obligated to prohibit further mineral development activities associated with these claims.

The process set forth in the proposed rule to evaluate the information regarding valid existing rights does not vest the agency with unbridled discretion to eliminate valid existing rights if the evidence provided confirms that valid existing rights have been established. Forest Service certified mineral examiners conduct field reviews and analyze information to form conclusions on the evidence of valid existing rights; their reports are reviewed by certified review examiners. Consequently, no change was made in the final rule in response to this comment.

Comment: There is a conflict of interest if the Forest Service goal is to eliminate mining, and the authorized officer has authority to determine validity of claims. One reviewer stated that if the goal of the Forest Service is to eliminate mining in the SRNRA, the Forest Service authorized officer would have a conflict of interest making valid existing rights determinations for mining claims located within the SRNRA.

Response: The goal of the Department in promulgating this rule is not to eliminate mining in the SRNRA. The goal of the Department in promulgating this rule is to comply with the Act and to allow the Forest Service to administer the SRNRA in a manner consistent with the purposes for which it was established. In making valid existing rights determinations, the agency strives to establish a system which provides for prompt, efficient, and accurate determinations. No conflict of interest implications are presented by this rule.

Comment: The rule should authorize the agency to modify a plan of operations. One reviewer felt that the proposed rule should expressly state that the Forest Service can initiate modification of a plan of operations, even though such authority exists in the agency's current regulations at 36 CFR part 228, subpart A.

Response: The proposed rule, at 36 CFR 292.60(c), specifically provided that other regulations applicable to the administration of National Forest System lands would continue to apply to the SRNRA, unless there was a conflict between them. Current rules at 36 CFR 228.4(e) authorize the Forest Service to request an operator to furnish a proposed modification of the plan of operations that addresses ways of minimizing a significant disturbance of surface resources not anticipated or foreseen when the plan of operations was originally approved. Nothing in the proposed rule conflicts with this provision; consequently, it remains in force and is applicable in the SRNRA. Therefore, there is no need to restate that the agency can initiate modification of a plan of operations in this rule.

Comment: The rule should include set timeframes for an initial response to an operator's submission of a plan of operations. One reviewer felt that the rule should include a provision requiring the agency to notify an operator within 30 days as to the completeness of the information provided on valid existing rights. This reviewer also encouraged the Forest Service to adopt a provision requiring immediate acknowledgement of receipt of a plan of operations.

Response: It would be inappropriate to include a provision in the rule requiring the agency to notify the operator within thirty days as to whether all the necessary information to evaluate a plan of operations has been submitted. The time necessary to review the information for completeness depends on several factors including, but not limited to, the amount of information to review in the plan of operations, other plans of operations already scheduled for review, the time of year when the plan of operations is received, and the availability of Forest Service certified mineral examiners to conduct the reviews.

Since 1991, the Six Rivers National Forest has established priorities for scheduling the review of proposed operations for valid existing rights as follows: (1) highest priority cases with unauthorized residential occupancy; (2) proposed activities on claims with known potential for significant resource disturbance; (3) proposed activities within the Siskiyou Wilderness and ''wild'' portions of designated Wild and Scenic Rivers; (4) proposed activities within the Middle Fork/Highway 199 Management Area; and (5) all other proposed activities. Once a mineral examination is scheduled in accordance with the above, its priority is not changed.

It is difficult and unrealistic to establish rigid timeframes for notifying operators of the completeness of the information submitted in their plan of operations due to the relatively short season during which field examinations may be conducted. For example, suction dredge field work must be done during the season prescribed by the California Department of Fish and Game.

In summary, due to current workload, weather, and other circumstances beyond the control of the agency, the time required for reviewing plans of operations for completeness, and the limited staff and budget to conduct mineral examinations, it is impracticable to establish a rigid deadline in this rule for notifying operators as to whether the information contained in their plans of operations regarding valid existing rights is complete.

The Forest Service also believes that it is unnecessary to include a specific provision in this rule requiring the agency to acknowledge receipt of a plan of operations submitted for review. If an operator believes that acknowledgment of receipt of a plan of operations is important, he or she may send it via registered or certified mail, return receipt requested.

Comment: Time limitations from 36 CFR 228.5 for reviewing a plan of operations should be expressly incorporated into the rule. One reviewer contended that the proposed rule eliminated the time limitations set forth in 36 CFR 228.5 for reviewing plans of operations. This reviewer requested that the rule be modified to specifically incorporate the timeframes in 36 CFR 228.5 for reviewing a plan of operations once the valid existing rights determination is complete.

Response: The Department disagrees with this reviewer. The proposed rule at § 292.60 made clear that plans of operations in the SRNRA are subject to 36 CFR part 228, subpart A, unless specifically exempted by these regulations. While the agency will make every effort to process plans of operations as expeditiously as possible, the Department has made no changes to the text of this section in the final rule.

Comment: The Forest Service authorized officer lacks the legal authority to make binding determinations regarding valid existing rights. On reviewer contends that the Forest Service has exceeded its authority under the General Mining Laws by including a provision in the proposed rule which arrogates unto itself the authority to make ''binding determination as to whether the operator has a valid mining claim.'' The reviewer states that this authority resides only in the Secretary of the Interior pursuant to the General Mining Laws.

Response: The Department of the Interior has primary jurisdiction to determine the validity of mining claims on public lands. However, the Forest Service need not await the outcome of a validity determination by the Secretary of the Interior in cases where an individual asserts a mining claim on National Forest System lands in bad faith. In such cases, the Forest Service may eject the individual as a trespasser in conformance with its authority under the Organic Act and other statutes which require the agency to regulate the occupancy and use of National Forest System lands to prevent their destruction.

Since 1957, the Forest Service has been conducting validity determinations involving mining claims on National Forest System lands in accordance with a Memorandum of Understanding (1957 MOU) with the Bureau of Land Management. Under the 1957 MOU, where mining claims involve National Forest System lands, the Forest Service conducts field examinations, writes reports, and makes determinations on valid existing rights. Forest Service validity determinations may be reviewed by the Department of the Interior which is the final administrative arbiter of the dispute.

The proposed rule did not claim to vest the Forest Service with the authority to make ''binding'' validity determinations involving mining claims in the SRNRA. Rather, this rule is consistent with the current agency practice elsewhere throughout the National Forest System in conformance with the 1957 MOU. With the exception

of mining claims that are asserted in bad faith, validity determinations by the Forest Service may be reviewed by the Department of the Interior as the final administrative arbiter of the dispute. Therefore, no change has been made to the text of the final rule as a result of this comment.

Comment: The rule should include provisions requiring prompt notification to the operator of Forest Service determinations of insufficient evidence of valid existing rights and the agency's recommendation of contest action. One reviewer felt that if the authorized officer determines that valid existing rights have not been established, the rule should specifically require the Forest Service to immediately request BLM to initiate a contest action and to notify the operator of this request.

Response: The proposed rule contained a provision requiring the authorized officer to notify the operator in writing if, upon review of the information submitted as part of the plan of operations, insufficient evidence of valid existing rights was presented. Since mining operations can only take place in the SRNRA if valid existing rights have been established, it would be incumbent upon the Forest Service to forward its findings and determination to the Bureau of Land Management with a recommendation for contest action if the operator persisted with plans to conduct mineral operations in the SRNRA. Obviously, contest actions would be unnecessary if the operator decides not to go forward with any mineral operations and abandons his or her claim(s) following the Forest Service's determination.

The Department believes that the Forest Service's standard procedures already provide for prompt request for contest action and timely notice to the operator of same sought by this reviewer and, hence, no change has been made in the final rule.

Comment: Potential for ''double jeopardy'' on proof of valid existing rights. One reviewer felt that the proposed rule would give the Forest Service ''two bites at the apple'' to challenge an operator's claim of valid existing rights. The reviewer believed that this would increase the operator's administrative burden to prove valid existing rights and would also be an inefficient use of Forest Service resources.

Response: The purpose of this provision is not to give the Forest Service ''two bites at the apple'' or to increase the time and expense associated with establishing valid existing rights. Rather, the purpose of this section is to ensure that the operator still possesses valid existing rights after the passage of time. As noted earlier in response to a comment about the continuity requirement in the definition of ''valid existing rights,'' an operator must be able to demonstrate not only that valid existing rights were established as of the date of the withdrawal of the federal land on which the claim is located, but he or she must also be able to prove that the valid existing rights were maintained continuously thereafter. This means, among other things, that the marketability of the minerals that are the subject of the claim must persist.

Several examples of when the Forest Service might conduct another determination of an operator's claim of valid existing rights may be illustrative.

When a Forest Service certified mineral examiner concludes that a claim contains discovery of a valuable mineral deposit, resulting in a finding that there is sufficient evidence of valid existing rights to process a plan of operations, and operations are approved, the approved operations should result in extraction of the valuable mineral deposit constituting the discovery. Upon the exhaustion of the valuable mineral deposit, there will no longer be sufficient evidence of valid existing rights to support a claim, and the claim holder would be expected to abandon or relinquish the claim. Should the holder not abandon or relinquish the claim, the Forest Service could challenge it and obtain a determination that the operator no longer possess valid existing rights.

Another situation that merits a second valid existing rights determination might occur when an operator fails to conduct or complete the mineral operations as described in a previously approved plan of operations and desires to reinitiate the mining activity. If the originally approved plan of operations has expired or is obsolete, the operator must be able to provide sufficient evidence of valid existing rights from the date of withdrawal and continuously thereafter to the date of determination related to the new proposal. In this situation, there would have been sufficient evidence of valid existing rights from the date of withdrawal to the date of the first valid existing rights determination, but the operator would need to provide additional evidence that there was a valuable mineral deposit from the first determination continuously to the present time. The term ''continuously'' within the context of these regulations means taking into consideration the relevant historic range of market prices and costs as well as the likelihood of their continuation or change.

The Forest Service has an obligation under the Act to ensure that development only occurs on claims with valid existing rights. Since a claim with valid existing rights at one point in time may not continue to have valid existing rights, it may be necessary for the claim holder to prove that valid existing rights have been established on more than one occasion since the date of withdrawal.

Comment: There is an improper reference to 36 CFR § 228.5(b). One reviewer noted that the reference to 36 CFR 228.5(b) in § 292.63(d) of the proposed rule should have been to 36 CFR 228.5(a).

Response: The reviewer is correct, and this citation has been corrected in the final rule.

Comment: Duration of plans of operations is not appropriate. Two reviewers noted that five years is too short a duration for a plan of operations and that the maximum term for such a plan should be 25 years. Their arguments in favor of a longer term are: (1) The high cost associated with preparing multiple short term plans of operation compared to preparing one long term plan; (2) the inefficient use of agency resources that would be required to review new plans of operation at five year intervals; and (3) the potentially adverse effects on the operator's financing arrangements.

In contrast to these views, one reviewer interpreted this provision of the proposed rule as providing for continual cooperative discussions between the operator and the Forest Service following the development and approval of plan of operations. This individual suggested the inclusion of a provision requiring reevaluations every five years for plans of operation approved for more than five years.

Response: The Forest Service is disinclined to approve plans of operations in the SRNRA for more than five years. The agency's current mining regulations require that a plan of operations be prepared for the entire life of the proposed mining operation, except for aspects of the operation that are unknown at the time the plan is prepared. Even in these cases, the mining regulations require the operator to describe in the plan the operations that are reasonably foreseeable at that time and to supplement or modify the plan if these operations are changed.

This rule does not change that requirement. Plans of operations for mineral development activities in the SRNRA should describe all the proposed operations throughout the

projected life of the mine. The only difference between this rule and the agency's current mining regulations concerns the duration for which the plans of operations may be approved. Under this rule, even though the plan of operations describes the entire mining operation which in some cases will exceed five years, the approval will only be valid for a 5-year period. Under the current mining regulations, the plan of operations may be approved for the full duration of the proposed operation.

The Department believes that assessing the effects of proposed mining operations in the SRNRA and prescribing appropriate mitigation over the entire projected life of the mine would be difficult in light of the dynamic environment of the SRNRA and the significant and fragile resource values for which the area was designated. The agency agrees that even after a plan of operations is approved, cooperative discussions between the Forest Service and the operator will be necessary to monitor ongoing impacts of the mining operation on SRNRA resource values and whether further adjustments in those operations are necessary.

The Department believes that it is appropriate and in the public interest to limit the approval period for plans of operations in the SRNRA to not more than five years. An operator may choose whether to submit a new plan of operations for each successive 5 year term or simply to resubmit the original plan with appropriate modifications. While the duration of approval of the plan of operations is not changed from that proposed, the text of § 292.63(e) in the final rule makes clear that the 5-year approval is different than the length of approval that may be granted under 36 CFR 228.5. No change was made in the final rule as a result of this comment.

Section 292.64—Plan of Operations Suspension

This section of the proposed rule would authorize the Forest Service to direct an operator to suspend mineral development activities even if a plan of operations has been approved. The proposed rule authorizes the Forest Service to suspend an operator's mineral operations if they are being conducted in violation of applicable law, regulation, or the terms and conditions of the operator's approved plan of operations. Except in cases in which the violations present an imminent threat of harm to public health, safety, or the environment, the Forest Service must notify the operator not less than thirty days in advance of the suspension. The thirty day notice should, in most instances, give the operator sufficient time to cure the violations prior to the suspension taking effect. In cases where mineral operations present an imminent threat of harm to public health, safety, or the environment (or where such harm is already occurring) regardless of whether the operator is in violation of applicable laws, regulations, or the terms and conditions of the plan of operations, the Forest Service is authorized to take immediate action to suspend the mineral development activity. In these cases, the rule directs the Forest Service to notify the operator of the suspension as soon as is reasonably practicable thereafter.

Comment: Suspension of a plan of operations without prior notice to the operator is a denial of due process. One reviewer felt that the suspension of a plan of operations without notice to the operator is a violation of constitutional requirements of due process.

Response: The proposed rule describes two scenarios under which the suspension of mineral operations may occur. The first scenario deals with mineral operations that are not being conducted in accordance with the applicable laws, regulations, or the approved plan of operations but do not present an immediate threat to public health, safety, or the environment. In these cases, the proposed rule specifically provides that the authorized officer will notify the operator not less than 30 days prior to the suspension during which time the operator may modify the operations and thus avoid the suspension. The second scenario deals with mineral operations that pose a ''threat of imminent harm to public health, safety, or the environment.'' In these cases, the proposed rule authorizes immediate suspension of operations but requires that the operator be notified of the basis for the suspension ''as soon as reasonably practicable following the suspension.''

The Supreme Court has held that the type of due process required under the Constitution varies depending upon the private interest affected by the government action, the risk of an erroneous deprivation of the private interest by the government action, and the Government's interest (including the functions involved and the fiscal and administrative burdens) that additional or substitute procedural requirements would entail. While the Supreme Court has maintained that due process must afford individuals an opportunity to be heard ''at a meaningful time and in a meaningful manner,'' it has not required that such opportunities must necessarily occur prior to the challenged government action in order to be constitutional. Indeed, there have been numerous cases in which the court has upheld procedures that offer an individual after-the-fact opportunities to challenge government actions against due process challenges. These procedures have been routinely upheld in contexts where government actions have been taken to abate an immediate threat to public health, safety, and welfare.

The only situation described in the proposed rule when ex post notice of a suspension would be provided is when a clear and present threat to public health, safety and welfare is presented. This is not a violation of constitutional standards of due process. Therefore, no changes have been made to the text of the final rule based on this comment.

Section 292.68, Indemnification

The proposed rule specified that the owners and/or operators of mining claims and the owners and/or lessees of outstanding mineral rights would be liable for the following: (1) indemnifying the United States for injury, loss, or damage which the United States incurs as a result of any mining operation in the SRNRA; (2) payments made by the United States in satisfaction of claims, demands or judgments for such injury, loss, or damage; and (3) costs incurred by the United States for any action resulting from noncompliance with an approved plan of operations or activities outside a mutually agreed to operating plan.

Comments: The indemnification provision is vague and of questionable legal authority. In addition to suggesting that this section was vague and potentially over inclusive, one reviewer requested the agency to specify the authority under which it may seek indemnification from operators to recover costs associated with, among other things, injury, loss, or damage to National Forest System lands and resources resulting from mineral operations in the SRNRA. This reviewer concluded that since this is a new provision for the SRNRA, there must be new statutory authority or a recent change in the law from which it is derived. If no such new authority exists, the reviewer argued that this provision must be deleted.

Response: The authority for the indemnification provision in the supplementary regulations for mining in the SRNRA is derived from the Organic Administration Act of 1897, 16 U.S.C. 551, which states in relevant part that,

> The Secretary of Agriculture shall make provisions for the protection against destruction by fire and depredations upon

the public forests and national forests which may have been set aside or which may hereafter be set aside * * * and he may make such rules and regulations and establish such service as will insure the objects of such reservations, namely, to regulate their occupancy and use and to preserve the forests thereon from destruction * * *

The reviewer's presumption that the Forest Service must be able to point to a recent change in the law to support the inclusion of an indemnification provision in this rule because it is ''new and unique'' in the SRNRA is unfounded. The authority has always existed, at least since the enactment of the Organic Administration Act in 1897. Similar indemnification provisions are incorporated into several other written instruments which authorize the use of National Forest System lands. For example, special use authorizations for outfitters and guides and ski area operators and the consent authorization for oil and gas lease operators and lessees contain indemnification provisions.

The Department does not find the indemnification provision unconstitutionally vague or overly inclusive. In *Village of Hoffman Estates* v. *The Flipside, Hoffman Estates, Inc.*, 455 U.S. 489 (1982), the Supreme Court enumerated a number of factors which affect the degree of vagueness which the Constitution tolerates. For example, a less strict vagueness test will apply if a regulation is economic in nature, does not contain criminal sanctions, and does not implicate constitutionally protected rights. In *United States* v. *Doremus*, 888 F.2d 630 (9th Cir. 1989), the United States Ninth Circuit Court of Appeals rejected a vagueness challenge to a Forest Service regulation prohibiting certain types of conduct related to mining activities on National Forest System lands.

This rule meets all the factors required by the Supreme Court ruling. However, it does not invoke criminal sanctions and does not affect constitutionally protected rights. The Department believes that the 9th Circuit's reasoning in *Doremus* is also instructive and relevant and that this rule would withstand a vagueness challenge under that ruling as well. Consequently, there have been no changes made to the text of the final rule based on this comment.

Regulatory Impact

This final rule has been reviewed under USDA procedures and Executive Order 12866 on Regulatory Planning and Review. It has been determined that this regulation is not a significant rule. This rule will not have an annual effect of $100 million or more on the economy and will not adversely affect productivity, competition, jobs, the environment, public health and safety, or State and local governments. This rule will not interfere with an action taken or planned by another agency nor raise new legal or policy issues. Finally, this action will not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs. In short, little or no effect on the National economy will result from this rule, since it affects only mining activities on National Forest System lands in the SRNRA. Accordingly, this final rule is not subject to OMB review under Executive Order 12866.

Moreover, this final rule has been considered in light of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et. seq.*), and it has been determined that this action will not have a significant economic impact on a substantial number of small entities as defined by the RFA because of its limited scope and application. Also, this proposed rule does not adversely affect competition, employment, investment, productivity, innovation, or the ability of United States based enterprises to compete in local or foreign markets.

Environmental Impact

After an initial conclusion that the proposed rule was categorically excluded from documentation in an environmental assessment (EA) or impact statement, it was determined that the Forest Service should prepare an EA. A copy of the EA and the Finding of No Significant Impact are available upon request by calling the contact listed earlier in this rulemaking under **FOR FURTHER INFORMATION CONTACT.**

Controlling Paperwork Burdens on the Public

In the proposed rule, the agency requested comment on two new information requirements. Proposed § 292.62(b) specified that in addition to the requirements of § 228.4, an operator must provide information to substantiate valid existing rights as part of a plan of operations. Proposed § 292.65(b) required those who wish to exercise outstanding mineral rights to submit an operating plan. Only one person commented on the first collection; no comments were received on the second collection. The one respondent said that the requirement for information supporting valid existing rights would be burdensome to the claim holder or operator. As stated in the preceding indepth response to this comment, the agency does not consider this information collection burdensome since most of the required information has been generated already by the claim holder or operator. The agency needs this information for verification of valid existing rights in order to authorize use, as required under the Smith River National Recreation Area Act of 1990 (16 U.S.C. 460bbb *et seq.*). Therefore, no changes were made in the final rule based on the comment regarding information requirements.

This information collection has been reviewed by the Office of Management and Budget according to the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and implementing regulations at 5 CFR part 1320. The information requirements in this rule have been assigned control number 0596–0138 for use through September 30, 1998.

No Takings Implications

In compliance with Executive Order 12630 and the Attorney General's Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings, the takings implication of this proposed rule have been reviewed and considered. It has been determined that there is no risk of a taking.

Civil Justice Reform Act

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. Upon adoption of this rule, (1) all State and local laws and regulations that are in conflict with this proposed rule or which would impede its full implementation would be preempted; (2) no retroactive effect would be given to this proposed rule and; (3) it would not require administrative proceedings before parties would file suit in court challenging its provisions.

List of Subjects in 36 CFR Part 292

Administrative practice and procedure, Environmental protection, Mineral resources, National forests, and National recreation areas.

Therefore, for the reasons set forth in the preamble, Part 292 of Chapter II of title 36 of the Code of Federal Regulations is amended by adding a new Subpart G to read as follows:

PART 292—NATIONAL RECREATION AREAS

Subpart G—Smith River National Recreation Area

Sec.

Subpart G—Smith River National Recreation Area

Authority: 16 U.S.C. 460bbb *et seq.*

§ 292.60 Purpose and scope.

(a) *Purpose.* The regulations of this subpart set forth the rules and procedures by which the Forest Service regulates mineral operations on National Forest System lands within the Smith River National Recreation Area as established by Congress in the Smith River National Recreation Area Act of 1990 (16 U.S.C. 460bbb *et seq.*).

(b) *Scope.* The rules of this subpart apply only to mineral operations on National Forest System lands within the Smith River National Recreation Area.

(c) *Applicability of other rules.* The rules of this subpart supplement existing Forest Service regulations concerning the review, approval, and administration of mineral operations on National Forest System lands including, but not limited to, those set forth at parts 228, 251, and 261 of this chapter.

(d) *Conflicts.* In the event of conflict or inconsistency between the rules of this subpart and other parts of this chapter, the rules of this subpart take precedence, to the extent allowable by law.

(e) *Applicability to ongoing operations.* Operations under an acceptable operating plan or an approved plan of operations in effect prior to the effective date of these regulations shall be for a limited time not to exceed 5 years. If ongoing operations have a shorter specified operating time, the shorter operating time shall remain in effect.

§ 292.61 Definitions.

The special terms used in this subpart have the following meaning:

Act means the Smith River National Recreation Area Act of 1990 (16 U.S.C. 460bbb *et seq.*)

Authorized officer means the Forest Service officer to whom authority has been delegated to take actions pursuant to the provisions of this subpart.

Hazardous substance means any substance so classified under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9601).

Operating plan means the document submitted in writing by the owner or lessee, or a representative acting on behalf of an owner or lessee, to exercise outstanding mineral rights for minerals underlying National Forest System lands.

Outstanding mineral rights means the rights owned by a party other than the surface owner at the time the surface was conveyed to the United States.

SRNRA is the abbreviation for the Smith River National Recreation Area, located within the Six Rivers National Forest, California.

Valid existing rights means mining claims on National Forest System lands in the SRNRA excluding the Siskiyou Wilderness (except for the Gasquet-Orleans Corridor addition) and wild segments of the Smith Wild and Scenic River (including the Middle Fork, North Fork, and South Fork and tributaries thereto) which: (1) were properly located prior to November 16, 1990, for a mineral that was locatable at that time; (2) were properly maintained thereafter under the applicable law; (3) were supported by a discovery of a valuable mineral deposit within the meaning of the general mining law prior to November 16, 1990, which discovery has been continuously maintained since that date; and (4) continue to be valid. For mining claims in the Siskiyou Wilderness (except for the Gasquet-Orleans Corridor addition), the location and discovery must have occurred prior to September 26, 1984. For mining claims in wild segments of the Smith Wild and Scenic River, the location and discovery must have occurred prior to January 19, 1981.

Valid Existing Rights

§ 292.62 Plan of operations—supplementary requirements.

(a) *Applicability*. In addition to the activities for which a plan of operations is required under § 228.4 of this part, a plan of operations is required when a proposed operation within the SRNRA involves mechanical or mechanized equipment, including a suction dredge and sluice.

(b) *Information to support valid existing rights*. A plan of operations within the SRNRA must include at least the following information relevant to the existence of valid existing rights from the date the affected area of land was withdrawn from mineral entry to the present:

(1) The mining claim recordation serial number assigned by the Bureau of Land Management;

(2) A copy of the original location notice and conveyance deeds, if ownership has changed since the date of location;

(3) A copy of the affidavit of assessment work or notice of intention to hold the mining claim since the date of recordation with the Bureau of Land Management;

(4) Verification by the Bureau of Land Management that the holding fees have been paid or have been exempted;

(5) Sketches or maps showing the location of past and present mineral workings on the claims and information sufficient to locate and define the mining claim corners and boundaries on the ground;

(6) For lode and placer mining claims—

(i) An identification of the valuable mineral that has been discovered;

(ii) An identification of the site within the claims where the deposit has been discovered and exposed;

(iii) Information on the quantity and quality of the deposit including copies of assays or test reports, the width, locations of veins, the size and extent of any deposit; and

(iv) Evidence of past and present sales of the valuable mineral; and

(7) For millsite claims, information proving that the millsite is associated with a valid mining claim and that the millsite is used or occupied for mining or milling purposes.

(c) *Minimum information on proposed operations.* A plan of operations must include the information required at 36 CFR 228.4 (c)(1) through (c)(3) which includes information about the proponent and a detailed description of the proposed operation. In addition, if the operator and claim owner are different, the operator must submit a copy of the authorization or agreement under which the proposed operations are to be conducted. A plan of operations must also address the environmental protection requirements of 36 CFR 228.8 which includes reclamation. In addition, when practicable, reclamation will proceed concurrently with the mineral operation.

§ 292.63 Plan of operations approval.

(a) Upon receipt of a plan of operations, the authorized officer shall review the information related to valid existing rights and notify the operator in writing that one of the following circumstances apply:

(1) That sufficient information on valid existing rights has been provided

and the date by which the Forest Service expects to complete the valid existing rights determination; or

(2) That sufficient information on valid existing rights has not been provided and the specific information that still needs to be provided.

(b) If upon receipt, review, and verification of all requested information, the authorized officer finds that there is not sufficient evidence of valid existing rights, the authorized officer shall so notify the operator in writing, provide the reasons for the determination, and advise that the proposed mineral operation cannot be conducted.

(c) If upon receipt, review, and verification of all requested information, the authorized officer finds that there is sufficient evidence of valid existing rights, the authorized officer shall so notify the operator, in writing, that a review of the proposed plan of operations is underway and the date by which the review is expected to be completed. A prior determination that there is sufficient evidence of valid existing rights shall not bar the authorized officer from requesting the Department of the Interior to file a mineral contest against a mining claim if the authorized officer has a reasonable basis to question that determination.

(d) Upon completion of the review of the plan of operations, the authorized officer shall ensure that the minimum information required by § 292.62(c) has been addressed and, pursuant to § 228.5(a) of this chapter, notify the operator in writing whether or not the plan of operations is approved.

(e) Notwithstanding the provisions of 36 CFR § 228.5, the period for which a plan of operations is approved within the SRNRA may not exceed five years and must be explicitly identified by the authorized officer in giving notice of approval of a plan of operations.

(f) If an operator desires to make substantive changes in the type, scope, or duration of mineral operations from those described in an approved plan of operations and those changes may result in resource impacts not anticipated when the original plan was approved, the operator must submit a supplemental plan or a modification for review and approval of the authorized officer pursuant to § 292.62 of this proposed rule.

§ 292.64 Plan of operations suspension.

The authorized officer may suspend mineral operations, in whole or in part, due to an operator's noncompliance with applicable statutes, regulations, or terms and conditions of the approved plan of operations. Except as otherwise provided in this section, prior to suspending operations, the authorized officer must first notify the operator in writing of the basis for the suspension and provide the operator with a reasonably sufficient time to respond to the notice of the authorized officer or to bring the mineral operations into conformance with applicable laws, regulations, or the terms and conditions of the approved plan of operations. Generally, the authorized officer shall notify the operator not less than thirty days prior to the date of the proposed suspension; however, in those cases that present a threat of imminent harm to public health, safety, or the environment, or where such harm is already occurring, the authorized officer may take immediate action to stop the threat or damage without prior notice. In such case, written notice and explanation of the action taken, shall be given the operator as soon as reasonably practicable following the suspension.

Outstanding Mineral Rights

§ 292.65 Operating plan requirements.

(a) Proposals for mineral operations involving outstanding mineral rights within the SRNRA must be documented in an operating plan and submitted in writing to the authorized officer for review at least 60 days in advance of surface occupancy.

(b) An operating plan for operations involving outstanding mineral rights within the SRNRA must include the following:

(1) The name and legal mailing address of the operator, owner, and any lessees, assigns, and designees;

(2) A copy of the deed or other legal instrument that conveyed the outstanding mineral rights;

(3) Sketches or maps showing the location of the outstanding mineral rights, the proposed area of operations, including but not limited to, existing and/or proposed roads or access routes identified for use, any new proposed road construction, and the approximate location and size of the areas to be disturbed, including existing or proposed structures, facilities, and other improvements to be used;

(4) A description of the type of operations which includes, at a minimum, a list of the type, size, location, and number of structures, facilities, and other improvements to be used;

(5) An identification of the hazardous substances and any other toxic materials, petroleum products, insecticides, pesticides, and herbicides that will be used during the mineral operation, and the means for disposing of such substances;

(6) An identification of the character and composition of the mineral wastes that will be used or generated and a method or strategy for their placement, control, isolation, or removal; and

(7) A reclamation plan to reduce or control on-site and off-site damage to natural resources resulting from mineral operations.

(i) The plan should provide, to the extent practicable, that reclamation proceed concurrently with the mineral operations and must show how public health and safety are maintained.

(ii) Reclamation measures to be identified and described in the plan include, but are not limited to, the following:

(A) Reduction and/or control of erosion, landslides, and water runoff;

(B) Rehabilitation of wildlife and fisheries habitat to be disturbed by the proposed mineral operation; and

(C) Protection of water quality.

(iii) The area of surface disturbance must be reclaimed to a condition or use that is consistent with the SRNRA Management Plan.

§ 292.66 Operating plan acceptance.

(a) Upon receipt of an operating plan, the authorized officer must review the information related to the ownership of the outstanding mineral rights and notify the operator in writing that one of the following circumstances apply:

(1) That sufficient information on ownership of the outstanding mineral rights has been provided and the date by which the review is expected to be completed; or

(2) That sufficient information on ownership of outstanding mineral rights has not been provided and the specific information that still needs to be provided.

(b) If the review shows that outstanding mineral rights have not been established, the authorized officer must notify the operator in writing of this finding, the reasons for such a finding, and that the proposed mineral operation cannot be conducted.

(c) If the review shows that outstanding mineral rights have been established, the authorized officer must notify the operator in writing of this finding, that review of the proposed operating plan is underway, and the date by which the review is expected to be completed.

(d) The authorized officer shall focus review of the operating plan to determine if all of the following criteria are met:

(1) The operating plan is consistent with the rights granted by the deed;

(2) The operating plan is consistent with the SRNRA Management Plan; and

(3) The operating plan uses only so much of the surface as is necessary for the proposed mineral operations.

(e) Upon completion of the review of the operating plan, the authorized officer shall notify the operator in writing that one of the following two circumstances apply:

(1) The operating plan meets the criteria of paragraphs (d)(1) through (d)(3) of this section, and, therefore, the Forest Service has no objections to commencement of operations and that the Forest Service intends to monitor operations to ensure that operations conform to the operating plan; or

(2) The operating plan does not meet all of the criteria in paragraphs (d)(1) through (d)(3) of this section and the reasons why the operating plan does not meet the criteria. In this event, the authorized officer shall propose changes to the operating plan and attempt to negotiate modifications that will enable the operating plan to meet the criteria in paragraphs (d)(1) through (d)(3) of this section.

(f) To conduct mineral operations beyond those described in an acceptable operating plan, the owner or lessee must submit in writing an amended operating plan to the authorized officer at the earliest practicable date. The authorized officer shall have not less than 60 days in which to review and respond to a proposed amendment before the new operations begin. The review will be conducted in accordance with paragraphs (d)(1) through (d)(3) of this section.

Mineral Materials

§ 292.67 Mineral material operations.

Subject to the provisions of part 228, subpart C and part 293 of this chapter, the authorized officer may approve contracts and permits for the sale or other disposal of mineral materials, including but not limited to, common varieties of gravel, sand, or stone. However, such contracts and permits may be approved only if the material is not within a designated wilderness area and is to be used for the construction and maintenance of roads and other facilities within the SRNRA and the four areas identified by the Act that are within the exterior boundaries of the SRNRA but are not classified as part of the SRNRA.

Indemnification

§ 292.68 Indemnification.

The owner and/or operator of mining claims and the owner and/or lessee of outstanding mineral rights are jointly and severally liable in accordance with Federal and State laws for indemnifying the United States for:

(a) Injury, loss, or damage, including fire suppression costs, which the United States incurs as a result of the mineral operations;

(b) Payments made by the United States in satisfaction of claims, demands or judgments for an injury, loss, or damage, including fire suppression costs, which result from the mineral operations; and

(c) Costs incurred by the United States for any action resulting from noncompliance with an approved plan of operations or activities outside a mutually agreed to operating plan.

Dated: March 28, 1996.

Mark Gaede,

Acting Deputy Under Secretary, Agriculture.

[FR Doc. 96–8097 Filed 4–2–96; 8:45 am]

BILLING CODE 3410–11–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN–111–1–7094a; FRL–5442–7]

Approval and Promulgation of Implementation Plans Tennessee: Revisions to Chattanooga/Hamilton County Regulations for Definitions and Ambient Air Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving revisions to the Chattanooga/Hamilton County portion of the Tennessee State Implementation Plan (SIP) submitted by the State of Tennessee through the Tennessee Department of Environment and Conservation on May 18, 1993. This submittal included revisions to the current regulations concerning definitions and ambient air quality standards for Chattanooga/Hamilton County. EPA finds that the regulations provide for consistency with the Clean Air Act as amended in 1990 (CAA) and corresponding Federal regulations.

DATES: This final rule is effective June 3, 1996 unless adverse or critical comments are received by May 3, 1996. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Written comments should be addressed to: Ms. Karen Borel, at the Regional Office Address listed below.

Copies of the material submitted by the State of Tennessee may be examined during normal business hours at the following locations:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street, NE., Atlanta, Georgia 30365.

Tennessee Division of Air Pollution Control, 9th Floor L&C Annex, 401 Church Street, Nashville, Tennessee 37243–1531.

Chattanooga-Hamilton County Air Pollution Control Bureau, 3511 Rossville Boulevard, Chattanooga, Tennessee 37407.

FOR FURTHER INFORMATION CONTACT: Interested persons wanting to examine documents relative to this action should make an appointment with the Region 4 Air Programs Branch at least 24 hours before the visiting day. To schedule the appointment or to request additional information, contact Karen C. Borel, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 EPA, 345 Courtland Street, NE, Atlanta, Georgia 30365. The telephone number is 404/347–3555 extension 4197. Reference file TN111–01–7094.

SUPPLEMENTARY INFORMATION: On May 18, 1993, the State of Tennessee submitted a formal revision to the Chattanooga/Hamilton County portion of its SIP incorporating changes to the ambient air quality standards for particulate matter and definitions. They also submitted changes to their asbestos emission standard, their hazardous air pollutants (HAP) standard and their new source performance standards (NSPS). In a letter from Mr. Doug Neeley, Chief of the Air Programs Branch in EPA Region 4, to Mr. John Walton, Director of the Division of Air Pollution Control of the Tennessee Department of Environment and Conservation, dated June 15, 1995, EPA requested that the NSPS, HAP, and asbestos related revisions be withdrawn by the State. This withdrawal was requested because the Federally enforceable National Emission Standards for Hazardous Air Pollutants (NESHAP) are contained in 40 CFR Parts 61 and 63, and the Federally enforceable NSPS are contained in 40 CFR Part 60; therefore, these are not required to be approved in the SIP. On October 3, 1995, the State of Tennessee officially withdrew their request to amend the NSPS Rule 15, the Emissions Standards for Hazardous Air

Contaminants Rule 16, and the Emission Standard for Asbestos Rule 17. Furthermore, the EPA is taking no action on the proposed revisions to Section 4–8 which address the asbestos related requirements for building demolition and renovation, in accordance with the requirements of Rule 17.

EPA is approving the following revisions. These revisions and additions are summarized in the following paragraphs. All codification references are to the City of Chattanooga's Code.

1. Section 4–2, Definitions

The following definitions have been revised.

A. Best Available Control Technology (BACT)—The revised definition specifies that BACT is applicable to emissions from any proposed major stationary source or major modification. This revised definition also allows a source to demonstrate that technological or economic limitations of the particular emissions unit would make the imposition of an emissions limitation infeasible; the source is allowed to propose an alternate method to satisfy the requirement for the application of BACT. Any proposed alternate method (design, equipment work practice, operations standard or combination thereof) should set forth the emissions reduction achievable by its implementation, and must be approved by the Director.

B. Volatile organic compound (VOC)—The definition for VOC has been revised in accordance with the definition in 40 CFR Part 52.100. The definition of a VOC as a compound of carbon with a vapor pressure greater than 0.1 millimeters of mercury at standard conditions has been replaced with the definition in 40 CFR Part 52.100(s).

2. Section 4–2, Definitions

The following definitions have been added.

A. Owner or operator of a demolition or renovation activity—this means any person who owns, leases, operates, controls, or supervises the facility being demolished or renovated or any person who owns, leases operates, controls or supervises the demolition or renovation, or both.

B. Primary Air Quality Standards: Primary ambient air quality standards define levels of air quality believed adequate, with an appropriate margin of safety, to protect public health.

C. Secondary Air Quality Standards: Secondary ambient air quality standards define levels of air quality believed adequate with an appropriate margin of safety, to protect the public welfare from any known anticipated adverse effects of the pollutant.

3. Section 4–41, Rule 21

In this rule, Chattanooga is adopting the Tennessee Air Pollution Control Regulations, Chapter 1200–3–3–.03. This consists of two tables. Table I contains the standards for Total Suspended Particulates (TSP), PM_{10}, Sulfur Dioxide, Carbon Monoxide, Ozone, Nitrogen Dioxide, and Lead. Table II is Tennessee's standards for gaseous fluorides (expressed as HF). These standards are part of the Tennessee Federally approved SIP and are acceptable for adoption into the Chattanooga/Hamilton County portion of the SIP.

4. Section 4–41, Rule 25.2(33)

The definition for VOC has been revised to bring it into accordance with the definition of VOC in 40 CFR Part 52.100. The previous definition is deleted and replaced with the definition in 40 CFR Part 52.100(s).

Final Action

EPA is approving the aforementioned revisions contained in the State's May 18, 1993, submittal. EPA is also approving these same revisions in the Hamilton County Code and the city/town codes of the remaining municipalities in Hamilton County (Soddy-Daisy, Ridgeside, Signal Mountain, Walden, Lookout Mountain, East Ridge, Red Bank, Collegedale, and Lakesite). However, EPA has not reviewed the substance of the regulations for Hamilton County or the other nine municipalities. These rules were submitted as being essentially the same as the City of Chattanooga's regulations. The EPA's approval of these additional ordinances for the County and the remaining nine municipalities does not imply any position with respect to the approvability of the substantive rules. To the extent EPA has issued any SIP calls to the State with respect to the adequacy of any of the rules subject to this submittal, EPA will continue to require the State to correct any such rule deficiencies despite EPA's approval.

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this Federal Register publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective June 3, 1996 unless adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the separate proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective June 3, 1996.

Under section 307(b)(1) of the Act, 42 U.S.C. 7607 (b)(1), petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 3, 1996. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2) of the Act, 42 U.S.C. 7607 (b)(2).)

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995, memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

Nothing in this action shall be construed as permitting or allowing or establishing a precedent for any future request for a revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities

with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. section 7410(a)(2) and 7410(k)(3).

Unfunded Mandates

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local, or tribal governments in the aggregate.

Through submission of this state implementation plan or plan revision, the State and any affected local or tribal governments have elected to adopt the program provided for under the Clean Air Act. These rules may bind State, local and tribal governments to perform certain actions and also require the private sector to perform certain duties. To the extent that the rules being approved by this action will impose no new requirements; such sources are already subject to these regulations under State law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action. EPA has also determined that this final action does not include a mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate or to the private sector.

List of Subjects in 40 CFR Part 52

Environmental Protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: February 15, 1996.

Phyllis P. Harris,

Acting Regional Administrator.

Part 52 of chapter I, title 40, *Code of Federal Regulations*, is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42.U.S.C. 7401–7671q.

Subpart RR—Tennessee

2. Section 52.2220, is amended by adding paragraph (c)(136) to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

(136) Revisions to the Chattanooga/Hamilton County Air Pollution Control Regulations submitted by the Tennessee Department of Environment and Conservation on May 18, 1993.

(i) Incorporation by reference.

(A) The Chattanooga City Code, Part II, Chapter 4, is revised as shown in the following paragraphs. These revisions were adopted on March 9, 1993.

(1) Section 4–2: the definitions for Best available control technology (BACT); Owner or operator of a demolition or renovation activity; Primary Air Quality Standards; and Secondary Air Quality Standards.

(2) Section 4–41: Rule 21, ''Ambient Air Quality Standards.''

(3) Section 4–41: Rule 25.2, subparagraph 33.

(B) The Hamilton County Air Pollution Control Regulation is revised as shown in the following paragraphs. These revisions were adopted on April 7, 1993.

(1) Section 16: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 9: Rule 25.2, subparagraph 33.

(3) Section 9: Rule 21, ''Ambient Air Quality Standards.''

(4) Section 25, ''Regulations cumulative.''

(C) The Soddy-Daisy Municipal Code, Title 8, *Health and Sanitation*, Chapter 1, *Air Pollution Control*, is revised as shown in the following paragraphs. These revisions were adopted on March 18, 1993.

(1) Section 8–102: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 8–141: Rule 25.2, subparagraph 21.

(3) Section 8–141: Rule 21, ''Ambient Air Quality Standards.''

(D) The Ridgeside Air Pollution Control Ordinance is revised as shown in the following paragraphs. These revisions were adopted on April 20, 1993.

(1) Section 2: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 41: Rule 25.2, subparagraph 21.

(3) Section 41: Rule 21, ''Ambient Air Quality Standards.''

(E) The Signal Mountain Air Pollution Control Ordinance is revised as shown in the following paragraphs. These revisions were adopted on March 8, 1993.

(1) Section 2: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 41: Rule 25.2, subparagraph 21.

(3) Section 41: Rule 21, ''Ambient Air Quality Standards.''

(F) The Walden Air Pollution Control Ordinance is revised as shown in the following paragraphs. These revisions were adopted on adopted March 9, 1993.

(1) Section 2: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 41: Rule 25.2, subparagraph 33.

(3) Section 41: Rule 21, ''Ambient Air Quality Standards.''

(G) The Lookout Mountain Air Pollution Control Ordinance is revised as shown in the following paragraphs. These revisions were adopted March 9, 1993.

(1) Section 2: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 41: Rule 25.2, subparagraph 21.

(3) Section 41: Rule 21, ''Ambient Air Quality Standards.''

(H) The Red Bank Municipal Code, Chapter 3, Title 8, is revised as shown in the following paragraphs. These revisions were adopted March 16, 1993.

(1) Section 8–302: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 8–341: Rule 25.2, subparagraph 21.

(3) Section 8–341: Rule 21, ''Ambient Air Quality Standards.''

(I) The Collegedale Municipal Code, Title 8, *Health and Sanitation,* Chapter 5, *Air Pollution Control,* is revised as shown in the following paragraphs. These revisions were adopted April 12, 1993.

(1) Section 8–502: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 8–541: Rule 25.2, subparagraph 33.

(3) Section 8–541: Rule 21, ''Ambient Air Quality Standards.''

(J) The Lakesite Municipal Code, Title 4, *Building, Utility, Housing and Air Pollution Control Codes,* Chapter 6, *Air Pollution Control Ordinance* is revised as shown in the following paragraphs. These revisions were adopted March 30, 1993.

(1) Section 2: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 41: Rule 25.2, subparagraph 21.

(3) Section 41: Rule 21, ''Ambient Air Quality Standards.''

(K) The East Ridge City Code, Title 8, Health and Sanitation, Chapter 7, Air Pollution Control is revised as shown in the following paragraphs. These revisions were adopted March 11, 1993.

(1) Section 8–702: the following definitions are added: Primary Air Quality Standards; Secondary Air Quality Standards; Owner or operator of a demolition or renovation activity; and Best available control technology (BACT).

(2) Section 8–741: Rule 25.2, subparagraph 21.

(3) Section 8–741: Rule 21, ''Ambient Air Quality Standards.''

(ii) Other material. None.

[FR Doc. 96–7917 Filed 4–2–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 60

CFR Correction

In title 40 of the Code of Federal Regulations, part 60, revised as of July 1, 1995, make the following correction:

§ 60.62 [Corrected]

On page 127, in § 60.62 remove paragraph (a)(3).

BILLING CODE 1505–01–D

40 CFR PART 180

[PP 4F4322/R2217; FRL–5356–4]

RIN 2070–AB78

Pesticide Tolerance for Tribenuron Methyl

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes tolerances for residues of the herbicide tribenuron methyl (methyl-2[[[[*N*-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl] benzoate) in or on the raw agricultural commodities (RACs) hay of grass forage, fodder and hay group (excluding Bermudagrass) at 0.10 ppm; and forage grass forage, fodder and hay group (excluding Bermudagrass) at 0.10 ppm. This regulation to establish a maximum permissible level for residues of tribenuron methyl was requested in a petition submitted by E.I. DuPont de Nemours Company, Inc. Agricultural Products, Walker Mill, Barley Mill Plaza, P.O. Box 80038. Wilmington, DE 19880–0038.

EFFECTIVE DATE: April 3, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket number, [PP 4F4322/R2217], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copies of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 4F4322/R2217]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller, Product Manager (23) Registration Division (7505C), Office of Pesticide Programs. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, 703–305–6224.

SUPPLEMENTARY INFORMATION: EPA issued a notice of filing, published in the Federal Register of July 13, l994 (59 FR 35719), which announced that DuPont, Agricultural Products, Walker's Mill, Barley Mill Plaza P.O. Box 80038, Wilmington, DE had submitted a pesticide petition, PP 4F4322, to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish tolerances for combined residues of the herbicide tribenuron methyl (methyl-2[[[[*N*-(4-methoxy-6-methyl 1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl]benzoate in or on grass, seed; grass seed straw; grass, seed cleanings (screenings) at 0.04 ppm. A second notice of filing was issued on February 1, l996, published in the Federal Register (61 FR 3696), which announced that DuPont had amended the petition by revising the requested tolerances to read: in or on the raw agricultural commodities hay of grass forage, fodder and hay group (excluding Bermudagrass) at 0.10 ppm; forage of grass forage, fodder and hay group (excluding Bermudagrass) at 0.10 ppm and forage regrowth at 0.10 ppm. The analytical method for determining residues is high performance liquid

chromatography with photo-conductivity detection.

There were no comments received in response to the notices of filing. The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. The following acute studies with tribenuron methyl (DPX-L5300):

Acute Oral, Rat: LD_{50} >5,000 mg/kg, Toxicity Category IV.

Acute Dermal, Rabbit: LC_{50} >2000 mg/kg, Toxicity Category IV.

Acute Inhalation, Rat: >6.7 mg/L/4hr, Toxicity Category IV.

Primary Eye Irritation, Rabbit: Toxicity Category IV.

Primary Dermal Irritation, Guinea Pig: Toxicity Category IV.

Dermal Sensitiation, Guinea Pig: nonsensitizing.

2. A 3–month feeding study, Rat: No-observed-effect-level (NOEL) = 7/8 mg/kg/day and Lowest effect level (LEL) = 118/135 mg/kg/day. Toxicity observed: decreased body weight gain, food consumption and food efficiency; decreased absolute heart, liver, and kidney weights; increased relative brain, heart, liver, kidney, testes, and spleen weights; decreased serum glucose and globulin; no histopathologic lesions; likely cachexia.

3. A 3–month feeding study, Dog: NOEL = 73.3/78.0 mg/kg/day (HDT).

4. A 28–day dermal, Rabbit; The limit dose, 1,000 mg/kg/day, resulted in serious toxicity and death, NOEL and LEL could not be defined. Toxicity included treatment site lesions, hypokinesia, decreased body weights and food consumption, and kidney pathology, but the cause of death could not be determined. Although the study was Core Supplementary, another study is not needed. Worker expsure is expected to be 4 to 5 orders of magnitude less than the limit dose.

5. Chronic feeding, Dog: NOEL (females) = 0.79 mg/kg/day, NOEL (males) = 8.16 mg/kg/day; LEL (males) = 8.18 mg/kg/day, with elevated serum bilirubin, AST, and urinary volume, and LEL (females) = 52.02 mg/kg/day with increased serum creatinine, bilirubin, AST, and globulin, decreased body weight gain of 18.2%.

6. Carcinogenicity, Mouse: NOEL (males) = 3 mg/kg/day and LEL (males) = 30 mg/kg/day, with bilateral seminiferous degeneration and oligospermia. Although frank toxicity was not observed in the females, Health Effects Division (HED) peer review judged the dose levels to be adequate. There was no evidence of carcinogenicity.

7. Developmental toxicity, Rat: Maternal NOEL = 20 mg/kg/day; Maternal LEL = 125 mg/kg/day, with decreased maternal body weight gain and food consumption; Developmental NOEL = 20 mg/kg/day; Developmental LEL = 125 mg/kg/day, with decreased body weight; at 500 mg/kg/day (HDT) there were increased resorptions, fetal deaths, and incomplete ossification.

8. Developmental toxicity, Rabbit: Maternal NOEL = 20 mg/kg/day, Maternal LEL = 80 mg/kg/day (HDT - decreased food consumption, increased abortions); Developmental NOEL = 20 mg/kg/day, Development LEL = 80 mg/kg/day (HDT - 10% decrease in body weight compared to controls, not statistically significant). Abortions were increased at 89 mg/kg/day. No terata were observed.

9. 2-generation reproduction, Rat: Paternal NOEL = 2.0 mg/kg/day, Paternal LEL = 21.0 mg/kg/day, with decreased body weight gain in F1a adult females; Reproductive NOEL = 2.5 mg/kg/day, Reproductive LEL = 25 mg/kg/day, with decreased body weight gain during lactation for F1b and F2b pups.

10. Chronic feeding/carcinogenicity, Rat: NOEL = 0.95/1.2 mg/kg/day, LEL = 10/13 mg/kg/day, with decreased body weight gain in both sexes. Statistically significant increase in mammary gland adenocarcinomas in female rats at 76 mg/kg/day, HDT. Health Effects Division Peer Review Committee classified tribenuron methyl a Category C (possible human carcinogen) under EPA's cancer assessment guidelines.

11. Gene mutation: Ames Assay: Negative for *Salmonella* strains TA97, TA98, TA100 and TA1535 with and without metabolic activation.

12. Structural chromosome: Micronucleus Assay in Mouse Bone Marrow. Negative at a cytotoxic dose. *In vivo* Cytogenetic Assay in Rat. Negative.

13. Other genotoxic effects: *In vitro* Point Mutation in CHO Cells. Negative.

14. Unscheduled DNA synthesis in rats. Negative.

15. Metabolism: Rats given a single dose of 20 or 1,800 mg/kg excreted 99% or 97%, respectively, of radiolabel within 96 hours. The major route of excretion is the urine (2 to 4 times the amount excreted in feces). No more than 1% of radiolabel was found in any one tissue or organ 7 days. Major metabolites in the urine and feces included metsulfuron methyl, saccharin, and *O*-dimethyl triazine amine. The two major metabolic routes are the demethylation of the carbamoyl methyl group and the hydrolysis of the carbamate moiety.

16. Estrogenic Activity in Rats: Weak estrogenic activity was observed in female rats.

The Reference Dose (RfD) is established at 0.008 mg/kg/day, based on the 1 year dog feeding study NOEL of 0.79 mg/kg/day and an uncertainty factor of 100. The NOEL is taken from a 1 year feeding study in dogs which demonstrated as an effect elevated serum bilirubin and AST levels. The result from the EPA Dietary Risk Evaluation System for chronic analysis of dietary risk from all raw agricultural commodities (RACs) for which tolerances have been established (40 CFR 180.451) was published (FRL–4759–4) in the Federal Register (59 FR 17755, April 14, l994). Based on the information published the Theoretical Maximum Residue Contribution (TMRC) for the general population is now estimated to be 7.8×10^{-5} mg/kg bwt/day, or 1% of the RfD (viz. 0.97). The addition of forage and hay of grasses associated with the use of tribenuron methyl in the culture of grass seeds in the states of Washington, Oregon and Idaho under a regional registration will not increase the risk by more than a fraction of 1%, because of the low potential for transfer of residues of tribenuron methyl in ruminants. In a lactating goat study with labeled tribenuron methyl at a level of 6.7 ppm there was a total of 0.5% of the administered dose found in the assayed tissues and organs. Based on this low potential for transfer of residues to tissues, the Agency has concluded that feeding studies and animal tolerances for tribenuron methyl are not required. The proposed tolerances for grass RACs are at the same level as established for barley, oats, and wheat straw in ruminant diets, the proposed tolerances for the grass RACs will not increase the dietary burden for residues of tribenuron methyl in ruminants. Therefore no tolerances are needed for secondary residues in animal tissues and in milk. There are no human dietary RACs associated with the proposed registration of tribenuron methyl for use in the production of grass seed.

Tribenuron methyl is considered a class C carcinogen with no Q^* established for quantification of potency. EPA considers the cancer risk from exposure to tribenuron methyl from use as registered under the Federal Insecticide, Fungicide and Rodenticide Act as amended to be negligible.

The petitioner requested a petition for tolerances with regional registration based on the claim that the pesticide would not be used in grass seed production areas other than in the state of Washington, Oregon, and Idaho,

because of the culture practices in those state. Residue chemistry data supporting this regulatory action were limited to data from the Pacific Northwestern states mentioned above.

An adequate analytical method, high performance liquid chromatography with photo-conductivity detection, is available for enforcement purposes.

There are presently no actions pending against the continued registration of this chemical. The pesticide is considered useful for the purpose for which the tolerances are being sought.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR 180.451 will protect the public health. Therefore the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register,file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines tht the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

EPA has established a record for this rulemaking under docket number [PP–4F4322/R2217] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 22, 1996.

Stephen L. Johnson,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:
Authority: 21 U.S.C. 346a and 371

2. In § 180.451 by revising the section heading to read as set forth below, designating the existing text as paragraph (a), and by adding a new paragraph (b), to read as follows:

§ 180.451 Tribenuron methyl; tolerances for residues.

(a) * * *

(b) Tolerances with regional registration, as defined in § 180.1(n) are established for residues of the herbicide tribenuron methyl (methyl-2-[[[[*N*-(4-methoxy-6-methyl-1,3,5- triazin-2-yl) methylamino] carbonyl]amino]sulfonyl]benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass forage, fodder and hay group (except Bermudagrass); forage	0.10
Grass forage, fodder and hay group (except Bermudagrass); hay	0.10

[FR Doc. 96–8145 Filed 4–2–96; 8:45 am]
BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 491

[BPD–728–F]

RIN 0938–AF14

Medicare Program; Payment for Federally Qualified Health Center Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These regulations establish, as a Medicare benefit, outpatient services furnished by a Federally Qualified Health Center (FQHC) and establish requirements for coverage and payment of FQHC services. An FQHC is one of the following: An entity that is receiving a grant under section 329, 330, or 340 of the Public Health Service (PHS) Act; a non-grant receiving entity that is determined by the Secretary to meet the PHS Act requirements for receiving a grant; certain native American health centers; and certain facilities that have previously been identified as Federally funded health centers.

These regulations implement certain provisions of the Omnibus Budget Reconciliation Act of 1990 and the Omnibus Budget Reconciliation Act of 1993.

EFFECTIVE DATE: These regulations are effective on May 3, 1996.

FOR FURTHER INFORMATION CONTACT: Helen Klein, (410) 786–4641 (FQHC coverage issues) Randy Ricktor, (410) 786–5650 (FQHC payment issues)

SUPPLEMENTARY INFORMATION:

I. Background

On June 12, 1992, we published in the Federal Register, at 57 FR 24961, a final rule with a comment period, which established a new Medicare benefit, outpatient services furnished by FQHCs. This benefit is authorized by section 4161(a) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), which amends section 1861(aa) of the Social Security Act (the Act). The statutory provisions are effective on October 1, 1991.

OBRA '90 defines an FQHC as an entity that is receiving a grant under section 329, 330, or 340 of the PHS Act; is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330, or 340 of the PHS Act; based on the recommendation of the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services, is determined by the Secretary to meet the requirements for receiving such a grant; or was treated by the Secretary, for purposes of Medicare Part B, as a Federally funded health center (FFHC) as of January 1, 1990.

Subsequent to the June 12, 1992 regulations, the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) further amended section 1861(aa) of the Act relating to the definition of FQHCs. Section 13556 of OBRA '93 expanded the definition of FQHCs to include outpatient programs operated by tribes, tribal organizations under the Indian Self-Determination Act, or by an urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act. This provision was effective as if it had been included in the OBRA '90 legislation. Thus, such organizations may qualify for FQHC status, and under certain circumstances, as early as October 1, 1991. We are implementing this provision in a separate Federal Register rule.

The Act defines FQHC services as the same type of services provided by rural health clinics (RHCs) under the Medicare program, plus preventive primary health services.

II. Provisions of the Final Rule With Comment Period

The rule described in considerable detail the requirements an entity must meet to qualify as an FQHC, what services the FQHC must furnish, and the methodology we will use to determine how much we pay an FQHC. We provided that an entity that meets the requirements must enter into a signed agreement with us and must terminate any other Medicare provider agreement.

Under provisions of our final rule, services that are payable under the Medicare program when furnished by an FQHC are the same outpatient services that are currently covered as RHC services, plus preventive services. FQHC services do not include services furnished to hospital patients. RHC services include services furnished by physicians, physician assistants, nurse practitioners, nurse-midwives, qualified clinical psychologists, clinical social workers, and services and supplies furnished incident to professional services of these practitioners. In certain home health agency shortage areas, RHC services may also include visiting nurses' services.

Preventive services include medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, well child care, including periodic screening, immunizations, voluntary family planning services, and services outlined in the recommendations of the U.S. Preventive Services Task Force for patients age 65 and older. Preventive services do not include eyeglasses, hearing aids, group or mass information programs or health education classes, or preventive dental services. Preventive services covered under special provisions of Medicare, such as screening mammography, may be provided by an FQHC only if the center meets the special provisions that govern those benefits.

Our regulations state that qualified clinical psychologists and clinical social workers who furnish FQHC services must be legally authorized to perform those services under State law. We clarified that nurse-midwives, clinical social workers, and clinical psychologists are employees of the FQHC.

Payment provisions for FQHCs parallel the provisions for payment of RHCs. We pay freestanding FQHCs on an all-inclusive rate basis, subject to a test of reasonableness. We apply payment limits to the all-inclusive rate per visit. We pay provider-based FQHCs in accordance with 42 CFR parts 405 and 413 of the Medicare regulations. For additional description, see the June 12, 1992 final rule (57 FR 24961). Issues regarding the interaction between managed care and Medicare entities, such as FQHCs, are under consideration by us, and therefore, not addressed in this final rule.

III. Analysis of and Responses to Public Comments

In response to the publication of the final rule with a comment period in the Federal Register on June 12, 1992, we received 48 public comments. The comments were submitted by a wide variety of health care centers, consultants and local and national organizations. We reviewed all the comments, and the comments and our responses are in the order that the issues appeared in the June 12, 1992 rule.

Qualification Requirements

Comment: A few commenters objected to application of the conditions for coverage requirements in 42 CFR part 491 to FQHCs and believed it is without legal basis. They noted that the language in the Medicaid law is nearly identical, and Medicaid does not place health and safety requirements on FQHCs. The commenters argued that by virtue of receiving grants under the PHS Act, these centers already must meet

stringent standards established by HRSA and further standards are unnecessary.

Response: When the Congress created the FQHC benefit, it envisioned that FQHC services would be provided under the same conditions as RHCs services are furnished. Thus, FQHC services are defined in section 1861(aa)(3)(A) of the Act as ''services of the type described in subparagraphs (A) through (C) of paragraph 1 of section 1861(aa).'' As a result, the services of FQHCs are to be identical to those of RHCs.

Similarly, section 1861(aa)(3)(B) of the Act provides that ''any reference to a rural health clinic or a physician described in paragraph (2)(B) is deemed a reference to a Federally qualified health center, respectively.'' This means that physician-directed FQHCs are to be treated identically to their RHC counterparts. Finally, section 1861(aa)(5) of the Act provides the same definitions of physician assistants, nurse practitioners and clinical nurse specialists for RHCs and FQHCs.

These provisions of the Act indicate that the Congress built upon the statutory and regulatory provisions for coverage and payment of RHCs and intended that we use those provisions as a model for the FQHC program. Therefore, we believe that the Congress expected us to apply the same rules to FQHCs that we apply to RHC services and to professionals providing RHC services.

Based on the above, we believe there is a rationale for applying all or part of the RHC requirements to the services furnished in FQHCs. While HRSA may monitor the health and safety standards for a subset of FQHCs that are grantees, for some FQHCs (in other words, ''look-alikes,'' which are entities that are not receiving grants under the PHS Act but meet grant requirements, and some former FFHCs), there is no other alternative for monitoring the quality of the service furnished. Without our oversight, there would be no assurance that facilities furnish safe services.

In addition, the Congress has given us the responsibility to establish standards to ensure the health and safety of beneficiaries in all other statutorily-created types of facilities, and it would be extraordinary to interpret the law as preventing application of such standards in regard to FQHCs. There is nothing in the law that would support the view that the Congress intended for us to be without the power to assure the safety and efficacy of FQHC services.

We believe the health and safety requirements we established are minimal and are not a burden on the vast majority of centers that want to provide high quality care. In fact, we informally surveyed RHCs and FQHCs regarding the difficulties involved in participating in the Medicare program, and no one noted concerns with the health and safety requirements we extended to FQHCs. Likewise, no commenters on this document raised concerns with any particular requirement. However, should further correspondence indicate documented difficulties with a specific condition, we will be open to considering refinement, as appropriate.

Finally, we note that we are implementing the requirements in a fashion that is as administratively simple as possible. That is, we are not surveying potential FQHCs prior to participation or on a routine basis. Rather, centers merely attest to meeting the requirements. The standards thus establish a set of expectations for FQHCs to monitor themselves and provide an enforcement mechanism for those very few centers that do not take adequate health and safety precautions. In the absence of such health and safety standards, we would have no means to protect beneficiaries from potentially serious health and safety threats that have materialized with other types of providers and suppliers over time. Given the statutory provision referencing RHC procedures, we are confident that the Congress intended that we place health and safety requirements on FQHCs.

We concede that Medicaid currently has no regulations for FQHCs, so it is premature to argue that the Medicaid program does not have health and safety requirements for FQHCs. However, the Medicaid program does require provider agreements between the State agency and an FQHC before the Medicaid program pays the FQHC.

Although the Medicare and Medicaid FQHC legislation is similar in language, the two programs are separate and autonomous. The Medicaid program is a Federal and State partnership and allows more flexibility in determining FQHC approval. Since Medicaid regulations have not yet been issued, we are not in a position to discuss any additional requirements that may be added.

Comment: Several commenters noted that the statutory provisions for FQHC eligibility refer to FQHCs using the term ''entity.'' The regulations require that each site be approved, which the commenters believed exceeds our statutory authority. If site-specific approval is maintained, the commenters suggested that we clarify that an entity may submit combined cost reports and use a combined payment rate for all sites within that entity.

Response: While we independently approve each site for Medicare participation and assign it a unique provider number, each site of a potential FQHC need not independently meet the PHS Act grant requirements. The fact that a site is within the scope of a grant or approved look-alike application is sufficient. However, each site must independently attest to meeting the conditions in part 491 subpart A.

We believe the site specific requirement also has advantages for Medicare beneficiaries and FQHCs and is supported by law. Section 1861(aa)(2)(K) of the Act gives us the authority to establish standards to ensure the health and safety of beneficiaries receiving services at RHCs, and consequently, we believe, at FQHCs. We believe that establishing specific requirements for individual site approval allows us to fulfill this role. If facilities are not independently approved, it is difficult to determine if each site is adequately meeting the required health and safety standards.

There are advantages to the FQHC in this policy. The site-specific approval requirement allows each site in the entity to continue to operate despite individual problems that may arise in other sites under the same corporate entity. Corporate entities are typically large private or public organizations which have, as their organizational components, facilities that must independently meet the conditions established in 42 CFR part 491, subpart A. By requiring individual site approval, all of the sites of an entity are not jeopardized if one site does not meet health and safety requirements. If we were to use entity-based approval, as suggested by the commenter, we would not allow an individual site that continues to meet all of the conditions to provide FQHC services if another site in that parent entity did not meet the Medicare safety standards. In addition, requiring site-specific approval enables us to provide enhanced service to our beneficiaries. Specifically, we are able to respond to beneficiary requests for the names and addresses of approved facilities that are providing Medicare FQHC services.

Although each site within a corporate entity is independently approved and given a unique Medicare provider number, entities have the option to file a single consolidated cost report for the entire entity or individual cost reports for each site within the entity. We provided instructions in the intermediary and RHC/FQHC manuals

that address payment for FQHC network entities.

Finally, we do not believe that the law intended that every site operated by an entity be entitled to FQHC status, especially if the sites are not within the scope of the PHS Act grant, without independently qualifying as ''look-alikes.'' Only by using site-specific approval can we carry out the statutory intent of providing FQHC status to a site that meets the conditions of the law, while excluding a site that is part of an entity, but falls outside the scope of a PHS Act grant or does not otherwise meet the FQHC eligibility criteria.

Comment: One commenter requested clarification of our position regarding provider-based FQHCs, which are not receiving grants under the PHS Act, but meet grant requirements as ''look-alikes.'' The commenter noted that the definition of a provider-based FQHC as an integral and subordinate part of a provider and HRSA governance requirements have prompted some centers to establish independent governance and yet remain located at or near hospital grounds. The commenter requested assurance that such co-location would not result in provider-based designation.

Response: Section 405.2462 defines a provider-based FQHC as a clinic or center that is an integral and subordinate part of a hospital, skilled nursing facility, or home health agency participating in Medicare (that is, a provider of services). The clinic or center is operated with other departments of the provider under common licensure, governance, and professional supervision. These stipulations must be met for us to consider an FQHC as provider-based. Simply being located in or near a hospital does not qualify an entity as a provider-based facility. The converse is also true. An entity may be provider-based despite the fact that it is located outside of the provider. A center with independent governance cannot be considered a provider-based FQHC.

The basis for HRSA governance requirement is to ensure that the services that are provided are responsive to the community. Therefore, HRSA requires that a center approved under sections 329 and 330 of the PHS Act have a governing board, the majority of which are users of the facility.

Comment: One commenter urged that we review the definition and scope of authority of community governing boards in FQHCs. The commenter noted that the requirement for community governing boards excludes from the FQHC benefit clinic facilities that are owned by academic health science centers.

Response: The definition and scope of authority of community governing boards are found in sections 329(f)(3)(G) and 330(e)(3)(G) of the PHS Act. The sections specify that the center has established a governing board which (1) is composed of individuals, a majority of whom are being served by the center and who, as a group, represent the individuals being served by the center, and (2) selects the services to be provided by the center, schedules the hours during which such services will be provided, approves the center's annual budget, approves the selection of a director for the center, and, except in the case of a public center, establishes general policies for the center.

The purpose of an FQHC is to provide community-based, family-oriented primary care. The statutory governance requirement ensures that the services that are provided are responsive to the health needs and concerns of the community. An academic health science center can qualify as an FQHC if its board meets the requirements of sections 329, 330 or 340 of the PHS Act and the provisions of this regulation.

Comment: One commenter noted that § 491.5 requires that a center be located in a rural or urban area that is designated as a shortage area. The commenter requested that shortage area be clearly defined in the regulations. Several commenters noted that the PHS law does not require the FQHC to be located in a medically underserved area, but merely to document that it serves a medically underserved population.

Response: Section 491.2 defines a shortage area as a geographic area designated by the Department as having either a shortage of personal health services (under section 1302 of the PHS Act) or a shortage of primary medical care manpower (under section 332 of that Act). The designation of shortage areas is quite complex and is handled by HRSA.

Section 491.5(d) specifies the criteria for designation of shortage areas. Factors considered include the ratio of primary care physicians practicing in the area to the resident population and the infant mortality rate.

The commenter is correct in that HRSA does not require that the FQHC be located in a shortage area. Rather HRSA requires that the FQHC either be located in a medically underserved area (MUA) or serve a medically underserved population (MUP).

According to 42 CFR 51c.102(e), an MUP is defined as the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services. This designation was developed because there were populations that required medical care but were located in areas that did not receive MUA designation. The Secretary analyzes the demographics and medical manpower of the population to determine whether or not the population should receive designation. Therefore, an MUP can be located in an area that is not an MUA.

In response to the concern expressed by this commenter, we are revising § 491.5(a) to specify that an FQHC may be located in a shortage area or may serve a medically underserved population. We are also adding a new paragraph (e) that defines medically underserved population in the same way as HRSA does, as indicated above.

Comment: Two commenters objected to application of the ''four walls test'' in § 491.5 to an FQHC. They believed that this provision limits cost-based payment to only those services provided at the clinic or center site. The commenters noted that it may be difficult to have some specialists come to the center site to provide care and recommended that all services furnished under arrangements with the FQHC be payable on a cost basis.

Response: The ''four walls test'' requires that the objects, equipment and supplies necessary for the provision of the services furnished directly by the clinic or center be housed in a permanent structure or mobile unit that has fixed, scheduled locations. The requirement that the clinic or center be housed in a permanent structure ensures that the equipment, records, supplies and whatever else is necessary to provide the defined services are in one permanent place.

The ''four walls test'' is not a requirement that limits cost-based payment to only those services provided at the clinic or center, and it does not restrict a physician from providing services off-site. A physician, including any specialist under contract to the FQHC, can have an agreement with the FQHC to provide FQHC services off-site.

For reasons discussed later in this preamble, we have reconsidered our policy on contracting for professional staff members other than physicians. FQHCs may provide services of physician assistants, nurse practitioners and other professionals under contract. These professionals may provide services in skilled nursing facilities or in the homes of beneficiaries. However, an FQHC may not bill services provided to hospital patients as FQHC services.

Comment: Several commenters noted that § 491.8 requires that nurse practitioners or physician assistants be

available to furnish patient care services at least 60 percent of the time. However, the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) changed the requirement to 50 percent. They recommended that we revise the regulation to state that such coverage is required 50 percent of the time.

Response: We note that the referenced RHC requirements pertaining to staffing mix percentages in § 491.8 do not apply to FQHCs. When the FQHC regulations were published on June 12, 1992, the existing RHC regulations had not been updated to include changes from the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), OBRA '89 and OBRA '90. As a result, the FQHC regulations were incorporated into the existing RHC regulations, which still reflected earlier statutory thresholds for such coverage. We are preparing to issue a proposed rule that incorporates these changes and will update the RHC provisions in § 491.8 and solicit public comment. We are, however, authorized by OBRA '90 to issue a final rule for FQHCs that includes only the OBRA '90 amendments.

Comment: One commenter objected to the exclusion of psychologists from the list of practitioners in § 491.8(a)(6), which specifies staff that must be available in order for the center to be open. The commenter recommended that we revise the regulation to include specialty providers in all areas of operation of the centers. Further, the commenter was concerned that the language with regard to medical direction in § 491.8(b)(1)(i) could be interpreted to require that a physician may supervise psychological services that are within the scope of the psychologist to furnish without medical direction.

Response: As noted above, OBRA '90 authorizes us to implement the FQHC regulations as a final rule. We do not have authority under that law to modify the RHC provisions without publishing a notice and soliciting public comment. When the FQHC regulations were published June 12, 1992, the existing RHC regulations had not been updated to include any changes in the law. As a result, the regulations concerning the policy board and medical supervision did not contemplate involvement of psychologists, as psychologists' services were not RHC covered services at the time the regulations were promulgated.

Section 1861(ii) of the Act provides coverage for clinical psychologist services that would otherwise be covered if furnished by a physician or as incident to a physician's service. In addition, under this statutory provision clinical psychologists can provide services as authorized under State law without the supervision of a physician. We are revising § 491.8(b)(1) to clarify that clinical psychologists can provide services, as permitted under State law, without the supervision of a physician in FQHCs.

Comment: Two commenters objected to the requirement in § 491.9(b)(2) regarding the development of patient care policies. This paragraph requires that the policy development committee of the center include at least one member who is not on the center's staff. They expressed concern that the use of non-staff personnel is an unnecessary expense and is burdensome. They also believed the requirement is unnecessary given the level of review already in place by HRSA for its grantees.

Response: We believe that the provisions of § 491.9(b)(2) are necessary to ensure the health and safety of beneficiaries. Patient care policies were developed to provide guidelines on how a facility will care for its patients. In addition, the policies ensure that the providers adhere to appropriate procedures and protocols. The requirement for a non-staff representative to assist in developing patient care policies is necessary to ensure that the services are responsive to the needs of the community. The non-staff representative does not have financial interests in the provider and, as such, will likely be more objective and unbiased in favor of the provider in the decision making process. This requirement is intended to ensure that the concerns of the population served will be paramount and that the provider will address the specific health needs of the community. Given the HRSA governance requirement for a constituent majority board, we believe this requirement will not be burdensome to most FQHCs.

Comment: One commenter objected to annual surveys of RHCs and FQHCs as wasteful.

Response: We are not planning to conduct routine surveys of FQHCs, and FQHCs will not be routinely required to submit documentation to HCFA demonstrating compliance with program requirements. However, we plan to survey an FQHC if we receive a complaint about a health and safety issue at the FQHC. During the survey, the FQHC must provide documentation of compliance with the requirements in part 491.

Comment: Two commenters noted that FQHC grantees are subject to extensive review by the HRSA on an annual basis. They believed this review is sufficient to meet any evaluation assurances that should be necessary. Therefore, the requirement in § 491.11 that a clinic or center carry out or arrange for an annual evaluation of its total program should not be applicable to FQHCs.

Response: An FQHC is expected to conduct annual evaluations in accordance with § 491.11, which specifies what the annual program evaluation must include and what the evaluation must determine, but it does not prescribe how the annual program evaluation must be conducted or the kind of evaluation that must be conducted. The purpose of the annual evaluation is to evaluate utilization of services, evaluate compliance with established policies, and determine if changes are needed. We would expect that every organization would conduct this self-assessment at least annually regardless of Medicare requirements.

With regard to the concern that HRSA reviews are adequate and, in support of elimination of this requirement for FQHCs, we note that not all FQHCs are grantees under the PHS Act; thus, all FQHCs would not be subject to the HRSA standards. In support of retaining the requirement, we note that the standard should not be burdensome to the centers because, to the extent that HRSA reviews cover the scope of the requirement, additional evaluation and documentation will not be necessary. Thus, should we survey an FQHC for compliance with part 491 conditions in response to a complaint, documentation submitted to HRSA for HRSA program purposes would be acceptable as evidence of compliance with 42 CFR 491.11 if the review included the items specified in the requirement.

Comment: Another commenter was in favor of annual compliance reporting and recommended that, to ease administrative burden, HCFA and HRSA use a single form, and HCFA provide additional details specifying when such reporting is to be completed and where it is to be forwarded.

Response: We are not requiring annual compliance reporting. FQHCs must review themselves, and they must maintain documentation of their review in the event that we choose to survey a center. We will evaluate an FQHC only if we discover a problem or receive a complaint. In such cases, the review would encompass only the matter addressed in the Medicare regulations, but we would coordinate the review with HRSA to avoid duplicative efforts. Section 491.11 requires that an FQHC perform an annual self-evaluation of its program. We believe this is a reasonable requirement so that an FQHC assesses utilization of services, compliance with

established policies, and determines if changes are needed.

Comment: One commenter wanted to know when a listing of FQHCs would be available.

Response: There is a list of FQHCs currently available from the Health Standards and Quality Bureau, System Management Branch, 6325 Security Blvd., Baltimore, Maryland, 21207. The charge for the list is $25.00. For more information, you may telephone Mike Moran at (410) 597–5851.

Content and Term of the Agreement

Comment: One commenter requested that we clarify the recertification process for FQHCs.

Response: For Medicare purposes, there will be no routine recertification of FQHCs. Once a facility is approved, it will remain a Medicare-participating FQHC until termination of the agreement, as provided in § 405.2436. We plan to survey an FQHC if we receive a complaint about a health and safety issue at an FQHC or if a health and safety problem is identified in another way.

HRSA has an annual process to determine eligibility for FQHC status. For grantees, this consists of an application process for funding, and for look-alikes, this consists of an annual application and review, either of which could result in HRSA recommending decertification of the FQHC to HCFA.

Comment: Two commenters noted that the RHC law and regulations provide that an RHC retains its status even if the area in which it is located loses its rural shortage area designation. They requested similar protection for FQHCs.

Response: Section 1861(aa)(2)(K) of the Act specifies that an RHC may maintain its approval even if the area in which it is located loses its rural shortage area designation. In accordance with the Act, § 491.5(b)(1) allows an RHC to retain its approval. The Act, however, does not include a similar provision for an FQHC.

We note that the current language in the regulation does not clearly state that the protection for area designation applies exclusively to RHCs. Therefore, we are revising § 491.5(b)(1) to clarify this.

Comment: One commenter objected to the requirement that centers must terminate other provider agreements prior to, or simultaneous with, signing an FQHC participation agreement. The commenter believed that there is no statutory support for this requirement, and this requirement may adversely affect some centers. One example cited by the commenter is that an RHC could be adversely affected if it gave up its RHC status to become an FQHC and the area is redesignated from medically underserved because the protection afforded an RHC is not offered to an FQHC.

Response: We are revising § 405.2430(a)(1)(iii) to clarify that a freestanding FQHC must terminate other provider agreements for entities that operate at the same time as the FQHC. The intent of this provision is to prohibit an entity from using the same space, staff, and resources simultaneously as two distinct provider types. We believe this provision is necessary to ensure the health and safety of our beneficiaries and to avoid program abuse.

We do not intend by this provision that an FQHC and another provider/supplier type may not be commonly owned or housed in the same building. Rather, the intent of the provision limiting freestanding FQHCs to a single provider agreement is to prevent the entity from using the same staff, space, and resources for two or more different provider types at the same time.

We believe that this provision is necessary to ensure the health and safety of our beneficiaries. That is, if an FQHC is using the same space, staff and resources as two different providers at the same time, there is no assurance that the staff will be devoting its efforts to the FQHC operation and not the other provider type. Without these assurances, it is possible that beneficiaries could come to the FQHC expecting to receive adequate health care, only to learn that the other provider type is using the FQHC's resources at that time.

In addition, we established a very simplified cost report mechanism for FQHCs. This cost report does not permit the allocation of costs among multiple provider types. If we were to allow the simultaneous use of the same space, staff and resources as multiple providers, we would need to develop a more sophisticated cost report. A more complicated report could place an administrative burden on the centers, the vast majority of which do not wish to engage in multiple provider activities.

We note that the Medicare program does not generally allow the concurrent use of a facility as multiple health care providers. For example, the regulations require that ambulatory surgical centers be used exclusively for providing surgery to patients who do not require hospitalization. Furthermore, the skilled nursing facility regulations require separate space, staff and resources (or distinct part) for its non-certified portion. Thus, we believe there is ample precedent for the requirement we are establishing.

Coinsurance

Comment: One commenter noted the distinction between the basis of coinsurance (charges) and the basis of payment (all inclusive rate) and asked for clarification.

Response: The commenter is correct. There is a difference between the basis of coinsurance and the basis of payment. In accordance with section 1833(a)(3) of the Act, payment for FQHC services may not exceed 80 percent of its cost. Section 1866(a)(2)(A) of the Act, referred to in section 1830(a)(3), addresses coinsurance liability of beneficiaries, providing that coinsurance be based on charges. Consequently, our regulations provide that an FQHC may not charge beneficiaries more than 20 percent of the charge for the service furnished regardless of the payment the FQHC receives from Medicare.

We believe that, on average, many FQHCs will recover their costs under this provision. While it is possible that, in situations involving minimal services, the FQHC will recover less than its cost, it will recover more than its costs in certain other visits involving high charge services.

We acknowledge that FQHCs must use a sliding fee schedule for beneficiaries within 200 percent of poverty levels. Thus, FQHCs with a high proportion of Medicare beneficiaries subject to the sliding fee could receive less than cost from their Medicare population. However, we believe that the law is clear regarding Medicare payment and beneficiary coinsurance liability.

Effective Date

Comment: One commenter requested clarification of the effective date for those centers that had previously obtained ''look-alike'' status under the Medicaid program.

Response: In accordance with § 405.2434(b)(2), an FQHC's effective date may be October 1, 1991, if it met all Federal requirements on that date and if it applied to be a Medicare FQHC by August 11, 1992. An entity that requested to become an FQHC by filing a signed agreement within 60 days of publication of the regulation could elect to choose an effective date from October 1, 1991 (the effective date of the law) up to and including August 11, 1992. An entity does not qualify as an FQHC on October 1, 1991 unless it met all Federal requirements on that date. The preamble to the June 12, 1992 regulation states that Medicare will pay for FQHC

services furnished on or after October 1, 1991 by entities that met the criteria in the regulation on that date and file a signed statement within 60 days of the date of publication.

More specifically, an entity that is not receiving a grant under the PHS Act but meets grant requirements, and applied for and obtained FQHC status under the Medicaid program, and was approved without a waiver could be paid for services from October 1991 if the entity met the requirements in part 491 and applied to Medicare timely. The earliest date for which an entity can qualify is October 1, 1991. HRSA makes a recommendation about an entity's status after the entity has applied and met all HRSA requirements, and we make the decision to approve the entity as an FQHC. If an entity was approved as a Medicaid FQHC ''look-alike'' without waiver after October 1, 1991, the earliest date of FQHC approval for such a center is the date we approve the entity as an FQHC.

Comment: One commenter objected to the August 11, 1992 date for filing for approval as an FQHC from October 1991. The commenter believed that we should permit exceptions to the August 11, 1992, date for centers that provide a ''good cause'' explanation for their delay.

Response: We and the National Association of Community Health Centers (NACHC) have made extensive efforts to assist centers in applying to become FQHCs. Letters were sent to each grantee, ''look-alike,'' and FFHC to make them aware of the process for FQHCs to receive payment as an FQHC from October 1, 1991.

We have already processed payment adjustments to take into account entities that acted timely to apply for FQHC status effective October 1, 1991. Making payment to 1991 for FQHCs that did not file in time would be administratively burdensome because it involves the entity refunding previously collected deductibles to beneficiaries and billing for past preventive services. We believe the ''window'' we permitted for FQHCs to qualify to October 1991 was generous, and we believe that our letters and the letters from NACHC gave facilities adequate time and information to apply and qualify. Therefore, we are maintaining the policy in our 1992 rule.

Scope of Services

Comment: One commenter believed the law defines FQHC services as those generally furnished by community health centers (CHCs). He noted that this is considerably different from RHC services and recommended revision of the scope of services to reflect this.

Response: The Act does not define FQHC services as the services provided by CHCs. Section 1861(aa)(3)(A) and (B) of the Act defines the scope of FQHC benefits in terms of those benefits enumerated in the RHC law (section 1861(aa)(1)(A)–(C) of the Act) and preventive primary health services that a center is required to provide under sections 329, 330 and 340 of the PHS Act. The law does not require that a center be a CHC to qualify as an FQHC; it does provide that a facility may qualify as an FQHC if it meets the requirements to become a CHC under section 330 of the PHS law. We do not have the authority to expand the FQHC scope of benefits beyond those specified in the law.

Comment: Several commenters objected to the regulation's definition of preventive primary health services. Some commenters believed that all services required under section 330 of the PHS Act, such as transportation services, should be covered as preventive services.

Response: Section 1861(aa)(3) of the Act specifies that FQHC services include those benefits defined as RHC services in section 1861(aa)(1)(A)–(C) of the Act and preventive primary health services that are required under sections 329, 330 and 340 of the PHS Act. A service must first be recognized as a preventive primary health service under PHS law and HRSA guidelines to be included as a preventive primary health service for Medicare FQHC purposes. If a service is not included as a primary preventive service under the PHS Act and the HRSA guidelines, there is no authority for Medicare to cover the service.

42 CFR parts 51c and 56 define preventive services as medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, perinatal services, well child care (including periodic screening), immunizations and voluntary family planning. Based on the U.S. Preventive Services Task Force Report for persons age 65 or older, HRSA further requires its grantees to provide additional preventive services that are specified in § 405.2448.

Transportation services are helpful in promoting access to preventive health care, especially for individuals living in underserved areas. Such services, however, are not defined as preventive services by HRSA, thus we do not have the authority to include such services as FQHC preventive services.

Comment: One commenter recommended that the rule be clarified to allow for the inclusion of advanced practice mental health nurses under the FQHC benefit. The commenter believed it was the intent of the law to include these practitioners under ''specialized nurse practitioners;'' however, they are not all technically classified as nurse practitioners.

Response: The Act does not recognize or specifically refer to the services of advanced practice mental health nurses. We do not have the authority to expand the FQHC scope of benefits beyond those the services of practitioners described in the Act. The FQHC scope of benefits includes some, but not all, categories of advanced practice nursing. For example, it does not include clinical nurse specialists. Other categories of advanced practice nursing such as physician assistants and nurse practitioners may provide mental health services covered under the FQHC benefit. Services provided by clinical nurse specialists, for example, could be covered only if they were ''incident to'' services as provided in section 1861(aa)(1)(B) of the Act. This section provides for coverage of services furnished incident to the services of physicians, certain mid-level practitioners, clinical psychologists, or clinical social workers.

Comment: Numerous commenters objected to the provision that limits FQHC services to those furnished outside a hospital. FQHCs routinely follow their patients to the hospital setting and noted that it is burdensome to bill the carrier separately for these services as non-FQHC services. Further, this mechanism provides an opportunity for duplicate billing. Some commenters noted that RHCs may bill for hospital services and believe the same policy should be applicable to FQHCs.

Response: There are two reasons why FQHC services are limited to those furnished outside of the hospital: (1) Section 1861(aa)(3) of the Act requires that FQHC services be provided only to outpatients, and (2) section 1862(a)(14) of the Act prohibits payment for services furnished to hospital patients, except as specified in the law. Section 1862(a)(14) of the Act, in enumerating those who may receive payment for services furnished in a hospital, does not include either RHCs or FQHCs. Therefore, payment cannot be made for FQHC services to hospital patients.

The Social Security Amendments of 1983, Pub. L. 98–21, on April 7, 1983, added section 1862(a)(14) to the Act. This section prohibits payment under Medicare for any service provided to a hospital inpatient that is not furnished by the hospital itself or furnished under arrangements made by the hospital with

the entity furnishing the service. Section 1862(a)(14) of the Act also states that certain services are specifically excluded from this prohibition. The exclusion is limited to physicians' services, services described by section 1861(s)(2)(K)(i) of the Act (certain physician assistant services, nurse practitioner, clinical nurse specialist, and nurse-midwife services), qualified psychologist services, and services of a certified registered nurse anesthetist.

Section 1862(a)(14) of the Act was further revised by section 9343(c) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Pub. L. 99–509, to apply to hospital outpatients as well as hospital inpatients. As a result, the law now prohibits payment, except as specifically enumerated, for both hospital outpatients and inpatients. By its terms, then, section 1862(a)(14) of the Act prohibits Medicare payment for FQHC services provided to a hospital patient.

However, we do not believe it is the intent of the law to prohibit FQHC practitioners from following their patients to a hospital setting. The law provides two alternative payment mechanisms for such services. First, the FQHC may look to the hospital for payment for the services. Second, FQHC practitioners can follow patients to a hospital and provide services, but the practitioner may not bill those services as FQHC services. Instead, FQHC physician visits are covered under other Part B provisions of Medicare as physician services, and the FQHC practitioner must bill the Medicare carrier to receive payment.

Section 1842(b)(6) of the Act provides that a facility, under certain conditions, may bill the program for the services of its employees. In such a case, it is not necessary that a FQHC practitioner employed by an FQHC bill for the services provided in hospitals; rather, the FQHC may bill the program on behalf of its employees using the form HCFA–1500. These bills must be sent to the local carrier instead of the intermediary processing cost-based claims are paid using the routine part B payment methodology (in most cases resource-based relative value system fee schedules).

Despite the commenters' allegations to the contrary, an RHC cannot bill for hospital services. The same statutory requirements that extend to an FQHC apply to an RHC as well.

Comment: Several commenters objected to the exclusion of diagnostic x-rays from the definition of FQHC services. They supported inclusion of such services under the FQHC benefit as incident to a physician's service. They argued that this would promote administrative ease in bill submission.

Response: Section 1861(aa)(1)(A) of the Act defines RHC (and, thus FQHC) services to include physicians' services and such services and supplies as are covered under section 1861(s)(2)(A) of the Act if furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10) of the Act (pneumococcal and influenza vaccine).

The technical component of x-ray services, as distinct from physician services, is covered under section 1861(s)(3) of the Act. Therefore, it is not included in the definition of FQHC services. We have no authority to change this requirement under current law. However, we are interpreting the law as permitting the professional component of the x-ray to be included as an FQHC-covered service as a physician service. Moreover, though the technical component of x-ray services is not covered under the FQHC benefit, it may be claimed under Part B of Medicare by billing the carrier.

Comment: One commenter noted that the exclusion of radiology and hospital services from the scope of FQHC services presents a problem in waiver of the deductible. By virtue of its mission, an FQHC is treating a population that generally has insufficient funds to meet necessary medical expenses. The exclusion of some services from the scope of FQHC services will result in a deductible liability for those excluded services and present a financial hardship for low income beneficiaries. The commenter recommended that we waive the deductible for all services provided in an FQHC, regardless of whether they are FQHC services or not.

Response: Section 1833(b)(5) of the Act provides that the Medicare deductible does not apply to FQHC services. Section 1861(aa)(3) (A) and (B) of the Act defines the scope of FQHC services in terms of those services furnished by an RHC and preventive primary health services that a center is required to provide under the PHS law and HRSA guidelines.

The rationale for excluding the technical component of radiology services to hospital inpatients from the definition of FQHC services has been discussed in the prior two responses. Section 1861(s)(3), and not 1861(s)(2)(A), of the Act is the basis for the diagnostic x-ray benefit; thus, the technical component of x-ray services is not included within the FQHC benefit. In accordance with sections 1861(aa)(3) and 1862(a)(14) of the Act, FQHC services cannot be provided to hospital patients. We have no authority to waive the deductible for these services, which are not FQHC services.

We acknowledge that paying the deductible for these services may be difficult for some beneficiaries. Beneficiaries suffering financial hardship may be eligible for assistance under the Qualified Medicare Beneficiaries (QMB) Program. A qualified Medicare beneficiary is an individual who is entitled to Medicare hospital insurance benefits under Part A, with or without payment of premiums, who also has an income that does not exceed 100 percent of the Federal poverty level and has resources that do not exceed twice the maximum amount established for Supplemental Security Income eligibility.

Under the QMB program, Federal financial participation is available to State Medicaid agencies for medical assistance for the beneficiary's Medicare cost sharing expenses. The expenses include Medicare Part A and Part B deductibles and coinsurance. Medicaid pays the coinsurance and the deductible. This will help beneficiaries to avoid the out-of-pocket costs. The QMB program provides a mechanism to assist those beneficiaries with limited means to pay the deductible.

Comment: One commenter noted that although nurse-midwives are mentioned in several places throughout the FQHC regulation, § 405.2446, which defines the FQHC covered scope of services, does not include nurse-midwives.

Response: We agree with the commenter and are revising § 405.2446 to include the services of nurse-midwives as covered FQHC services. We intend to propose a change to the definition of nurse-midwife in a proposed rule on RHCs currently in process, which will also affect FQHCs. In the meantime, State law governs which nurse-midwives qualify to provide services in FQHCs.

Comment: One commenter recommended coverage of clinical nurse specialists as FQHC practitioners. These health care practitioners are registered nurses with master's degrees in a defined clinical area of nursing. They are similar to nurse practitioners and are educated and trained to provide preventive services and primary care. OBRA '90 recognizes these health care practitioners as independent providers in rural areas. Therefore, the commenter believed that we should cover the individual services of these practitioners within the scope of FQHC services. In addition, the commenter wanted the phrase ''clinical nurse specialist'' added to the definition of an FQHC visit.

Response: The Act does not clearly provide coverage for clinical nurse specialists services in an RHC or FQHC. Although the definition of a clinical nurse specialist is included in section 1861(aa)(5) of the Act, the Act does not explicitly include these practitioners in the scope of the benefit.

Comment: One commenter recommended that the adjective ''specialized'' be removed as a modifier to nurse practitioner as most States do not use this term in licensing nurse practitioners.

Response: We have been advised by nursing associations that the term ''nurse practitioner,'' which is defined in § 405.2401(c)(17), encompasses all specialties among nurse practitioners. Consequently, it is not necessary to use the term ''specialized'' and we are removing the definition of ''specialized nurse practitioner'' from § 405.2401.

Primary Preventive Services

Comment: Several commenters objected that we did not include dental services as preventive care covered under the FQHC benefit. They noted that the U.S. Preventive Services Task Force Report includes an oral health component and argued that such services are essential for elderly patients. Further, preventive primary dental services are separately mandated in section 329 and 330 of the PHS Act. Therefore, the commenters believed that the Congress did not intend to exclude dental services from the FQHC benefit and that its failure to amend section 1862(a)(12) of the Act was a technical oversight.

Response: Dental services are not included in the HRSA definition of preventive primary health services; they are considered a separate benefit under HRSA services. The PHS Act provides for preventive dental services as a primary health care benefit separate from preventive primary health services. That is, section 329(a)(6)(C) of the PHS Act defines preventive primary health services, while a different section of the law, section 329(a)(6)(F), defines preventive dental services. In defining the scope of FQHC preventive services, the Act specifically refers only to preventive primary health care services in sections 329, 330 and 340 of the PHS Act.

Further, section 1862 of the Act contains an exclusion for dental services, prohibiting payment for services in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting the teeth. OBRA '90 did not amend section 1862(a)(12) of the Act to remove the exclusion of dental services for FQHCs. However, it did amend other provisions of section 1862(a). As a result, the regulations exclude dental services from the definition of FQHC preventive primary health services and will continue to do so.

Although the U.S. Preventive Services Task Force Report includes an oral health component for the elderly, that oral component is categorized as a counseling service by the Task Force. The report intended that a primary care practitioner would briefly examine a patient's mouth for visible signs of disease and counsel the patient to see a dentist if there is a need for routine prophylactic services. If the beneficiary had need of prophylactic or other dental services, he or she would be referred to a dentist. The oral health component is not the same as dental services.

Comment: Several commenters objected to the exclusion of screening mammography services as an FQHC preventive service. Although this service is payable under Part B, they note that application of the deductible and having to make an appointment to have the mammogram performed at another facility would deter some of the most needy population from getting this valuable service.

Response: Sections 1834(c) and 1861(s)(13) of the Act provide for coverage of screening mammography for certain women entitled to Medicare, subject to frequency limitations, quality standards and special payment rules. The Act provides coverage of screening mammography services only in a facility that meets the Medicare requirements for certification. An FQHC may provide and bill for screening mammography services under the mammography benefit as long as it meets the applicable quality standards and coverage requirements. The quality standards are designed to protect the health and safety of Medicare beneficiaries.

As explained above, the scope of benefits under FQHCs does not include radiological services. In addition, the Act contains special provisions for the coverage of screening mammography as a Medicare benefit, and those provisions apply to FQHCs in the same manner as they apply to other entities.

Comment: One commenter believed that we should recognize services listed in the U.S. Preventive Services Task Force Report for people under age 65 as preventive services for purposes of the FQHC benefit.

Response: By definition, the Medicare program is a Federal health insurance program for people age 65 or older and certain disabled individuals. Section 1861(aa)(3)(B) of the Act specifies that FQHC services include preventive primary health services that a center is required to provide under sections 329, 330 and 340 of the PHS Act. A service must first be recognized as a preventive primary health service under HRSA guidelines in order to be included as an FQHC preventive primary health service.

HRSA defines preventive primary health services in 42 CFR parts 51c and 55 as medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, perinatal services, well child care (including periodic screening), immunizations, and voluntary family planning services. These are the required preventive primary health services as defined by HRSA. Thus, these are the preventive primary health services that we require in an FQHC.

In preparing the final rule with comment period for FQHC preventive services, we noted that this list of services was not likely to significantly benefit the majority of Medicare beneficiaries. We worked with HRSA to expand the HRSA-required preventive primary health services. The ''Guide to Clinical Preventive Services,'' prepared under the supervision of the U.S. Preventive Services Task Force, provides further recommendations for clinical practice on additional preventive interventions. HRSA adopted the policy that the list of preventive primary health services recommended by the task force in the ''Guide to Clinical Preventive Services'' for people aged 65 or older is consistent with the preventive primary health services that its grantees are already required to provide.

The commenter believed that we should recognize services recommended for people under age 65 as preventive services for purposes of the FQHC benefit. The ''Guide to Clinical Preventive Services'' lists the same preventive services for both the under age 65 and the over age 65 populations, with the exception of counseling regarding sexual practices. The sexual practices category includes sexually transmitted diseases, partner selection, contraceptive devices, and unintended pregnancy. Since, the HRSA regulations at 42 CFR part 55 already include the majority of these services under preventive health education and family planning, we do not believe it is appropriate to explicitly include these in the list of preventive primary care services under Medicare.

Comment: One commenter noted the value of proper nutrition in health outcomes, particularly with diseases of

hypertension, obesity and diabetes. The commenter requested clarification regarding the provision of dietician services under the ''incident to'' provision if they are provided by a consultant.

Response: The FQHC benefit includes services furnished by certain professionals. Section 1861(aa)(1) of the Act defines these professionals as a physician, nurse practitioner, physician assistant, clinical psychologist or clinical social worker. The benefit also includes services furnished ''incident to'' the services of these professionals as long as the individual furnishing the service is an employee of the FQHC.

Dietician services could be covered FQHC services if provided to the beneficiary as ''incident to'' services. Dietician services must meet the criteria for ''incident to'' services established in sections 406 and 410 of the Medicare RHC and FQHC Manual. These sections state that services and supplies incident to a physician's or mid-level practitioner's professional services are covered as FQHC services as long as they are: furnished as an incidental, although integral, part of a professional's services; of a type commonly furnished either without charge or included in the FQHC's bill; of a type commonly furnished in a physician's office; services provided by clinic employees other than those services listed in section 400A of the Medicare RHC and FQHC Manual furnished under the direct, personal supervision of a physician or mid-level practitioner; and furnished by a member of the clinic or center's staff who is an employee of the clinic or center. These criteria follow the longstanding criteria for services ''incident to'' physician services.

The Medicare RHC and FQHC Manual provides that there must be a physician's or mid-level practitioner's personal service furnished to which the non-physician's services is an incidental, although integral, part. This does not mean, however, that each occasion of service by a nonphysician need also always be the occasion of the actual rendition of personal professional services by the physician or mid-level practitioner. This requirement is also met for nonphysician services furnished during a course of treatment in which the physician or mid-level practitioner performs an initial and subsequent service with a frequency that reflects his or her active participation in, and management of, the course of treatment. This means that there must have first been a direct, personal, professional service furnished by a physician or mid-level practitioner to initiate the course of treatment of which the nonphysician service is an incidental part. In addition, there must be subsequent services performed by the physician or mid-level practitioner of a frequency that indicates his or her continuing active participation in and arranging the patient's course of treatment.

Dietician services that are provided in an FQHC may be covered if they are provided directly by a physician or appropriate mid-level practitioner or are incident to his or her services. This does not include services that are provided independently by a dietician without the active involvement of the FQHC physician or mid-level practitioners.

Consistent with our longstanding policy, as reflected in section 406 of the Medicare RHC and FQHC Manual, ''incident to'' services must be furnished by a member of the clinic staff who is an employee of the clinic. Thus, in order for dietician services to be covered FQHC services, the dietician must be an employee of the FQHC. To determine the employer/employee relationship, the ''usual common law rules,'' that are referred to in section 210(j)(2) of the Act, are applied. In applying these rules, we consider not only who pays a person's salary and fringe benefits but also other factors including who has hiring and firing authority and who pays Federal Income Contributions Act (FICA) taxes and withholds income tax.

The requirement that personnel who perform ''incident to'' services must be employees of the clinic or center for purposes of coverage is a longstanding Medicare policy. The basis for this requirement is in section 1861(s)(2)(A) of the Act. This section limits coverage of ''incident to'' services to those services that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills. We have consistently interpreted this provision to exclude coverage of ''incident to'' services provided by non-employees of physicians, and in this case, of clinics. In addition, the employer/employee relationship requirement ensures that physicians will have the authority to exercise appropriate medical supervision and management control over the qualifications and performance of non-physicians for whose services he or she will be billing Medicare. Since the PHS Act encourages FQHCs to contract to provide services, we do not wish to create barriers to, and burdens on, FQHCs that wish to contract for non-physician professional services. Therefore, payment may be made for services provided by FQHC contracted professionals. However, this FQHC provision does not apply to RHC services. We plan to address this issue in a future proposed rule.

Comment: One commenter recommended that nutritional education and counseling be listed as a separate preventive primary health service.

Response: As noted above, the Act links preventive primary health services to the PHS requirements. Although HRSA guidelines include nutritional assessment, they do not include nutritional counseling and education. Because the HRSA guidelines do not specifically include nutritional education and counseling as a preventive primary health service, we do not have the authority to include these as preventive services in the FQHC regulations.

Nutritional education and counseling are tools to maintain or improve an individual's nutritional status. Generally, nutritional education and counseling can be defined as a means of educating the patient. Nutritional education and counseling for a Medicare beneficiary could be covered if it is provided to the beneficiary as a service that is ''incident to'' the service of a particular practitioner. The beneficiary must see an attending FQHC professional for a medical reason to which the nutritional education and counseling is incident. For example, nutritional education for a diabetic patient being actively monitored by an FQHC practitioner could be covered as an ''incident to'' service.

We note that encounters with a nurse or dietitian that are not associated with a visit by an FQHC practitioner are not billable as visits. The costs of the personnel providing the educational services, however, may be included in the center's allowable costs.

Comment: One commenter requested clarification of what is meant by nutrition assessment and who could perform the assessment. The commenter recommended that a registered dietitian is the best qualified professional to provide the service.

Response: HRSA guidelines include nutritional assessments and referrals as preventive primary health services; therefore they are covered as FQHC preventive primary health services. Because nutritional assessments are FQHC covered preventive services, any professional in an FQHC can provide these services. We believe that most physicians, nurse practitioners, and physician assistants, have the skills necessary to conduct a nutritional assessment as a preventive primary health service for Medicare beneficiaries.

However, the physician may use the services of a dietician employed by the FQHC for those beneficiaries who require extensive assistance in making dietary changes. As noted above, the services of a dietician may be covered under the FQHC benefit when the service is provided to the beneficiary as ''incident to'' the services of a physician, nurse practitioner, or a physician's assistant service. An FQHC professional must see the beneficiary for a medical reason to which the services of a dietician are incident. The initial face-to-face encounter with the attending professional is necessary for the service to be billed as an FQHC visit. The definition of a visit is discussed at § 405.2463.

Comment: Several commenters voiced strong objections to the exclusion of group counseling as a preventive service. They believed it is more efficient for the center to furnish needed counseling services, such as diabetic education, in a group setting rather than to use valuable physician time.

Response: As noted above, the Act links the definition of preventive primary health services under the FQHC benefit to the PHS law. Group counseling is not included as a preventive primary health service in the PHS law. As a result, we do not have the authority to include such services as FQHC preventive services.

In addition, group counseling is seldom a medical service, and generally, no active medical treatment is provided during a classroom situation. Moreover, there is an absence of scientific evidence that group counseling, such as smoking cessation classes, alters behavior or health status of individuals. Although group counseling services, such as diabetic education, are not covered preventive services, individual counseling services could be considered covered FQHC services if they are provided to the beneficiary as an ''incident to'' service.

Comment: One commenter noted that items five and six in the preventive services list both say prenatal. The commenter believed that one of the preventive services should be perinatal care.

Response: Section 1861(aa)(3)(B) of the Act specifies that FQHC services include preventive primary health services that a center is required to provide under sections 329, 330 and 340 of the PHS Act. In developing the FQHC regulations, we looked to 42 CFR parts 51c and 56 of the HRSA regulations. These regulations are repeated in § 405.2448 exactly as they are in the HRSA regulations; the HRSA regulations do not include perinatal services. However, the PHS law (see 45 U.S.C 329(a)(6)(C)) does provide for perinatal services. Therefore, we are revising § 405.2448 to include perinatal care as a covered preventive service.

Comment: Several commenters objected to the requirement in the preventive services definition that services be furnished by a physician or an employee of the center. The commenters noted that many centers make extensive use of contract services in the provision of preventive care services that may not be needed on a daily basis.

Response: The FQHC benefit includes a provision for services furnished ''incident to'' the services of FQHC professionals as long as the individuals furnishing the services are employees of the FQHC. As we noted above, it is a longstanding Medicare policy, based on our interpretation of section 1861(s)(2)(A) of the Act, that an individual who performs ''incident to'' services must be an employee of the clinic or center for purposes of coverage.

The list of FQHC preventive primary health services includes the type of services that does not generally require the skill level of a specialist. It is our intent that preventive primary health services, for the most part, involve a screening process to detect health conditions that could indicate adverse health outcomes. Patients should be referred for diagnostic services if the initial screening indicates a potential problem. Thus, we believe that the preventive primary health services specified in the regulations can be provided by the staff of the FQHC. As a result, we are retaining the requirement that FQHC preventive services be provided by either a physician or an employee of the center.

Comment: One commenter questioned how his facility, which provides noninvasive diagnostic services can be reimbursed through FQHCs.

Response: It is not clear what the commenter meant by ''noninvasive diagnostic services.'' Diagnostic laboratory services must be billed by the entity providing the services. Consequently, if the commenter intended to refer to laboratory services, the entity must bill for such services itself. As noted previously, diagnostic radiological services are not covered FQHC services. Thus, an entity could not be paid under the FQHC benefit for the technical component of radiological services. Although diagnostic radiological services are not covered FQHC services, a supplier can be paid for these services furnished to FQHC patients under normal Medicare Part B payment rules.

Comment: One commenter expressed concern that physicians and nurse practitioners are untrained in hearing testing and the fitting of hearing aids. The commenter recommended that Medicare ensure that beneficiaries have access to hearing aid distributors either for the initial FQHC covered hearing screening service or for follow-up services. The commenter suggested that we require that any patient whose screening shows that follow-up care is necessary be referred to a State licensed or National Board for Certification-Hearing Instrument Sciences (NBC-HIS) certified hearing aid distributor.

Response: According to section 1862(a)(7) of the Act, diagnostic audiological services for the purpose of fitting a hearing aid are not Medicare covered services. It would be inappropriate for the Medicare program to regulate referrals for such noncovered services.

The HRSA guidelines provide that hearing screening is a preventive primary health service. The skills that are needed to provide diagnostic services for hearing screening are minimal, and they can be acquired by staff with minimal training. Therefore, we believe that FQHC staff generally are qualified to perform hearing screening services for Medicare beneficiaries.

According to the Medicare Carrier's Manual, section 2070.3, additional diagnostic services beyond hearing screening are covered by Medicare when a physician orders such testing for the purpose of obtaining additional information necessary for his or her evaluation of the need for or appropriate type of medical or surgical treatment for a hearing deficit or related medical problem. However, additional service is not covered when the medical or surgical treatment is already known by the physician or is not under consideration and the diagnostic services are performed only to determine the need for or the appropriate type of hearing aid.

Comment: One commenter advised us of an upcoming HRSA directive requiring testing for tuberculosis of certain high risk patients. Since this will be a required preventive primary health service for all grantees, the commenter recommended that the Medicare list of preventive services be similarly amended.

Response: Since the Act links the definition of primary preventive services in an FQHC to the services required by HRSA of its grantees under sections 329, 330 and 340 of the PHS Act, we believe that the regulations should reflect HRSA guidelines. HRSA has sent a memorandum to grantees to

notify them that tuberculosis testing will be included as a preventive primary health service. Therefore, we are revising § 405.2448 to specify that FQHC covered preventive primary health services include testing of certain high risk patients for tuberculosis.

Clinical Psychologist and Clinical Social Workers

Comment: One commenter requested clarification as to why the RHC regulations were not similarly amended to include clinical psychologists and clinical social workers in accordance with changes made in the law years earlier.

Response: OBRA '87 added coverage of clinical psychologists in RHCs and OBRA '89 added coverage of clinical social workers in RHCs. We are in the process of developing a proposed rule to make those changes to the RHC regulations. Unlike the OBRA '89 provisions affecting RHCs, OBRA '90 authorized us to issue final regulations and add coverage of FQHCs without first issuing a proposed rule and soliciting public comment.

Comment: One commenter noted that the regulations state that clinical psychologist and clinical social worker services are covered if provided by a center employee. The commenter believed that it is often more efficient to contract for such service in the FQHC setting and recommends modification of the regulations to cover such purchased services.

Response: Previously, we permitted facilities to contract only for physician services. After considering the comment, we came to the conclusion that it would be inconsistent with the provisions of the PHS Act (as explained elsewhere in this preamble) to prohibit an FQHC from contracting for the services of clinical psychologists and clinical social workers. Therefore, we are revising § 405.2450 to provide that the services of clinical psychologists and clinical social workers may be covered if they are furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC. We are also revising §§ 405.2468 and 491.9(a)(3) to clarify that a clinical social worker or clinical psychologist may furnish services under contract to the FQHC.

Comment: One commenter objected to the limitation on clinical social worker service to those necessary to the diagnosis or treatment of mental illnesses. They noted that, given the special needs of the patient population served by FQHCs, social workers may perform other health related services for patients.

Response: Section 1861(hh)(2) of the Act provides that clinical social worker services include services performed by a clinical social worker for the diagnosis and treatment of mental illnesses. The Act does not indicate that any different definition of services provided by a clinical social worker should apply for purposes of the FQHC benefit.

The comment implies that the services of clinical social workers are needed to provide non-medical services to the FQHC population. Even if such services might be helpful to the FQHC population, non-medical services are not covered by Medicare under any circumstances.

Comment: Several commenters objected to the application of the 62½ percent mental health limitation to the FQHC clinical psychologist and clinical social worker. They argued that if the Congress had intended this limitation to apply, it would have explicitly stated so in the Act.

Response: Section 1833(c) of the Act states:

> Notwithstanding any other provision of this part, with respect to expenses incurred in any calendar year in connection with the treatment of mental, psychoneurotic and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b) only 62½ percent of such expenses.

This section of the Act clearly indicates that there is a mental health treatment limitation of 62½ percent for clinical psychologist and clinical social worker and other practitioner treatment services consistent with State law and makes clear that the limitation applies unless it is explicitly waived elsewhere in the law. This result is consistent with section 1861(hh)(2) of the Act, which defines clinical social worker services as services performed by a clinical social worker for the diagnosis and treatment of mental illnesses.

Since there is no statutory exception for FQHCs, the limitation on payment for mental health treatment applies to all FQHCs, free-standing and provider-based.

Payment Issues

Productivity Screening Guidelines

Comment: A commenter stated that the productivity standard of 4200 visits for a full time equivalent physician is not a reasonable standard and acknowledged that HRSA uses this standard but stated that HRSA applies the standard differently in regard to HRSA's encounters as opposed to HCFA's visits.

Response: Our use of the term ''visit'' is meant to be synonymous with the term ''encounter'' used by HRSA. The same concern about conflicting use of terms by us and HRSA was raised when we implemented productivity screens for the RHC program. At that time, we and HRSA agreed on the meaning of the terms ''encounter,'' as used by HRSA, and ''visit,'' as used by us; they were to be used interchangeably. (This issue was addressed in a final notice, Rural Health Clinic Payment Limits and Productivity Screening Guidelines, published in the Federal Register on December 1, 1982 at 47 FR 54165). We and HRSA agreed to a common definition of these two terms to eliminate any difficulties caused by the use of different terms. Clinics also found it difficult to comply with the separate productivity guidelines and reporting requirements used by us and HRSA. As a result we adopted the productivity screening guidelines used by HRSA. We continue to use the HRSA guidelines.

Since the time that we and HRSA originally reached agreement on the common meaning of ''encounter'' and ''visit,'' the RHC program has expanded and the FQHC program has been implemented. We have reexamined our definition. We are modifying the definition of a ''visit'' to accommodate the addition of clinical psychologists and clinical social workers (§ 405.2463). This change is discussed in more detail in answer to other comments. We will continue to use the HRSA productivity guideline of 4200 visits for full time equivalent.

Comment: A number of commenters stated that the screening guidelines are not appropriate for all FQHCs. For instance, a commenter stated that, without special attention, small rural health centers and those in frontier areas would be penalized by the productivity and overhead screens. Two other commenters stated that the standard should be lowered and that separate and lower standards should be developed to apply to FQHCs with home visiting and teaching programs. The commenter stated that Federal policy is clearly moving in the direction of providing incentives to increase the number of primary care physicians and that health centers will be increasingly asked to take on the role of residency training and argued that a productivity standard should not impede this policy direction. Additionally, two other commenters stated that the hourly standard, used in the past by the FFHCs, of 2.4 visits per hour is a more realistic standard than the one we had published.

Response: We use the same guidelines applied by HRSA in the grant review process and the ongoing monitoring of its programs. We believe it is appropriate to use uniform productivity guidelines rather than developing separate guidelines. If, however, an FQHC cannot meet these guidelines, the FQHC's intermediary has the authority to modify the productivity guidelines. An FQHC that has atypical circumstances may request exceptions to the guidelines from its intermediary.

Provider-Based/Freestanding FQHCs

Comment: Commenters questioned the need for different payment methodologies for freestanding and provider-based FQHCs and why provider-based FQHCs use an intermediary other than the intermediary used by the freestanding FQHCs and stated that the Act does not provide for a distinction between provider-based and freestanding FQHCs.

Response: As we stated in the June 12, 1992 final rule, the same qualification and coverage rules apply to both provider-based FQHCs and independent FQHCs. Section 1833(a)(3) of the Act allows the Secretary latitude in defining the payment methodology for FQHCs. Consistent with the RHC payment methodology, we believe, at this time, that two different methodologies should apply to provider-based and freestanding FQHCs, as well. Like an RHC, an FQHC that is an integral part of a provider should follow the rules applicable to the provider, since it is a provider component. Having the provider's intermediary pay the FQHC under the same cost reporting and payment procedures used by other components of the provider is more efficient, both from the standpoint of the intermediary and the provider. This promotes consistency and rationality in the payment system, eliminates duplicate audits and minimizes the possibility of program abuse.

Comment: A commenter pointed out that there is a cap for payment to freestanding FQHCs but not provider-based FQHCs.

Response: While there is no payment limit (cap) for provider-based FQHCs as there is for freestanding FQHCs, the allowable costs of provider-based FQHCs' are controlled by the Medicare principles of reimbursement. These principles permit us to determine if costs are reasonable and limit reimbursable costs to those that are allowable and necessary for the efficient delivery of services.

Comment: One commenter stated that freestanding FQHCs electing payment on a reasonable charge basis will not be reimbursed for preventive services and requested that the regulation clarify that provider-based FQHCs will be paid for preventive services. Another commenter suggested that the payment for these additional preventive services be specifically addressed and recommended that payment for these services be on an actual cost basis.

Response: All freestanding FQHCs are paid on an all-inclusive rate basis subject to tests of reasonableness. Freestanding FQHCs do not have the option to elect payment on a reasonable charge basis. Further, § 405.2446(b) specifies that FQHC services that are paid for under the Medicare program include preventive services specified in § 405.2448. This coverage applies to all FQHCs, freestanding as well as provider based. In addition, we do not believe that it is necessary to address specifically the payment method for these preventive services. Except for their purpose, these preventive services do not differ from the other services provided in a provider-based FQHC and therefore, are paid under the same reasonable cost principles as all other services.

Comment: One commenter questioned whether the lesser of costs or charges limitation, which currently is applied to provider-based FQHCs, should be applicable to any type of FQHC, as section 1833(a)(2) of the Act specifically provides that this limitation does not apply to FQHCs.

Response: Section 1833(a)(2) of the Act requires that the lesser of costs or charges limitation apply with respect to the facilities not excepted under that subparagraph; the requirement simply does not apply to FQHCs. Authority for payment for FQHCs is contained in section 1833(a)(3) of the Act, which provides that payment for FQHCs is based on reasonable costs that are ''related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations * * *''.

Given this broad grant of authority to use ''other tests of reasonableness,'' we are authorized to apply tests of reasonableness that are required to be applied to other Medicare facilities, such as the lesser of costs or charges provision.

Visits

Comment: Several commenters expressed concern with the number of visits per day we allow for payment purposes. They suggested that if a patient sees more than one physician or practitioner or has a medical and mental health service on the same day more than one visit should be allowed.

Response: We have considered the comments, and we are amending the regulations to permit payment for more than one visit per day under certain circumstances. We are revising the definition of visit in § 405.2401 and moving it to § 405.2463, ''What constitutes a visit.'' We now provide that Medicare pays for an additional visit per day if a patient has a ''medical visit'' and an ''other health visit'' on the same day. A ''medical visit'' is defined as a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse. An ''other health visit'' is defined as a face-to-face encounter between an FQHC patient and a clinical psychologist, clinical social worker, or other health professional for therapeutic mental health services. This change permits payment for more than one visit, but it does not change any other part of the method for determining allowable visits. We still would allow only one medical visit per day. Readers should note that an increase in visits will affect the FQHC all-inclusive rate calculation, as provided in § 405.2464.

Pneumococcal Vaccine

Comment: A commenter noted that the preamble stated that pneumococcal vaccine would be paid at 100 percent of the Medicare reasonable cost of the vaccine and its administration. However, the Annual Reconciliation section of the regulation did not address how we would pay for pneumococcal vaccine.

Response: We are revising § 405.2466(b), Annual Reconciliation, to provide that, for RHCs and FQHCs, payment for pneumococcal vaccine and its administration is made at 100 percent of Medicare reasonable cost.

Additionally, we are making a corresponding revision to the Annual Reconciliation section of the regulation for influenza vaccine. In accordance with sections 4071 and 4072 of OBRA '87, influenza vaccine and its administration became a covered Medicare service under section 1861(s)(10)(A) of the Act effective May 1, 1993.

Section 1833(a)(3) of the Act specifies that services described in section 1861(s)(10)(A) are exempt from payment at 80 percent of reasonable costs. For RHCs and FQHCs, payment for influenza vaccine and its administration is at 100 percent of reasonable cost. Like pneumococcal vaccine, influenza vaccine will be treated as a pass through

and not included in the all-inclusive rate or subject to the payment limit.

Prior to this change, costs of influenza vaccine were included in the calculation of the all-inclusive rate and subject to the FQHC payment limit. Therefore, the FQHC payment limit(s) has been adjusted to reflect the removal of influenza vaccine from the calculation of the all-inclusive rate. Removal of the influenza vaccine and its administration results in a reduction of approximately 1 percent to the FQHC payment limits.

Note: Influenza vaccine costs were included in the original calculation of the preventive service adjustment as discussed in the June 12, 1992 final rule, at 57 FR 24972.

Contracted Services

Comment: A commenter stated that if a physician is an independent contractor on the staff of the facility and not a physician whose services are purchased on a limited basis the physician should not be characterized as a contracted physician that is subject to the fee schedule.

Response: To determine whether a physician is considered an employee, the ''usual common law rules,'' referred to in section 210(j)(2) of the Act, are applied. These rules not only consider who pays the practitioner's salary but other factors such as who has hiring and firing authority, and who pays FICA taxes and withholds income tax. When a physician is considered staff of the FQHC, the physician's salary is included on the cost report and is used in determining the facility's all-inclusive payment rate.

Comment: A commenter stated that the allowable cost of contracted physician services is limited to the resource based relative value scale (RBRVS) fee schedule for the Medicare program, which is significantly below market. The commenter further stated that this limit would restrict the FQHCs' ability to attract needed physicians and specialists to their communities. The commenter stated that we should establish another test of reasonableness.

Additionally, another commenter stated that a more appropriate test of reasonableness for contracted services would be the amount that non-participating physicians may receive for services they provide to Medicare beneficiaries.

Response: We believe that payment for contracted physician services should be limited to amounts accepted by the large majority of physicians. According to the Report to Congress on Physician Participation, Assignment, and Extra Billing in the Medicare Program, dated October 2, 1992, there has been a continuing increase in the number of physicians accepting assignment on claims. When a physician accepts assignment on a claim, he or she agrees to accept the Medicare allowed amount as payment in full for the services provided to the beneficiary. The Report to Congress stated that allowed charges for Medicare assigned claims represented 83.6 percent of the total allowed charges in 1991. This is consistent with trends indicating that physician assignment rates have increased and have maintained a high level. Moreover, readers should note that the limit on contracted physician services is a screening guideline and not an absolute payment limit. The guideline is applied to assess the reasonableness of payments for physician services purchased by the center. The fiscal intermediary may modify application of this screen for atypical circumstances. For example, the screen may be modified if the intermediary determines that access to care is significantly affected. We believe that the amounts paid under the physician fee schedule are appropriate limits for contracted physician services.

Payment Limit

In response to the FQHC payment methodology published on June 12, 1992, we received comments from 18 commenters regarding the application of a payment limit. Six of these were from health centers and eight were from organizations and persons representing the health centers' interests. The remaining four commenters were organizations representing hospitals, physicians, and nurses. Discussion of comments regarding the FQHC payment limit have been organized into the following categories: General Payment Limit; Adjustment For Projected FQHC Visit Mix; Primary Care Family Practice Adjustment; Urban and Rural Determination; Urban and Rural Payment Difference; and Exceptions Option.

General Payment Limit

Comment: Many of the commenters questioned the method used to calculate the payment limits. Commenters stated that a payment limit of this nature is not required by the Congress, is not consistent with Congressional intent and exceeds statutory authority. Commenters were concerned that we used the RHC payment limit as a base for determining the reasonable costs for FQHC services. In addition, commenters stated that the payment limit methodology is not based on empirical data, not based on cost and is not equitable.

Response: The same statutory payment authority applies to RHCs and FQHCs. This authority provides the Secretary latitude in determining a payment methodology and in determining costs based on tests of reasonableness defined in regulations. In order to implement this new benefit in a manner consistent with the language of the law, we adopted the RHC methodology for use in the FQHC program. We believe that the Congress designed the FQHC program as a parallel program to the RHC program. Not only is the payment authority identical but the core services are also the same. The Congress added preventive services to this core set of services for FQHCs, and these services are unique to the FQHC program.

Inherent in the adoption of the RHC methodology is the use of the productivity screens and an overall limit on payment. The RHC payment limit established for independent facilities in 1978 and updated in 1982 was not only accepted by the Congress, it was written into law in OBRA '87 as a test of reasonableness for costs of RHC services, including clinical psychologist services, which were added to the benefit in the same legislation. The law provided for an update to the limit for 1988 and an annual update each year thereafter. We agree that an annual update is important for the viability of both the RHC and FQHC benefits. We also believe that, while it is critical to apply an overall limit to ensure efficiency and economy, we must establish a limit that takes into account the differences in the two benefits.

The FQHC methodology we created adjusts for differences between the RHC and FQHC benefits using available cost data. We have made adjustments to the RHC limit accounting for the general increase in physician payments resulting from the physician fee schedule amounts, a projected higher ratio in FQHCs than in RHCs of physician visits compared to mid-level practitioner visits, the addition of primary preventive services, and the fact that some FQHCs are located in urban areas.

In constructing our preventive service adjustment, we used allowable charge data. We believe that the calculation of this adjustment is consistent with the methodology used to compute the RHC limit, which used allowable charge data and is now statutorily set. We do not see any conflict between our methods and the intent of the Congress.

Comment: One commenter stated that the payment limits are unreasonable with respect to actual reasonable costs. The commenter stated that FFHCs in

Massachusetts received rates in the $78 to $88 range with a limit of approximately $96. The commenter contended that the FQHC payment limits understate the actual cost per visit for these section 329 and 330 grantees that were previously paid as FFHCs. Another commenter recommended that we adopt the FFHC State-wide payment limits for the next 3 years while the reasonable costs of FQHCs are studied. The commenter stated that a limit should be developed based on future data.

Response: We do not believe it is appropriate to compare FFHC and FQHC limits. The FQHC payment methodology and scope of services is different from those in the former FFHC program. The comments indicate confusion regarding the differences between the two benefits. Even with these basic differences, we are concerned that we do not disadvantage centers that were paid as FFHCs and that is why we are allowing an exception for these entities for a 3-year period.

FFHCs were formerly paid on a ''cost related to reasonable charge basis,'' which also resulted in an all-inclusive rate per visit based on facility-specific costs. Application and computation of the FFHC all-inclusive rate is significantly different from application and computation of the FQHC rate. The FQHC all-inclusive rate is paid when there is an encounter between a patient and a physician, physician assistant, nurse practitioner, clinical psychologist, or clinical social worker. The FFHC all-inclusive rate was paid only when there was an encounter between a patient and a physician. The FQHC all-inclusive rate per visit is calculated based on total allowable FQHC cost divided by physician, physician assistant, nurse practitioner, clinical psychologist, and clinical social worker visits. The FFHC rate per visit was calculated based on total allowable FFHC costs divided by physician visits. As a result, the FFHC all-inclusive rate formula had a divisor of only physician visits thus yielding a higher rate per visit.

Further, the scope of services for the FQHC and FFHC benefits is different. Section 1861(aa)(3) of the Act identifies FQHC services as physician, physician assistant, nurse practitioner, clinical psychologist and clinical social worker services, and services and supplies incident to the services of these practitioners. In addition, preventive primary health services that a center is required to provide under sections 329, 330 and 340 of the PHS Act are also included as FQHC services. Medicare freestanding FQHCs are paid an all-inclusive rate for these services for each encounter that meets the definition of a visit. FQHCs could receive additional payment for Medicare covered services that are outside of the FQHC scope of services.

The FFHC scope of services could potentially have included all Medicare Part B services. Therefore, total allowable FFHC services could have included a broader array of services. Medicare Part B services outside of the FQHC scope of services (such as other diagnostic and therapeutic services that a clinic obtains from an independent laboratory) were covered FFHC services, and included in the rate paid to FFHCs. All Medicare Part B services performed in an FFHC were included in determining the all-inclusive rate and paid for under the FFHC methodology for each FFHC visit. For these reasons, we do not believe the FFHC payment limits are appropriate for the FQHC benefit.

Comment: One commenter stated that the use of FFHC information in combination with RHC data to develop the FQHC payment limits does not assure adequate reasonable cost reimbursement for all FQHCs. The RHC and FFHC programs are optional programs in which organizations choose to participate. Entities granted FQHC status under OBRA '90 that did not participate in the FFHC program may be significantly different from FFHCs and RHCs in case load.

Response: As discussed in a prior response, we believe that the Congress designed the FQHC program as a parallel program to the RHC program, and we used the RHC payment limit as a basis for developing the FQHC payment limits. We adjusted the RHC payment limit based on FFHC data for a projected higher physician visit mix and for the urban differential. We understand the concern that the cost experience of FFHCs may not necessarily be representative of the costs of FQHCs as a whole. We analyzed 1990 data provided by the Public Health Service's Bureau of Primary Health Care Common Reporting Requirements (BCRR) Report to determine whether the cost per encounter would differ for FFHCs and other section 329 and 330 grantees. The data indicate that the median cost per visit for FFHCs was slightly higher than the median cost per visit for community and migrant health centers that were not paid as FFHCs. Since FFHC costs were actually higher than other section 329 and 330 grantees, we believe that using FFHC data would result in adequate reasonable cost payments.

We also considered the application of a case mix adjustment; however, we do not believe one is necessary given the FQHC scope of services. We believe that, since the primary mission of the FQHC program is to provide outpatient primary care services, the services should not vary substantially from one patient population to another.

As discussed in the preamble to the June 12, 1992 final rule with comment period, we will collect and analyze FQHC cost report data to determine if a payment limit adjustment is necessary. If after analysis, we find it necessary to adjust the methodology used to determine the FQHC limits currently in place, we will issue a proposed notice and the public will have an opportunity to comment.

Comment: One commenter stated that we should describe the specific tests of reasonableness in regulation text so that these methods may not be changed without public review and comment.

Response: We agree that a change in specific tests of reasonableness used to determine the all-inclusive rate should receive the benefit of public notice and comment. We will issue a proposed notice and the public will have the opportunity to comment if it is necessary for us to change the productivity or utilization screens used to determine the FQHC all-inclusive rate or to change the methodology used to calculate the FQHC payment limit.

Adjustment for Projected FQHC Visit Mix

Comment: One commenter stated that the Secretary did not use factual data to determine the difference in cost created by the projected difference in case mix. The commenter believed there is no evidence that the ratio of physician to mid-level payments made under Part B have any relation to cost.

Response: Since entities eligible for section 329, 330, and 340 grants will comprise the majority of entities qualifying for the FQHC program, we anticipate that the frequency of physician services in FQHCs will be comparable to the frequency of such services in the former FFHC program, which consisted of section 329 and 330 grantees paid an all-inclusive rate. As discussed in the preamble to the June 12, 1992 rule, we studied RHC and FFHC visit data to determine whether there is a difference in the number of physician visits as a percentage of total visits between the RHC benefit and FFHC program. Visit data from RHC cost reports indicated that physician visits were 59 percent of total visits while data from FFHC cost reports indicated that

physicians visits were 83 percent of total visits.

We recognize that no specific FQHC study has been conducted to determine the differences in costs between the services of a physician and those of a mid-level practitioner. We used the amount of payment for nurse practitioners and physician assistants under usual Part B rules as a measure of the cost differences between a physician and a mid-level practitioner. Under Medicare Part B, the amount of payments for nurse practitioners (section 1833(r)(2)(B) of the Act) and physician assistants (section 1842(b)(12)(B) of the Act) are generally 75 percent (in the case of services provided in a hospital) and 85 percent (in the case of other services) of what a physician would be paid for the same service. We used the midpoint of these two percentages to arrive at 80 percent as proxy for the cost differences between mid-level practitioners and physicians.

Lacking more specific FQHC cost data, we believe that the payment amount under Medicare Part B is a reasonable basis for determining average cost differences between visits of physicians and mid-level practitioners and for increasing the payment limit to account for the projected higher number of physician visits under the FQHC benefit as compared to the RHC benefit. As discussed earlier, we plan to evaluate actual FQHC cost data. After analysis, we will determine the appropriateness of the visit mix adjustment.

Primary Care Family Practice Adjustment (15 Percent)

Comment: Section 6102 of OBRA '89 added section 1848 of the Act, which is the authority for the physician fee schedule. During the first year of transition to the physician fee schedule there was a general increase in payment of 15 percent for services provided by primary care and family practice physicians. As discussed in the preamble to the interim final rule, we made an adjustment to the FQHC payment limits accounting for this increase.

One commenter stated that the 15 percent adjustment to the payment limit only covers the first year of the transition to the fee schedule. The remaining 4 years to fully implement the fee schedule will result in further increases. These increases should be recognized.

Response: We have given consideration to the commenter's position. By 1996, the average payment amount for services typically provided by family practice physicians will increase by an estimated 28 percent under the fee schedule, as compared to reasonable charge payments. Since our intent in creating and applying the family practice adjustment is to reflect the circumstances of physicians being paid under the fee schedule, we have decided to provide a comparable increase to the FQHC payment limits. We are increasing the practitioner component of the FQHC payment limits by 13 percent to bring the total increase amount to 28 percent to simulate the estimated increase in average payment amounts for primary care physicians. This adjustment will be phased in over 3 years. For calendar year 1994, we have increased the practitioner portion of the FQHC payment limits by 6.5 percent to correspond with the increase in payments for primary care services which has resulted from the continued transition to the full physician fee schedule. We previously announced this increase in the RHC/FQHC Manual. We will increase the payment limits by 3.25 percent in calendar year 1995 and calendar year 1996 to account for the full 28 percent increase.

The 28 percent increase is based on estimates published in the Federal Register (56 FR 59618) regarding the physician fee schedule regulation dated November 25, 1991; Table 1—Physician Fee Schedule Impact By Specialty. The 28 percent increase reflects the original estimation of the difference in payment amounts between what would have been paid under the reasonable charges payment methodology as compared to payments under the RBRVS fee schedule for services typically provided by family practice physicians. We believe it provides the most appropriate representation of the estimated differences in payment amounts. We have decided not to reflect the impact of the Medicare Volume Performance Standards since FQHC services are not subject to these targets. By adjusting the FQHC limits, we would avoid disadvantaging FQHC physicians and practitioners relative to physicians paid under the fee schedule.

Comment: One commenter stated that payments for other practitioners should also reflect the 15 percent increase.

Response: Implementation of the physician fee schedule resulted in a general estimated increase of 15 percent in 1992 for family practice physicians. We applied this increase to the practitioner component of the payment limit which resulted in a $6.99 increase for fiscal year 1991. This increase applies to the payment limit for each FQHC visit, mid-level practitioner covered visits, as well as physician visits.

Urban and Rural Determination

Comment: Two commenters indicated that the determination of urban and rural is unclear. Specific concerns focused on the need for clarification of specific population standards and whether adjustments to the classification (as provided for hospitals in § 412.230) are applicable to FQHCs.

Response: The definition of urban and rural is based entirely upon the most recent available data from the Bureau of Census and issued by the Office of Management and Budget. To be classified as an urban center, an FQHC must be located in a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Primary Metropolitan Statistical Areas (PMSAs) and Consolidated Metropolitan Statistical Areas (CMSAs) are considered as urban for FQHC classification purposes. FQHCs that are not in an MSA, PMSA, CMSA or NECMA cannot be reclassified as an urban FQHC.

Urban areas can either be ''large'' or ''other.'' A large urban area means an urban area with a population of over one million (or more than 970,000 in NECMAs). An ''other'' urban area is an urban area that is not a large urban area and at a minimum includes a city with a population of 50,000 or more provided that the component county/counties of the metropolitan statistical area have a total population of at least 100,000. The intermediary classifies FQHCs based on these criteria.

Urban and Rural Payment Difference

Comment: Many commenters expressed concerns regarding the urban payment differential. Specific concerns include:

- Historical differences in payment policy have affected the recruitment and retention of qualified health professionals and have caused a false perception that rural areas are less expensive.
- Labor, transportation and other costs can be higher in rural areas.
- Rural centers may expand services to compensate for the closing of small rural hospitals. Thus, they may be providing the only available radiology and laboratory services in the area.
- The FFHC study used to determine urban and rural cost differences was not appropriate. Urban and rural visit mix and services are not necessarily comparable and cost differences are not related to location; cost differences are more likely the result of rural facilities providing a more limited scope of

services. Therefore, we do not think this factor is relevant to payment limits.

Response: Our analysis of FFHC all-inclusive rates indicates a difference in urban and rural costs. FFHCs were authorized to provide the same scope of services regardless of urban or rural status. The analysis of FFHC all-inclusive rates included 128 urban and 85 rural FFHCs throughout the country. The analysis indicates that the median all-inclusive rate for FFHCs located in urban areas (as determined by using Bureau of Census data) is 16.3 percent higher than the median all-inclusive rate in rural areas. Since FFHCs were subject to the same State-wide payment limit without regard to urban/rural location, rural FFHCs did not have different incentives than urban FFHCs to hold down costs. Further, we obtained data from the Public Health Service based on the BCRR Report data and compared the cost per visit of 129 urban and 260 rural Community/Migrant Health Centers (section 329/330 grantees) that did not participate in the FFHC program. The BCRR Report cost data indicated that the cost per visit for services was significantly higher in urban centers as compared to rural centers. While different costs are reported on the BCRR Report as compared to the Medicare cost report, we believe these data support our use of FFHC cost data as proxy for urban and rural FQHC cost differences. We will closely study urban and rural cost differences in the FQHC cost data analysis.

We understand that rural centers might expand services to compensate for the closing of small rural hospitals and that many of these services may be outside of the FQHC benefit. While the expansion of services may extend beyond the FQHC scope of services, the Medicare per visit payment limits apply to covered FQHC services only. Medicare FQHCs can receive additional payments through the carrier for Medicare Part B services that are not included as FQHC covered services. Therefore, we do not think this factor is relevant to setting the payment limits.

Comment: Some commenters believed that the urban and rural payment limit difference is inconsistent with general Federal policy direction. They stated that the Congress recognized that urban and rural providers should be treated equally by terminating the urban and rural Prospective Payment System (PPS) payment differential in fiscal year 1995.

Response: We would like to clarify that the Congress has not eliminated geographic payment differences for payment of PPS hospitals. Effective in fiscal year 1995, there will be two PPS standardized amounts, large urban and other. The rural and other urban PPS standardized amounts will be combined into one amount and a separate large urban standardized amount will continue to distinguish large urban areas. The hospital wage index will be applied to these standardized amounts. As such, payment amounts will generally be higher in urban areas as compared to rural areas. Given the current data limitations, alternative geographic payment limit adjustments are not feasible at this time. As mentioned previously, we will closely study urban and rural cost differences in the FQHC cost data analysis.

MEI Index

Comment: One commenter expressed concern that separate application of the MEI to urban and rural payment limits will steadily exacerbate the urban-rural differential.

Response: Although we recognize that the dollar difference between urban and rural payment limits will increase, the percentage difference of 16.3 percent will remain constant.

Comment: One commenter requested clarification regarding publication of the MEI increase.

Response: The annual MEI updates applicable to the FQHC payment limits will be announced in the RHC and FQHC manual, HCFA Publication 27 of the HCFA Program Instructions Issuances System.

We note that the preamble of the June 12, 1992 rule stated that FQHC payment limits would be updated by the MEI applicable to primary care physicians. We would like to clarify that in the absence of a specific MEI applicable to primary care physicians, the FQHC payment limits will be updated by the general MEI.

Exceptions Option

Comment: Two commenters expressed opposition to the exceptions option. They stated that the exceptions option is an unreasonable imposition creating unnecessary administrative costs. In addition, requiring FQHCs to wait an entire year to file an exception will create cash flow problems for those granted an exception. Regional payment limits were also suggested as an alternative to the exceptions process.

Response: The exceptions process allows former FFHCs the opportunity to retain the FFHC method of payment with minor adjustments for the FQHC scope of services for a 3-year period under certain conditions. No FQHC is required to seek an exception; rather a center may choose this option if the center can document a disadvantage due to a decrease in revenues as a result of the application of the FQHC payment limit. As discussed in the preamble of the interim final rule, this determination will be made based on a filing of the FFHC cost report.

Any additional administrative costs resulting from the exceptions option are allowable costs that can be included in the determination of the all-inclusive rate. However, we expect exceptions to be limited in number and do not expect former FFHCs to be adversely affected. We believe it is essential that all centers, including former FFHCs, file based on the FQHC methodology so that we can gather cost data for our analysis.

We considered developing regional limits; however, we decided not to do so. We believe that the Congress designed the FQHC benefit to parallel the RHC benefit. Therefore, we want the FQHC payment methods to be as consistent as possible with the RHC payment methods, which do not include regional cost limits. As discussed earlier, we will collect and analyze FQHC cost data to determine if any changes are necessary.

Billing Issues

Comment: Two commenters requested clarification of the billing mechanism for non-FQHC services. One commenter noted that provisions for assignment of physician claims directly to the center were necessary so that the employment relationship between the physician and center is not disrupted.

Response: In order to bill for non-FQHC services a clinic must have a separate Part B billing number. The FQHC must obtain the billing number from the Medicare Part B carrier. Entities that already have supplier numbers for use in billing Part B carriers need to contact the carriers' Provider Relations Staff to see if their FQHC status necessitates the issuance of new Part B billing numbers. FQHC provider numbers assigned for the purpose of billing the intermediary (Aetna) cannot be used to bill Part B carriers. HCFA regional offices and Medicare carriers have been requested to assist FQHCs that require new Part B billing numbers.

We agree with the commenter on the issue of provisions of assignment. Section 1842(b)(6) of the Act specifies that Medicare may pay the center in which the physician provides services if there is a contractual arrangement between the facility and the provider. Therefore, there are existing provisions for assignment of physician claims directly to the center.

Comment: One commenter noted the difference in billing practices between Medicaid and Medicare, and

recommended that all FQHC services for both programs be billed on the HCFA–1500 using Common Procedure Terminology (CPT) Codes.

Response: There is no requirement for Medicare and Medicaid billing to be the same. Since payment for services covered under the FQHC benefit is made on a cost-related basis, claims are processed by a fiscal intermediary. All freestanding FQHC claims are processed by Aetna. Provider-based FQHC claims are processed by the intermediary that handles the main provider's claims.

The Medicare Fiscal Intermediaries' systems are set up to process bills using the HCFA–1450 and the Carriers' systems are set up to process claims using the HCFA–1500. The HCFA–1450 has different data elements from the HCFA–1500. To use the HCFA–1500 for cost-related payment would require a complete revision of the billing systems maintained by our contractors.

To recap, freestanding FQHCs must use the HCFA–1500 to bill for non FQHC services since they are not paid on a cost basis. The local Part B carrier pays for such services subject to the routine Part B coverage and payment provisions. Provider-based FQHCs bill the intermediary for all services on the HCFA–1450.

IV. Provisions of the Final Regulations

For the most part, as stated elsewhere in this preamble, this final rule does not change the provisions of the prior final rule on which we solicited comments. Those provisions of this final rule that differ significantly from the earlier rule are:

- The definition of specialized nurse practitioner is removed (§ 405.2401 and § 405.2468);
- A freestanding FQHC must terminate other provider agreements at the same time it becomes an FQHC (§ 405.2430(a)(1)(iii));
- The services of FQHC staff may be furnished under contract (§§ 405.2450, 405.2468(b)(1), and 491.8(a)(3));
- In the definition of ''visit,'' (now in § 405.2463) an allowance is made for two visits per day if the patient has a ''medical'' and an ''other'' health visit on the same day (§ 405.2463);
- Nurse-midwife services are added to the list of covered FQHC services (§ 405.2446);
- Perinatal care and tuberculosis testing for certain high risk patients are added to the list of preventive services that are covered by an FQHC (§ 405.2448);
- Payment for pneumococcal and influenza vaccines and their administration at 100 percent of Medicare reasonable cost is added to § 405.2466 (Note that payment for pneumococcal vaccine is not a new provision, as it was included in the June 12, 1992 final rule);
- We clarify that FQHCs must be located in a medically undeserved area or serve a medically undeserved population (§ 491.5);
- RHCs, but not FQHCs, retain certification even if the area loses its rural shortage designation (§ 491.5);
- Clinical psychologists provide FQHC services without the supervision of a physician (§ 491.8);
- We clarify that we have adjusted the FQHC payment limits to correspond with the estimated increase in payments for primary care services resulting from the continued transition to the full fee schedule. The current calendar year payment limits reflect this policy and a further increase is forthcoming in 1995.

V. Collection of Information Requirements

This final rule does not contain any information collection or recordkeeping requirements that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

A. Introduction

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all FFHCs, FQHCs, and RHCs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

B. Provisions of the Final Regulations

This final rule incorporates, with only minor technical and clarifying changes, the provisions of the final rule with comment published June 12, 1992 (57 FR 24961) which provided for coverage and payment of services provided by FQHCs, a category of health facility established by section 4161 of OBRA '90 and modified by OBRA '93. FQHC services are defined as the same type of primary health care services provided by rural health clinics under the Medicare program, plus preventive primary health services (services not previously covered by Medicare). An FQHC is an entity that is receiving a grant under section 329, 330, or 340 of the PHS Act; a non-grant receiving entity that is determined by the Secretary to meet the PHS Act requirements for receiving such a grant; a facility that has been identified by the Secretary as a comprehensive federally funded health center as of January 1, 1990; or is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act as of October 1, 1991. As of March 1994, there were 1,260 participating FQHCs.

C. Positive Effect of Regulations

In the initial regulatory impact statement, we indicated that the provisions of the final rule with comment will expand Medicare payment to community and migrant health center grantees and similar entities that qualify as FQHCs and serve the working poor. We noted that reporting requirements are less burdensome than previous requirements under the FFHC payment methodology (FQHCs are required to submit 2 cost reports annually, FFHCs were required to submit 3). In addition, these provisions benefit both beneficiaries and FQHCs by expanding Medicare coverage and payment to include primary and preventive health care services furnished by physicians and other health practitioners.

D. Comments on Initial Regulatory Impact Statement

We received one comment on the initial regulatory impact statement published in the Federal Register June 12, 1992. The commenter stated that the final rule with comment failed to include a certification that the rule would not have an effect on small entities. We disagree with the commenter. The final paragraph of the regulatory impact statement stated that we determined, and the Secretary certified, that the final rule did not meet the requirements to be determined a major rule, nor did it meet criteria as having a significant economic impact on a substantial number of small entities.

E. Summary

Because this final regulation makes only minor technical and clarifying changes to the final rule with comment published June 12, 1992, we are not preparing analyses for either the RFA or section 1102(b) of the Act, since we have determined, and the Secretary certifies, that this final rule will not result in a significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR chapter IV is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

A. Part 405, subpart X, is amended as follows:

1. The authority citation for subpart X continues to read as follows:

Authority: Secs. 1102, 1833, 1861(aa), 1871 of the Social Security Act; 42 U.S.C. 1302, 1395l, 1395x(aa), and 1395hh.

§ 405.2401 Scope and definitions. [Amended]

2. In § 405.2401, paragraph (b) is amended by removing the definitions of ''specialized nurse-practitioner'' and ''visit.''

3. Section 405.2430 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 405.2430 Basic requirements.

(a) Filing procedures. (1) * * *

(iii) The FQHC terminates other provider agreements, unless the FQHC assures HCFA that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

* * * * *

4. Section 405.2446 is amended by revising paragraph (b) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional services, as specified in § 405.2413.

(3) Nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as an incident to a nurse practitioner or physician assistant services, as specified in § 405.2415.

(5) Clinical psychologist and clinical social worker services specified in § 405.2450.

(6) Services and supplies furnished as an incident to a clinical psychologist or clinical social worker services, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Nurse-midwife services specified in § 405.2401.

(9) Preventive primary services specified in § 405.2448 of this subpart.

* * * * *

5. In § 405.2448(b), the semicolon at the end of each paragraph is changed to a period, paragraph (b)(20) is redesignated as (b)(21), paragraphs (b)(6) and (b)(19) are revised, and a new paragraph (b)(20) is added to read as follows:

§ 405.2448 Preventive primary services.

* * * * *

(b) * * *

(6) Perinatal services.

* * * * *

(19) Risk assessment and initial counseling regarding risks.

(20) Tuberculosis testing for high risk patients.

* * * * *

6. Section 405.2450 is amended by revising paragraph (a)(1) to read as follows:

§ 405.2450 Clinical psychologist and clinical social worker services.

(a) For clinical psychologist or clinical social worker professional services to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

* * * * *

7. A new § 405.2463 is added to read as follows:

§ 405.2463 What constitutes a visit.

(a) *Visit.* (1) A visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(2) For FQHCs, a visit also means a face-to-face encounter between a patient and a qualified clinical psychologist or clinical social worker.

(3) Encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when one of the following conditions exist:

(i) After the first encounter, the patient suffers illness or injury requiring additional diagnosis or treatment.

(ii) For FQHCs, the patient has a medical visit and an other health visit, as defined in paragraphs (b) and (c) of this section.

(4) *Payment.* (i) Medicare pays for two visits per day when the conditions in paragraph (a)(3) of this section are met.

(ii) In all other cases, payment is limited to one visit per day.

(b) *Medical visit.* For purposes of paragraph (a)(3) of this section, a medical visit is a face-to-face encounter between an FQHC patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(c) *Other health visit.* For purposes of paragraph (a)(3) of this section, an other health visit is a face-to-face encounter between an FQHC patient and a clinical psychologist, clinical social worker, or other health professional for mental health services.

8. Section 405.2466 is amended by adding a new paragraph (b)(1)(iv) to read as follows:

§ 405.2466 Annual reconciliation.

* * * * *

(b) * * *

(1) * * *

(iv) For rural health clinics and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost.

* * * * *

9. Section 405.2468 is amended by revising paragraphs (b)(1) and (b)(3), and (d)(2) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(b) * * *

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, nurse-midwife, visiting nurse, qualified clinical psychologist, and clinical social worker who owns, is employed by, or furnishes services under contract to an FQHC. (RHCs are not paid for services furnished by contracted individuals other than physicians.)

* * * * *

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, or clinical social worker.

* * * * *

(d) * * *

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, and clinical social workers.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other clinic or center personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the clinic or center, subject to the limitation that the costs of physician services purchased by the clinic or center may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

* * * * *

B. Part 491 is amended as follows:

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

1. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302) and sec 353 of the Public Health Services Act (42 U.S.C. 263a).

2. In part 491, the term, ''Federally qualified health center'' is changed to ''FQHC'' wherever the term appears.

3. Section 491.5 is amended by revising paragraphs (a) and (b)(1), and adding new paragraphs (e) and (f) to read as follows:

§ 491.5 Location of clinic or center.

(a) *Basic requirements.* (1) An RHC is located in a rural area that is designated as a shortage area.

(2) An FQHC is located in a rural or urban area that is designated as either a shortage area or an area that has a medically underserved population.

(3) Both the RHC and the FQHC may be permanent or mobile units.

(i) *Permanent unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a permanent structure.

(ii) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a mobile structure, which has fixed, scheduled location(s).

(iii) *Permanent unit in more than one location.* If clinic or center services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic or for approval as an FQHC.

(b) *Exceptions.* (1) HCFA does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

* * * * *

(e) *Medically underserved population.* A medically underserved population includes the following:

(1) A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.

(2) A population group that is designated by PHS as having a shortage of personal health services.

(f) *Requirements specific to FQHCs.* An FQHC approved for participation in Medicare must meet one of the following criteria:

(1) Furnish services to a medically underserved population.

(2) Be located in a medically underserved area, as demonstrated by an application approved by PHS.

4. Section 491.8 is amended by revising paragraphs (a)(3), (a)(6) and (b)(1)(i) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) *Staffing.* * * *

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the center.

* * * * *

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates.

(b) *Physician responsibilities.* (1) The physician—

(i) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 6, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: March 18, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–7787 Filed 4–2–96; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA–7176]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the base (1% annual chance) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Acting Associate Director, Mitigation Directorate, reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street, SW, Washington, DC 20472, (202) 646–2756.

SUPPLEMENTARY INFORMATION: The modified base flood elevations are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities.

The changes in base flood elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Acting Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This interim rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 65 is amended to read as follows:

PART 65—[AMENDED]

1. The authority citation for Part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

State and County	Location	Dates and Name of Newspaper Where Notice Was Published	Chief Executive Officer of Community	Effective Date of Modification	Community Number
California: Contra Costa	City of Clayton	March 7, 1996, March 14, 1996, *Contra Costa Times.*	The Honorable Robert Kendall, Mayor, City of Clayton, P.O. Box 280, Clayton, California 94517.	February 5, 1996	060027
California: Contra Costa	City of Concord	March 7, 1996, March 14, 1996, *Contra Costa Times.*	The Honorable Lou Rosas, Mayor, City of Concord, 1950 Parkside Drive, Concord, California 94519.	February 5, 1996	065022
California: Sonoma	City of Cotati	February 7, 1996, February 14, 1996, *Press Democrat.*	The Honorable John Dell'Osso, Mayor, City of Cotati, 201 West Sierra Avenue, Cotati, California 94931.	January 11, 1996	060377
California: San Luis Obispo.	City of El Paso de Robles.	February 8, 1996, February 15, 1996, *Daily Press.*	The Honorable Walter Macklin, Mayor, City of El Paso de Robles, 1000 Spring Street, El Paso de Robles, California 93446.	January 11, 1996	060308

State and County	Location	Dates and Name of Newspaper Where Notice Was Published	Chief Executive Officer of Community	Effective Date of Modification	Community Number
Colorado: Arapahoe	Unincorporated Areas ...	February 15, 1996, February 22, 1996, *The Villager*.	The Honorable Thomas R. Eggert, Chairperson, Arapahoe County Board of Commissioners, 5334 South Prince Street, Littleton, Colorado 80166.	January 16, 1996	080011
Colorado: Archuleta	Unincorporated Areas ...	February 22, 1996, February 29, 1996, *Pagosa Springs Sun*.	The Honorable Bill Tallon, Chairman, Archuleta Board of County Commissioners, P.O. Box 1507, Pagosa Springs, Colorado 81147.	January 23, 1996	080273
Colorado: Boulder	City of Boulder	February 22, 1996, February 29, 1996, *Daily Camera*.	The Honorable Leslie Durgin, Mayor, City of Boulder, P.O. Box 791, Boulder, Colorado 80306.	January 16, 1996	080024
Colorado: El Paso	City of Colorado Springs	February 21, 1996, February 28, 1996, *Gazette Telegraph*.	The Honorable Robert Isaac, Mayor, City of Colorado Springs, P.O. Box 1575, Colorado Springs, Colorado 80901.	January 22, 1996	080060
Colorado: Jefferson	City of Golden	February 9, 1996, February 16, 1996, *Golden Transcript*.	The Honorable Marvin Kaye, Mayor, City of Golden, City Hall, 911 10th Street, Golden, Colorado 80401.	January 11, 1996	080090
Colorado: Arapahoe and Douglas.	City of Littleton	February 29, 1996, March 7, 1996, *Littleton Independent*.	The Honorable Dennis Reynolds, Mayor, City of Littleton, 2255 West Berry Avenue, Littleton, Colorado 80165.	February 6, 1996	080017
Colorado: Archuleta	Town of Pagosa Springs.	February 22, 1996, February 29, 1996, *Pagosa Springs Sun*.	The Honorable Ross Aragon, Mayor, Town of Pagosa Springs, P.O. Box 1859, Pagosa Springs, Colorado 81147.	January 23, 1996	080019
Oklahoma: Garfield	City of Enid	February 22, 1996, February 29, 1996, *Enid News and Eagle*.	The Honorable Michael G. Cooper, Mayor, City of Enid, P.O. Box 1768, Enid, Oklahoma 73702–1768.	January 23, 1996	400062
Oklahoma: Canadian	City of Oklahoma City ...	February 15, 1996, February 22, 1996, *Journal Record*.	The Honorable Ronald J. Norick, Mayor, City of Oklahoma City, 200 North Walker Avenue, Oklahoma City, Oklahoma 73102.	January 22, 1996	405378

State and County	Location	Dates and Name of Newspaper Where Notice Was Published	Chief Executive Officer of Community	Effective Date of Modification	Community Number
Texas: Travis	City of Austin	February 22, 1996, February 29, 1996, *Austin American Statesman*.	The Honorable Bruce Todd, Mayor, City of Austin, P.O. Box 1088, Austin, Texas 78767.	January 19, 1996	480624
Texas: Denton	Unincorporated Areas	February 21, 1996, February 28, 1996, *Lewisville Leader*.	The Honorable Jeff Moseley, Denton County Judge, Denton County Commissioner's Court, Courthouse on the Square, 110 West Hickory, Denton, Texas 76201.	February 2, 1996	480774
Texas: Denton	City of Lewisville	February 21, 1996, February 28, 1996, *Lewisville Leader*.	The Honorable Bobbie J. Mitchell, Mayor, City of Lewisville, P.O. Box 299002, Lewisville, Texas 75029.	February 2, 1996	480195
Texas: Dallas	City of Mesquite	March 7, 1996, March 14, 1996, *Mesquite News*.	The Honorable Cathye Ray, Mayor, City of Mesquite, P.O. Box 850137, Mesquite, Texas 75185–0137.	January 31, 1996	485490
Texas: Collin	City of Plano	February 21, 1996, February 28, 1996, *Plano Star Courier*.	The Honorable James N. Muns, Mayor, City of Plano, P.O. Box 860358, Plano, Texas 75086–0358.	January 29, 1996	480140

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: March 25, 1996.

Richard W. Krimm,

Acting Associate Director for Mitigation.

[FR Doc. 96–8125 Filed 4–2–96; 8:45 am]

BILLING CODE 6718–04–P

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Modified base (1% annual chance) flood elevations are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATE: The effective dates for these modified base flood elevations are indicated on the following table and revise the Flood Insurance Rate Map(s) in effect for each listed community prior to this date.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street, SW, Washington, DC 20472, (202) 646–2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below of the final determinations of modified base flood elevations for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Acting Associate Director has resolved any appeals resulting from this notification.

The modified base flood elevations are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection.

The modifications are made pursuant to Section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 et seq., and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that

the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities.

These modified elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

The changes in base flood elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Acting Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 65 is amended to read as follows:

PART 65—[AMENDED]

1. The authority citation for Part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

States and County	Location	Dates and Name of Newspaper Where Notice Was Published	Chief Executive Officer of Community	Effective Date of Modification	Community Number
California: Ventura (FEMA Docket No. 7162).	City of Camarillo	October 27, 1995, November 3, 1995, *Camarillo Star.*	The Honorable Michael Morgan, Mayor, City of Camarillo, P.O. Box 248, Camarillo, California 93011.	September 26, 1995	065020
California: Fresno (FEMA Docket No. 7162).	City of Clovis	October 10, 1995, October 17, 1995, *Fresno Bee.*	The Honorable Harry Armstrong, Mayor, City of Clovis, 1033 Fifth Street, Clovis, California 93612.	September 20, 1995	060044
California: Fresno (FEMA Docket No. 7162).	City of Fresno	October 10, 1995, October 17, 1995, *Fresno Bee.*	The Honorable Jim Patterson, Mayor, City of Fresno, 2600 Fresno Street, Fresno, California 93721–3604.	September 20, 1995	060048
California: Fresno (FEMA Docket No. 7162).	Unincorporated Areas ...	October 10, 1995, October 17, 1995, *Fresno Bee.*	The Honorable Sharon Levy, Chairman, Fresno County Board of Supervisors, 2281 Tulare Street, Hall of Records, Room 301, Fresno, California 93721–2198.	September 20, 1995	065029
California: Santa Barbara (FEMA Docket No. 7167).	City of Santa Barbara ...	November 2, 1995, November 9, 1995, *Santa Barbara News Press.*	The Honorable Harriet Miller, Mayor, City of Santa Barbara, City Hall, P.O. Box 1990, Santa Barbara, California 93102–1990.	October 11, 1995	060335

States and County	Location	Dates and Name of Newspaper Where Notice Was Published	Chief Executive Officer of Community	Effective Date of Modification	Community Number
California: Santa Clara (FEMA Docket No. 7162).	City of Saratoga	October 25, 1995, November 1, 1995, *Saratoga News*.	The Honorable Ann Marie Burger, Mayor, City of Saratoga, 13777 Fruitvale Avenue, Saratoga, California 95070.	October 6, 1995	060351
California: Ventura (FEMA Docket No. 7162).	Unincorporated Areas ...	October 27, 1995, November 3, 1995, *Ventura County Star*.	The Honorable Maggie Kildee, Chairperson, Ventura County Board of Supervisors, 800 South Victoria Avenue, Ventura, California 93009.	September 26, 1995	060413
Colorado: Adams, Arapahoe, and Douglas (FEMA Docket No. 7162).	City of Aurora	October 25, 1995, November 1, 1995, *The Aurora Sentinel*.	The Honorable Paul E. Tauer, Mayor, City of Aurora, 1470 South Havana Street, Aurora, Colorado 80012.	October 11, 1995	080002
Colorado: El Paso (FEMA Docket No. 7167).	City of Colorado Springs	November 21, 1995, November 28, 1995, *Gazette Telegraph*.	The Honorable Robert M. Isaac, Mayor, City of Colorado Springs, P.O. Box 1575, Colorado Springs, Colorado 80901.	October 25, 1995	080060
Colorado: El Paso (FEMA Docket No. 7167).	Unincorporated Areas ...	November 21, 1995, November 28, 1995, *Gazette Telegraph*.	The Honorable Loren Whittemore, Chairperson, El Paso County Board of Commissioner, 27 East Vermijo, Third Floor, Colorado Springs, Colorado 80903–2225.	October 25, 1995	080059
Hawaii: Maui (FEMA Docket No. 7160).	Unincorporated Areas ...	September 20, 1995, September 27, 1995, *Maui News*.	The Honorable Linda Crockett Lingle, Mayor, Maui County, 250 South High Street, Wailuku, Maui, Hawaii 96793.	August 17, 1995	150003
Louisiana: Rapides Parish (FEMA Docket No. 7162).	Rapides Parish	October 12, 1995, October 19, 1995, *Alexandria Daily Town Talk*.	The Honorable Myron K. Lawson, President, Rapides Parish Police Jury, P.O. Box 1150, Alexandria, Louisiana 71309–1150.	September 20, 1995	220145
Missouri: Greene (FEMA Docket No. 7167).	Unincorporated Areas ...	November 3, 1995, November 10, 1995, *News-Leader*.	The Honorable David L. Coonrod, Presiding Commissioner, Greene County Commission, 940 Boonville Avenue, Springfield, Missouri 65802.	October 18, 1995	290782
Nebraska: Douglas (FEMA Docket No. 7162).	City of Omaha	October 11, 1995, October 18, 1995, *Omaha World Herald*.	The Honorable Hal Daub, Mayor, City of Omaha, City Hall, 1819 Farnam Street, Suite 300, Omaha, Nebraska 68183.	September 14, 1995	315274

States and County	Location	Dates and Name of Newspaper Where Notice Was Published	Chief Executive Officer of Community	Effective Date of Modification	Community Number
Oklahoma: Cleveland (FEMA Docket No. 7167).	City of Norman	October 24, 1995, October 31, 1995, *Norman Transcript*.	The Honorable William Nations, Mayor, City of Norman, 201 West Gray, Norman, Oklahoma 73070.	October 18, 1995	400046
Oklahoma: Oklahoma (FEMA Docket No. 7167).	City of Oklahoma City ...	October 22, 1995, October 29, 1995, *Journal Record*.	The Honorable Ronald J. Norick, Mayor, City of Oklahoma City, 200 North Walker Avenue, Oklahoma City, Oklahoma 73102.	November 2, 1995	405378
Oregon: Jefferson (FEMA Docket No. 7162).	City of Culver	October 4, 1995, October 11, 1995, *Madras Pioneer*.	The Honorable Joanne G. Heare, Mayor, City of Culver, P.O. Box 256, Culver, Oregon 97734.	September 6, 1995	410290
Oregon: Marion and (FEMA Docket No. 7162).	City of Salem	October 26, 1995, November 2, 1995, *Stateman Journal*.	The Honorable Roger Gertenrich, Mayor, City of Salem, City Hall, 555 Liberty Street Southeast, Salem, Oregon 97301–3503.	October 6, 1995	410167
Texas: Tarrant (FEMA Docket No. 7162).	City of Arlington	October 19, 1995, October 26, 1995, *Fort Worth Star Telegram*.	The Honorable Richard Greene, Mayor, City of Arlington, P.O. Box 231, Arlington, Texas 76004–0231.	September 27, 1995	485454
Texas: Tarrant (FEMA Docket No. 7167).	City of Bedford	November 2, 1995, November 9, 1995, *Fort Worth Star Telegram*.	The Honorable Rick D. Hurt, Mayor, City of Bedford, P.O. Box 157, Bedford, Texas 76095–0157.	October 13, 1995	480585
Texas: Coryell (FEMA Docket No. 7162).	City of Copperas Cove .	October 12, 1995, October 19, 1995, *Killeen Daily Herald*.	The Honorable J. A. Darosett, Mayor, City of Copperas Cove, P.O. Drawer 1449, Copperas Cove, Texas 76522.	September 19, 1995	480155
Texas: El Paso (FEMA Docket No. 7167).	City of El Paso	November 7, 1995, November 14, 1995, *El Paso Times*.	The Honorable William S. Tilney, Mayor, City of El Paso, Two Civic Center Plaza, El Paso, Texas 79901.	October 18, 1995	480214
Texas: El Paso (FEMA Docket No. 7162).	City of El Paso	October 19, 1995, October 26, 1995, *El Paso Times*.	The Honorable Larry Francis, Mayor, City of El Paso, El Paso, Texas 79901–1196.	September 15, 1995	480214
Texas: Bexar (FEMA Docket No. 7162).	City of Fair Oaks Ranch	October 18, 1995, October 25, 1995, *Hill County Recorder*.	The Honorable E. L. Gaubatz, Mayor, City of Fair Oaks Ranch, 7286 Dietz Elkhorn, Fair Oaks Ranch, Texas 78015.	September 13, 1995	481644

States and County	Location	Dates and Name of Newspaper Where Notice Was Published	Chief Executive Officer of Community	Effective Date of Modification	Community Number
Texas: Williamson (FEMA Docket No. 7167).	City of Georgetown	November 22, 1995, November 29, 1995, *Williamson County Sun*.	The Honorable Leo Wood, Mayor, City of Georgetown, P.O. Box 409, Georgetown, Texas 78627.	November 8, 1995	480668
Texas: Gregg and Rusk (FEMA Docket No. 7160).	City of Kilgore	September 22, 1995, September 29, 1995, *Kilgore News Herald*.	The Honorable Bill Wilson, Mayor, City of Kilgore, P.O. Box 1125, Kilgore Texas.	August 23, 1995	480263
Texas: Tarrant (FEMA Docket No. 7167).	City of Pantego	November 22, 1995, November 29, 1995, *Fort Worth Commercial Reporter*.	The Honorable Susan Abercrombie, Mayor, Town of Pantego, 1614 South Bowen Road, Pantego, Texas 76013.	October 31, 1995	481116
Texas: Collin (FEMA Docket No. 7162).	City of Plano	October 19, 1995, October 26, 1995, *Dallas Morning News*.	The Honorable James N. Muns, Mayor, City of Plano, P.O. Box 860358, Plano, Texas 75086–0358.	September 27, 1995	480140
Texas: Tom Green (FEMA Docket No. 7162).	City of San Angelo	October 20, 1995, October 27, 1995, *San Angelo Standard Times*.	The Honorable Dick Funk, Mayor, City of San Angelo, P.O. Box 1751, San Angelo, Texas 76902–1751.	September 27, 1995	480623
Texas: Williamson (FEMA Docket No. 7167).	Unincorporated Areas ...	November 22, 1995, November 29, 1995, *Williamson County Sun*.	The Honorable John Doerfler, Williamson County Judge, County Courthouse, 710 Main Street, Georgetown, Texas 78626.	November 8, 1995	481079

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: March 25, 1996.

Richard W. Krimm,

Acting Associate Director for Mitigation.

[FR Doc. 96–8126 Filed 4–2–96; 8:45 am]

BILLING CODE 6718–04–P

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Base (1% annual chance) flood elevations and modified base flood elevations are made final for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the FIRM is available for inspection as indicated in the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street, SW, Washington, DC 20472, (202) 646–2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes final determinations listed below of base flood elevations and modified base flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the Federal Register.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR Part 67.

FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR Part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The base flood elevations and modified base flood elevations are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Acting Associate Director for Mitigation certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 67 is amended to read as follows:

PART 67—[AMENDED]

1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
ARIZONA	
Flagstaff (City), Coconino County (FEMA Docket No. 7163)	
Clay Avenue Wash:	
At Milton Road	*6,894
Approximately 450 feet upstream of Malpais Lane	*6,899
Approximately 80 feet upstream of Blackbird Forest Street	*6,901
At Chateau Drive	*6,905
Approximately 980 feet upstream of Chateau Drive	*6,930
Approximately 1,300 feet upstream of Chateau Drive	*6,931
Maps are available for inspection at the City of Flagstaff City Hall, 211 West Aspen Avenue, Flagstaff, Arizona.	
ARKANSAS	
Pulaski County (Unincorporated Areas) (FEMA Docket No. 7161)	
Little Maumelle River:	
At confluence of Nowlin Creek	*269
Approximately 120 feet upstream of State Highway 10	*295
Just downstream of Ferndale Cutoff Road	*358
Just upstream of Grimmett Lane	*476
Just upstream of Brush Mountain Trail	*564
Kinley Creek:	
Approximately 1,000 feet upstream of confluence with Nowlin Creek	*295
Approximately 150 feet upstream of State Highway 10	*310
Just upstream of Garrison Road	*396
Just upstream of Copper Creek Lane	*428
Nowlin Creek:	
Approximately 1,700 feet above mouth	*270
Approximately 150 feet downstream of Barrett Road	*281
Just downstream of Goodson Road	*330
Approximately 100 feet upstream of county road	*400
At upstream Limits of Detailed Study located at a county road	*500
McHenry Creek:	
Approximately 1,150 feet upstream of Lawson Road	*359
Approximately 200 feet upstream of Lawson Road	*406
Approximately 150 feet upstream of Green Bear Road	*489
Just upstream of Colonel Glenn Road	*546
Maps are available for inspection at the Planning Department, Pulaski County, 501 West Markham Street, Suite A, Little Rock, Arkansas.	
CALIFORNIA	
Cathedral (City), Riverside County (FEMA Docket No. 7126)	
Whitewater River:	
Approximately 1,400 feet downstream of Date Palm Road	*283
At Date Palm Road	*291
Approximately 1,850 feet downstream of Cathedral Canyon Drive	*297
Approximately 1,700 feet upstream of Cathedral Canyon Drive	*317
Approximately 2,000 feet downstream of 34th Avenue (Dinah Shore Drive)	*320
Approximately 2,000 feet upstream of 34th Avenue (Dinah Shore Drive)	*341
At Ramon Road	*362
Approximately 4,000 feet upstream of Ramon Road	*388
Approximately 4,200 feet downstream of Vista Chino Road	*414
Approximately 1,750 feet downstream of Vista Chino Road	*433
Approximately 1,500 feet upstream of Vista Chino Road	*455
Approximately 4,250 feet upstream of Vista Chino Road	*476
Whitewater River Left Overbank Flooding:	
Approximately 10,400 feet downstream of 34th Avenue (Dinah Shore Drive)	None
Approximately 8,600 feet downstream of 34th Avenue (Dinah Shore Drive)	None
Approximately 5,700 feet downstream of 34th Avenue (Dinah Shore Drive)	None
Approximately 1,600 feet downstream of 34th Avenue (Dinah Shore Drive)	None
Approximately 400 feet upstream of 34th Avenue (Dinah Shore Drive)	None
Approximately 100 feet upstream of Ramon Road	None
Approximately 100 feet upstream of 30th Avenue	None
Approximately 100 feet downstream of Vista Chino Road	None
Approximately 1,800 feet upstream of Vista Chino Road	None

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Maps are available for inspection at the Building and Planning Department, City of Cathedral City, 35325 Date Palm Drive, #136, Cathedral City, California.	
Cloverdale (City), Sonoma County (FEMA Docket No. 7161)	
Cloverdale Creek:	
At confluence with Russian River	*302
Just upstream of Southern Pacific Railroad bridge	*315
Just upstream of Third Street	*338
Approximately 200 feet upstream of Cloverdale Boulevard	*374
Approximately 100 feet upstream of Portofino Way	*385
Maps are available for inspection at the City of Cloverdale, Department of Public Works, 124 North Cloverdale Boulevard, Cloverdale, California	
Coalinga (City), Fresno County (FEMA Docket No. 7161)	
Warthan Creek:	
At confluence with Los Gatos Creek	*643
Approximately 200 feet downstream of Jayne Avenue (both levees intact)	*658
Approximately 200 feet downstream of Jayne Avenue (right levee failed)	*657
Approximately 200 feet downstream of Jayne Avenue (left levee failed)	*656
Approximately 5,000 feet upstream of Jayne Avenue	*675
Los Gatos Creek:	
Approximately 3,150 feet downstream of confluence with Warthan Creek (levee intact)	*633
Approximately 3,150 feet downstream of confluence with Warthan Creek (right levee failed)	*638
Just downstream of Southern Pacific Railroad (abandoned railroad)	*652
Approximately 1,600 feet upstream of confluence with Coalmine Canyon Creek	*683
Maps are available for inspection at the Planning Department, City of Coalinga, 155 West Durin Street, Coalinga, California.	
Corona (City), Riverside County (FEMA Docket No. 7126)	
Arlington Channel:	
Approximately 600 feet downstream of Riverside Freeway	*604
Approximately 200 feet upstream of Riverside Freeway	*612
Approximately 200 feet downstream of Parkridge Avenue	*625
Approximately 3,800 feet upstream of Parkridge Avenue	*647
Approximately 900 feet upstream of Atchison, Topeka, and Santa Fe Railroad	*664
South Norco Channel Tributary A:	
Approximately 3,150 feet upstream of Hamner Avenue	*617
Approximately 4,900 feet upstream of Hamner Avenue	*629
Temescal Wash:	
Approximately 900 feet downstream of Lincoln Avenue	*563
Approximately 400 feet upstream of Lincoln Avenue	*572
At Cota Street	*572
Approximately 600 feet upstream of River Road	*580
Approximately 150 feet upstream of Joy Street	*591
Approximately 100 feet downstream of Atchison, Topeka, and Santa Fe Railroad	*605
Approximately 1,600 feet upstream of Magnolia Avenue	*653
Approximately 2,800 feet upstream of Magnolia Avenue	*660
Approximately 4,600 feet upstream of Magnolia Avenue	*667
Approximately 6,600 feet upstream of Magnolia Avenue	*634
Maps are available for inspection at the Public Works Department, City of Corona, 815 West 6th Street, Corona, California.	
Fresno County (Unincorporated Areas) (FEMA Docket No. 7161)	
Warthan Creek:	
Approximately 1,200 feet upstream of confluence with Los Gatos Creek	*648
Approximately 5,000 feet upstream of Jayne Avenue	*675
Approximately 5,900 feet upstream of Alcalde Road	*739
Lost Gatos Creek:	
Approximately 9,000 feet downstream of Southern Pacific Railroad	*618
Approximately 3,200 feet downstream of Southern Pacific Railroad	*641
Approximately 3,000 feet upstream of State Highway 198	*683
At Gayle Avenue	*760
Maps are available for inspection at the Fresno County Library, Fresno, California.	
Lake Elsinore (City), Riverside County (FEMA Docket No. 7126)	
Temescal Wash:	
Approximately 800 feet downstream of Temescal Canyon Road	*1,214
At Lake Street	*1,222
Approximately 2,400 feet upstream of Lake Street	*1,230
Approximately 5,700 feet upstream of Lake Street	*1,243
Approximately 8,600 feet upstream of Lake Street	*1,250
Approximately 3,600 feet downstream of Nichols Road	*1,253
Approximately 150 feet downstream of Atchison, Topeka, and Santa Fe Railroad	*1,257
Approximately 400 feet upstream of Atchison, Topeka, and Santa Fe Railroad	*1,258
Maps are available for inspection at City Hall, City of Lake Elsinore, 130 South Main Street, Lake Elsinore, California.	
Palm Desert (City), Riverside County (FEMA Docket No. 7126)	
Whitewater River-left overbank flooding: At Monterey Avenue	None
Maps are available for inspection at the Public Works Department, City of Palm Desert, 73510 Fred Waring Drive, Palm Desert, California.	
Palm Springs (City), Riverside County (FEMA Docket No. 7126)	
Palm Canyon Wash:	
Approximately 460 feet downstream of Bogert Drive	*537
Approximately 1,240 feet upstream of Bogert Trail	*548
Tahquitz Creek:	
Approximately 2,100 feet downstream of Farrell Drive	*378
Approximately 1,100 feet downstream of Farrell Drive	*382
Approximately 1,800 feet upstream of Farrell Drive	*395
Approximately 700 feet downstream of Sunrise Way	*398
Approximately 2,300 feet upstream of Sunrise Way	*408
Approximately 1,650 feet downstream of Palm Canyon Drive	*418
At Palm Canyon Drive	*443

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Whitewater River:	
At 34th Avenue (Dinah Shore Drive)	*332
Approximately 1,900 feet downstream of Vista Chino Road	*432
Approximately 500 feet downstream of Bogie Road	*477
Maps are available for inspection at the Engineering Department, City of Palm Springs, 3200 East Tahquitz Canyon Way, Palm Springs, California.	
Rancho Mirage (City), Riverside County (FEMA Docket No. 7126)	
Whitewater River-left overbank flooding:	
At Monterey Avenue	None
Approximately 2,300 feet upstream of Monterey Avenue	None
Approximately 2,500 feet downstream of Country Club Drive	None
Approximately 2,150 feet upstream of Country Club Drive	None
Approximately 2,100 feet upstream of Wonder Palms Drive (Frank Sinatra Lane)	None
Approximately 6,000 feet upstream of Wonder Palms Drive	None
Approximately 10,200 feet upstream of Wonder Palms Drive	None
Maps are available for inspection at the Engineering Department, City of Rancho Mirage, 69825 Highway 111, Rancho Mirage, California.	
Solano County (Unincorporated Areas) (FEMA Docket No. 7161)	
Alamo Creek:	
At Leisure Town Road	*86
Approximately 550 feet upstream of Vanden Road	*96
Approximately 4,700 feet upstream of Pleasant Valley Road	*232
At Pleasant Valley Road	*256
Ulatis Creek:	
Approximately 12,400 feet upstream of Leisure Town Road	*125
Approximately 14,650 feet upstream of Leisure Town Road	*139
Just downstream of Fruitvale Road	*193
Approximately 4,600 feet upstream of Fruitvale Road	*224
Bucktown Creek:	
At confluence with Ulatis Creek	*222
Approximately 1,000 feet upstream of confluence with Ulatis Creek	*224
Encinosa Creek:	
Approximately 450 feet downstream of Pleasant Valley Road	*231
At Pleasant Valley Road (upstream crossing)	*241
Laguna Creek:	
Approximately 100 feet upstream of Highway 80	*202
Approximately 450 feet downstream of Cherry Glen Road	*213
Maps are available for inspection at the Solano Department of Environmental Management, 601 Texas Street, Fairfield, California.	
IDAHO	
Ada County (Unincorporated Areas) (FEMA Docket No. 7163)	
Cottonwood Gulch:	
Approximately 7,615 feet above Garrison Road at the City of Boise corporate limits	*2,898
Approximately 9,100 feet above Garrison Road	*2,930
Approximately 100 feet upstream of Shaw Mountain Road	*2,953
Approximately 1,280 feet above Shaw Mountain Road	*2,980
Approximately 2,280 feet above Shaw Mountain Road	*3,010
Stuart Gulch:	
Approximately 1,900 feet downstream of Cartwright Road at the City of Boise corporate limits	*2,826
Approximately 1,360 feet downstream of Cartwright Road	*2,840
Approximately 500 feet downstream of Cartwright Road	*2,861
Hulls Gulch:	
Approximately 700 feet downstream of McCord Lane at the City of Boise corporate limits	*2,864
At McCord Lane	*2,903
Approximately 2,300 feet upstream of McCord Lane	*2,971
Maps are available for inspection at the Ada County Development Services Office, 650 Main Street, Boise, Idaho.	
Boise (City), Ada County (FEMA Docket No. 7163)	
Stuart Gulch:	
Approximately 100 feet upstream of Stuart Gulch Road	*2,692
Approximately 3,000 feet upstream of Stuart Gulch Road at an unnamed road	*2,745
Approximately 4,600 feet upstream of Stuart Gulch Road at an unnamed road	*2,785
Approximately 5,000 feet upstream of Stuart Gulch Road	*2,795
Approximately 7,010 feet upstream of Stuart Gulch Road at the City of Boise corporate limits	*2,826
Stuart Gulch Split Flow Channel:	
At the convergence with Stuart Gulch, approximately 2,350 feet upstream of Stuart Gulch Road	*2,725
Approximately 2,200 feet upstream of the convergence with Stuart Gulch at an unnamed road	*2,775
At the divergence from Stuart Gulch	*2,800
Crane Gulch:	
At Hill Road	*2,732
Just upstream of Parkhill Drive	*2,732
Just upstream of Cottonwood Court	*2,773
Just upstream of Ranch Road	*2,795
Just downstream of Curling Drive	*2,865
Hulls Gulch:	
Just upstream of the intersection of 9th Street and Heron Street	*2,735
Approximately 1,400 feet downstream of Mile High Road at 9th Street	*2,761
Approximately 1,000 feet upstream of Mile High Road	*2,826
Approximately 2,300 feet upstream of Mile High Road at the City of Boise corporate limits	*2,864
Cottonwood Gulch:	
Approximately 1,100 feet upstream of Garrison Road	*2,748
At confluence with Freestone Creek	*2,793
Approximately 4,300 feet upstream of confluence with Freestone Creek at the City of Boise corporate limits	*2,878
Approximately 5,085 feet upstream of confluence with Freestone Creek at the City of Boise corporate limits	*2,898
Maps are available for inspection at the Office of Community Planning and Development, City Hall, 150 North Capitol Boulevard, Boise, Idaho.	

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
IOWA	
Elkader (City), Clayton County (FEMA Docket No. 7161)	
Turkey River:	
Approximately 1.0 mile downstream of Iowa 13	*718
Just upstream of Iowa 13	*722
Just upstream of dam	*735
At corporate limit	*738
Maps are available for inspection at 207 North Main Street, Elkader, Iowa.	
KANSAS	
Derby (City), Sedgwick County (FEMA Docket No. 7153)	
Spring Creek:	
Just upstream of State Highway 15	*1,251
At confluence of Dry Creek	*1,265
Just downstream of Rock Road	*1,269
Approximately 4,300 feet upstream of Rock Road, at the City of Derby corporate limits	*1,275
Dry Creek:	
Approximately 1,300 feet downstream of Meadowlark Road	*1,284
Just downstream of Meadowlark Road	*1,287
Approximately 4,500 feet downstream of 63rd Street	*1,296
Just downstream of 63rd Street	*1,307
Maps are available for inspection at Derby City Hall, 611 North Mulberry, Derby, Kansas.	
LOUISIANA	
St. Mary Parish (Unincorporated Areas) (FEMA Docket No. 7157)	
Lower Atchafalaya (Berwick Bay):	
Approximately 11,880 feet downstream of Southern Pacific Railroad (SPRR)	*10
Approximately 10,820 feet upstream of SPRR	*12
Ponding Areas:	
Ponding area west of the City of Patterson, from north of SPRR to Bayou Teche	*1.5
Ponding area west of Town of Berwick, from north of SPRR to Bayou Teche	*1.5
Ponding area south of SPRR, north of the southern portion of levee ring	*1.5
Maps are available for inspection at St. Mary Parish Courthouse, 500 Main Street, 5th Floor, Franklin, Louisiana.	
NEBRASKA	
Dakota County (Unincorporated Areas) (FEMA Docket No. 7146)	
Omaha Creek:	
At extraterritorial limit, south of Omaha Creek Ditch	*1,093
At extraterritorial limit, north of Omaha Creek Ditch	*1,094
Maps are available for inspection at 505 East 33rd, South Sioux City, Nebraska.	
Homer (Village), Dakota County (FEMA Docket No. 7146)	
Omaha Creek:	
At extraterritorial limits on riverside of right and left levees	*1,095
At extraterritorial limits on landward side of right and left levees	*1,094
Approximately 1,850 feet downstream of U.S. Highway 77	*1,097
Just upstream of U.S. Highway 77	*1,102
Just upstream of John Street	*1,111
At confluence of Fiddlers Creek	*1,116
At confluence of Wiggle Creek	*1,118
At upstream extraterritorial limit	*1,120
Omaha Creek Old Channel:	
At extraterritorial limits	*1,096
At divergence from Omaha Creek	*1,104
Maps are available for inspection at City Hall, 110 John Street, Homer, Nebraska.	
NEW MEXICO	
Sandoval County (Incorporated Areas) (FEMA Docket No. 7161)	
Arkansas Channel:	
At confluence with West Branch of Black's Arroyo	*5,499
Approximately 30 feet upstream of Lisbon Avenue	*5,508
Approximately 20 feet upstream of Comanche Road	*5,529
Approximately 500 feet upstream of Comanche Road (Limit of Detailed Study)	*5,546
Arroyo D:	
At confluence with Tributary B	*5,286
Approximately 20 feet upstream of 23rd Street	*5,289
Approximately 500 feet upstream of 23rd Street (Limit of Detailed Study)	*5,299
Arroyo de los Lomitas Negras:	
At the inlet to the Dulcelina Curtis Channel	*5,098
Approximately 1,000 feet upstream of the inlet to the Dulcelina Curtis Channel	*5,100
Approximately 100 feet downstream of State Highway 528 (Limit of Detailed Study)	*5,121
Arroyo de los Montoyas:	
At the inlet to the Harvey Jones Channel	*5,079
Approximately 2,500 feet upstream of the inlet to the Harvey Jones Channel	*5,100
At the Village of Corrales/City of Rio Rancho corporate limits	*5,135
Approximately 5,500 feet upstream of the inlet to the Harvey Jones Channel (Limit of Detailed Study)	*5,140
East Branch of Black's Arroyo:	
Approximately 120 feet upstream of the Sandoval/Bernalillo County Line	*5,178
Approximately 100 feet upstream of 19th Street	*5,240
Approximately 120 feet upstream of 18th Street	*5,255
Approximately 40 feet upstream of Southern Boulevard	*5,355
Approximately 40 feet upstream of Western Hills Drive	*5,432
Approximately 600 feet upstream of Lema Road (Limit of Detailed Study)	*5,459
West Branch of Black's Arroyo:	
At the Sandoval/Bernalillo County Line	*5,200
Approximately 100 feet upstream of 19th Avenue	*5,266
Approximately 70 feet upstream of Southern Boulevard	*5,433
Approximately 20 feet upstream of Tarpon Avenue	*5,531
Approximately 4,200 feet upstream of Tarpon Avenue (Limit of Detailed Study)	*5,561
Jemez River:	
Approximately 250 feet downstream of the Jemez Indian Reservation boundary	*5,602
At confluence with Rio Guadalupe	*5,656
At the Village of Jemez Springs downstream corporate limits	*5,984
Approximately 10,560 feet upstream of Jemez Springs downstream corporate limits	*6,145

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Approximately 100 feet upstream of Jemez Springs upstream corporate limits	*6,305
Approximately 1,200 feet upstream of confluence with San Antonio Creek (Limit of Detailed Study)	*6,801
Nicklaus Channel:	
At confluence with the East Branch of Black's Arroyo	*5,367
Approximately 60 feet upstream of Fairway Loop	*5,393
Approximately 900 feet upstream of Lema Road (Limit of Detailed Study)	*5,418
Player Channel:	
At confluence with the East Branch of Black's Arroyo	*5,355
Approximately 20 feet upstream of Trevino Drive	*5,375
Approximately 500 feet upstream of Trevino Drive (Limit of Detailed Study)	*5,380
San Antonio Channel:	
At confluence with the Jemez River	*6,765
Approximately 10,000 feet upstream of confluence with the Jemez River	*7.156
At confluence of Sulphur Creek	*7,616
Approximately 8,300 feet upstream of confluence of Sulphur Creek (Limit of Detailed Study)	*7,719
Spur Channel:	
At confluence with the West Branch of Black's Arroyo	*5,375
Approximately 40 feet upstream of Southern Boulevard	*5,462
Approximately 1,100 feet upstream of Spur Road (Limit of Detailed Study)	*5,508
Sugar Channel:	
At confluence with the West Branch of Black's Arroyo	*5,520
Approximately 20 feet upstream of Montego Drive	*5,551
Approximately 400 feet upstream of Montego Drive (Limit of Detailed Study)	*5,561
Tributary A:	
At confluence with the West Branch of Black's Arroyo	*5,275
Approximately 100 feet upstream of 15th Street	*5,362
Approximately 1,000 feet upstream of Villa Road (Limit of Detailed Study)	*5,520
Tributary B:	
At confluence with the East Branch of Black's Arroyo	*5,200
Approximately 120 feet upstream of 18th Avenue	*5,259
Approximately 200 feet upstream of 14th Avenue	*5,312
Approximately 800 feet upstream of 22nd Street (Limit of Detailed Study)	*5,355
Zone AH: Shallow flooding east of the Dulcelina Curtis Channel	*5,033
Maps are available for inspection at 711 Camino Del Pueblo, Bernalillo, New Mexico.	
Maps are available for inspection at Highway 4, Village Hall, Jemez Springs, New Mexico.	
Maps are available for inspection at 4324 Carrales Road, Corrales, New Mexico.	
Maps are available for inspection at 3900 Southern Boulevard, Rio Rancho, New Mexico.	
Sierra County (Unincorporated Areas), Williamsburg (Village), Truth or Consequences (City) (FEMA Docket No. 7161)	
Rio Grande:	
Approximately 1,500 feet downstream of the Village of Williamsburg corporate limits (Limit of Detailed Study)	*4,231
At Village of Williamsburg downstream corporate limits	*4,231
At Village of Williamsburg upstream corporate limits	*4,233
At City of Truth or Consequences downstream corporate limits	*4,233
Approximately 20,600 feet upstream of the Limit of Detailed Study (Magnolia Street)	*4,244
At City of Truth or Consequences upstream corporate limits	4,257
Approximately 6,500 feet upstream of Highway 51 (Limit of Detailed Study)	*4,257
Sierra County maps are available for inspection at 300 Date Street, Truth or Consequences, New Mexico.	
City of Truth or Consequences maps are available for inspection at 505 Sims Street, Truth or Consequences, New Mexico.	
Village of Williamsburg maps are available for inspection at Village Hall, Williamsburg, New Mexico.	
OKLAHOMA	
Chandler (City), Lincoln County (FEMA Docket No. 7161)	
Bellcow Creek:	
Approximately 1,350 feet downstream of U.S. Highway 66	*831
Just upstream of U.S. Highway 66	*834
Approximately 100 feet upstream of First Street	*845
At Lake Road	*855
Bellcalf Creek:	
Approximately 700 feet downstream of Lake Road	*855
Approximately 100 feet upstream of Lake Road	*857
Approximately 3,750 feet upstream of Lake Road	*867
Chigger Creek:	
Approximately 70 feet upstream of Park Road	*838
Just upstream of First Street	*852
Approximately 90 feet upstream of Chigger Road	*868
Indian Creek:	
Approximately 100 feet upstream of Iowa Avenue	*853
Just upstream of Eighth Street	*892
Approximately 900 feet upstream of Eighth Street	*898
Maps are available for inspection at 200 South Cleveland, Chandler, Oklahoma.	
Lincoln County (Unincorporated Areas) (FEMA Docket No. 7161)	
Bellcow Creek:	
Approximately 4,500 feet downstream of confluence of Indian Creek	*823
Just downstream of U.S. Highway 66	*833
Just downstream of Interstate Highway 44	*850
Approximately 2,100 feet upstream of Lake Road	*856
Bellcalf Creek:	
Approximately 700 feet downstream of Lake Road	*855
Just downstream of Lake Road	*856
Approximately 3,450 feet upstream of Lake Road	*866
Indian Creek:	
Just upstream of State Highway 18	*829
Just downstream of Iowa Avenue	*850
Maps are available for inspection at the Lincoln County Courthouse, Chandler, Oklahoma.	
Noble County (Unincorporated Areas) (FEMA Docket No. 7157)	
Cow Creek:	
Approximately 5,400 feet downstream of Atchison, Topeka, and Santa Fe Railroad	*968
Just upstream of Atchison, Topeka, and Santa Fe Railroad	*974

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Approximately 6,600 feet upstream of confluence of Calf Creek	*1,001
Golf Course Tributary:	
Approximately 3,700 feet downstream of U.S. Route 77	*972
At 7th Street	*992
Just downstream of 15th Street	*1,017
Just upstream of 15th Street	*1,023
Golf Course Lake Tributary:	
Approximately 500 feet downstream of Quail Creek Road	*995
Approximately 300 feet upstream of Quail Creek Road	*1,001
Wills Lake Tributary:	
Approximately 1,200 feet downstream of U.S. Route 64	*977
At U.S. Route 64	*987
Unnamed Tributary to Cow Creek:	
Approximately 2,600 feet downstream of Interstate Route 88	*988
Approximately 1,000 feet upstream of Interstate Route 88	1,008

Maps are available for inspection at 300 Courthouse Drive, Perry, Oklahoma.

Pauls Valley (City), Garvin County (FEMA Docket No. 7153)

Rush Creek:	
Approximately 2,700 feet downstream of Gulf, Colorado and Santa Fe Railroad, at the extraterritorial limits	*856
At U.S. Highway 77 (Chickasaw Avenue)	*873
Just downstream of South Paul Street	*877
Approximately 500 feet upstream of Interstate Highway 35	*886
Approximately 1,800 feet upstream of Interstate Highway 35	*887
Rush Creek (Area North of Levee):	
On the projection of Leslie Avenue, between Rush Creek and the railroad	*869
At intersection of Garvin Avenue and Chickasaw Street	*873
At intersection of Grant Avenue and Pine Street	*875
At intersection of Agnew Avenue and Pine Street	*878

Maps are available for inspection at City Hall, City of Pauls Valley, 220 West Paul Avenue, Pauls Valley, Oklahoma.

Perry (City), Noble County (FEMA Docket No. 7157)

Cow Creek:	
Just upstream of Ivanhoe Street at corporate limits	*978
Just downstream of U.S. Highway 64	*980
Just downstream of Cedar Street	*984
At confluence with South of Highway 77 Tributary	*992
At southernmost corporate limits	*996
Calf Creek:	
At confluence with Cow Creek	*989
Just upstream of Cedar Street	*1,018
Just upstream of 15th Street	*1,020
Just upstream of 25th Street	*1,047
Just upstream of St. Louis-San Francisco Railroad	*1,063
Just upstream of Interstate Highway 35	*1,083
Cherokee Strip Tributary:	
At confluence with Calf Creek	*1,048
Just upstream of U.S. Highway 64	*1,049
Just upstream of Interstate Highway 35	*1,090
Ditch Witch Tributary:	
At confluence with Calf Creek	*1,029
Just upstream of U.S. Highway 64	*1,032
South of Highway 77 Tributary:	
At confluence with Cow Creek	*992
Just upstream of Atchison, Topeka, and Santa Fe Railroad at corporate limits	*998
Unnamed Tributary A of Calf Creek:	
At confluence with Calf Creek	*1,023
Just upstream of St. Louis-San Francisco Railroad	*1,023
Unnamed Tributary B of Calf Creek:	
At confluence with Calf Creek	*1,025
Approximately 2,000 feet upstream of confluence with Calf Creek	*1,035
Just upstream of St. Louis-San Francisco Railroad	*1,052
Unnamed Tributary C of Calf Creek:	
At confluence with Calf Creek	*1,024
Just upstream of St. Louis-San Francisco Railroad	*1,027
Leo Park Tributary:	
At confluence with Cow Creek	*984
Just upstream of Cedar Street	*988
Approximately 1,200 feet upstream of Cedar Street	*990
Golf Course Tributary:	
Just upstream of easternmost corporate limits	*973
Just upstream of U.S. Route 77	*980
Just upstream of 7th Street	*992
Just downstream of 15th Street	*1,018
Golf Course Lake Tributary:	
At confluence with Golf Course Tributary	*995
Just upstream of Quail Creek Road	*1,001
Brookwood Park Tributary:	
At confluence with Golf Course Tributary	*978
Just upstream of U.S. Route 77	*997
Just upstream of 7th Street	*1,009
Just upstream of 9th Street	*1,019
Wills Lake Tributary:	
Approximately 600 feet upstream of confluence with Cow Creek	*980
Just downstream of U.S. Route 64	*986

Maps are available for inspection at 732 Delaware, Perry, Oklahoma.

TEXAS

Uvalde (City), Uvalde County (FEMA Docket No. 7163)

Cooks Slough:	
Approximately 500 feet downstream of West Main Street	*899
Just downstream of Fort Clark Street	*901
Approximately 4,300 feet downstream of Benson Road	*908
Approximately 300 feet downstream of Benson Road	*917

Maps are available for inspection at Uvalde City Hall, Highway 90, Uvalde, Texas.

Uvalde County (Unincorporated Areas) (FEMA Docket No. 7163)

Cooks Slough:	
Approximately 1,100 feet upstream of U.S. Highway 83 (or 100 feet upstream of South Grove Street)	*893
Just downstream of the grade control structure	*904
Approximately 2,470 feet upstream of Benson Road (FM 1052)	*920

Maps are available for inspection at the County Judge's Office, Uvalde County Courthouse, Courthouse Square, Corner of Main and Getty Streets, Uvalde, Texas.

UTAH

Wendover (Town), Tooele County (FEMA Docket No. 7161)

Drainage along north side of Interstate Highway 80:	

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Approximately 2,700 feet north of Interstate Highway 80 adjacent to corporate limits	#2
Approximately 2,000 feet north of Interstate Highway 80 adjacent to corporate limits	#1
Approximately 1,000 feet north of Interstate Highway 80 adjacent to corporate limits	#2
Approximately 500 feet north of Interstate Highway 80 adjacent to corporate limits	#1
Approximately 100 feet north of Interstate Highway 80 and 300 feet due east of corporate limits	*4,349
Approximately 100 feet north of Interstate Highway 80 and 1,300 feet due east of corporate limits	*4,344
Approximately 100 feet north of Interstate Highway 80 and 2,800 feet due east of corporate limits	*4,339
Drainage along south side of Interstate Highway 80:	
Approximately 100 feet south of Interstate Highway 80 and 200 feet due east of corporate limits	#3
Approximately 700 feet south of Interstate Highway 80 and 450 feet east of corporate limits	#2
Approximately 1,500 feet south of Interstate Highway 80 and 1,000 feet due east of corporate limits	#1
Approximately 100 feet north of Union Pacific Railroad and 3,000 feet due east of corporate limits	*4,245
Maps are available for inspection at 195 South First Street, Wendover, Utah.	
WASHINGTON	
Ferry County (Unincorporated Areas) (FEMA Docket No. 7163)	
Kettle River—Reach 7 (Near Curlew):	
Approximately 73.96 miles upstream of confluence with the Columbia River	*1,806
Approximately 74.66 miles upstream of confluence with the Columbia River	*1,810
Approximately 75.17 miles upstream of confluence with the Columbia River	*1,812
Approximately 75.52 miles upstream of confluence with the Columbia River	*1,814
Approximately 75.84 miles upstream of confluence with the Columbia River	*1,815
Kettle River—Reach 1 (Near Barstow):	
Approximately 9.87 miles upstream of confluence with the Columbia River	*1,306
Approximately 10.36 miles upstream of confluence with the Columbia River	*1,309
Approximately 10.86 miles upstream of confluence with the Columbia River	*1,312
Kettle River—Reach 2 (Near Orient):	
Approximately 18.62 miles upstream of confluence with the Columbia River	*1,389
Approximately 18.77 miles upstream of confluence with the Columbia River	*1,390
Approximately 19.17 miles upstream of confluence with the Columbia River	*1,391
Kettle River—Reach 3 (Near Laurier):	
Approximately 27.24 miles upstream of confluence with the Columbia River	*1,435
Approximately 27.53 miles upstream of confluence with the Columbia River	*1,438
Approximately 28.00 miles upstream of confluence with the Columbia River	*1,441
Approximately 28.26 miles upstream of confluence with the Columbia River	*1,443
Kettle River—Reach 4 (Near Danville):	
Approximately 58.0 miles upstream of confluence with the Columbia River	*1,732
Approximately 58.43 miles upstream of confluence with the Columbia River	*1,733
Kettle River—Reach 5 (Near Curlew):	
Approximately 64.87 miles upstream of confluence with the Columbia River	*1,764
Approximately 65.17 miles upstream of confluence with the Columbia River	*1,765
Approximately 65.45 miles upstream of confluence with the Columbia River	*1,766
Kettle River—Reach 8 (Near Ferry):	
Approximately 84.78 miles upstream of confluence with the Columbia River	*1,864
Approximately 85.15 miles upstream of confluence with the Columbia River	*1,866
Approximately 85.58 miles upstream of confluence with the Columbia River	*1,868
Maps are available for inspection at the Ferry County Planning Department, 146 North Clark, Suite 7, Republic, Washington.	
Stevens County (Unincorporated Areas) (FEMA Docket No. 7163)	
Kettle River—Reach 1 (Near Barstow):	
Approximately 9.87 miles upstream of confluence with the Columbia River	*1,306
Approximately 10.5 miles upstream of confluence with the Columbia River	*1,310
Approximately 10.86 miles upstream of confluence with the Columbia River	*1,312
Kettle River—Reach 2 (Near Orient):	
Approximately 18.62 miles upstream of confluence with the Columbia River	*1,389
Approximately 19.17 miles upstream of confluence with the Columbia River	*1,391
Kettle River—Reach 3 (Near Laurier):	
Approximately 27.24 miles upstream of confluence with the Columbia River	*1,435
Approximately 27.8 miles upstream of confluence with the Columbia River	*1,440
Approximately 28.26 miles upstream of confluence with the Columbia River	*1,443
Maps are available for inspection at the Stevens County Planning Department, 260 South Oak Street, Colville, Washington.	

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: March 25, 1996.

Richard W. Krimm,

Acting Associate Director for Mitigation.

[FR Doc. 96–8124 Filed 4–2–96; 8:45 am]

BILLING CODE 6718–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[FCC 96–94]

Pioneers' Preference Payments for Initial Authorizations in the Broadband Personal Communications Service

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission released this Order specifying the payment obligations and procedures for the Pioneers' preference recipients in the Broadband Personal Communications Service. This Order is necessary to inform the parties to this action of their obligations and to explain the procedures for payments. The intended effect of this action is to ensure the parties have the information they require for timely and accurate payments.

EFFECTIVE DATE: June 3, 1996.

FOR FURTHER INFORMATION CONTACT: Lisa Warner, (202) 418–0620, Wireless Telecommunications Bureau, Commercial Wireless Division.

SUPPLEMENTARY INFORMATION: This is the text of the *Order,* adopted March 8, 1996, released March 11, 1996 concerning: American Personal Communications, File No. 15000–CW–L–94, Call Sign: KNLF200; Cox Cable Communications, Inc., File No. 15001–CW–L–94, Call Sign: KNLF201; Omnipoint Communications, Inc., File No. 15002–CW–L–94, Call Sign: KNLF202. This order is available for inspection and copying during normal business hours the Commercial Wireless Division Legal Branch, Room 7130, 2025M Street, N.W., Washington, D.C., and also may be purchased from the Commission's copy contractor, International Transcription Service, at (202) 857–3800, 2100 M Street, N.W., Suite 140, Washington, D.C. 20037.

Order

I. Introduction and Background

1. By this action we specify the payment obligations and procedures for the Pioneers' preference recipients in the Broadband Personal Communications Service (''PCS''): American Personal Communications (''APC''), Cox Cable Communications, Inc. (''Cox''), and Omnipoint Communications, Inc. (''Omnipoint'') (collectively, ''Pioneers''). The Pioneers will pay to the United States Treasury a sum of $701,780,378, plus interest, over the next five years. The action is taken pursuant to legislation implementing the General Agreement on Tariffs and Trade (''GATT legislation''), enacted December 8, 1994.

2. In December 1993, the Commission granted Pioneers' preferences to APC, Cox and Omnipoint for their innovative work in the development of PCS in the 2 GHz band. The Commission determined that, if otherwise qualified, APC would be licensed to use Channel Block A in the Washington-Baltimore Major Trading Area (''MTA''); Cox would be licensed to use Channel Block A in the Los Angeles-San Diego MTA; and Omnipoint would be licensed to use Channel Block A in the New York MTA.

3. On December 13, 1994, we granted the Broadband PCS license applications filed by APC, Cox, and Omnipoint based upon their Pioneers' preference awards (''*Pioneers Licensing Order*''). Each grant is conditioned on, *inter alia,* each licensee paying to the United States Treasury an amount equal to 85 percent of the adjusted value of its license calculated in accordance with Section 801 of the GATT legislation. The adjusted value of the licenses are based on the high bids for comparable licenses in the broadband PCS auction for the A and B frequency blocks. The GATT legislation provides that payments are not to commence until that auction is completed and after the Pioneers' license grants have become final and no longer subject to administrative or judicial review. At the time we adopted the *Pioneers Licensing Order,* the auction for the A and B block licenses was not completed and the Pioneers' preferences and license grants, as well as the constitutionality of the GATT legislation, had become the subject of several judicial challenges. The A and B block auction was completed on March 13, 1995, and the litigation has concluded. Accordingly, the Pioneers' license conditions are subject to this subsequent *Order* specifying payment procedures and amounts.

II. Discussion

A. Payment Amounts

4. Section 801 of the GATT legislation amended Section 309(j) of the Communications Act of 1934 to require that the Commission recover a portion of the value of a pioneer's preference recipient's license, and establishes a payment formula of 85 percent of the adjusted value of the license. Based on the formula in the GATT legislation, we calculated the average per population price established by competitive bidding for frequency blocks A and B in the twenty largest MTAs, excluding the MTAs awarded to the Pioneers, to be $15.48. We then reduced this average per capita bid amount by 15 percent to obtain the adjusted per capita value of the Pioneers' licenses, which we determined to be $13.16. Finally, we multiplied this discounted per population figure by the 1990 Census population figures for the respective service areas of the Pioneers' licenses. As a result of this calculation, we have determined that the Pioneers are required to pay the following amounts for their licenses: APC for the Washington-Baltimore MTA—$102,343,539; Cox for the Los Angeles-San Diego MTA—$251,918,526; and Omnipoint for the New York MTA—$347,518,309. We note that these amounts compare with $211,771,000 paid for the competitive B block license in Washington-Baltimore (a 52 percent difference); $493,500,000 paid for the Los Angeles-San Diego MTA B block license (a 49 percent difference); and $442,712,000 paid for the New York MTA B block license (a 22 percent difference).

B. Commencement of Payments

5. The GATT legislation further directs that the Pioneers are to commence their payments no later than either the date of completion of the auction of comparable licenses, or thirty days after Pioneers' preferences are awarded and the licenses are no longer subject to administrative or judicial review. The Commission commenced its auction of licenses for broadband PCS operations on frequency blocks A and B on December 5, 1994, and completed this auction on March 13, 1995. At the time the auction was completed, however, several judicial challenges to both the GATT legislation and the Pioneers' awards remained pending, delaying the finality of the licenses awarded to the Pioneers. That litigation has ended. Pursuant to the GATT legislation, the license grants (and the underlying pioneer's preferences) are not subject to further administrative or judicial review. Accordingly, Pioneers' installment payments will commence 30 days after the adoption of this Order, on April 8, 1996.

C. Interest Rate

6. The GATT legislation states that the Pioneers shall be permitted to pay for the licenses through guaranteed installment payments over a period of five years subject to: (1) The payment only of interest on unpaid balances during the first two years; and (2) payment of the unpaid balance and interest thereon after the end of such two years in accordance with the regulations prescribed by the Commission. The text of the statute is silent on the interest rate to be charged except for its reference to the Commission's regulations. The House Committee Report describing this provision states that payment of the principal and interest should be ''in a manner consistent with the installment payment rules adopted by the Commission as part of its general competitive bidding regulations.'' The

House Committee Report also states that ''[t]he Committee anticipates that the Commission will calculate interest payments based on the prevailing prime rate.'' The overall goal of the pioneer's preference provisions in the GATT legislation was to ''ensure that holders of a pioneer's preference pay an equitable amount for use of their spectrum.''

7. Based on the language and legislative history, we conclude that the GATT legislation provides the Commission discretion to establish an interest rate for the Pioneer's payments that is ''in accordance with [our] regulations,'' and that the legislative history indicates that Congress intended that the Commission would use certain established guidelines in setting the rate; *i.e.*, the ''general'' competitive bidding regulations and the prevailing prime rate. The Commission's general competitive bidding regulations establish guidelines for imposing installment payment plans for auctioned licenses. These rules provide the Commission, on a service-by-service basis, the flexibility to ''vary the interest rate and the payment schedule for installment payments.'' Specifically, Section 1.2110(e)(3) of the Commission's rules provides that, unless other terms are specified in the rules of particular services, installment plans will: (1) impose interest based on the rate of U.S. Treasury obligations (with maturities close to the duration of the license term); (2) allow installments to be paid over the full license term; (3) begin with interest-only payments for the first two years; and (4) amortize principal and interest over the remaining term of the license.

8. In applying these general rules to specific services, the Commission has adopted a range of interest rates for installment plans based on the circumstances of the service and the objectives behind permitting installment payments—typically to small businesses. For example, in the Interactive Video and Data Service auction rules, the Commission adopted an interest rate for small business installment payments based on the five-year U.S. Treasury note rate. In the auction for narrowband PCS regional licenses, we permitted certain designated entities to pay installments at the 10-year U.S. Treasury Note rate, plus 2.5 percent. Our competitive bidding rules for frequency block C in broadband PCS (smaller Basic Trading Area licenses) make available three different interest rates depending on the economic size of the winning bidder: 10-year U.S. Treasury Note, plus 3.5 percent; 10-year U.S. Treasury Note, plus 2.5 percent; and 10-year U.S. Treasury Note. Eligibility for the lower, flat 10-year Treasury Note interest rate is limited to small businesses in the ''entrepreneurs' block'' auction. We have no specific installment payment rules for frequency blocks A and B in broadband PCS.

9. For each of the Pioneer's installment payments, we have decided, within our discretion, to impose an interest rate equal to the five-year Treasury Note, plus 2.5 percent, as of the date of adoption of this Order. We typically use the U.S. Treasury obligations of maturity equal to the license term because the license and payment terms are of the same duration. Here the license and payment term are different, and we will use the rate for U.S. Treasury obligations with maturity at the end of the payment term. Thus, starting with the five-year Treasury Note rate as a basis for the Pioneers' interest rate is consistent with the operation of our general installment payment rules and the GATT legislation.

10. We add 2.5 percent to the base Treasury Note rate for several reasons. First, we believe that this interest rate will help fulfill the purpose of the GATT legislation by ensuring that the pioneer's preference recipients pay an ''equitable amount'' for use of the spectrum. Although the Pioneer's licenses were granted over 13 months ago, and one Pioneer has begun operating, none of the Pioneer's have paid for their use of the spectrum. In comparing similarly situated licensees, the Pioneers received a discount on the value of the license and can pay over time, *supra* para. 4, whereas the other A and B block licenses in broadband PCS were required to make their payments in full shortly after license grant. The Pioneers have been adequately rewarded for their innovations by receiving guaranteed licenses at discount. Second, this rate is below the prime rate benchmark referenced in the legislative history, which is currently 8.5 percent. Assuming that the prime rate is what the Pioneers would be able to obtain if private financing is sought, this rate for government financing of the license costs will further benefit the Pioneers, who will avoid the higher interest rates and other transactional costs associated with using private sources to finance their license payment. Finally, this approach to establishing an interest rate is fully consistent with our ''general'' rules for imposing installment payment plans and our experience in fashioning an interest rate that best fits the circumstances.

11. With respect to the actual interest rate, the five-year T-Note rate on the adoption date of this Order, with maturity in February of 2001 (the closest to the duration of the payment term) is 5.25 percent. Accordingly, the amounts to be paid by the Pioneers will be subject to 5.25 plus 2.5 percent, for a total interest rate of 7.75 percent. Interest will begin accruing as of the adoption of this Order.

D. Installment Payment Terms and Conditions

12. As to the other aspects of the installment payments, the statute leaves us little discretion to establish different terms. As noted above and contrary to our ''general'' installment payment rules, the statute precludes the Commission from allowing installment payments for the duration of the 10-year license term. The GATT legislation specifically provides for a five-year payment period. In addition, like our general installment payment rules, interest-only payments are permitted for the first two years. Thereafter, unpaid principal balance and interest will be amortized over the remaining three years.

13. The first interest payment will be due on April 8, 1996, thirty (30) days after the adoption of this Order. The first payments will be the following: APC—$660,968.69; Cox—$1,626,973.81; and Omnipoint—$2,244,389.08. Thereafter the Pioneers' payments will be due on a quarterly basis on the last day of each quarter. Thus, the second payment will be due on April 30, 1996. The second payment will be the following: APC—$1,321,937.38; Cox—$3,253,947.62; and Omnipoint—$4,488,778.16. The remaining payment dates and amounts are established in the attached schedule.

14. In addition, the Pioneers' installment payments will be ''guaranteed'' by their licenses. Consistent with our general competitive bidding rules, the Pioneers' licenses will continue to be conditioned upon the full and timely performance of their respective payment obligations under their installment plans. The license conditions will be modified to reflect the specific terms of the payments set forth above. If a Pioneer is more than ninety (90) days delinquent in any payment, it shall be deemed to be in default and the Commission's general rules will apply.

E. Omnipoint's Request for Special Installment Terms

15. We have decided not to differentiate among the three Pioneers when establishing the installment

payment terms and not to compare their situation to that of applicants for the broadband PCS entrepreneurs' block licenses. Omnipoint recently suggested that the Commission's new rules for small business pioneers should be applied to it and has requested that its payment terms be as equivalent as possible to the block C small business installment payment plan. Omnipoint specifically asks for interest-only payments for five years and a single, lump-sum payment due at the end of the fifth year. We deny this request for the following reasons.

16. First, we do not believe that the GATT legislation contemplates different treatment for the Pioneers or the type of deferred-principal payment plan requested by Omnipoint. As noted above, the text of the statute states that the installment payment terms shall be ''the payment only of interest on unpaid balances during the first 2 years * * * and * * * *payment of the unpaid balance and interest thereon after the end of such 2 years in accordance with the regulations prescribed by the Commission.*'' The House Commerce Committee Report's section-by-section analysis says, ''[t]he pioneers shall pay interest only for the first two years, and interest *and principal for the next three years,* pursuant to the Commission's regulations.'' The House Report also states that payment of the principal and interest should be ''in a manner consistent with the installment payment rules adopted by the Commission *as part of its general competitive bidding regulations.*'' These rules referenced in the statute and the legislative history are found in Section 1.2110(e)(3) of the Commission's rules and state:

Unless other terms are specified in the rules of particular services, such [installment] plans will

* * * * *

(iii) begin with interest-only payments for the first two years; and

(iv) *amortize principal and interest over the remaining term of the license.*

There are no Commission rules that would allow an entity making installment payments to wait until the end of the payment term to make one lump sum principal payment. We believe that the text of the statute and its legislative history, read in conjunction with the Commission's rules, shows that Congress intended that each Pioneer, including Omnipoint, shall begin paying principal in the third year.

17. Second, we do not believe that Congress or the Commission's rule cited by Omnipoint contemplate a comparison of Omnipoint with the C-Block small business applicants. Congress determined in the GATT legislation that ''''the most reasonably comparable licenses'' for purposes of determining the value of the Pioneers'' licenses were ''the broadband licenses in the personal communications service for blocks A and B for the 20 largest markets (ranked by population) in which no applicant has obtained preferential treatment.'''' The broadband PCS Pioneers' installment payments are governed by the provisions in Section 309(j)(13)(E) of the Act discussed above. Thus, our new rules, adopted pursuant to Section 309(j)(13)(C) of the Act, governing installment payments for future pioneer's preference recipients that are similarly situated to designated entities participating in an auction do not apply here.

18. However, even if the new rules did apply to Omnipoint, we believe that Omnipoint has misconstrued the purpose of the rule it cites, which states ''a pioneer that qualifies as a designated entity will be eligible for installment payments under the same terms and conditions as other designated entities in that *service.* In the order adopting this rule, the Commission rejected a similar deferred payment proposal offered by Omnipoint. The Commission, instead, adopted its proposal ''that if an entity receiving a pioneer's preference would be eligible for installment payments *in the auction for that service,* the entity could pay for its pioneer's preference *license* in installments under comparable terms and conditions to *similarly situated licensees* over a period not to exceed five years. In the auction in which Omnipoint would have had to participate to obtain its MTA license, installment payments were not available to small businesses. While the auction rules in the broadband PCS ''service'' provide an installment payment option to small businesses obtaining smaller C-Block, BTA licenses, Omnipoint received a substantially larger A Block MTA license for its pioneer's preference. This situation was expressly contemplated when the Commission had earlier rejected Omnipoint's deferred payment proposal, stating, ''if a small business pioneer chooses, it may apply for a license in a service as a designated entity either in addition to *or in lieu of* its acceptance of a guaranteed pioneer's preference license.'' We note that an affiliate of Omnipoint's is currently actively participating in the C-block auction.

19. Finally, as a policy matter, we have previously determined that the pioneer's preference rule and the rules for the entrepreneurs' blocks were designed to meet different goals. The Commission permitted entrepreneurs and small businesses to pay for their licenses in installments in order to assist businesses who are likely to have difficulty obtaining adequate financing to obtain licenses in a competitive bidding environment. We determined that installment payments would be an effective way to efficiently promote the participation of small businesses in the provision of broadband PCS. The pioneer's preference program, on the other hand, is designed to reward a particular entity for its innovative contributions to a new service by guaranteeing it a license, at a discounted price, without requiring it to participate in an auction. When we provided that future small business pioneers could obtain similar payment terms as similarly situated licensees, we did not intend to merge these two separate policy objectives. Rather, we clarify that, as a matter of fairness and convenience, a small business pioneers preference recipient should get the same or similar installment payment terms that are available to other small businesses that obtained comparable licenses in an auction.

F. Other Matters

As a final matter, we note that, on September 22, 1995, a pleading styled ''Petition to Deny'' was filed against Omnipoint by Whitestone Wireless, L.P., Southern Personal Communications Systems, and Minco, P.C.S. The 30-day period to file petitions to deny against the Pioneers expired on September 26, 1994. Moreover, the GATT legislation states that the grant of Omnipoint's license and underlying pioneer's preference awards shall not be subject to administrative or judicial review. We therefore dismiss the Whitestone Petition as untimely and moot.

G. Payment Schedule Attention: Pioneer's Preference Recipients Broadband Personal Communications Service

The first interest payment will be due on April 8, 1996, (30) thirty days after the adoption of this Order. The first payment will be the following: APC $660,968.69; Cox $1,626,973.81; Omnipoint $2,244,389.08. Thereafter, the Pioneer's payments will be due on a quarterly basis on the last day of each quarter. Thus, the second payment will be due on April 30, 1996. The second payment will be the following: APC $1,321,937.38; Cox $3,253,947.62; Omnipoint $4,488,778.16.

The remaining payment dates and amounts are established in the attached

schedule. Mailed remittances must be *actually received* no later than April 8, 1996. Hand-carried or couriered remittances can be delivered up through 11:59 P.M. on Monday, April 8, 1996. Remittances received after 11:59 P.M. on Monday, April 8, 1996, will be considered late filed.

H. Instructions for the First and Second Installment Payments

Payments must be made in U.S. dollars, must be in the form of a wire transfer or cashier's check, and must be made payable to the ''Federal Communications Commission'' or ''FCC''. Installment payments whether being paid by wire transfer or cashier's check, must be accompanied by a completed FCC Remittance Advice, Form 159.

A. Form 159

Pioneers must submit an FCC Form 159 when making any payments to the Commission's lockbox bank. Failure to accurately complete your FCC Form 159 could result in a delay in processing your remittance. Before completing an FCC Form 159, read the instructions below. Also, a correctly completed sample FCC Remittance Advice (Form 159) is attached.

(1) You must complete all of the blocks in the Payor Information Section, (Blocks 1 through 10). It is extremely important that you enter your taxpayer identification number (TIN) in with a prefix of ''0'' in block number 1. Blocks 2 through 10 are self explanatory.

(2) You must complete the following blocks for each ''Item Number Information'' in accordance with the Instructions For Using FCC Form 159 (but only if the names of the ''payor'' and the ''applicant'' are different): Block numbers 11, 13, 19, 20, and 21.

(3) You must complete the following auction-specific information in blocks 12(A), 14(A), 15(A), 16(a) and 17(A). Block 12(A)—FCC Call Sign,enter your respective call sign; block 14(A)—Payment Type Code, enter the letters ''ACHD''; block 15(A)—Quantity, enter ''1''; block 16(A)—Fee Due, enter the amount remitted; and block 17(A)—FCC Code 1, enter ''P''.

B. Paying by Cashier's Check

Each cashier's check and corresponding FCC Remittance Advice (Form 159) must be in an individual envelope and specifically addressed to: Mellon Bank, P.O. Box #358850, Pittsburgh, PA 15251–5850, Attn: Auction Payment. If delivering an auction payment in person or by courier, the check and FCC Remittance Advice (Form 159) must be delivered to Mellon Bank, Three Mellon Bank Center, 525 William Penn Way, 27th Floor, Room 153–2713, Pittsburgh, PA 15259–0001, (Attn: Wholesale Lockbox Shift Supervisor).

C. Paying by Wire Transfer

If making an auction payment by wire transfer, fax a completed FCC Remittance Advice (Form 159) to Mellon Bank at (412) 236–5702 at least one hour before placing the order for the wire transfer. On the cover sheet of the fax indicate ''Wire Transfer—Auction Payment for Auction Event # ''P''. When wiring funds, please give your bank the following information:

ABA Routing Number: 043000261;

Receiving Bank: Mellon Pittsburgh;

BNF: FCC/AC—9116106;

OBI Field: (Skip one space between each information item) ''AUCTIONPAY'';

FCC Account No. (Exactly as on Form 159, Block #1);

Payor Name (Exactly as on Form 159, Block #3);

Payment Type Code (Exactly as on Form 159, Block #14);

FCC Code 1 (Exactly as on Form 159, Block #17.

For further information, please contact Regina W. Dorsey, Chief, Billings and Collections Branch at (202) 418–1995 (voice) or (202) 418–2843 (fax).

Remaining 19 Quarterly Payments

Please see the attached Auction Installment Payment Program (AIP). Inside the program package you will find the Masterfile Maintenance Form (Page 19). Please read the package information and complete this form. Return the form to the address listed on the form. Beginning with payment number 2 (payment number one was split into two payments, both of which are due in the month of April) due July 31, 1996, use the AIP program.

III. Ordering Clauses

20. Accordingly, it is ordered that, effective April 8, 1996, the payment condition on American Personal Communications' license, call sign KNLF200, is modified as follows:

This authorization requires that American Personal Communications shall pay to the United States Treasury $102,343,539, plus interest, pursuant to the terms and procedures in the above schedule of payments (and accompanying instructions).

21. It is further ordered that, effective April 8, 1996, the payment condition on Cox Cable Communications, Inc.'s license, call sign KNLF201, is modified as follows:

This authorization requires that Cox Cable Communications, Inc. shall pay to the United States Treasury $251,918,526, plus interest, pursuant to the terms and procedures in the above schedule of payments (and accompanying instructions).

22. It is further ordered that, effective April 8, 1996, the payment condition on Omnipoint Communications, Inc.'s license, call sign KNLF202, is modified as follows:

This authorization requires that Omnipoint Communications, Inc. shall pay to the United States Treasury $347,518,309, plus interest, pursuant to the terms and procedures in the above schedule of payments (and accompanying instructions).

23. It is further ordered that the pleading styled a ''Petition to Deny the Award of a Pioneer Preference License to Omnipoint Corporation'', filed by Whitestone Wireless, L.P., Southern Personal Communications Systems; and Minco P.C.S., on September 22, 1995, is hereby dismissed.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96–7965 Filed 4–2–96; 8:45 am]

BILLING CODE 6712–01–P

47 CFR Part 73

[MM Docket No. 95–164; RM–8716]

Radio Broadcasting Services; Cornell, WI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Action taken in this document allots Channel 260C3 to Cornell, Wisconsin, in response to a petition filed by Flambeau Broadcasting Co. *See* 60 FR 56034, November 6, 1995. The coordinates for Channel 260C3 at Cornell are 45–10–56 and 91–12–20. There is a site restriction 4.9 kilometers (3 miles) west of the community. Canadian concurrence has been obtained for this allotment. With this action, this proceeding is terminated.

DATES: Effective May 13, 1996. The window period for filing applications will open on May 13, 1996, and close on June 13, 1996.

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

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MM Docket No. 95–164, adopted March 19, 1996, and released March 29, 1996. 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 Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

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: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Wisconsin, is amended by adding Cornell, Channel 260C3.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 96–8121 Filed 4–2–96; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Parts 382, 383, 390, 391 and 392

[FHWA Docket Nos. MC–92–19 and MC–92–23]

RIN 2125–AD46

Commercial Driver's License Program and Controlled Substances and Alcohol Use and Testing

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule; technical correction.

SUMMARY: This document corrects the final rule on alcohol and drug testing rules and the regulations implementing the commercial driver's license program which was published in the issue of March 8, 1996, in FR Doc. 96–5373 on page 9564. In part 383, a reference to a nonexistent paragraph was inadvertently inserted and, by this document, is removed.

EFFECTIVE DATE: March 8, 1996.

FOR FURTHER INFORMATION CONTACT: For information regarding program issues: Office of Motor Carrier Research and Standards, (202) 366–1790, For information regarding legal issues: Office of the Chief Counsel, Motor Carrier Law Division, (202)366–0834, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: The FHWA hereby corrects 49 CFR part 383 as published on March 8, 1996, in FR Doc. 96–5373 on page 9564, in the introductory paragraph of § 383.3(d), by replacing the words '', (d)(2), and (d)(3) of this section'' with the words ''and (d)(2) of this section''.

Authority: 49 U.S.C. 322; 23 U.S.C. 315.

Issued on: March 27, 1996.

Edward V.A. Kussy,

Acting Chief Counsel.

[FR Doc. 96–8157 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–22–P

49 CFR Parts 383 and 395

RIN 2125–AD83

Exemptions From Federal Motor Carrier Safety Regulations

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The National Highway System Designation Act of 1995 creates exemptions from certain requirements of the Federal Motor Carrier Safety Regulations (FMCSRs) for employers engaged in: The transportation of agricultural commodities and farm supplies, the transportation of ground water drilling rigs, the transportation of construction materials and equipment, the operation of utility service vehicles, and the operation of snow and ice removal equipment within the boundaries of an eligible unit of local government. These exemptions relate to the hours-of-service and the commercial driver's license requirements of the regulations. This final rule amends the FMCSRs to conform to these statutory exemptions.

EFFECTIVE DATES: This rule is effective April 3, 1996 except § 383.3(d)(3) and §§ 395.1(n) and (o), pertaining to the transportation of snow and ice removal equipment, construction materials and equipment, and drivers of utility service vehicles, are not effective until May 26, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Robert F. Schultz, Jr., Office of Motor Carrier Research and Standards, (202) 366–2718, or Ms. Grace Reidy, Office of the Chief Counsel, (202) 366–6226, Federal Highway Administration, DOT, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background and Notices

On November 28, 1995, the President signed the National Highway Systems Designation Act of 1995, Pub. L. 104–59, 109 Stat. 568 (1995)(NHS Act). Section 345 of this Act creates five specific exemptions from certain provisions of the FMCSRs (49 CFR 390.1 *et seq.*).

The first exemption applies to drivers transporting agricultural commodities or farm supplies during planting and harvesting seasons, if the transportation is limited to the area within a 100 air mile radius of the source of the commodities or the distribution point for the farm supplies. These drivers are exempt from the maximum driving and on-duty time regulations of the FMCSRs.

The second exemption relates to drivers who are primarily involved in the transportation of ground water drilling rigs. These rigs include any vehicle, machine, tractor, trailer, semi-trailer, or specialized mobile equipment propelled or drawn by mechanical power and used on highways to transport water well field operating equipment, including water well drilling and pump service rigs equipped to access ground water. Current regulations forbid drivers from operating CMVs after they have been on duty a certain number of hours over a 7 or 8 day span. Specifically, if the employing motor carrier *does not* operate 7 days a week, the cutoff is 60 hours over a 7-day span; if the employing motor carrier *does* operate 7 days a week, the cutoff is either 60 hours over a 7-day span, or 70 hours over an 8-day span. The water drilling rig exception in the NHS Act permits these drivers to ''restart the clock,'' which means that at any point at which the driver is off-duty for 24 or more consecutive hours, the period of 7 or 8 days ends as of the beginning of that off-duty period, and the clock restarts for purposes of computing the 7 or 8 day period when the driver goes on duty again. Thus, this exemption enables the motor carrier to designate the time of day at which the period of 7 or 8 days begins. The definition of ''24-hour period'' in the NHS Act authorizes the carrier to designate the time of day at which the 24-hour period begins, which may vary between the various terminals from which drivers are dispatched.

The third exemption applies to drivers used primarily in the transportation of construction materials and equipment, which is defined as the transportation of construction and pavement materials, construction equipment, and construction maintenance vehicles. The driver must be en route to or from an ''active construction site,'' which must be at a stage between initial mobilization of equipment and materials to the site, and final completion of the construction project. The construction site must also be within a 50 air-mile radius of the driver's normal work reporting location, and this exemption does not apply to the transportation of hazardous materials in a quantity requiring placarding. This exemption allows these construction drivers to restart the calculation of a 7 or 8 day period under the hours of service regulations in the same fashion as provided in the third exemption.

The fourth exemption applies these same provisions to drivers of utility service vehicles. In order to qualify as a utility service vehicle, the vehicle must be operated primarily within the service area of the utility's subscribers. In addition, it must be used in the furtherance of repairing, maintaining, or operating any physical facilities necessary for the delivery of public utility service and must be engaged in any activity necessarily related to the ultimate delivery of public utility services to the consumer, including travel to, from, upon, or between activity sites. The public utility, which includes those delivering electric, gas, water, sanitary sewer, telephone, and television service, need not be the actual owner of the vehicle in question. This exemption likewise enables utility drivers to restart the calculation of a 7 or 8 day period after the driver has been off duty for at least 24 hours consecutively.

The fifth and final exemption permits a State to exempt by waiver the requirement for a commercial driver's license (CDL) for back-up snow removal drivers employed by an eligible unit of local government. The vehicle must be operated within the boundaries of a city, town, borough, county, parish, district, or other unit of local government created pursuant to State law which has a total population of 3,000 or less. In addition, the vehicle must be operated by an employee of that local government for the purpose of removing snow or ice from a roadway by plowing, sanding, or salting. This waiver may only be granted where the employee who ordinarily operates the vehicle is unavailable or in need of additional assistance due to snow emergency. This provision does not affect the requirement that the customary operator of the vehicle have a CDL.

For each of the exemptions described above, other than the water well drilling exemption, the NHS Act provides the Secretary with the authority to negate or modify the exemption upon a determination, after a rulemaking proceeding, that the exemption is not in the public interest and would have a significant adverse impact on the safety of commercial motor vehicles. The Federal Highway Administration (FHWA) has decided not to proceed with such a rulemaking proceeding at this time. Nevertheless, the FHWA is required by the statute to monitor the safety performance of drivers of vehicles that are subject to an exemption and report to Congress if a determination is made that public safety has been adversely affected by one of these exemptions.

The FHWA is investigating the issues surrounding maximum driving and on-duty time of truck drivers. At the Truck and Bus Summit held in March 1995, in Kansas City, Missouri, participants representing every segment of the U.S. trucking industry were assembled by the FHWA. The number one issue of concern to the participants was driver fatigue. In addition, the FHWA is also about to complete a multi-year, cooperative government-industry research effort designed to generate quantitative information about the impact of fatigue on motor carrier operations. The project will provide an empirical basis for reevaluating the restrictions on hours-of-service of CMV drivers.

In addition, the FHWA invited and received comments on the issue of waiver of the hours of service regulations for those transporting crops and farm supplies. 59 FR 63322; December 8, 1994. Docket comments were received from over 175 respondents, almost all of which were in support of the waiver concept.

Rulemaking Analyses and Notices

The FHWA is amending Parts 383 and 395 of the FMCSRs by proceeding directly to a final rule. The FHWA finds that prior notice and opportunity for comment are unnecessary under 5 U.S.C. 553(b)(3)(B) and that good cause exists to dispense with the 30-day delayed effective date ordinarily required under 5 U.S.C. 553(d) because these changes are statutorily mandated. The FHWA has also determined that prior notice and opportunity for comment are not required under Department of Transportation's regulatory policies and procedures, as it is anticipated that such action would not result in the receipt of useful information.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

These changes are being made to conform the FHWA's regulations to statutory exemptions already authorized by section 345 of the NHS Act. At this point, the FHWA is unable to predict what the impact of these changes will be. However, pursuant to the obligations imposed upon the Secretary by the NHS Act, the FHWA intends to monitor the impact of these changes.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this action on small entities. This rule merely amends the FMCSRs to conform them to the exemptions granted in the NHS Act. These exemptions are likely to lessen the financial burden of complying with the relevant FMCSRs, but only for limited classes of operations. The FHWA certifies that this action will not have a significant impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. As provided in section 345(b) of the NHS Act, these regulatory changes do not preempt any State laws or regulations concerning the safe operation of commercial motor vehicles. This action does not impose any additional cost or burden on any State. In addition, this rule would have no effect on the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not contain a collection of information requirement

for purposes of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) and has determined that this action would not have any effect on the quality of the environment. Therefore, an environmental impact statement is not required.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in Parts 383 and 395

Commercial driver's license documents, Commercial motor vehicles, Driver's hours of service, Highways and roads, Motor carriers licensing and testing procedures, Motor vehicle safety, Reporting and recordkeeping requirements.

Issued on: March 26, 1996.

Rodney E. Slater,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA hereby amends title 49, Code of Federal Regulations, subtitle B, chapter III, subchapter B, parts 383 and 395 as set forth below:

PART 383—[AMENDED]

1. The authority citation for part 383 is revised to read as follows:

Authority: 49 U.S.C. 31101 *et seq.*, 31136, and 31502; sec. 345, Pub. L. 104–59, 109 Stat. 568, 613; and 49 CFR 1.48.

2. Section 383.3(d) is amended by revising the heading and the introductory paragraph, and by adding a new paragraph (d)(3) to read as follows:

§ 383.3 Applicability.

* * * * *

(d) *Exception for farmers, firefighters, emergency response vehicle drivers, and drivers removing snow and ice.* A State may, at its discretion, exempt individuals identified in paragraphs (d)(1), (d)(2), and (d)(3) of this section from the requirements of this part. The use of this waiver is limited to the driver's home State unless there is a reciprocity agreement with adjoining States.

* * * * *

(3)(i) A driver, employed by an eligible unit of local government, operating a commercial motor vehicle within the boundaries of that unit for the purpose of removing snow or ice from a roadway by plowing, sanding, or salting, if

(A) The properly licensed employee who ordinarily operates a commercial motor vehicle for these purposes is unable to operate the vehicle; or

(B) The employing governmental entity determines that a snow or ice emergency exists that requires additional assistance.

(ii) This exemption shall not preempt State laws and regulations concerning the safe operation of commercial motor vehicles.

* * * * *

3. Section 383.5 is amended by adding the definition ''Eligible unit of local government'' in alphabetical order to read as follows:

§ 383.5 Definitions.

* * * * *

Eligible unit of local government means a city, town, borough, county, parish, district, or other public body created by or pursuant to State law which has a total population of 3,000 individuals or less.

* * * * *

PART 395—[AMENDED]

4. The authority citation for part 395 is revised to read as follows:

Authority: 49 U.S.C. 31133, 31136, and 31502; sec. 345, Pub.L. 104–59, 109 Stat. 568, 613; and 49 CFR 1.48.

5. Section 395.1 is amended by revising paragraph (a) and by adding paragraphs (l), (m), (n), and (o) to read as follows:

§ 395.1 Scope of rules in this part.

(a) *General.* (1) The rules in this part apply to all motor carriers and drivers, except as provided in paragraphs (b) through (n) of this section.

(2) The exceptions from Federal requirements contained in paragraphs (l) through (n) do not preempt State laws and regulations governing the safe operation of commercial motor vehicles.

* * * * *

(l) *Agricultural operations.* The provisions of § 395.3 shall not apply to drivers transporting agricultural commodities or farm supplies for agricultural purposes in a State if such transportation:

(1) Is limited to an area within a 100 air mile radius from the source of the commodities or the distribution point for the farm supplies, and

(2) Is conducted during the planting and harvesting seasons within such State, as determined by the State.

(m) *Ground water well drilling operations.* In the instance of a driver of a commercial motor vehicle who is used primarily in the transportation and operations of a ground water well drilling rig, any period of 7 or 8 consecutive days may end with the beginning of any off-duty period of 24 or more successive hours.

(n) Construction materials and equipment. In the instance of a driver of a commercial motor vehicle who is used primarily in the transportation of construction materials and equipment, any period of 7 or 8 consecutive days may end with the beginning of any off-duty period of 24 or more successive hours.

(o) *Utility service vehicles.* In the instance of a driver of a utility service vehicle, any period of 7 or 8 consecutive days may end with the beginning of any off-duty period of 24 or more successive hours.

6. Section 395.2 is amended by adding three definitions, alphabetically, to read as follows:

§ 395.2 Definitions.

* * * * *

Ground water well drilling rig means any vehicle, machine, tractor, trailer, semi-trailer, or specialized mobile equipment propelled or drawn by mechanical power and used on highways to transport water well field operating equipment, including water well drilling and pump service rigs equipped to access ground water.

* * * * *

Transportation of construction materials and equipment means the transportation of construction and pavement materials, construction equipment, and construction maintenance vehicles, by a driver to or from an active construction site (a construction site between mobilization of equipment and materials to the site to the final completion of the construction project) within a 50 air mile radius of the normal work reporting location of the driver. This paragraph does not apply to the transportation of material found by the Secretary to be hazardous under 49 U.S.C. 5103 in a quantity requiring placarding under regulations issued to carry out such section.

* * * * *

Utility service vehicle means any commercial motor vehicle:

(1) Used in the furtherance of repairing, maintaining, or operating any

structures or any other physical facilities necessary for the delivery of public utility services, including the furnishing of electric, gas, water, sanitary sewer, telephone, and television cable or community antenna service;

(2) While engaged in any activity necessarily related to the ultimate delivery of such public utility services to consumers, including travel or movement to, from, upon, or between activity sites (including occasional travel or movement outside the service area necessitated by any utility emergency as determined by the utility provider); and

(3) Except for any occasional emergency use, operated primarily within the service area of a utility's subscribers or consumers, without regard to whether the vehicle is owned, leased, or rented by the utility.

[FR Doc. 96–8158 Filed 4–2–96; 8:45 am]
BILLING CODE 4910–22–P

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION

49 CFR Part 533

[Docket No. 94–20; Notice 4]

RIN 2127–AF16

Light Truck Average Fuel Economy Standard, Model Year 1998

AGENCY: National Highway Traffic Safety Administration (NHTSA).

ACTION: Final rule.

SUMMARY: This final rule establishes the average fuel economy standard for light trucks manufactured in model year (MY) 1998. The issuance of the standard is required by statute. Pursuant to section 330 of the fiscal year (FY) 1996 DOT Appropriations Act, the light truck standard for MY 1998 is 20.7 mpg.

DATES: The amendment is effective May 3, 1996. The standard applies to the 1998 model year. Petitions for reconsideration must be submitted within 45 days of publication.

ADDRESSES: Petitions for reconsideration should be submitted to: Administrator, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mr. Otto G. Matheke, III, Office of Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590 (202–366–5263).

SUPPLEMENTARY INFORMATION:

I. Background

In December 1975, during the aftermath of the energy crisis created by the oil embargo of 1973–74, Congress enacted the Energy Policy and Conservation Act. Congress included a provision in that Act establishing an automotive fuel economy regulatory program. That provision added Title V, ''Improving Automotive Efficiency,'' to the Motor Vehicle Information and Cost Saving Act. Title V has been amended and recodified without substantive change as Chapter 329 of Title 49 of the United States Code. Chapter 329 provides for the issuance of average fuel economy standards for passenger automobiles and automobiles that are not passenger automobiles (light trucks).

Section 32902(a) of Chapter 329 states that the Secretary of Transportation shall prescribe by regulation corporate average fuel economy (CAFE) standards for light trucks for each model year. That section also states that ''[e]ach standard shall be the maximum feasible average fuel economy level that the Secretary decides the manufacturers can achieve in that model year.'' (The Secretary has delegated the authority to implement the automotive fuel economy program to the Administrator of NHTSA. 49 CFR 1.50(f).) Section 32902(f) provides that in determining the maximum feasible average fuel economy level, NHTSA shall consider four criteria: technological feasibility, economic practicability, the effect of other motor vehicle standards of the Government on fuel economy, and the need of the United States to conserve energy. Pursuant to this authority, the agency has set light truck CAFE standards through MY 1997. See 49 CFR 533.5(a). The standard for MY 1997 is 20.7 mpg. 59 FR 16312 (April 6, 1994).

NHTSA began the process of establishing light truck CAFE standards for model years after MY 1997 by publishing an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register. 59 FR 16324 (April 6, 1994). The ANPRM outlined the agency's intention to set standards for some or all of model years 1998 to 2006.

Subsequent to reviewing the comments submitted in response to the ANPRM, the agency decided to defer rulemaking for MY's 1999–2006. NHTSA thereafter issued a notice of proposed rulemaking (NPRM) limited to MY 1998, which proposed to set the light truck CAFE standard for that year at 20.7 mpg. 61 FR 145 (January 3, 1996). On November 15, 1995, the Department of Transportation and Related Agencies Appropriations Act for Fiscal Year 1996 was enacted. Pub. L. 104–50. Section 330 of that Act provides:

> None of the funds in this Act shall be available to prepare, propose, or promulgate any regulations * * * prescribing corporate average fuel economy standards for automobiles * * * in any model year that differs from standards promulgated for such automobiles prior to enactment of this section.

Because light truck CAFE standards must be set no later than eighteen months before the beginning of the model year in question, the deadline for NHTSA to set the MY 1998 standard is approximately April 1, 1996. However, the agency cannot promulgate such a standard without the expenditure of funds, and it may not spend any funds in violation of the terms of section 330 of the FY 1996 Appropriations Act. Therefore, to ascertain the limits of its authority to promulgate CAFE standards during FY 1996, NHTSA must interpret the phrase ''differs from standards promulgated for such automobiles prior to enactment of this section.''

In the agency's view, the most compelling meaning of the phrase is to preclude the expenditure of funds to adopt a CAFE standard for any model year at any level other than the level of the CAFE standards previously established for MY 1997; i.e., 20.7 mpg for light trucks and 27.5 mpg for passenger cars.

The agency examined the legislative history of section 330 to seek additional insight into Congressional intent. Section 330 was reported out of the House Committee on Appropriations in its enacted form as part of H.R. 2002. The original Committee print of the House Report to accompany H.R. 2002 stated, at page 112, that the section precluded NHTSA from prescribing CAFE standards that ''differ from those previously enacted:''

> The Committee has adopted a general provision (Sec. 330) that prohibits NHTSA or the Department from prescribing corporate average fuel economy standards for automobiles that differ from those previously enacted.

This language was modified somewhat in the final version of the House report to accompany H.R. 2002, but repeated the command that CAFE standards promulgated in FY 1996 should not ''differ from those previously enacted.'' The report stated:

> The Committee has adopted a general provision (Sec. 330) that prohibits funds to be used to prepare, prescribe or promulgate corporate average fuel economy standards for automobiles that differ from those previously enacted. The limitation does not preclude the Secretary of Transportation, in order to meet

lead time requirements of the law, from preparing, proposing and issuing a CAFE standard for model year 1998 automobiles that is identical to the CAFE standard for such automobiles for model year 1997.

H.R. Rep. 104–177, at 113.

The addition of the second sentence to this report language suggests that the Committee wanted to clarify that, regardless of what the maximum feasible average fuel economy level might be for MY 1998 light trucks, NHTSA was not precluded from setting the CAFE standard for such automobiles at a level ''identical'' to the MY 1997 level of 20.7 mpg. There is no indication that the Committee intended to authorize the MY 1998 light truck standard to be set at any other level.

The next relevant item of legislative history is the remarks during the House floor debate on H.R. 2002 by Congressman DeLay, who originally offered this provision during consideration of the bill by the Transportation Subcommittee of the Appropriations Committee. Congressman DeLay began by describing the section as imposing ''a 1-year freeze on the ability of NHTSA to increase the CAFE standards for passenger cars and light trucks and vans.'' He added:

[I]t was my intent that NHTSA would withhold any further action directed toward increasing CAFE standards, and that *the CAFE standards for light trucks and vans for the 1998 model year,* which must be issued during fiscal 1996 to meet industry's lead time requirements, *should be identical to the standard that is currently in effect for those vehicles for the 1997 model year.* This intent is clearly stated in the committee report which accompanies the legislation.

141 Cong. Rec. H7605 (daily ed. July 25, 1995) (emphasis supplied).

These comments, offered by the sponsor of the provision in question, clearly reflect Congressman DeLay's intent that NHTSA should set the MY 1998 light truck standard ''identical to'' the 20.7 mpg level in effect for MY 1997, without regard to any determination the agency might otherwise have reached with respect to the maximum feasible average fuel economy level for MY 1998. His remarks also characterize the Committee report as reflecting the same intent.

In its original consideration of H.R. 2002, the Senate deleted section 330. See S. Rep. No. 104–126, at 145. However, the provision was restored by the Conference Committee, which described its action as follows:

Amendment No. 155: Restores House language deleted by the Senate that prohibits the use of funds to prepare, propose or promulgate any regulations that prescribe changes in the corporate average fuel economy standards for automobiles.

H.R. Rep. 104–286, at 73.

Numerous courts have held that, compared to other items of legislative history, the Conference Report is generally the most authoritative source of Congressional intent. In this case, that report unambiguously describes section 330 as prohibiting the use of FY 1996 funds to promulgate ''any regulations that prescribe changes'' in CAFE standards.

As described above, each of the relevant items of legislative history supports the agency's view that section 330 precludes NHTSA from preparing, proposing, or issuing any CAFE standard that is not identical to those previously established for MY 1997. Accordingly, NHTSA is setting the MY 1998 light truck CAFE standard at the MY 1997 level of 20.7 mpg.

NHTSA recognizes that setting the MY 1998 standard at 20.7 mpg without making a determination as to the maximum feasible average fuel economy level for that model year could be inconsistent with the second sentence of 49 U.S.C. § 32902(a), which states that ''[e]ach [light truck] standard shall be the maximum feasible average fuel economy level that the Secretary decides the manufacturers can achieve in that model year.''

However, the only other possible interpretation of the language ''differs from standards promulgated for such automobiles prior to enactment of this section'' in section 330 is that NHTSA may issue CAFE standards at a level equal to that of *any* previously promulgated standard. Under this interpretation, during FY 1996 NHTSA would be able to set the ''combined'' (i.e., two-wheel drive and four-wheel drive) light truck CAFE standard for MY 1998 (and for future model years) at one of 10 specific levels as follows (see 49 CFR 533.5(a)):

Combined Standard (MPG)	Model Years
17.5	1982
19.0	1983
19.5	1985
20.0	1984, 1986, 1990
20.2	1991, 1992
20.4	1993
20.5	1987, 1988, 1989, 1994
20.6	1995
20.7	1996, 1997
21.0	*1985

*In model year 1985, the combined standard was originally promulgated as 21.0 mpg before it was amended to 19.5 mpg.

Similarly, under this interpretation, the agency would be authorized to amend the passenger car CAFE standard to one of seven specific levels, ranging from 18.0 mpg to 27.0 mpg, but to no points in between. See 49 CFR 531.5(a).

Such an interpretation, however, could also conflict with the ''maximum feasible'' provision of 49 U.S.C. § 32902(a) because the maximum feasible level calculated by NHTSA under the criteria it has traditionally applied might not be identical to one of the previously promulgated standards. Moreover, those previously promulgated standards include 21.0 mpg, a level in excess of the MY 1997 standard, which would clearly contravene the intent, expressed in every item of relevant legislative history, to ''freeze'' NHTSA's ability to increase the CAFE standards above the MY 1997 level of 20.7 mpg.

Finally, it is inherently illogical to assume that Congress intended to limit so arbitrarily the possible levels at which NHTSA can set future CAFE standards; i.e., that previously promulgated standards of 20.0 mpg, 20.2 mpg, or 20.4 mpg are permissible, but 20.1 mpg and 20.3 mpg are not permissible, even if one of them were determined to be the maximum feasible level. In contrast, the interpretation adopted by the agency in this notice is logical in the context of the Appropriations Act restrictions. ''Freezing'' the MY 1998 standard at 20.7 mpg comports with Congressman DeLay's declaration that ''[t]he purpose of Section 330 is to establish a pause in this rulemaking process, to give the Congress an opportunity to review the CAFE program,'' 141 Cong. Rec. H7605 (daily ed. July 25, 1995), and the expectation that the established standard for MY 1997 of 20.7 mpg would not be an unreasonable level for the industry to achieve in MY 1998.

The agency is of course aware that repeals by implication of substantive statutory provisions are generally disfavored, particularly where the claimed repeal rests upon language in an appropriations act. However, as demonstrated above, both of the theoretically plausible textual readings of the 1996 DOT Appropriations Act language could conflict with the ''maximum feasible'' requirement, so the agency must choose the one which is most consistent with the legislative intent expressed in the legislative history.

Further, under the present circumstances, where issuance of a light truck standard at a level other than 20.7 mpg is prohibited by a recent Act of Congress, the only other alternative would be to decline to issue any light truck standard at all for MY 1998. That course of action would also constitute a ''repeal'' of the statutory duty set forth in the first sentence of section 32902(a)

to issue annual light truck CAFE standards. It would also do more violence to the statutory scheme of Chapter 329 than the establishment of a 20.7 mpg standard for MY 1998. Finally, failure to set any standard would conflict with Congress's express direction in the House Committee report that NHTSA not be precluded ''from preparing, proposing and issuing a CAFE standard for model year 1998 automobiles that is identical to the CAFE standard for such automobiles for model year 1997.''

II. Impact Analyses

A. Economic Impacts

The agency has not prepared a Final Regulatory Impact Analysis because of the restrictions imposed by Section 330 of the FY 1996 DOT Appropriations Act. The rule was reviewed by the Office of Management and Budget under Executive Order 12866 and is considered significant under the Department's regulatory procedures.

B. Environmental Impacts

NHTSA has not conducted an evaluation of the impacts of this action under the National Environmental Policy Act. There is no requirement for such an evaluation where Congress has eliminated the agency's discretion by precluding any action other than the one announced in this notice.

C. Impacts on Small Entities

NHTSA has not conducted an evaluation of this action pursuant to the Regulatory Flexibility Act. As Congress has eliminated the agency's discretion by precluding any action other than the one taken in this notice, such an evaluation is unnecessary. Past evaluations indicate, however, that few, if any, light truck manufacturers would have been classified as a ''small business'' under the Regulatory Flexibility Act.

D. Impact of Federalism

This action has been not been analyzed in accordance with the principles and criteria contained in Executive Order 12612. The preparation of a Federalism Assessment is not required where Congress has precluded any action other than the one published in this notice. As a historical matter, prior light truck standards have not had sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

E. Department of Energy Review

In accordance with section 49 U.S.C. § 32902(j), NHTSA submitted this final rule to the Department of Energy for review. That Department made no unaccommodated comments.

III. Conclusion

Based on the foregoing, the agency is establishing a combined average fuel economy standard for non-passenger automobiles (light trucks) for MY 1998 at 20.7 mpg.

List of Subjects in 49 CFR Part 533

49 CFR Part 533

Energy conservation, Motor vehicles.

PART 533—[AMENDED]

In consideration of the foregoing, 49 CFR Part 533 is amended as follows:

1. The authority citation for part 533 is revised to read as follows:

Authority: 49 U.S.C. 32902; delegation of authority at 49 CFR 1.50.

2. Section 533.5(a) is amended by revising Table IV to read as follows:

§ 533.5 Requirements.

* * * * *

TABLE IV

Model year	Standard
1996	20.7
1997	20.7
1998	20.7

* * * * *

Issued On: March 29, 1996.

Ricardo Martinez,

Administrator.

[FR Doc. 96–8156 Filed 3–29–96; 3:38 pm]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 251

[Docket No. 960301056–6056–01; I.D. 021596D]

RIN 0648–AI76

Financial Aid Program Procedures; Removal of Conditional Fisheries Regulations

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS abolishes the Financial Aid Program Procedures regulations in accordance with the President's Regulatory Reform Initiative, which directs that unnecessary regulations be abolished.

EFFECTIVE DATE: April 3, 1996.

ADDRESSES: Michael L. Grable, Chief, Financial Services Division, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Charles L. Cooper, Program Leader, 301–713–2396.

SUPPLEMENTARY INFORMATION: In 1973, NMFS established the regulations contained in 50 CFR part 251 to provide a central statement of NMFS policy related to restricting the use of financial assistance programs in certain fisheries in which the use of these programs has been determined to be inconsistent with the wise use of the fishery resources involved. These fisheries are designated as ''Conditional Fisheries.'' The programs involved are the Fisheries Capital Construction Fund Program (46 U.S.C. 1177) and the Fisheries Obligation Guarantee Program (46 U.S.C. 1271–1279).

In March 1995, President Clinton issued a directive to Federal agencies regarding their responsibilities under his Regulatory Reform Initiative. This initiative is part of the National Performance Review and calls for immediate, comprehensive regulatory reform. The President directed all agencies to undertake an exhaustive review of all their regulations with an emphasis on eliminating or modifying those that are obsolete or otherwise in need of reform. NMFS has determined that the regulations pertaining to Conditional Fisheries are unnecessary and should be abolished, because NMFS has long-standing practices governing the use of the Fisheries Obligation Guarantee Fund Program and the Fisheries Capital Construction Fund Program that contain adequate safeguards against using these programs in ways that would be inconsistent with the wise use of fisheries resources. To ensure that the Fisheries Capital Construction Fund Program will not be used in ways that would be inconsistent with the wise use of fishery resources, those fisheries which had been designated as ''Conditional Fisheries'' shall continue to be ''closed fisheries'' pursuant to the Interim Capital Construction Fund agreements. The fisheries involved are the fishery for yellowfin tuna in the area regulated by the Inter-American Tropical Tuna Commission, the fishery for American lobster in the Gulf of Maine, the fishery for salmon in Washington, Oregon, and California, the fishery for king crab in

Alaska, the fishery for surf clams, and the fishery for Atlantic Groundfish.

Classification

Because this rule eliminates an unnecessary regulation, no useful purpose would be served by providing prior notice and opportunity for comment on this rule. Accordingly, under 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries, NOAA, for good cause, finds that it is unnecessary to provide such notice and opportunity for comment. Also, because this rule is only administrative in nature and is not a ''substantive rule'' under 5 U.S.C. 533(d), it will be immediately effective upon publication.

This final rule has been determined to be not significant for the purposes of E.O. 12866.

List of Subjects in 50 CFR Part 251

Administrative practice and procedure, Fisheries, Fishing vessels, Loan programs-business.

Dated: March 27, 1996.

Charles Karnella,

Acting Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, under the authority at 16 U.S.C. 742, 50 CFR part 251 is removed.

[FR Doc. 96–7888 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–22–F

50 CFR Part 641

[Docket No. 94113–4354; I.D. 032896A]

Reef Fish Fishery of the Gulf of Mexico; Closure of the Commercial Red Snapper Component

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS closes the commercial fishery for red snapper in the exclusive economic zone (EEZ) of the Gulf of Mexico. NMFS has projected that the annual commercial quota for red snapper will be reached on April 4, 1996. This closure is necessary to protect the red snapper resource.

EFFECTIVE DATE: Closure is effective 12:01 a.m., local time, April 5, 1996, through December 31, 1996.

FOR FURTHER INFORMATION CONTACT: Robert Sadler, 813–570–5305.

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf of Mexico is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Gulf of Mexico Fishery Management Council and is implemented through regulations at 50 CFR part 641 under the authority of the Magnuson Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq*.). Those regulations set the commercial quota for red snapper in the Gulf of Mexico at 3.06 million lb (1.39 million kg) for the current fishing year, January 1 through December 31, 1996.

Under 50 CFR 641.26, NMFS is required to close the commercial fishery for a species or species group when the quota for that species or species group is reached, or is projected to be reached, by publishing a notification to that effect in the Federal Register. Based on current statistics, NMFS has projected that the commercial quota of 3.06 million lb (1.39 million kg) for red snapper will be reached on April 4, 1996. Accordingly, the commercial fishery in the EEZ in the Gulf of Mexico for red snapper is closed effective 12:01 a.m., local time, April 5, 1996, through December 31, 1996, the end of the fishing year. A vessel with a valid reef fish permit having red snapper on board must land and barter, trade, or sell such red snapper prior to 12:01 a.m., local time, April 5, 1996.

During the closure, the bag limit applies to all harvests of red snapper from the EEZ in the Gulf of Mexico. The daily bag limit for red snapper is five per person. From 12:01 a.m., local time, April 5, 1996, through December 31, 1996, the purchase, barter, trade, or sale of red snapper taken from the EEZ is prohibited. This prohibition does not apply to trade in red snapper that were harvested, landed, and bartered, traded, or sold prior to 12:01 a.m., local time, April 5, 1996, and were held in cold storage by a dealer or processor.

Classification

This action is taken under 50 CFR 641.26 and is exempt from review under E.O. 12866.

Dated: March 28, 1996.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96–8177 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 61, No. 65
Wednesday, April 3, 1996

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM–123; Notice No. SC–96–2–NM]

Special Conditions: Embraer (Brazil) Aircraft Corporation Model EMB–145 Airplane; High-Intensity Radiated Fields

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This document proposes special conditions for the Embraer Model EMB–145 airplane. This new airplane will utilize new avionics/electronic systems that provide critical data to the flightcrew. The applicable regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high-intensity radiated fields. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Comments must be received on or before May 20, 1996.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, Attn: Rules Docket (ANM–7), Docket No. NM–123, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; or delivered in duplicate to the Office of the Assistant Chief Counsel at the above address. Comments must be marked: Docket No. NM–123. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT:

Gerry Lakin, FAA, Standardization Branch, ANM–113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; telephone (206) 227–1187; facsimile (206) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of these proposed special conditions by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator before further rulemaking action is taken on these proposals. The proposals contained in this notice may be changed in light of comments received. All comments submitted will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. NM–123.'' The postcard will be date stamped and returned to the commenter.

Background

On August 30, 1989, Embraer Aircraft Corporation, Caixa Postal 343, 12227–901 Sao Jose dos Campos, Sao Paulo SP Brasil, applied for a new type certificate in the transport airplane category for the Model EMB–145 airplane. The EMB–145 is a T–tail, low swept wing, small transport airplane powered by two Allison GMA–3007A turbofan engines mounted on pylons extending from the aft fuselage. Each engine will be capable of delivering 7,040 pounds thrust. The flight controls will be powered and capable of manual reversion. The airplane has a seating capacity of up to 50 passengers, and a maximum takeoff weight of 42,328 pounds.

Type Certification Basis

Under the provisions of § 21.17 of the FAR, Embraer must show, except as provided in § 25.2, that the Model EMB–145 meets the applicable provisions of part 25, effective February 1, 1965, as amended by Amendments 25–1 through 25–75. In addition, the proposed certificate basis for the Model EMB–145 includes part 34, effective September 10, 1990, plus any amendments in effect at the time of certification; and part 36, effective December 1, 1969, as amended by Amendment 36–1 through the amendment in effect at the time of certification. No exemptions are anticipated. The special conditions that may be developed as a result of this notice will form an additional part of the type of certification basis. In addition, the certification basis may include other special conditions that are not relevant to these proposed special conditions.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25, as amended) do not contain adequate or appropriate safety standards for the Embraer Model EMB–145 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR after public notice, as required by §§ 11.28 and 11.29, and become part of the type certification basis in accordance with § 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

The Model EMB–145 incorporates new avionic/electronic installations, including a digital Electronic Flight Instrument System (EFIS), Air Data System, Attitude and Heading Reference System (AHRS), Navigation and Communication System, Autopilot System, and a Full Authority Digital Engine Control (FADEC) system that controls critical engine parameters. These systems may be vulnerable to high-intensity radiated fields (HIRF) external to the airplane.

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are proposed for the Embraer Model EMB–145, which would require that new technology electrical and electronic systems, such as the EFIS, FADEC, AHRS, etc., be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraphs 1 or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10KHz to 18GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–100 KHz	50	50
100 KHz–500 KHz	60	60
500 KHz–2000 KHz	70	70
2 MHz–30 MHz	200	200
30 MHz–100 MHz	30	30
100 MHz–200 MHz	150	33
200 MHz–400 MHz	70	70
400 MHz–700 MHz	4,020	935
700 MHz–1000 MHz	1,700	170
1 GHz–2 GHz	5,000	990
2 GHz–4 GHz	6,680	840
4 GHz–6 GHz	6,850	310
6 GHz–8 GHz	3,600	670
8 GHz–12 GHz	3,500	1,270
12 GHz–18 GHz	3,500	360
18 GHz–40 GHz	2,100	750

As discussed above, the proposed special conditions would be applicable initially to the Embraer Model EMB–145. Should Embraer apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101(a)(1).

Conclusion

This action affects only certain design features on the Embraer Model EMB–145 airplane. It is not a rule of general applicability and affects only the manufacturer who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for the Embraer Model EMB–145 series airplanes.

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high-intensity radiated fields.

2. For the purpose of these special conditions, the following definition applies: *Critical Functions.* Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on March 25, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–8037 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–13–M

FEDERAL TRADE COMMISSION

16 CFR Part 254

Request for Comments Concerning Guides for Private Vocational Schools

AGENCY: Federal Trade Commission.

ACTION: Request for public comments.

SUMMARY: The Federal Trade Commission (the ''Commission'') is requesting public comments on its Guide for Private Vocational Schools. The Commission is also requesting comments about the overall costs and benefits of the guides and their overall regulatory and economic impact as part of its systematic review of all current Commission regulations and guides.

DATES: Written comments will be accepted until May 3, 1996.

ADDRESSES: Comments should be directed to: Secretary, Federal Trade Commission, Room H–159, Sixth and Pennsylvania Ave., N.W., Washington, D.C. 20580. Comments about the Guides for Private Vocational Schools should be identified as ''16 CFR Part 254—Comment.''

FOR FURTHER INFORMATION CONTACT: Joseph J. Koman, Jr., Federal Trade Commission, Bureau of Consumer Protection, Division of Enforcement, Room S–4302, 601 Pennsylvania Ave., N.W., Washington, D.C. 20580, (202) 326–3014, or Walter Gross III, Federal Trade Commission, Bureau of Consumer Protection, Division of Service Industry Practices, Room H–200, Sixth Street and Pennsylvania Ave., N.W., Washington, D.C. 20580, (202) 326–3319.

SUPPLEMENTARY INFORMATION: The Commission has determined, as part of its oversight responsibilities, to review rules and guides periodically. These reviews seek information about the costs and benefits of the Commission's rules and guides and their regulatory and economic impact. The information obtained assists the Commission in identifying rules and guides that warrant modification or recision.

At this time, the Commission solicits written public comments concerning the Commission's Guides for Private Vocational Schools, 16 CFR Part 254. These guides, like the other industry guides issued by the Commission, ''are

administrative interpretations of laws administered by the Commission for the guidance of the public in conducting its affairs in conformity with legal requirements.'' 16 CFR 1.5. Conduct inconsistent with the guides may result in corrective action by the Commission under applicable statutory provisions.

The Private Vocational Schools Guides provide guidance about acceptable and unacceptable claims made in advertising, or other promotional materials, however disseminated, for resident or correspondence courses or training or instruction programs by private career or vocational schools. Specifically, the guides pertain to claims about the nature of the school, its accreditation, programs of instruction or methods of teaching and available employment opportunities. The guides also include provisions on representations concerning financial assistance, appropriate disclosures as to the nature of courses or training programs offered, pictorial or other misrepresentations, deceptive prices, and sales, collection and credit practices.

Accordingly, the Commission solicits public comments on the following questions:

1. Is there a continuing need for the Guides?

a. What benefits have the Guides provided to purchasers of the products or services affected by the Guides?

b. Have the Guides imposed costs on purchasers?

2. What changes, if any, should be made to the Guides to increase the benefits of the Guides to purchasers?

a. How would these changes affect the costs the Guides impose on firms subject to their requirements?

3. What significant burdens or costs, including costs of adherence, have the Guides imposed on firms subject to their requirements?

a. Have the Guides provided benefits to such firms?

4. What changes, if any, should be made to the Guides to reduce the burdens or costs imposed on firms subject to their requirements?

a. How would these changes affect the benefits provided by the Guides?

5. Do the Guides overlap or conflict with other federal, state, or local laws or regulations?

6. Since the Guides were issued, what effects, if any, have changes in relevant technology or economic conditions had on the Guides?

7. Are there problems today in the marketing of vocational school programs or correspondence courses? If yes, what is the nature of these problems? Do the Guides adequately address any problems that may exists?

Authority: 15 U.S.C. 41–58.

List of Subjects in 16 CFR Part 254

Advertising, Trade practices.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–8134 Filed 4–2–96; 8:45 am]

BILLING CODE 6750–01–M

16 CFR Part 406

Deceptive Advertising and Labeling of Previously Used Lubricating Oil

AGENCY: Federal Trade Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Federal Trade Commission (the ''Commission'') proposes to commence a rulemaking proceeding to repeal its Trade Regulation Rule on Deceptive Advertising and Labeling of Previously Used Lubricating Oil (''the Used Oil Rule'' or ''the Rule''), 16 CFR Part 406. The Commission is soliciting written comments, data, and arguments concerning this proposal. The Commission also is requesting comments about the overall costs and benefits of the Rule and its overall regulatory and economic impact as a part of its systematic review of all current Commission regulations and guides.

DATES: Written comments must be submitted on or before May 3, 1996.

ADDRESSES: Written comments should be identified as ''16 CFR Part 406 Comment'' and sent to Secretary, Federal Trade Commission, room 159, Sixth Street and Pennsylvania Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Neil Blickman, Attorney, Federal Trade Commission, Bureau of Consumer Protection, Division of Enforcement, Washington, DC 20580, (202) 326–3038.

SUPPLEMENTARY INFORMATION:

Part A—Background Information

This notice is being published pursuant to Section 18 of the Federal Trade Commission (''FTC'') Act, 15 U.S.C. 57a *et seq.*, the provisions of Part 1, Subpart B of the Commission's Rules of Practice, 16 CFR 1.7 *et seq.*, and 5 U.S.C. 551 *et seq.* This authority permits the Commission to promulgate, modify, and repeal trade regulation rules that define with specificity acts or practices that are unfair or deceptive in or affecting commerce within the meaning of Section 5(a)(1) of the FTC Act, 15 U.S.C. 45(a)(1).

Based on the Commission's finding that the new or used status of a lubricant was material to consumers, the Used Oil Rule was promulgated by the Commission on August 14, 1964 to prevent deception of those who prefer new and unused lubricating oil. The Rule requires that advertising, promotional material, and labels for lubricant made from used oil disclose such previous use. The Rule prohibits any representation that used lubricating oil is new or unused. In addition, it prohibits use of the term ''re-refined,'' or any similar term, to describe previously used lubricating oil unless the physical and chemical contaminants have been removed by a refining process.

On October 15, 1980, the Used Oil Recycling Act suspended the provision of the Used Oil Rule requiring labels to disclose the origin of lubricants made from used oil,[1] until the Commission issued rules under the Energy Policy and Conservation Act of 1975 (''EPCA''). The legislative history indicates congressional concern that the Used Oil Rule's labeling requirement had an adverse impact on consumer acceptance of recycled oil, provided no useful information to consumers concerning the performance of the oil, and inhibited recycling. Moreover, the origin labeling requirements in the Used Oil Rule may be inconsistent with the intent of section 383 of EPCA, which is that ''oil should be labeled on the basis of performance characteristics and fitness for intended use, and not on the basis of the origin of the oil.'' [2]

Accordingly, on April 8, 1981, the Commission published a notice announcing the statutory suspension of the origin labeling requirements of the Used Oil Rule. In the same notice, the Commission suspended enforcement of those portions of the Used Oil Rule requiring that advertising and promotional material disclose the origin of lubricants made from used oil.[3]

The purposes of the recycled oil section of EPCA are to encourage the recycling of used oil, to promote the use of recycled oil, to reduce consumption of new oil by promoting increased utilization of recycled oil, and to reduce environmental hazards and wasteful practices associated with the disposal of used oil.[4] To achieve these goals, section 383 of EPCA directs the National Institute of Standards and Technology

[1] 42 U.S.C. 6363 note.

[2] See Legislative History Pub. L. 96–463, U.S. Code Cong. and Adm. News, pp. 4354–4356 (1980).

[3] 46 FR 20979.

[4] 42 U.S.C. 6363(a).

(''NIST'') to develop test procedures for the determination of the substantial equivalency of re-refined or otherwise processed used oil or blend of oil (consisting of such re-refined or otherwise processed used oil and new oil or additives) with new oil distributed for a particular end use and to report such test procedures to the Commission.[5] Within 90 days after receiving such report from NIST, the Commission is required to prescribe, by rule, the substantial equivalency test procedures, as well as labeling standards applicable to containers of recycled oil.[6] EPCA further requires that the Commission's rule permit any container of processed used oil to bear a label indicating any particular end use, such as for use as engine lubricating oil, so long as a determination of ''substantial equivalency'' with new oil has been made in accordance with the test procedures prescribed by the Commission.[7]

On July 27, 1995, NIST reported to the Commission test procedures for determining the substantial equivalency of re-refined or otherwise processed used engine oils with new engine oils. To implement EPCA's statutory directive, therefore, the Commission issued, and thereafter published on October 31, 1995, a rule (covering recycled engine oil) entitled Test Procedures and Labeling Standards for Recycled Oil (''Recycled Oil Rule''), 16 CFR Part 311.[8] The Recycled Oil Rule adopts the test procedures developed by NIST, and allows (although it does not require) a manufacturer to represent on a recycled engine-oil container label that the oil is substantially equivalent to new engine oil, as long as the determination of equivalency is based on the NIST test procedures.

The EPCA further provides that once the Recycled Oil Rule becomes final, no Commission order or rule, and no law, regulation, or order of any State (or political subdivision thereof), may remain in effect if it has labeling requirements with respect to the comparative characteristics of recycled oil with new oil that are not identical to the labels permitted by this rule.[9] Also, no rule or order of the Commission may require any container of recycled oil to also bear a label containing any term, phrase, or description connoting less than substantial equivalency of such recycled oil with new oil.[10]

Under EPCA, the Recycled Oil Rule preempts the Used Oil Rule's labeling and advertising requirements for engine oils. For non-engine oils, the Used Oil Rule's labeling disclosure provisions continue to be subject to the Congressional stay, and the advertising disclosure provisions continue to be subject to the Commission's stay. The only part of the Used Oil Rule not affected by the stays is that section which prohibits the deceptive use of the term ''re-refined.'' When the Commission published the Recycled Oil Rule in October 1995, it also stated that as part of its regulatory review process, it would consider the continuing need for the Used Oil Rule.[11]

Part B—Objectives

Based on the foregoing, the Commission has tentatively determined that to eliminate unnecessary duplication, and any inconsistency with EPCA's goals, a separate Used Oil Rule is no longer necessary.[12] The objective of this notice is to solicit comment on whether the Commission should initiate a rulemaking proceeding to repeal the Used Oil Rule.

Part C—Alternative Actions

The Commission is not considering any alternative other than the possibility of repealing the Used Oil Rule.

Part D—Request for Comments

Members of the public are invited to comment on any issues or concerns they believe are relevant or appropriate to the Commission's review of the Used Oil Rule. The Commission requests that factual data upon which the comments are based be submitted with the comments. In this section, the Commission identifies the issues on which it solicits public comments. The identification of issues is designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted.

Questions

(1) Is there a continuing need for the Rule?

(a) What benefits has the Rule provided to purchasers of the products affected by the Rule?

(b) Has the Rule imposed costs on purchasers?

(2) What changes, if any, should be made to the Rule to increase the benefits of the Rule to purchasers?

(a) How would these changes affect the costs the Rule imposes on firms subject to its requirements?

(3) What significant burdens or costs, including costs of compliance, has the Rule imposed on firms subject to its requirements?

(a) Has the Rule provided benefits to such firms?

(4) What changes, if any, should be made to the Rule to reduce the burdens or costs imposed on firms subject to its requirements?

(a) How would these changes affect the benefits provided by the Rule?

(5) Does the Rule overlap or conflict with other federal, state, or local laws or regulations?

(6) Since the Rule was issued, what effects, if any, have changes in relevant technology or economic conditions had on the Rule?

(7) Is misrepresentation of the re-refined quality of used lubricating oil by manufacturers and distributors of such oil a significant problem in the marketplace?

(8) Should the Rule, or any portion of it, be kept in effect, or should it be repealed?

(9) How would repealing the Rule affect the benefits experienced by consumers?

(10) How would repealing the Rule affect the benefits and burdens experienced by firms subject to the Rule's requirements?

(11) Is the Recycled Oil Rule likely to provide all or most of the benefits now provided by the Used Oil Rule?

Authority: Section 18(d)(2)(B) of the Federal Trade Commission Act, 15 U.S.C. 57a(d)(2)(B).

List of Subjects in 16 CFR Part 406

Advertising, Labeling, Trade practices, Used lubricating oil.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–8180 Filed 4–2–96; 8:45 am]

BILLING CODE 6750–01–M

[5] 42 U.S.C. 6363(c).

[6] 42 U.S.C. 6363(d)

[7] 42 U.S.C. 6363(d) (1) (B).

[8] 60 FR 55414 (Oct. 31, 1995).

[9] 42 U.S.C. 6363(e)(1).

[10] 42 U.S.C. 6363(e)(2).

[11] 60 FR 55414, 55417.

[12] Repealing the used Oil Rule would eliminate the Commission's ability to obtain civil penalties for any future misrepresentations of the re-refined quality of oil. However, the Commission has tentatively determined that repealing the Rule would not seriously jeopardize the Commission's ability to act effectively. The Recycled Oil Rule defines re-refined oil to mean used oil from which physical and chemical contaminants acquired through use have been removed. Any significant problems that might arise could be addressed on a case-by-case basis, administratively under Section 5 of the FTC Act, 15 U.S.C. 45, or through Section 13(b) actions, 15 U.S.C. 53(b), filed in federal district court. Prosecuting serious misrepresentations in district court allows the Commission to obtain injunctive relief as well as equitable remedies, such as redress or disgorgement.

16 CFR Parts 700, 701, 702, and 239

Request for Comments Concerning Interpretations of Magnuson-Moss Warranty Act; Rule Governing Disclosure of Written Consumer Product Warranty Terms and Conditions; Rule Governing Pre-Sale Availability of Written Warranty Terms; and Guides for the Advertising of Warranties and Guarantees

AGENCY: Federal Trade Commission.

ACTION: Request for public comments.

SUMMARY: The Federal Trade Commission (''the Commission'') is requesting public comment on a set of warranty-related rules and guides: (1) its Interpretations of the Magnuson-Moss Warranty Act (''Interpretations''); (2) its Rule Governing Disclosure of Written Consumer Product Warranty Terms and Conditions (''Rule 701''); (3) its Rule Governing Pre-Sale Availability of Written Warranty Terms (''Rule 702''); and (4) its Guides for the Advertising of Warranties and Guarantees (''Guides''). The Commission is also requesting comments about the overall costs and benefits of these rules and guides and their overall regulatory and economic impact as part of its systematic review of all current Commission regulations and guides.

The Interpretations represent the Commission's views on various aspects of the Magnuson-Moss Warranty Act (''the Act''), 15 U.S.C. *et seq.*, and are intended to clarify the Act's requirements. They are similar to industry guides in that they are advisory in nature, but failure to comply with them may result in corrective action by the Commission under the applicable statutory provisions. Rule 701 specifies the information that must appear in a written warranty on a consumer product. Rule 702 details the obligations of sellers and warrantors to make warranty information available to consumers prior to purchase. The Guides are intended to help advertisers avoid or deceptive practices in the advertising of warranties or guarantees.

DATES: Written comments will be accepted until June 3, 1996.

ADDRESS: Comments should be directed to: Secretary, Federal Trade Commission, Room H–159, Sixth and Pennsylvania Ave., N.W., Washington, D.C. 20580. Comments about the Interpretations, Rules, and/or Guides should be identified as ''Warranty Rules—Comment.''

FOR FURTHER INFORMATION CONTACT: Carole I. Danielson, Investigator, Division of Marketing Practices, Federal Trade Commission, Washington, D.C. 20580, (202) 326–3115.

SUPPLEMENTARY INFORMATION: The Commission has determined, as part of its oversight responsibilities, to review rules and guides periodically. Pursuant to these reviews, the Commission seeks information about the costs and benefits of the rules and guides under review, as well as their regulatory and economic impact. The information obtained will assist the Commission in identifying rules and guides that warrant modification or rescission. At this time, the Commission in identifying rules and guides that warrant modification or rescission. At this time, the Commission solicits written public comments concerning its warranty rules and guides: (1) the Commission's Interpretations of the Magnuson-Moss Warranty Act, 16 CFR Part 700; (2) the Rule Governing Disclosure of Written Consumer Product Warranty Terms and Conditions, 16 CFR Part 701; (3) the Rule Governing Pre-Sale Availability of Written Warranty Terms, 16 CFR Part 702; and (4) the Guides for the Advertising of Warranties and Guarantees, 16 CFR Part 239. These four rules and guides are being reviewed together because all four pertain to warranties.

A. Background

1. 16 CFR Part 700: Interpretations of the Magnuson-Moss Warranty Act (''Interpretations''). The Magnuson-Moss Warranty Act, 15 U.S.C. 2301 *et seq.*, which governs written warranties on consumer products, was signed into law on January 4, 1975. After the Act was passed, the Commission received many questions concerning the Act's requirements. In response to these inquiries, the Commission decided to provide guidance in order to ease compliance with the requirements of the Act. Initially, the Commission published, on June 18, 1975, a policy statement in the Federal Register (40 FR 25721) to provide interim guidance during the initial implementation of the Act. However, as the Commission continued to receive questions and requests for advisory opinions, it determined that guidance of a more permanent nature was appropriate. Therefore, on July 13, 1977, the Commission published in the Federal Register (42 FR 36112) its Interpretations of the Magnuson-Moss Warranty Act to assist warrantors and suppliers of consumer products in complying with the Act.

These Interpretations apply to consumer products distributed in commerce and sold with a written warranty. They represent the Commission's views on various terms and provisions of the Act that are not entirely clear on the face of the statute. Thus, they are intended to clarify the Act's requirements for consumers, manufacturers, importers, distributors, and retailers attempting to comply with them. They are not substantive rules, and do not have the force or effect of statutory provisions; like industry guides, they are advisory in nature. Nonetheless, failure to comply with the Interpretations could result in enforcement action by the Commission under the applicable statutory provisions.

The Interpretations cover a wide range of subjects, including which types of products are considered ''consumer products'' under the Act; whether warrantors have a duty to install under a full warranty; how to distinguish between ''written warranty,'' ''service contract,'' and ''insurance''; what constitutes an ''expression of general policy'' and the requirements for expressions of general policy; the use of warranty registration cards under full and limited warranties; and what may be an illegal tying arrangement under Section 102(c) of the Act.

2. 16 CFR Part 701: Disclosure of Written Consumer Product Warranty Terms and Conditions (''Rule 701''). The language of the Act and its legislative history indicate that Congress intended that the Commission promulgate rules regarding the disclosure of written warranty terms and conditions. Accordingly, on December 31, 1975, the Commission published in the Federal Register (40 FR 60188) its Rules Governing Disclosure of Written Consumer Product Warranty Terms and Conditions. Rule 701 establishes requirements for warrantors for disclosing the terms and conditions of written warranties on consumer products actually costing the consumer more than $15.00. It tracks the disclosure requirements suggested in Section 102(a) of the Act. It also specifies the information that must appear in the written warranty, as well as the exact language that must be used for certain disclosures. Under Rule 701, the information must be disclosed in simple, easily understood, and concise language in a single document. In promulgating Rule 701, the Commission determined that the items required to be disclosed are material facts about product warranties, the nondisclosure of which would be deceptive or misleading.

In addition to specifying the information that must appear in a written warranty, Rule 701 also requires

that, if the warrantor uses a warranty registration or owner registration card, the warranty must disclose whether return of the registration card is a condition precedent to warranty coverage. Finally, it clarifies that, in connection with some ''seal of approval'' programs, the disclosures required by the Rule do not have to be given in the actual seal itself, but rather must be made in a publication.

3. Pre-Sale Availability of Written Warranty Terms, 16 CFR Part 702 (''Rule 702''). Section 102(b)(1)(A) of the Act directs the Commission to prescribe rules requiring that the terms of any written warranty on a consumer product be made available to the prospective purchaser prior to the sale of the product. Accordingly, on December 31, 1975, the Commission published in the Federal Register (40 FR 60189) its Rules Governing the Pre-Sale Availability of Written Warranty Terms (''Rule 702''). In promulgating Rule 702, the Commission determined that the availability of warranty information prior to sale is an important tool for consumers in making a purchasing decision either about the product itself or about buying a service contract for the product. The Rule was amended on March 12, 1987 (52 FR 7569).

Rule 702 establishes requirements for sellers and warrantors for making the terms of any written warranty on a consumer product available to the consumer prior to sale. Among other things, the Rule require sellers to make warranty information readily available either by (1) displaying it in close proximity to the product or (2) furnishing it on request and posting signs in prominent locations advising consumers that warranty information is available. The Rule requires warrantors to provide materials to enable sellers to comply with the Rule's requirements, and also sets out the methods by which warranty information can be made available prior to the sale if the product is sold through catalogs, mail order or door-to-door sales.

4. Guides for the Advertising of Warranties and Guarantees, 16 CFR Part 239 (''Guides''). In May, 1985, the Commission published in the Federal Register its Guides for the Advertising of Warranties and Guarantees, 16 CFR Part 239 (50 FR 18470, May 1, 1985 and 50 FR 20899, May 21, 1985). The Guides were intended to help advertisers avoid unfair or deceptive practices when advertising warranties or guarantees. They took the place of the Commission's ''Guides Against Deceptive Advertising of Guarantees,'' 16 CFR Part 239, adopted April 26, 1960, which had become outdated due to developments in Commission case law and, more importantly, changes in circumstances brought about by the Magnuson-Moss Warranty Act and by Rules 701 and 702 under that Act. The 1985 Guides advise that advertisements mentioning warranties or guarantees should contain a disclosure that the actual warranty document is available for consumers to read before they buy the advertised product. In addition, the Guides set forth advice for using the terms ''satisfaction guarantees,'' ''lifetime,'' and similar representations. Finally, the Guides advise that sellers or manufacturers should not advertise that a product is warranted or guaranteed unless they promptly and fully perform their warranty obligations.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act provides for analysis of the potential impact on small businesses of Rules proposed by federal agencies. (5 U.S.C. 603, 604). Rules 701 and 702 are the only warranty-related matters currently under review that require such an analysis. In 1987, the Commission conducted a Regulatory Flexibility Act analysis of Rule 702 in connection with its amendment of that Rule. *See* 52 FR 7569. This is the first review of Rule 701 since it was promulgated in 1975 and thus presents the first opportunity to conduct such an analysis for that Rule. Therefore, this notice includes questions to elicit information for that analysis.

The Commission believes that a very high percentage of businesses subject to Rule 701 are ''small'' based on Small Business Administration size standards. Unfortunately, the available data do not provide a precise measurement of the impact Rule 701 has had on small businesses nor the economic impact that would result from leaving the Rule unchanged.

For example, in the regulatory analysis conducted for Rule 702, the Commission's investigation found that nearly all the manufacturers (11,365 companies or 97 percent) and nearly all retailers (952,916 companies or 99.3 percent) affected by Rule 702 were considered ''small'' using the size standards promulgated by the Small Business Administration. That investigation indicated that, if the companies were compared according to annual receipts, small retailers would represent about 47 percent and small manufacturers about 23 percent of the gross annual receipts in their respective industries.

In 1984, the FTC's Office of Impact Evaluation issued a study evaluating the Impact of the Warranty Rules [Market Facts, *Warranty Rules Consumer Follow-Up: Evaluation Study, Final Report*, Washington, D.C., July 1984 (''the Study'')]. The Study found that some type of warranty was offered for 87 percent of the consumer products surveyed. Of those warranted products, almost 63 percent carried only a manufacturer's warranty, about 12 percent were warranted only by the retailer, and about 13 percent were covered by both a manufacturer's and a retailer's warranty. Thus, the costs of Rule 701 would appear to fall principally on manufacturers, since those entities are more likely to provide a written warranty. However, we do not know how many of those manufacturers or retailers who give written warranties are also small entities.

Section 102 of the Magnuson-Moss Warranty Act, 15 U.S.C. 2301 *et seq.*, requires warrantors who use written warranties to disclose fully and conspicuously the terms and conditions of the warranty. The Act lists a number of items that may be included in any rules requiring disclosure that the Commission might prescribe, and, in Rule 701, the Commission tracked those items. In promulgating the Rule, the Commission attempted to comply with the congressional mandate in Section 102 of the Act while minimizing the economic impact on affected business. For example, the Commission limited the disclosure requirements to warranties on consumer products actually costing the consumer more than $15.00. Furthermore, the Commission exempted ''seal of approval'' programs from providing the disclosures on the actual seal.

The Commission nonetheless wishes to ensure that no substantial economic impact is being overlooked. Therefore, public comment is requested on the effect of Rule 701 on the costs to, profitability and competitiveness of, and employment in small entities.

C. Issues for Comment

At this time, the Commission solicits written public comments on the following questions with regard to the Interpretations, Rule 701, Rule 702, and the Guides:

1. Is there a continuing need for these Interpretations, Rules, and Guides?

2. Have the Interpretations, Rules, and Guides had a significant economic impact (costs or burdens) on consumers? What significant benefits or costs (including costs of compliance) have they had on firms who are subject to their requirements?

3. What benefits have the Interpretations, Rules, and Guides provide to consumers who purchase the

warranted products or services affected by the Act?

(a) What changes, if any, should be made to the Interpretations, Rules, and Guides to increase the benefits to consumers?

(b) How would these changes affect the costs the Interpretations, Rules, and Guides impose on firms subject to their requirements?

4. What changes, if any, should be made to the Interpretations, Rules and Guides to minimize any burden or cost imposed on firms subject to their requirements?

5. Do the Interpretations, Rules, and Guides overlap or conflict with other federal, state, or local government laws or regulations?

6. Since the Interpretations, Rules, and Guides were issued, have changed in technology or economic conditions affected the need or purpose for them?

7. What has been the effect of Rule 701 on the costs, profitability, competitiveness, and employment of small business entities?

(a) What would be the economic impact on small businesses from leaving Rule 701 unchanged?

(b) Are there regulatory alternatives that would reduce any adverse economic impact of Rule 701, yet comply with the mandate of the Magnuson-Moss Warranty Act?

(c) What are the aggregate costs and benefits of Rule 701? Are there provisions in the Rule that are not necessary to implement the Magnuson-Moss Warranty Act or that have imposed costs not outweighed by benefits? Who has benefited and who has borne the cost? Have the costs or benefits of the Rule dissipated over time?

List of Subjects in 16 CFR Part 700

Warranties, trade practices.

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–8181 Filed 4–2–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 71, 170, and 171

[Docket No. 95N–0220]

RIN 0910–AA66

Substances Approved for Use in the Preparation of Meat and Poultry Products; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period for a proposed rule that appeared in the Federal Register of December 29, 1995 (60 FR 67490). The document proposed to amend FDA's regulations governing the review of petitions for the approval of food and color additives and substances generally recognized as safe (GRAS) to provide for joint review of such petitions by the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA), when meat or poultry product uses are proposed. The closing date for submission of comments was March 14, 1996. This action is being taken in response to a request for additional time to answer comments.

DATES: Written comments by June 3, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: George H. Pauli, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 29, 1995 (60 FR 67490), FDA published a proposal to amend the regulations governing the review of petitions for the approval of food and color additives and GRAS substances to provide for joint review of such petitions by FSIS when meat or poultry product uses are proposed. By agreement between USDA and FDA, such listings would eliminate the need for a separate FSIS rulemaking to allow the use in meat and poultry products of FDA-approved substances. Interested persons were given until March 14, 1996, to submit comments on the proposal. FSIS published a companion document in the same issue of the Federal Register (60 FR 67459) and is extending its comment period for 60 days. In response to a request for additional time to answer comments, as well as for consistency with FSIS, FDA is reopening the comment period on FDA's proposal for 60 days.

Interested persons may, on or before June 3, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8166 Filed 4–2–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Parts 2509, 2520 and 2550

RIN 1210–AA51

Removal of Interpretive Bulletins and Regulations Relating to the Employee Retirement Income Security Act of 1974

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Proposed rule.

SUMMARY: This document contains a notice of a proposal to remove from the Code of Federal Regulations certain interpretive bulletins and regulations (or portions thereof) under the Employee Retirement Income Security Act of 1974 (ERISA, 29 U.S.C. 1001, *et. seq.*) that the Department of Labor (the Department) believes are obsolete (collectively, the obsolete regulations). The obsolete regulations generally provided transitional relief for plan sponsors, plan administrators, and others subject to the requirements of title I of ERISA, in coming into compliance with ERISA's requirements in the first several years following ERISA's enactment in 1974. Because the election periods or dates of applicability under these rules have expired, the Department believes that the regulations are no longer

needed. In other instances, the obsolete regulations are unnecessary because they merely provide notice of a rescission or withdrawal of prior guidance or regulations, or were rendered ineffective by a subsequent Supreme Court decision.

DATES: Comments must be received by June 3, 1996.

ADDRESSES: All written comments and requests for a public hearing (preferably three copies) should be sent to: Pension and Welfare Benefits Administration, Office of Regulations and Interpretations, Room N–5669, 200 Constitution Avenue, N.W., Washington, D.C. 20010. This notice, as well as all comments received from interested persons, will be available for public inspection in the Public Disclosure Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5638, 200 Constitution Ave., N.W., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Katherine D. Lewis, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor, Rm. N–5669, 200 Constitution Avenue, N.W., Washington, D.C. 20210 (telephone (202) 219–7461), or Vicki Shteir-Dunn, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, Rm. N–4611, 200 Constitution Ave., N.W., Washington, D.C. 20210 (telephone (202) 219–8610).

SUPPLEMENTARY INFORMATION: In accordance with the President's Executive Order No. 12866 of September 1993, ''Regulatory Planning and Review,'' and the President's directive of April 24, 1995, ''Regulatory Reinvention Initiative,'' the Department has undertaken to identify and eliminate regulations which are no longer needed. Pursuant to a review of regulations under the Employee Retirement Income Security Act of 1974 (ERISA), the Department identified 28 interpretative bulletins and regulations (or portions thereof) which it believes to be obsolete. Nearly all of these interpretive bulletins and regulations were issued over fifteen years ago. This document proposes the removal of these interpretive bulletins, regulations and paragraphs of regulations from the Code of Federal Regulations. In order to ensure that members of the public have the opportunity to comment on the proposed removal, the Department is publishing this notice as a notice of proposed rulemaking.

The proposal would remove the obsolete regulations prospectively, as of the date of publication of a final rule, and would have no effect on their legal effectiveness prior to that date. Following is a brief description of each of the obsolete interpretive bulletins and regulations (or portions thereof) proposed for removal by the Department. All of these items are presently contained in title 29 of the Code of Federal Regulations.

I. Part 2509—Interpretive Bulletins Relating to the Employee Retirement Income Security Act of 1974

The Department is proposing to remove interpretive bulletins 75–1, 75–7, 76–2 and 76–3 from subchapter A, part 2509 of the Code of Federal Regulations (29 CFR §§ 2509.75–1, 2509.75–7, 2509.76–2 and 2509.76–3). In addition, the Department is proposing to remove paragraph (b) of interpretive bulletin 75–2 (29 CFR 2509.75–2).

Interpretive bulletin 75–1 outlines and clarifies section 414(c)(4) of ERISA, which provides that sections 406 and 407(a) of ERISA (relating to prohibited transactions) are not applicable to the provision of certain services between a plan and a party in interest before June 30, 1977, if certain conditions described in that section are met. Interpretive bulletin 75–7 supplemental interpretive bulletin 75–1 and provided examples of its application. Interpretive bulletins 76–2 and 76–3 merely gave notice of the rescission or withdrawal of earlier guidance relating to the definition of ''seasonal industries,'' a matter now under the jurisdiction of the Internal Revenue Service pursuant to Reorganization Plan No. 4 of 1978. Paragraph (b) of interpretive bulletin 75–2 took the position that consideration paid for a contract or policy of insurance issued to a plan would not be considered plan assets if placed in the general account of the issuing insurance company, and therefore could not give rise to prohibited transactions. This interpretation may no longer be relied on as a result of the December 13, 1993 Supreme Court decision in *John Hancock Mutual Life Insurance Co.* v. *Harris Trust & Savings Bank*, 114 S. Ct. 517 (1993), and therefore, has no force or effect.

II. Part 2520—Rules and Regulations for Reporting and Disclosure

The Department is proposing to remove ten regulations and provisions of two other regulations from subchapter C, part 2520 of the Code of Federal Regulations (29 CFR Part 2520), pertaining to reporting and disclosure under ERISA.

From subpart C of Part 2520, the Department proposes to remove § 103–6(b)(1)(ii), which defined the current value of plan assets for purposes of schedules of reportable transactions for plan years beginning in 1975. The remainder of § 103–6(b)(1) would be revised to eliminate the reference to § 103–6(b)(1)(ii), and to otherwise conform to this change. The Department also proposes to remove § 103–7. This regulation, which provided special accounting rules for plans filing the annual report for plan years beginning in 1975, applied only with respect to plan years beginning in 1975 and not to any subsequent plan years.

The Department proposes to remove the following seven regulations from subpart D of part 2520. The Department's regulation at § 104–2 postponed the effective date of annual reporting requirements for non-calendar year plans and extended the reporting requirements under prior legislation for such plans until the end of the first plan year beginning after January 1, 1975. This regulation does not apply to subsequent plan years. The Department's regulation at § 104–3 deferred certain reporting and disclosure requirements for welfare plans, and provided an alternative method of compliance for pension plans, until May 30, 1976. The Department's regulation at § 104–5 deferred, until no later than November 16, 1977, the application of certain reporting and disclosure requirements relating to the summary plan description for welfare plans. The Department's regulation at § 104–6 provided an alternative method of compliance for pension plans which elected to defer the summary plan description reporting and disclosure requirements. The availability of the deferral expired on November 16, 1977. The Department's regulation at § 104–28 provided an extension of time for filing and disclosure of the initial summary plan description for certain employee benefit plans that became subject to part 1 of title I of ERISA on or before July 17, 1977. The regulation does not apply to any subsequent summary plan descriptions. The Department's regulation at § 104–45 provided a temporary exemption and alternative method of compliance with respect to the requirement to report insurance fees and commissions for insured plans with fewer than 100 participants. The regulation applies only to annual reports required to be filed for the plan years beginning in 1975 and 1976, and does not apply to annual reports filed for subsequent plan years.

From subpart F of part 2520, the Department proposes to remove and reserve certain paragraphs of § 104b–2 and § 104b–4, and to remove §§ 104b–5 and 104b–12.

With respect to § 104b–2, the Department proposes to revise paragraphs (b)(1) and (b)(2), and to remove and reserve paragraphs (c), (d), (e), (f) and (h). Paragraphs (b)(1) and (b)(2) establish the periods within which updated summary plan descriptions must be furnished to participants and beneficiaries receiving benefits under the plan (which differ depending on whether there have been amendments to the plan). In both cases, the periods for providing an updated summary plan description are no later than 210 days after the end of the plan year within which occurs the later of a date certain (November 16, 1983 or November 16, 1987) or a period of years after the last date a change in the information required to be disclosed by section 102 of ERISA or § 102–3 would have been reflected in the most recently distributed summary plan description. The proposed revisions to paragraphs (b)(1) and (b)(2) would eliminate the references to the dates certain.

Paragraph (c) of § 104b–2 pertained to plans making elections under § 2520.104–5 and 2520.104–6, for which the election periods expired in 1977. Paragraph (d) of the regulation provided an alternative method of compliance for plans using a Form EBS–1 with a print date of April 1975 as the summary plan description. The Form EBS–1 was eliminated in 1976. Paragraph (e) of the regulation provided an alternative method of compliance with ERISA's summary plan description requirements for plans which filed and disclosed an initial summary plan description on or before May 30, 1976, in reliance upon earlier guidance of the Department. The availability of the alternative method of compliance was conditioned on the disclosure by such plans, prior to November 16, 1977, of a statement of ERISA rights which complied with § 2520.102–3(t). Paragraph (f) of the regulation provided an alternative method of compliance for plans which were not described in paragraphs (d) or (e) and which met certain requirements. The alternative method of compliance under paragraph (f) expired on November 16, 1977. Paragraph (h) of the regulation merely refers to §§ 2520.104–5 and 2520.104–6, both of which authorize alternative methods of compliance which expired on November 16, 1977.

With respect to § 104b–4, the Department proposes to remove paragraph (d). This paragraph required certain plans to furnish information to certain classes of participants or beneficiaries by November 16, 1977.

The Department also proposes to remove § 104b–5 and § 104b–12. The Department's regulation at § 104b–5 created a new disclosure document, the ''ERISA Notice'', for use as an interim disclosure document by welfare and pension benefit plans electing to use the deferral until November 16, 1977 provided under §§ 2520.104–5 and 2520.104–6. The Department's regulation at § 104b–12 provided multiemployer plans lacking records of covered participants with optional methods of distributing the first summary annual report to participants covered under the plan. The regulation generally applied to reports distributed before February 15, 1977.

III. Part 2550—Rules and Regulations for Fiduciary Responsibility

The Department is proposing to remove eight regulations from subchapter F, part 2550 of title 29 of the Code of Federal Regulations, pertaining to fiduciary responsibility under ERISA. These include §§ 407a–3, 407a–4, 407c–3, 414b–1, 414c–1, 414c–2, 414c–3 and 414c–4, all of which provide transitional relief for the first several years following ERISA's enactment.

The Department's regulation at § 407a–3 provided plan administrators with prospective guidance clarifying the meaning of section 407(a)(3)(B) of ERISA. This guidance assisted plan administrators in determining whether their plans held qualifying employer securities and/or qualifying employer real property the fair market value of which, on any date between January 1, 1975 and December 31, 1984, did not exceed ten percent of the fair market value of the plan's assets, and thus would not be subject to the ten percent holding limitation contained in section 407(a)(3)(A) of ERISA. The period for which plan administrators needed such prospective guidance was from January 1, 1975 until December 31, 1984. Accordingly, the need for such guidance no longer exists.

The Department's regulation at § 407a–4 clarifies the requirements of section 407(a)(4) of ERISA, which required that plans divest, by December 31, 1979, 50 percent of the qualifying employer securities and qualifying real property which they would be required to divest before January 1, 1985, under section 407(a)(3) or 407(c) of ERISA. Accordingly, the transactions addressed by the regulation were transactions that were required to occur on or before December 3,1 1979.

The Department's regulation at § 407c–3 describes an election plans could make, prior to January 1, 1976, to utilize an alternative method of calculating the value of employer securities for purposes of satisfying the limitations of section 407(a)(3) of ERISA on the holding of such securities or real property. The regulation also provided that after making such an election, and before January 1, 1985, the plan could not acquire any real property. There are no provisions in the regulation that remain applicable after January 1, 1985.

The Department's regulation at § 414b–1 provided guidance to plans applying to the Department of Labor, in accordance with section 414(b)(1) of ERISA, for postponement, until no later than January 1, 1976, of the effective date of certain provisions of ERISA. Applications for such postponement generally had to be submitted to the Department on or before December 31, 1974.

The Department's regulations at §§ 414c–1, 414c–2, and 414c–3 provided guidance concerning transitional rules relating to certain types of transactions prior to June 30, 1984, after which the rules became inapplicable. Specifically, § 414c–1 relates to certain loans or other extensions of credit prior to June 30, 1984; § 414c–2 relates to certain leases or joint uses of property prior to June 30, 1984; and § 414c–3 relates to certain sales, exchanges, or other dispositions of property prior to June 30, 1984. The Department's regulation at § 414c–4 provides guidance regarding a transitional rule relating to the provision of certain services until June 30, 1977, after which the rule is inapplicable.

Executive Order 12866

The Department has determined that this proposed regulatory action is not a ''significant rule'' within the meaning of Executive Order 12866 concerning Federal regulations, because it is not likely to result in: (1) an annual effect on the economy of $100 million or more, or an adverse and material effect on sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) the creation of a serious inconsistency or interference with an action taken or planned by another agency; (3) a material alteration in the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) the raising of novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Regulatory Flexibility Act

This proposal will not have a significant economic impact on a substantial number of small employers.

Paperwork Reduction Act

This proposal is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) because it contains no ''collection of information'' as defined in 44 U.S.C. 3502(3).

List of Subjects

29 CFR Part 2509

Employee benefit plans, Pensions.

29 CFR Part 2520

Employee benefit plans, Pensions, Reporting requirements.

29 CFR Part 2550

Employee benefit plans, Pensions, Prohibited transactions.

Authority

For the reasons described in the preamble, Parts 2509, 2520, and 2550 of Chapter XXV of Title 29 of the Code of Federal Regulations, are proposed to be amended as set forth below:

PART 2509—INTERPRETIVE BULLETINS RELATING TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

1. The authority citation for part 2509 is revised to read as follows:

Authority: 29 U.S.C. 1135. Sections 2509.75–10 and 2509.75–2 also issued under 29 U.S.C. 1052, 1053, 1054. Secretary of Labor's Order No. 1–87 (52 FR 13139).

§ 2509.75–1 [Removed]

2. Section 2509.75–1 is removed.

§ 2509.75–2 [Amended]

3. Section 2509.75–2 is amended by removing and reserving paragraph (b).

§§ 2509.75–7, 2509.76–2, 2509.76–3 [Removed]

4. Sections §§ 2509.75–7, 2509.76–2, 2509.76–3 are removed.

PART 2520—RULES AND REGULATIONS FOR REPORTING AND DISCLOSURE

5. The authority citation for part 2520 continues to read as follows:

Authority: Secs. 101, 102, 103, 204, 105, 109, 110, 111(b)(2), , 111(c), and 505, Pub. L. 93–406, 88 Stat. 840–52 and 894 (29 U.S.C. 1021–25, 1029–31, 1135); Secretary of Labor's Order No. 27–74, 13–76, 1–87, and Labor Management Services Administration Order No. 2–6.

Subpart C of Part 2520—[Amended]

6. Section 2520.103–6 is amended by revising paragraph (b)(1) to read as follows:

§ 2520.103–6 Definition of reportable transaction for Annual Return/Report.

* * * * *

(b) *Definitions.* (1) Except as provided in paragraphs (c)(2) and (d)(1)(vi) (relating to assets acquired or disposed of during the plan year), ''current value'' shall mean the current value, as defined in section 3(26) of the Act, of plan assets as of the beginning of the plan year, or the end of the previous plan year.

* * * * *

7. Subpart C of part 2520 is amended by removing § 2520.103–7.

Subpart D of Part 2520—[Amended]

8. Subpart D of part 2520 is amended by removing §§ 2520.104–2, 2520.104–3, 2520.104–5, 2520.104–6, 2520.104–28, and 2520.104–45.

Subpart F of Part 2520—[Amended]

9. Section 2520.104b–2 is amended by revising paragraphs (b)(1) and (b)(2) to read as follows:

§ 2520.104b–2 Summary plan description.

* * * * *

(b) *Periods for furnishing updated summary plan description.* (1) For purposes of the requirement to furnish the updated summary plan description to each participant and each beneficiary receiving benefits under the plan (other than beneficiaries receiving benefits under a welfare plan) required by section 104(b)(1) of the Act, the administrator of an employee benefit plan shall furnish such updated summary plan description no later than 210 days following the end of the plan year which occurs five years after the last date a change in the information required to be disclosed by section 102 or 29 CFR 2520.102–3 would have been reflected in the most recently distributed summary plan description (or updated summary plan description) as described in section 102 of the Act.

(2) In the case of a plan to which no amendments have been made between the end of the time period covered by the last distributed summary plan description (or updated summary plan description), described in section 102 of the Act, and the next occurring applicable date described in paragraph (b)(1) of this section, for purposes of the requirement to furnish the updated summary plan description to each participant, and to each beneficiary receiving benefits under the plan (other than beneficiaries receiving benefits under a welfare plan), reburied by section 204(b)(1) of the Act, the administrator of an employee benefit plan shall furnish such updated summary plan description no later than 210 days following the end of the plan year which occurs ten years after the last date a change in the information required to be disclosed by section 102 or 29 CFR 2520.102–3 would have been reflected in the most recently distributed summary plan description (or updated summary plan description), as described in section 102 of the Act.

* * * * *

§ 2520.104b–2 [Amended]

10. Subpart F of part 2520 is amended by removing and reserving paragraphs (c), (d), (e), (f) and (h) of § 2520.104b–2.

§ 2520.104b–4 [Amended]

11. Subpart F of part 2520 is amended by removing paragraph (d) of § 2520.104b–4.

§§ 2520.1046–5, 2520.104b–12 [Amended]

12. Subpart F of part 2520 is amended by removing §§ 2520.104b–5 and 2520.104b–12.

PART 2550—RULES AND REGULATIONS FOR FIDUCIARY RESPONSIBILITY

13. The authority citation for part 2550 is revised to read as follows:

Authority: 29 U.S.C. 1135. Section 2550.401b–1 also issued under sec. 102, Reorganization Plan No. 4 of 1978 (43 FR 47713, Oct. 17, 1978), effective December 31, 1978 (44 FR 1065, Jan. 3, 1979), 3 CFR, 1978 Comp., 332. Section 2550.404c–1 also issued under 29 U.S.C. 1104. Section 2550.407c–3 also issued under 29 U.S.C. 1104. Section 2550.407c–3 also issued under 29 U.S.C. 1107. Section 2550.408b–1 also issued under sec. 102 Reorganization Plan No. 4 of 1978 (43 FR 47713, Oct. 17, 1978), effective December 31, 1978 (44 FR 1065, Jan. 3, 1979), 3 CFR 1978 Comp., 332, *reprinted in* 5 U.S.C. app. at 1163 (1982), and under 29 U.S.C. 1108(b)(1). Section 2550.412–1 also issued under 29 U.S.C. 1112. Secretary of Labor's Order No. 1–87 (52 FR 13139).

§§ 2550.407a–3, 2550.407a–4, 2550.407c–3, 2550.414b–1, 2550.414c–1, 2550.414c–2, 2550.414c–3, 2550.414c–4 [Removed]

15. Sections 2550.407a–3, 2550.407a–4, 2550.407c–3, 2550.414b–1, 2550.414c–1, 2550.414c–2, 2550.414c–3 and 2550.414c–4 are removed.

Signed at Washington, DC, this 27th day of March, 1996.

Olena Berg,

Assistant Secretary for Pension and Welfare Benefits, U.S. Department of Labor.

[FR Doc. 96–7878 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–29–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN–111–1–7094b; FRL–5442–8]

Approval and Promulgation of Implementation Plans; Tennessee: Revisions to Chattanooga/Hamilton County Regulations for Definitions of Ambient Air Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the State implementation plan (SIP) revision submitted by the State of Tennessee for the purpose of incorporating changes to regulations for ambient air standards for particulate matter and changes to several definitions in the Chattanooga/Hamilton County portion of the Tennessee SIP. In the final rules section of this Federal Register, the EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by May 3, 1996.

ADDRESSES: Written comments on this action should be addressed to Karen Borel, at the EPA Regional Office listed below. Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street, NE., Atlanta, Georgia 30365.

Chattanooga-Hamilton County Air Pollution Control Bureau, 3511 Rossville Boulevard, Chattanooga, Tennessee 37407.

FOR FURTHER INFORMATION CONTACT: Karen C. Borel, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia 30365. The telephone number is 404/347–3555 x4197. Reference file TN111–01–7094.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this Federal Register.

Dated: February 15, 1996.

Phyllis P. Harris,

Acting Regional Administrator.

[FR Doc. 96–7918 Filed 4–2–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[OPP–300396; FRL 4971–1]

RIN 2070–AC18

Pesticide Chemicals; Various Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to revoke tolerances for residues of 10 pesticide chemicals in or on certain raw agricultural commmodities (RACs). EPA is taking this action because there are no current registrations for these uses. The applicable registrations for these pesticide uses have been canceled because of nonpayment of maintenance fees and/or voluntary registrant company request.

DATES: Comments identified by the docket number, [OPP-300396], must be received on or before June 3, 1996.

ADDRESSES: Submit written comments by mail to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Public Docket, Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures as set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 1132 at the above address, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number, [OPP-300396]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT By mail: Owen F. Beeder, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8351; e-mail: beeder.owen@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This document proposes the revocation of tolerances established under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a) for residues of the herbicides 2-chloro-*N*,*N*-diallylacetamide (allidochlor), chloramben, 2,3,6-trichlorophenylacetic acid (chlorfenac), chloroxuron, and diethatyl-ethyl; the fungicides biphenyl, sec-butylamine, and chlorosulfamic acid; and the insecticides calcium cyanide and chlorthiophos in or on certain raw agricultural commodities (RACs). EPA is initiating this action because all registered uses of these pesticide chemicals in or on RACs have

been canceled. The registrations for these pesticide chemicals were canceled because the registrant failed to pay the required maintenance fee and/or the registrant voluntarily canceled all registered uses of the pesticide.

Because there are no current food use registrations for any of these 10 pesticide chemicals EPA proposes to immediately revoke the tolerances for all of the pesticides listed above with the exception of chloramben, chloroxuron and diethatyl ethyl. Although no usages in 1992 have been found for the herbicides chloramben, chloroxuron and diethatyl ethyl, and their registered products were canceled over 3 years ago (except for diethatyl ethyl, for which the last product was canceled in April 1993), each of the herbicides still had usages on certain crops as late as 1994 and 1995. EPA has therefore decided to delay the revocation of chloramben, chloroxuron and diethatyl ethyl until March 1, 1999, instead of immediately, to allow domestic growers who may still have stocks on hand to use up their supplies and permit any treated raw commodities and products processed from such commodities to move through marketing channels, and, therefore, result in little or no domestic impacts. EPA is effecting this delayed revocation by including an expiration date in the tolerance. An import tolerance for tomatoes is established on chlorthiophos although there is no active registration. The Agency has been advised by the registrant (E.M. Industries) that the registrant no longer has an interest in maintaining the import tolerance. Therefore, the Agency is proposing to revoke the inactive import tolerance on chlorthiophos. The Agency is not recommending the establishment of action levels in place of these regulations. Since there are no food use registrations associated with these tolerances; hence, no legal use in the United States, and since these pesticides are either not persistent, or sufficient time has elapsed since their prior use for residues to dissipate, residues should not appear in any domestically produced commodities.

The tolerances listed in 40 CFR part 180 being proposed for revocation are as follows: § 180.125 (calcium cyanide), § 180.141 (biphenyl), § 180.201 (chlorosulfamic acid), § 180.216 (chloroxuron), § 180.266 (chloramben), § 180.282 (2-chloro-N,N-diallylacetamide (allidochlor)), § 180.283 (2,3,6-trichlorophenylacetic acid) (chlorfenac)), § 180.321 (sec-butylamine), § 180.398 (chlorthiophos), and § 180.402 (diethatyl-ethyl).

Any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains the ingredient listed herein, may request within 30 days after the publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Interested persons are invited to submit written comments on the proposed regulation. Further, EPA is soliciting comments from anyone adversely affected by revocation of these tolerances, exemptions from tolerance, and food additive and feed additive regulations. EPA requests that anyone adversely affected by these revocations submit information pertaining to why and provide specific information as follows:

1. Are there any existing stocks of the chemicals?
2. If so, how much?
3. When will the stocks be depleted?
4. How long would the commodities treated with these chemicals be in the channels of trade?
5. Are any of these pesticide chemicals used in foreign countries?
6. Would residues of these pesticide chemicals be present in or on commodities grown in foreign countries and imported into the United States?

Comments must bear a notation indicating the document control number, [OPP-300396]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch at the above address from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays.

A record has been established for this rulemaking under docket number [PP OPP-300396] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, it has been determined that this rule is not a ''significant regulatory action,'' because it does not meet any of the regulatory-significance criteria listed above.

This proposed rule has been reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601 et seq.), and EPA has determined that it will not have a significant economic impact on any small businesses, governments, or organizations. Accordingly, I certify that this proposed rule does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

This proposed regulatory action does not contain any information collection requirements subject to review by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

This proposed rule contains no Federal mandates under Title II of the Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, for State, local, or tribal governments or the private sector because it would not impose enforceable duties on them.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 26, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

§ 180.125 [Removed]

2. By removing § 180.125 *Calcium cyanide; tolerances for residues.*

§ 180.141 [Removed]

3. By removing § 180.141 *Biphenyl; tolerances for residues.*

§ 180.201 [Removed]

4. By removing § 180.201 *Chlorosulfamic acid; tolerances for residues.*

5. By revising § 180.216 *Chloroxuron; tolerances for residues*, to read as follows:

§ 180.216 Chloroxuron; tolerances for residues.

A time-limited tolerance, with an expiration date of March 1, 1999, is established for negligible residues of the herbicide chloroxuron (3-[p-(p-chlorophenoxy)phenyl]-1,1-dimethylurea) and its metabolites containing the p-(p-chlorophenoxy)aniline moiety calculated as chlorxuron in or on the raw agricultural commodities: soybeans and soybean forage, carrots, celery, onions, (dry bulb), and strawberries.

6. By revising § 180.266 *Chloramben; tolerances for residues*, to read as follows:

§ 180.266 Chloramben; tolerances for residues.

A time-limited tolerance, with an expiration date of March 1, 1999, is established for negligible residues of the herbicide chloramben (3-amino-2,5-dichlorobenzoic acid) in or on the raw agricultural commodities: dried beans; lima beans; snap beans; bean vines; cantaloupes; corn, field, forage, corn, fodder; corn, field, grain; cucumbers; peanuts; peanut forage; pigeon peas, pidgeon pea forage, peppers, pumpkins, soybeans, soybean forage, summer squash; winter squash; sunflower seed, sweet potatoes and tomatoes.

§ 180.282 [Removed]

7. By removing § 180.282 *2-Chloro-N,N-diallylacetamide; tolerances for residues.*

§ 180.283 [Removed]

8. By removing § 180.283 *2,3,6-Trichlorophenylacetic acid; tolerances for residues.*

§ 180.321 [Removed]

9. By removing § 180.321 *sec-Butylamine; tolerances for residues.*

§ 180.398 [Removed]

10. By removing § 180.398 *Chlorthiophos; tolerances for residues.*

11. By revising § 180.402 *Diethatyl-ethyl*, to read as follows:

§ 180.402 Diethatyl-ethyl; tolerances for residues.

A time-limited tolerance, with an expiration date of March 1, 1999, is established for negligible residues of the herbicide diethatyl-ethyl and its metabolites determinable as the *N*-acetyl *N*-(2,6-diethylphenyl) glycine derivative in or on the raw agricultural commodities: red beet roots, red beet tops, spinach, sugar beet roots and sugar beet tops.

[FR Doc. 96–8146 Filed 4–2–96; 8:45 am]
BILLING CODE 6560–50–F

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40 CFR Part 261

[FRL–5448–4]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule and request for comment.

SUMMARY: The Environmental Protection Agency (EPA or Agency) today is proposing to grant a petition submitted by United Technologies Automotive (UTA), Detroit, Michigan, to exclude (or ''delist''), conditionally, on a one-time, upfront basis, a certain solid waste generated by UTA's chemical stabilization treatment of lagoon sludge at the Highway 61 Industrial Site in Memphis, Tennessee, from the lists of hazardous wastes in §§ 261.31 and 261.32. Based on careful analyses of the waste-specific information provided by the petitioner, the Agency has concluded that UTA's petitioned waste will not adversely affect human health and the environment. This action responds to UTA's petition to delist this waste on a ''generator-specific'' basis from the hazardous waste lists. If the proposed decision is finalized, the petitioned waste will not be subject to regulation under Subtitle C of the Resource Conservation and Recovery Act (RCRA).

The Agency is also proposing to use two methods to evaluate the potential impact of the petitioned waste on human health and the environment: (1) A fate and transport model (the EPA Composite Model for Landfills, ''EPACML'' model) , based on the waste-specific information provided by the petitioner; and (2) the generic delisting levels in § 261.3(c)(2)(ii)(C)(1) for nonwastewater residues generated from treatment of the listed hazardous waste F006, by high temperature metal recovery (HTMR). Specifically, EPA proposes to use the EPACML model to calculate the concentration of each hazardous constituent that may be present in an extract of the petitioned waste obtained by means of the Toxicity Characteristic Leaching Procedure (TCLP), which will not have an adverse impact on groundwater if the petitioned waste is delisted and then disposed in a Subtitle D landfill. EPA will compare the concentration for each hazardous constituent calculated by the EPACML model to the generic delisting level for that constituent in § 261.3(c)(2)(ii)(C)(1). EPA proposes to use the lower of these two concentrations as the delisting level for each hazardous constituent in the waste.

DATES: EPA is requesting public comments on this proposed decision and on the applicability of the fate and transport model and the generic delisting levels used to evaluate the petition. Comments will be accepted until May 20, 1996. Comments postmarked after the close of the comment period will be stamped ''late.''

Any person may request a hearing on this proposed decision by filing a request with Richard D. Green, Acting Director of the Waste Management Division, EPA, Region 4, whose address appears below, by April 18, 1996. The request must contain the information prescribed in § 260.20(d).

ADDRESSES: Send three copies of your comments to Jeaneanne M. Gettle, Acting Chief, RCRA Compliance Section, U.S. Environmental Protection

Agency, Region 4, 345 Courtland Street, NE., Atlanta, Georgia 30365. Identify your comments at the top with this regulatory docket number: R4–96–UTEP

Requests for a hearing should be addressed to Richard D. Green, Acting Director, Waste Management Division, U.S. Environmental Protection Agency, Region 4, 345 Courtland Street, NE., Atlanta, Georgia 30365.

The RCRA regulatory docket for this proposed rule is located at the EPA Library, U.S. Environmental Protection Agency, Region 4, 345 Courtland Street, N.E., Atlanta, Georgia 30365, and is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays.

The public may copy material from any regulatory docket at no cost for the first 100 pages, and at a cost of $0.15 per page for additional copies.

Copies of the petition are available during normal business hours at the following addresses for inspection and copying: Tennessee Department of Environment and Conservation, 5th Floor, L & C Tower, 401 Church Street, Nashville, Tennessee 37243–1535; and U.S. EPA Region 4, Library, 345 Courtland Street, NE., Atlanta, Georgia 30365; (404) 347–4216.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline, toll free at (800) 424–9346, or at (703) 412–9810. For technical information concerning this notice, contact Judy Sophianopoulos, RCRA Compliance Section, (Mail Code 4WD–RCRA), U.S. Environmental Protection Agency, Region 4, 345 Courtland Street, NE., Atlanta, Georgia 30365, (404) 347–3555, x6408, or call, toll free, (800) 241–1754, and leave a message, with your name and phone number, for Ms. Sophianopoulos to return your call. You may also contact Jerry Ingram, Tennessee Department of Environment and Conservation, 5th Floor, L & C Tower, 401 Church Street, Nashville, Tennessee 37243–1535, (615) 532–0850.

SUPPLEMENTARY INFORMATION:

I. Background

A. Authority

On January 16, 1981, as part of its final and interim final regulations implementing Section 3001 of RCRA, EPA published an amended list of hazardous wastes from non-specific and specific sources. This list has been amended several times, and is published in §§ 261.31 and 261.32. These wastes are listed as hazardous because they exhibit one or more of the characteristics of hazardous wastes identified in Subpart C of part 261 (i.e., ignitability, corrosivity, reactivity, and toxicity) or meet the criteria for listing contained in § 261.11 (a)(2) or (a)(3).

Individual waste streams may vary, however, depending on raw materials, industrial processes, and other factors. Thus, while a waste that is described in these regulations generally is hazardous, a specific waste from an individual facility meeting the listing description may not be. For this reason, §§ 260.20 and 260.22 provide an exclusion procedure, allowing persons to demonstrate that a specific waste from a particular generating facility should not be regulated as a hazardous waste.

To have their wastes excluded, petitioners must show, first, that wastes generated at their facilities do not meet any of the criteria for which the wastes were listed. See § 260.22(a) and the background documents for the listed wastes. Second, the Administrator must determine, where he/she has a reasonable basis to believe that factors (including additional constituents) other than those for which the waste was listed could cause the waste to be a hazardous waste, that such factors do not warrant retaining the waste as a hazardous waste. Accordingly, a petitioner also must demonstrate that the waste does not exhibit any of the hazardous waste characteristics (i.e., ignitability, reactivity, corrosivity, and toxicity), and must present sufficient information for the Agency to determine whether the waste contains any other toxicants at hazardous levels. See § 260.22(a), 42 U.S.C. § 6921(f), and the background documents for the listed wastes. Although wastes which are ''delisted'' (i.e., excluded) have been evaluated to determine whether or not they exhibit any of the characteristics of hazardous waste, generators remain obligated under RCRA to determine whether or not their wastes continue to be nonhazardous based on the hazardous waste characteristics (i.e., characteristics which may be promulgated subsequent to a delisting decision.)

In addition, residues from the treatment, storage, or disposal of listed hazardous wastes and mixtures containing listed hazardous wastes are also considered hazardous wastes. See §§ 261.3(a)(2)(iv) and (c)(2)(i), referred to as the ''mixture'' and ''derived-from'' rules, respectively. Such wastes are also eligible for exclusion and remain hazardous wastes until excluded. On December 6, 1991, the U.S. Court of Appeals for the District of Columbia vacated the ''mixture/derived-from'' rules and remanded them to the Agency on procedural grounds. *Shell Oil Co.* v. *EPA*, 950 F.2d 741 (D.C. Cir. 1991). On March 3, 1992, EPA reinstated the mixture and derived-from rules, and solicited comments on other ways to regulate waste mixtures and residues (57 *FR* 7628, Mar. 3, 1992). The Agency plans to address issues related to waste mixtures and residues in a future rulemaking.

On October 10, 1995, the Administrator delegated to the Regional Administrators the authority to evaluate and approve or deny petitions submitted in accordance with §§ 260.20 and 260.22, by generators within their Regions [National Delegation of Authority 8–19], in States not yet authorized to administer a delisting program in lieu of the Federal program. On March 11, 1996, the Regional Administrator of EPA, Region 4, redelegated delisting authority to the Director of the Waste Management Division [Regional Delegation of Authority 8–19].

B. Approach Used To Evaluate This Petition

This petition requests a delisting for a hazardous waste listed as F006. In making the initial delisting determination, the Agency evaluated the petitioned waste against the listing criteria and factors cited in §§ 261.11 (a)(2) and (a)(3). Based on this review, the Agency agrees with the petitioner that the waste is nonhazardous with respect to the original listing criteria. (If the Agency had found, based on this review, that the waste remained hazardous based on the factors for which the waste was originally listed, EPA would have proposed to deny the petition.) EPA then evaluated the waste with respect to other factors or criteria to assess whether there is a reasonable basis to believe that such additional factors could cause the waste to be hazardous. See §§ 260.22 (a) and (d). The Agency considered whether the waste is acutely toxic, and considered the toxicity of the constituents, the concentration of the constituents in the waste, their tendency to migrate and to bioaccumulate, their persistence in the environment once released from the waste, plausible and specific types of management of the petitioned waste, the quantities of waste generated, and waste variability.

For this delisting determination, the Agency used such information to identify plausible exposure routes (i.e., groundwater, surface water, air) for hazardous constituents present in the petitioned waste. The Agency determined that disposal in a Subtitle D landfill is the most reasonable, worst-case disposal scenario for UTA's petitioned waste, and that the major exposure route of concern would be

ingestion of contaminated groundwater. Therefore, the Agency is proposing to use a particular fate and transport model (the ''EPACML'' model) to predict the maximum allowable concentrations of hazardous constituents that may be released from the petitioned waste after disposal and to determine the potential impact of the disposal of UTA's petitioned waste on human health and the environment.

Specifically, the Agency used the maximum estimated waste volume and the maximum reported leachate concentrations as inputs to estimate the constituent concentrations in the groundwater at a hypothetical receptor well downgradient from the disposal site. The calculated receptor well concentrations (referred to as compliance-point concentrations) were then compared directly to the health-based levels used in delisting decision-making for the hazardous constituents of concern.

EPA believes that this fate and transport model represents a reasonable worst-case scenario for disposal of the petitioned waste in a landfill, and that a reasonable worst-case scenario is appropriate when evaluating whether a waste should be relieved of the protective management constraints of RCRA Subtitle C. The use of a reasonable worst-case scenario results in conservative values for the compliance-point concentrations and ensures that the waste, once removed from hazardous waste regulation, will not pose a threat to human health or the environment. Because a delisted waste is no longer subject to hazardous waste control, the Agency is generally unable to predict and does not control how a waste will be managed after delisting. Therefore, EPA currently believes that it is inappropriate to consider extensive site-specific factors when applying the fate and transport model.

For example, a generator may petition the Agency for delisting of a metal hydroxide sludge which is currently being managed in an on-site landfill and provide site-specific data, such as the nearest drinking water well, permeability of the aquifer, and dispersivities. If the Agency were to base its evaluation solely on these site-specific factors, the Agency might conclude that the waste, at that specific location, cannot affect the closest well, and the Agency might grant the petition. Upon promulgation of the exclusion, however, the generator is under no obligation to continue to manage the waste at the on-site landfill. In fact, the generator may well choose to either send the delisted waste off site immediately, or eventually reach the capacity of the on-site facility and subsequently send the waste off site to a facility which may have very different hydrogeological and exposure conditions.

The Agency also considers the applicability of groundwater monitoring data during the evaluation of delisting petitions. In this case, the Agency determined that, because UTA is seeking a delisting for treated lagoon wastes which will be generated during a removal action under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and may be managed ultimately either on site or off site, groundwater monitoring data collected from the areas where the petitioned waste is contained prior to treatment, are necessary to determine whether hazardous constituents have already migrated to the underlying groundwater. Groundwater monitoring data collected from UTA's monitoring wells will help characterize the potential impact (if any) of the disposal of UTA's waste on human health and the environment.

UTA petitioned the Agency for an upfront, conditional, one-time exclusion based on analytical data on samples from a treatability study and on samples of untreated waste. Similar to other facilities seeking upfront exclusions, this upfront exclusion would be contingent upon UTA conducting analytical testing of representative samples of the petitioned waste as soon as the treatment system is brought on-line. This testing would be necessary to demonstrate that the treated waste is a nonhazardous waste (*i.e.,* meets the Agency's verification testing conditions).

From the evaluation of UTA's delisting petition, a list of constituents was developed for the verification testing conditions. Proposed maximum allowable leachable concentrations for these constituents, and a total concentration for one, were derived as described in Section II.D. and Section II.E. of this preamble.

The Agency encourages the use of upfront delisting petitions because they have the advantage of allowing the applicant to know what treatment levels for constituents will be sufficient to render specific wastes nonhazardous, before investing in new or modified waste treatment systems. Therefore, upfront delistngs will allow new facilities to receive exclusions prior to generating wastes, which, without upfront exclusions would unnecessarily have been considered hazardous. Upfront delistings for existing facilities can be processed concurrently during construction or permitting activities; therefore, new or modified treatment systems should be capable of producing wastes that are considered nonhazardous sooner than would otherwise be possible. At the same time, conditional testing requirements to verify that the delisting levels are achieved by the fully operational treatment systems will ensure that only nonhazardous wastes are removed from Subtitle C control.

In the past, the Agency has granted numerous conditional delistings, including conditional delistings for waste treatment facilities located at multiple sites (see 51 FR 41323, November 14, 1986, and 51 FR 41494, November 17, 1986), as well as an upfront delisting that allows an additional treatment unit to be added at the same site (see 56 FR 32993, July 18, 1991), and an upfront delisting that allows new treatment units at different sites to be added, provided the verification testing conditions are satisfied (see 60 FR 31107, June 13, 1995).

The Agency provides notice and an opportunity for comment before granting or denying a final exclusion. Thus, a final decision will not be made until all timely public comments (including those at public hearings, if any) on today's proposal are addressed. Late comments will be considered to the extent possible.

II. Disposition of Delisting Petition United Technologies Automotive, Detroit, Michigan

A. Petition for Exclusion

United Technologies Automotive (UTA), located in Detroit, Michigan, is seeking a delisting for treated lagoon waste which will be generated during a removal action under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). The removal action is required by the Unilateral Administrative Order (''the UAO'') issued to UTA by EPA, on January 26, 1995. The waste to be treated was generated prior to 1980 in seven lagoons formerly used to manage electroplating wastewater at the Highway 61 Industrial Site in Memphis, Tennessee (''the Site''). Notwithstanding the fact that the waste was generated prior to 1980, the waste so generated meets the listing definition of EPA Hazardous Waste No. F006—''Wastewater treatment sludges from electroplating operations except from the following processes: (1) Sulfuric acid anodizing of aluminum; (2) tin plating on carbon steel; (3) zinc plating (segregated basis) on carbon steel; (4) aluminum or zinc-aluminum

plating on carbon steel; (5) cleaning/stripping associated with tin, zinc, and aluminum plating on carbon steel; and (6) chemical etching and milling of aluminum''—when it is actively managed by excavation and treatment after the effective date of the listing of F006. (Original listing of F006 by Interim Final Rule in 45 FR 33112–33133, May 19, 1980; Modified in 45 FR 74384–74892, Nov. 12, 1980; and clarified by Interpretative Rule in 51 FR 43350–43351, Dec. 2, 1986). See 51 FR 40577, Nov. 7, 1986; 53 FR 31147–31148, Aug. 17, 1988; 53 FR 51444 and 51445, Dec. 21, 1988; 55 FR 22678, June 1, 1990; and *Chemical Waste Management* v. *EPA*, 869 F.2d at 1535–37 (D.C. Cir. 1989), for Agency position on active management. UTA proposes to treat the sludge by chemical stabilization, and to delist the treatment residue, which is also classified as F006 by application of § 261.3(c)(2)(i), the derived-from rule. By application of the ''contained-in policy,'' any lagoon soil excavated and treated with the sludge must also be managed as F006. See memorandum, dated February 17, 1995, from Devereaux Barnes to Norm Niedergang, and Region 4 Guidance Number TSC–92–02, dated August 1992.

UTA petitioned the Administrator, in October 1995, to exclude, on a one-time, upfront basis, the treatment residue generated from chemical stabilization of sludges removed from six of the seven lagoons located at the Site. Sludges from Lagoon 7 will not be removed and treated, because constituent concentrations were found, by total analysis of these samples, to be below the cleanup levels required by the UAO. On November 21, 1995, in accordance with the delegation of delisting authority by the Administrator to the Regional Administrators, UTA submitted to EPA, Region 4, the petition to delist F006 generated by chemical stabilization of sludges from the six lagoons at the Site.

The hazardous constituents of concern for which F006 was listed are cadmium, hexavalent chromium, nickel, and cyanide (complexed). Chemically stabilized sludge and soil from the six lagoons at the Site is the waste which is the subject of this petition. UTA petitioned the Agency to exclude its waste because it does not believe that the waste meets the criteria of the listing.

UTA claims that its chemically stabilized sludge/soil is not hazardous because the constituents of concern, although present in the waste, are present in either insignificant concentrations or, if present at significant levels, are essentially in immobile forms. UTA also believes that this waste is not hazardous for any other reason (i.e., there are no additional constituents or factors that could cause the waste to be hazardous). Review of this petition included consideration of the original listing criteria, as well as the additional factors required by the Hazardous and Solid Waste Amendments (HSWA) of 1984. See Section 222 of HSWA, 42 USC 6921(f), and 40 CFR 260.22(d)(2)–(4). Today's proposal to grant this petition for delisting is the result of the Agency's evaluation of UTA's petition.

B. Background

On November 21, 1995, UTA petitioned EPA, Region 4, to exclude the chemically stabilized sludge and soil from Lagoons 1–6 at the Highway 61 Industrial Site in Memphis, Tennessee (''the Site''), and subsequently provided additional information, in response to a request by EPA. After evaluating the petition and the additional information, the Agency proposes to approve UTA's petition to exclude the subject waste, because the Agency believes that the petitioned waste is eligible for an exclusion based on the current evaluation criteria. Therefore, the Agency hereby proposes to grant UTA's petition. The Agency's evaluation of UTA's petitioned waste, which consists of the chemically stabilized sludge and soil from Lagoons 1–6 at the Site, is the subject of today's proposal.

In support of its petition, UTA submitted: (1) detailed descriptions of the waste and history of its management; (2) detailed descriptions of all previously known and current activities at the Site; (3) results from total constituent analyses for arsenic, barium, cadmium, chromium, lead, mercury, selenium, and silver, (the eight Toxicity Characteristic (TC) metals listed in § 261.24); the priority pollutant metals, including nickel, (a hazardous constituent for which F006 is listed), antimony,and thallium; and cyanide; (4) results for the eight Toxicity Characteristic (TC) metals from the Toxicity Characteristic Leaching Procedure (TCLP; Method 1311 in ''Test Methods for Evaluating Solid Waste, Physical/Chemical Methods,'' EPA Publication SW–846 [Third Edition (November 1986), as amended by Updates I (July 1992), II (September 1994), IIA (August 1993), and IIB (January 1995)]; methods in this publication are referred to in today's proposed rule as ''SW–846,'' followed by the appropriate method number); (5) results from the Multiple Extraction Procedure (MEP; SW–846 Method 1320) for cadmium and chromium; (6) results from the analysis for total petroleum hydrocarbons (TPH, Method 418.1 in ''Methods for Chemical Analysis of Water and Wastes,'' EPA Publication EPA–600/4–79–020; (7) results from characteristics testing for ignitability, corrosivity, and reactivity; (8) results from total constituent analyses for 33 volatile organic compounds and 64 semivolatile organic constituents, including the TC organic constituents; and (9) groundwater monitoring data collected from wells monitoring the on-site lagoons.

UTA's petition states that electroplating operations at the Site were conducted between the early 1960s and 1973, and no electroplating wastewater sludge was generated after 1973. Lagoons 1–7 contained electroplating wastewaters and were allegedly used for oxidation purposes. UTA reported that the sludge generated in the lagoons has a moisture content of approximately 56%.

A CERCLA Unilateral Administrative Order issued on January 26, 1995 (''the UAO''), required that sludge from lagoons at the Site be excavated, stabilized, and disposed of, as part of an emergency removal action. UTA estimates that the total volume of the chemically stabilized sludge and soil from Lagoons 1–6 at the Site will be 11,500 cubic yards. (Site Lagoon 7 met the cleanup standards of the UAO, and did not require removal.)

The UAO required UTA to develop a Removal Action Work Plan Sampling Protocol. EPA approved the Removal Action Work Plan, including the Sampling Protocol, on March 30, 1995. UTA's sampling and analysis methods were conducted in accordance with the approved Removal Action Work Plan.

UTA's sampling demonstration included data on 225 samples of untreated waste from Lagoons 1–7, collected in April 1995, and 4 samples of treated waste from Lagoons 1–6, collected in September 1995.

UTA conducted sampling and analysis of the seven Site lagoons, ranging in size from approximately ¼–1 acre, in accordance with the Sampling Protocol of the Removal Action Work Plan required by the UAO. Each lagoon was divided into a minimum of 4 quadrants; grab samples of sludge or soil in each quadrant to be analyzed for all constituents except volatile organic compounds (VOCs), were composited. VOC analysis was performed on a minimum of two grab samples per lagoon. A total of 225 samples were collected and analyzed. The sampling and analysis were performed in order to obtain representative samples of each

lagoon and determine whether the following Site soil removal cleanup levels required by the UAO were met; areas not meeting these levels were subject to the removal action:

TABLE 1.—SITE CLEANUP LEVELS

Parameter	Clean-up level, parts per million (ppm)
Total Petroleum Hydrocarbons (TPH)	100
Cadmium (total)	60
Chromium (total)	400
Chromium VI	205
Lead	500

With the exception of total petroleum hydrocarbons (TPH), all contaminants in treated and untreated waste were analyzed using SW–846 methods. All composite samples of untreated wastes were analyzed for TPH, using Method 418.1, in ''Methods for Chemical Analysis of Water and Wastes,'' EPA Publication EPA–600/4–79–020).

All composite samples of untreated wastes were analyzed for 64 semivolatile organic compounds (SVOCs), otherwise known as base-neutral or acid extractables (BNAs, SW–846 extraction Method 3550, SW–846 analysis Method 8270); and the eight RCRA TC metals, arsenic, barium, cadmium, chromium, lead, mercury, selenium, and silver (SW–846 Method 6010 for all except mercury; SW–846 Method 7471 for mercury). One composite sample of untreated waste from each lagoon, except Lagoon 1 and Lagoon 3, was analyzed for metals on the Target Analyte List (TAL) (SW–846 Method 6010), which includes aluminum, antimony, beryllium, calcium, cobalt, copper, iron, magnesium, manganese, nickel, potassium, sodium, thallium, vanadium, and zinc, in addition to the RCRA TC metals. These metals are also referred to as ''priority pollutant metals,'' regulated under the Clean Water Act and the Safe Drinking Water Act. Toxic TAL metals antimony, beryllium, and thallium, and RCRA TC metals mercury, selenium, and silver were not detected in the untreated waste samples above the quantitation limits of 10.0, 1.0, 1.0, 0.09, 1.0 and 1.0 mg/kg, respectively. The concentrations of all metals which were detected in the untreated waste, except for cadmium and chromium, were low enough that the UAO did not set cleanup levels for them. Concentrations of metals which were detected in untreated wastes are presented in Table 2. SVOCs were undetected in most of the untreated waste samples at quantitation limits ranging from 0.33–0.83 mg/kg. Table 2 shows the SVOCs that were detected in untreated waste samples; their concentrations were low enough that the UAO did not require cleanup levels for them. At least two grab samples of untreated waste from each lagoon were analyzed for 33 VOCs by SW–846 Method 8240; these VOCs were not detected in most of the samples of untreated waste at quantitation limits ranging from 0.005–0.010 mg/kg. The VOCs detected in untreated waste are shown in Table 2. The concentrations detected in the untreated waste were low enough that the UAO did not establish cleanup levels for VOCs.

All of the analyses summarized in the preceding paragraph are methods for total analysis of the samples; that is, the samples were subjected to the appropriate SW–846 method without prior extraction by means of the Toxicity Characteristic Leaching Procedure (TCLP). The analytical result obtained in a total analysis is the concentration of contaminant on a weight/weight basis, in units of milligrams of contaminant per kilogram of sample (mg/kg). The result of a TCLP analysis is the concentration of contaminant on a weight/volume basis in an extract of the sample obtained by means of the TCLP, in units of milligrams of contaminant per liter of TCLP extract.

The RCRA TC metals cadmium and total chromium were analyzed in all composite samples of untreated waste using SW–846 Method 6010, with a reported quantitation limit (total analysis on unextracted sample) of 1.0 mg/kg for each. Results are presented in Table 2. A total analysis for hexavalent chromium was conducted on all samples (both composite and grab) of untreated waste (SW–846 Method 7197), and was not detected in any of the samples, at a quantitation limit of 10.0 mg/kg. Therefore, UTA concluded that the total chromium concentrations in the untreated lagoon samples were due to trivalent chromium. Based on the analytical results for the untreated waste samples, UTA identified cadmium, trivalent chromium, and TPH as the only constituents of concern in the Site lagoons, because these were the only constituents found with concentrations above the cleanup levels required by the UAO. TCLP extracts of two samples of untreated waste from Lagoon 6 were prepared and analyzed, because constituent concentrations by total analysis (analysis of the unextracted samples) exceeded the cleanup levels required by the UAO, to a greater extent than any of the other samples. TCLP results for untreated waste samples from Lagoon 6, as well as total analysis results for untreated waste samples from all lagoons, are presented in Table 2.

TABLE 2.—CONCENTRATIONS IN UNTREATED SAMPLES FROM SITE LAGOONS 1 THROUGH 7

Constituent	Maximum concentration [1] in lagoons 1–7: (total analysis in mg/kg; TCLP in mg/l)						
	Lagoon 1	Lagoon 2	Lagoon 3	Lagoon 4	Lagoon 5	Lagoon 6	Lagoon 7
Arsenic (total)	3.1	4.5	4.5	4.1	4.7	3.0	4.6
Barium (total)	144	79.3	91.6	89.5	71.2	370	71.5
Cadmium (total)	1010	345	383	239	141	1590	11.2
Cadmium (TCLP)	NA	NA	NA	NA	NA	26.0	.....
Chromium (total)	1320	219	578	345	292	943	13.1
Chromium (TCLP)	NA	NA	NA	NA	NA	<0.50	.....
Lead (total)	19.5	10.10	25.9	9.0	9.5	26.2	17.9
Nickel (total)	.....	12	.....	10.2	8.7	7.0	13.1
TPH (total)	440	217	278	100	58.7	272	52.7
Acetone (total)	0.492	—	0.482	0.219	3.07	4.54	0.556
Bis(2-ethylhexyl) phthalate (total)	0.47	—	1.37	1.40	—	0.77	—
Chlorobenzene (total)	0.015	—	0.078	—	—	—	—
Di-n-butylphthalate (total)	—	—	—	0.63	—	—	—

TABLE 2.—CONCENTRATIONS IN UNTREATED SAMPLES FROM SITE LAGOONS 1 THROUGH 7—Continued

Constituent	Maximum concentration [1] in lagoons 1–7: (total analysis in mg/kg; TCLP in mg/l)						
	Lagoon 1	Lagoon 2	Lagoon 3	Lagoon 4	Lagoon 5	Lagoon 6	Lagoon 7
1,2-dichloroethene (total)	0.020	0.060	0.020	—	0.007	—	—
Vinyl chloride (total)	0.015	0.055	—	—	—	—	—

[1] The concentration level for each constituent in each lagoon in Table 2 is the maximum found for that lagoon; the values for each lagoon are not necessarily from the same sample. Frequently, a sample with a maximum concentration level for one constituent did not contain maximum levels for all constituents.

< denotes undetected at the practical quantitation limit, the number to the right of the symbol <. NA means not analyzed.

—Denotes analyzed but not detected.

UTA reported that one sample of untreated waste from each lagoon was tested for the hazardous characteristics of corrosivity, ignitability, and reactivity for cyanide and sulfide, and that none of the samples exhibited these hazardous characteristics.

UTA conducted a treatability study on samples of lagoon sludge in order to determine the optimum conditions for chemical stabilization. UTA found that the most effective chemical stabilization recipe to achieve maximum immobilization of cadmium and chromium and maxium compressive strength in the petitioned waste was 20% lime kiln dust (LKD) and 5% portland cement (PC). Treatability study samples #32 and #36 were composite sludge samples from Lagoons 1 through 6, and were chemically stabilized with two different recipes. Sample #32 was stabilized with 20% LKD only, and sample #36 was stabilized with 20% LKD and 5% PC. Samples #6–32 and #6–36 were composite samples from Lagoon 6, the most contaminated lagoon. Sample #6–32 was chemically stabilized with 20% LKD only, and sample #6–36 was chemically stabilized with 20% LKD and 5% PC. UTA reported that, prior to treatment, samples #32, #36, #6–32, #6–36 were subjected to total analysis for cadmium and chromium (SW–846 Method 6010). After treatment, SW–846 Method 6010 was performed on TCLP extracts of treated samples to determine concentrations of cadmium and chromium in the extracts. Total analysis for 33 VOCs was performed on treated samples (not on TCLP extracts), using SW–846 Method 8240. VOCs were not detected in any of the samples of treated waste at quantitation limits ranging from 0.005–0.010 mg/kg. Analytical results for treatability study samples are shown in Table 3. UTA informed EPA during a meeting on December 13, 1995, that these analytical results are for chemically stabilized, but not fully cured, waste samples. Samples from Lagoon 7 were not included in the treatability study, because constituent concentrations were found, by total analysis of these samples, to be below the cleanup levels required by the UAO. Therefore, the UAO does not require removal of Lagoon 7 sludge and soil.

UTA believes that the treatability study of chemical stabilization of the lagoon waste indicated that cadmium and chromium concentrations in the TCLP extracts were reduced to levels which would meet delisting criteria, and that TPH constituents were removed in the offgas from the chemical stabilization process.

If UTA's delisting petition is approved, UTA proposes to dispose of the delisted waste either (a) onsite in accordance with a Closure/Post-Closure Plan approved by the State of Tennessee or (b) in an off-site Subtitle D landfill. Therefore, UTA subjected treatability study samples #32 and #36, after treatment, to the Multiple Extraction Procedure (MEP). The MEP (SW–846 Method 1320) is a test developed by the Agency to assist in predicting the long-term leachability of stabilized wastes. The MEP consists of a TCLP extraction of a sample followed by nine sequential extractions of the same sample, using a synthetic acid rain extraction fluid (prepared by adding a 60/40 weight mixture of sulfuric acid and nitric acid to distilled deionized water until the pH is 3.0 ± 0.2). The sample which is subjected to the nine sequential extractions consists of the solid phase remaining after, and separated from, the initial TCLP extract. The Agency designed the MEP to simulate multiple washings of percolating rainfall in the field, and estimates that these extractions simulate approximately 1,000 years of rainfall. (See 47 *FR* 52687, Nov. 22, 1982.) MEP results for samples #32 and #36 are presented in Table 3. In response to a request by EPA for additional information, UTA reported a quantitation limit of 0.01 mg/l for cadmium and chromium in the MEP test on samples #32 and #36. Samples #32, #36, #6–32, and #6–36 were also tested by the synthetic precipitation leaching procedure (SPLP, SW–846 Method 1312), which consists of a single extraction by the same synthetic acid rain solution used in the MEP. Total analysis, TCLP, SPLP, and MEP results for stabilized, but not fully cured, treatability study samples are presented in Table 3.

TABLE 3.—ANALYTICAL RESULTS (PPM) FOR TREATED SAMPLES OF SITE LAGOON SLUDGE

[Chemically Stabilized, But Not Fully Cured]

Sample [1]	Totals (untreated)		TCLP (treated)		SPLP (treated)		Multiple extraction procedure (treated)			
	Cadmium (Cd)	Chromium (Cr)	Cd	Cr	Cr	Cr	Maximum conc./extract number		Concentration in final extract	
							Cd	Cr	Cd	Cr
36	543	449	<0.10	<0.50	<0.01	0.07	0.56/6	0.07/1	0.03	0.02
6–36	777	289	<0.10	<0.50	.....	.....	.....	.....	.....	.....
32	543	449	<0.10	<0.50	<0.01	0.04	0.80/6	0.06/7	0.05	0.03

TABLE 3.—ANALYTICAL RESULTS (PPM) FOR TREATED SAMPLES OF SITE LAGOON SLUDGE—Continued

[Chemically Stabilized, But Not Fully Cured]

Sample [1]	Totals (untreated)		TCLP (treated)		SPLP (treated)		Multiple extraction procedure (treated)			
	Cadmium (Cd)	Chromium (Cr)	Cd	Cr	Cr	Cr	Maximum conc./extract number		Concentration in final extract	
							Cd	Cr	Cd	Cr
6–32	777	289	<0.10	<0.50	.....	.....	.....	.....	.....	.....

[1] Sample 36 (composite of Lagoons 1–6) was stabilized with 20% lime kiln dust (LKD) and 5% portland cement (PC); Sample 6–36 (composite from Lagoon 6) was stabilized with 20% LKD and 5% PC; Sample 32 (composite of Lagoons 1–6) was stabilized with 20% LKD only; Sample 6–32 (composite from Lagoon 6) was stabilized with 20% LKD only.

< Denotes that the constituent was not detected above the practical quantitation limit, the number to the right of the symbol <.

UTA included Site groundwater monitoring data in its delisting petition, because disposal option (a) above involves onsite disposal of the treated waste. These data are shown in Table 4, and were obtained by sampling 5 groundwater monitoring wells which had been installed to assess the impact of untreated lagoon waste on Site groundwater. The wells were installed upgradient, cross-gradient, and downgradient to the Site lagoons in accordance with the Removal Action Work Plan required by the UAO. The wells were sampled and analyzed for cadmium and chromium in July 1995.

Table 4.—GROUNDWATER RESULT SUMMARY (PPM) UNTREATED LAGOON WASTE

Constituent	MW–1	MW–2	MW–3	MW–4	MW–5	State of Tennessee MCL	Federal MCL
Cadmium	<0.005	<0.005	<0.005	<0.005	<0.005	0.01	0.005
Chromium	0.010	<0.010	0.011	<0.010	<0.010	0.05	0.10

< Denotes that the constituent was not detected above the practical quantitation limit, the number to the right of the symbol <.

Monitoring wells are numbered consecutively MW–1—MW–5.

MCL is the maximum contaminant level allowable in drinking water, as established by the Safe Drinking Water Act; MCLs for the State of Tennessee are the levels adopted by State law.

UTA believes that the groundwater results summarized in Table 4 indicate that land disposal of chemically stabilized waste from Site Lagoons 1–6 will not have an adverse impact on groundwater quality, because UTA believes that the data in Table 4 demonstrate that the untreated lagoon waste has not adversely affected groundwater quality.

In addition to the data in Table 4, the groundwater monitoring information submitted by UTA also included: (1) Well location information; and (2) water level contour maps.

EPA does not generally verify submitted test data before proposing delisting decisions. The sworn affidavit submitted with this petition binds the petitioner to present truthful and accurate results. The Agency, however, has maintained a spot-check sampling and analysis program to verify the representative nature of data for some percentage of the submitted petitions. A spot-check visit to a selected facility may be initiated before finalizing a delisting petition or after granting an exclusion.

The Agency reviews a petitioner's estimates and, on occasion, has requested a petitioner to re-evaluate estimated waste volume. EPA accepts UTA's estimate of 11,500 cubic yards.

D. Agency Evaluation

The Agency considered the appropriateness of alternative waste management scenarios for UTA's chemically stabilized sludge and soil and decided, based on the information provided in the petition, that disposal in a Subtitle D landfill is the most reasonable, worst-case scenario for this waste. Under a landfill disposal scenario, the major exposure route of concern for any hazardous constituents would be ingestion of contaminated groundwater. The Agency, therefore, evaluated UTA's petitioned waste using the EPA's Composite Model for Landfills (EPACML), as modified for delisting evaluations, which predicts the potential for groundwater contamination from wastes that are landfilled. For metal constituents in 40 CFR 261.3(c)(2)(ii)(C)(1), EPA also evaluated UTA's petitioned waste by comparing generic delisting levels in § 261.3(c)(2)(ii)(C)(1) with EPACML levels. See 60 *FR* 31108–31115, June 13, 1995, a Final Rule in which EPA evaluated a petition and approved an exclusion based on comparing these generic delisting levels with EPACML levels, and selecting the generic delisting levels if they were lower than the levels generated from the EPACML model. The EPACML model is more sophisticated than the Vertical Horizontal Spread (VHS) model used previously by the Agency for evaluating delisting petitions. See 56 *FR* 32993, July 18, 1991; and 56 *FR* 67197, Dec. 30, 1991 for a detailed description of the EPACML model, the disposal assumptions, the modifications made for delisting, and the benefits of replacing the VHS model with the EPACML model for delisting. This model, which includes both unsaturated and saturated zone transport modules, was used to predict reasonable worst-case contaminant levels in groundwater at a compliance point (i.e., a receptor well serving as a drinking-water supply). Specifically, the model estimated the dilution/attenuation factor (DAF) resulting from subsurface processes such as three-dimensional dispersion and dilution from groundwater recharge for a specific volume of waste.

The Agency requests public comments on its use of the EPACML model and generic delisting levels in § 261.3(c)(2)(ii)(C)(1) as applied to the evaluation of UTA's waste. EPA will

consider all comments on the validity of the EPACML model and generic delisting levels in § 261.3(c)(2)(ii)(C)(1) and the appropriateness for their use here to evaluate the potential for groundwater contamination if UTA's petitioned waste is disposed of in any Subtitle D landfill.

For the evaluation of UTA's petitioned waste, the Agency used the EPACML model to evaluate the mobility of hazardous inorganic constituents detected in the extract of samples of UTA's petitioned waste. The Agency's evaluation, using UTA's estimated one-time waste volume of 11,500 cubic yards and the EPACML modified for delisting yielded a dilution/attenuation factor (DAF) of 100. See Table 5, which is a list of DAFs calculated by the EPACML model, modified for delisting, for landfills receiving different annual volumes of waste. The DAFs in Table 5 include a scaling factor of 20, because the average life of a subtitle D landfill is 20 years and the typical delisting petition is for continuously generated waste which is sent to a landfill at a certain annual rate. That annual rate, the volume of waste in cubic yards per year, can be converted to a landfill size for input into the EPACML model to generate a DAF, with the assumption that the annual rate supplied by the delisting petitioner is multiplied by 20 prior to the conversion. The Agency has completed these calculations for a range of annual waste volumes and they are summarized in Table 5. The Agency need not use the scaling factor of 20 for a petitioned one-time exclusion. Therefore, instead of a DAF of 34 obtained from Table 5 for 11,500 cubic yards, the Agency could eliminate the scaling factor of 20 by dividing 11,500 cubic yards by 20, thereby obtaining a waste volume of 575 and the maximum possible DAF of 100 in Table 5. See 55 *FR* 11826, March 29, 1990; 56 *FR* 32993, July 18, 1991; and 56 *FR* 67197, Dec. 30, 1991 for a detailed description of the EPACML model, the disposal assumptions, and the modifications made for delisting. See also 60 *FR* 62801, Dec. 7, 1995, for a previous delisting proposal in which the Agency obtained a DAF of 48, instead of 14.8, from a table containing the same landfill DAFs and waste volumes as Table 5, for a one-time exclusion of a volume of waste equal to 110,000 cubic yards. (See docket for this rule for further details on the use of the EPACML model in evaluating UTA's waste.)

TABLE 5.—DILUTION/ATTENUATION FACTORS (DAFS) FOR LANDFILLS CALCULATED BY THE EPACML MODEL, MODIFIED FOR DELISTING

Waste volume in cubic yards per year [1]	DAF (95th percentile) [2]
1,000	[3] 100
1,250	96
1,500	90
1,750	84
2,000	79
2,500	74
3,000	68
4,000	57
5,000	54
6,000	48
7,000	45
8,000	43
9,000	40
10,000	36
12,500	33
15,000	29
20,000	27
25,000	24
30,000	23
40,000	20
50,000	19
60,000	17
80,000	17
90,000	16
100,000	15
150,000	14
200,000	13
250,000	12
300,000	12

[1] The waste volume includes a scaling factor of 20; see 56 *FR* 32993, July 18, 1991; and 56 *FR* 67197, Dec. 30, 1991, and text of today's proposed rule, for a discussion of the use of the scaling factor.

[2] The DAFs calculated by the EPACML are a probability distribution based on a range of values for each model input parameter; the input parameters include such variables as landfill size, climatic data, and hydrogeologic data. The 95th percentile DAF represents a value in which one can have 95% confidence that a contaminant's concentration will be reduced by a factor equal to the DAF, as the contaminant moves from the bottom of the landfill through the subsurface environment to a receptor well. For example, if the 95th percentile DAF is 10, and the leachate concentration of cadmium at the bottom of the landfill is 0.05 mg/l, one can be 95% confident that the receptor well concentration of cadmium will not exceed 0.005 mg/l. See 55 *FR* 11826, March 29, 1990; 56 *FR* 32993, July 18, 1991; and 56 *FR* 67197, December 30, 1991.

[3] DAF cutoff is 100, corresponding to the Toxicity Characteristic Rule (55 *FR* 11826, March 29, 1990).

The Agency calculated delisting levels for UTA's chemically stabilized F006, based on the EPACML Model, as shown in Table 6.

TABLE 6.—EPACML-BASED DELISTING LEVELS FOR CADMIUM AND CHROMIUM IN LANDFILL WASTE (TCLP, MG/L)

Constituent	Waste volume (cubic yards, one-time exclusion)		MCL (mg/l)	Allowable TCLP [1] leachate concentration (mg/l) for waste, with scaling factor of 20 and DAF of 34=34×MCL	Allowable TCLP [1] leachate concentration (mg/l) for waste, without scaling factor and DAF of 100=100×MCL
	Volume; DAF with scaling factor=20	Volume; DAF without scaling factor=20			
Cadmium	11,500; 34	575; 100	0.005	0.17	0.5
Chromium	11,500; 34	575; 100	0.10	3.4	10

[1] As of September 25, 1990 the Agency adopted the TCLP as a replacement for and improvement upon the Extraction Procedure (EP) leachate test in its hazardous waste regulatory program. Thus, the Agency now requires that petitioners provide TCLP data rather than EP data in support of their petitions. The Agency believes that the maximum leachable concentrations of samples analyzed using the TCLP will be more representative of the potential mobility of constituents from UTA's petitioned waste than if EP extracts of samples were analyzed.

These calculated delisting levels are the concentrations in the TCLP extracts of the waste that the EPACML model predicts will not result in contaminant levels above MCLs in groundwater at receptor wells. The confidence level of this prediction is 95%, which is also the level required for evaluating groundwater monitoring data subject to 40 CFR part 264. See 56 *FR* 32998, July 18, 1981. The Agency uses maximum contaminant levels, when they are available, as the health-based levels for groundwater. See the ''Docket Report on Health-based Levels and Solubilities Used in the Evaluation of Delisting Petitions, Submitted Under 40 CFR § 260.20 and § 260.22,'' December 1994, located in the RCRA public docket, for the Agency's methods of calculating health-based levels for evaluating delisting petitions from MCLs, and when MCLs are not available.

The Agency did not evaluate the mobility of constituents that were undetected in UTA's petitioned waste because the non-detectable values were obtained using the appropriate SW–846 analytical test methods and adequate detection limits (see Tables 2 and 3). The Agency believes that it is inappropriate to evaluate non-detectable concentrations of a constituent of concern in its modeling efforts for RCRA delistings if the non-detectable value was obtained using the appropriate analytical method. If a constituent cannot be detected (when using the appropriate analytical method with an adequate detection limit), the Agency believes it is reasonable to assume that the constituent is not present and therefore does not present a threat to either human health or the environment.

The Agency did not calculate EPACML-based delisting levels in the petitioned waste for arsenic, barium, VOCs, and SVOCs because levels of these constituents in the untreated waste were below the health-based levels used in delisting decision-making, and VOCs were undetected in the petitioned (treated) waste. See Tables 2, 3, and 7.

TABLE 7.—MAXIMUM CONCENTRATIONS IN UNTREATED SAMPLES FROM SITE LAGOONS

Constituent	Maximum concentration [1] in site lagoons (total analysis, mg/kg)	Maximum [2] concentration in TCLP leachate, (mg/l), calculated from total concentration	TCLP leachate concentration divided by DAF of 100 [3] (mg/l)	Health-based level [4] (mg/l)
Arsenic	4.7	0.8	0.008	0.05
Barium	370	60	0.6	2
Lead	26.2	4	0.04	0.015
Nickel	13.1	2	0.02	0.1
Bis(2-ethylhexyl)phthalate	1.40	0.2	0.002	0.006
Di-n-butylphthalate	0.63	0.1	0.001	4

[1] The concentration level for each constituent in Table 7 is the maximum concentration found for that constituent in Site lagoons.

[2] The maximum possible concentration in a TCLP leachate of untreated waste, assuming all the constituent is leachable, and assuming the dilution factor of 20 for the TCLP on 100% solids has been reduced to 6 by a moisture content of 70% in the untreated waste.

[3] The DAF of 100 was obtained from Table 5 for a one-time waste volume of 11,500 cubic yards of stabilized waste, by eliminating the scaling factor of 20. See 55 *FR* 11826, March 29, 1990; 56 *FR* 32993, July 18, 1991; and 56 *FR* 67197, Dec. 30, 1991 for a detailed description of the EPACML model, the disposal assumptions, and the modifications made for delisting. See also 60 *FR* 62801, Dec. 7, 1995, for delisting proposal for a one-time exclusion and a DAF obtained by eliminating the scaling factor of 20.

[4] See the ''Docket Report on Health-based Levels and Solubilities Used in the Evaluation of Delisting Petitions, Submitted Under 40 CFR § 260.20 and § 260.22,'' December 1994, located in the RCRA public docket, for the Agency's methods of calculating health-based levels for evaluating delisting petitions from MCLs, and when MCLs are not available.

Lead is the only constituent which exceeds the health-based level, based on the assumptions made in the calculations for Table 7. Since this was found for the maximum lead level in untreated waste, the Agency believes that lead in the petitioned waste, which will be treated and cured, will not adversely affect either human health or the environment.

UTA submitted analytical results for tests of reactive cyanide and reactive sulfide in the untreated lagoon waste; the concentrations of reactive cyanide and reactive sulfide were well below the

Agency's interim standards of 250 mg/kg and 500 mg/kg, respectively. See ''Interim Agency Thresholds for Toxic Gas Generation,'' July 12, 1985, internal Agency Memorandum in the RCRA public docket, and SW–846 Chapter 7, Section 7.3.3.2. Therefore, reactive cyanide and sulfide levels in UTA's petitioned waste would not cause this waste to be considered a hazardous waste for Subtitle C purposes and are not of concern.

Although lead, nickel, and cyanide concentrations in untreated waste indicate they may not pose a significant threat, the Agency proposes to select as delisting levels for the petitioned waste the generic delisting levels for cadmium, chromium, lead, nickel, and cyanide in 40 CFR 261.3(c)(2)(ii)(C)(1). These levels are lower than the EPACML-based levels; both generic and EPACML-based levels are presented in Table 8.

TABLE 8.—GENERIC DELISTING LEVELS AND EPACML-BASED DELISTING LEVELS

Constituent	Generic delisting level from § 261.3 (TCLP, mg/l, except for cyanide)	EPACML-based delisting level DAF = 100 (TCLP, mg/l) (level = DAF × MCL = 100 × MCL)
Cadmium	0.050	0.50
Chromium	0.33	10
Lead	0.15	1.5
Nickel	1.0	10
Cyanide (total) (mg/kg) [1]	1.8	20

[1] The cyanide (total, not amenable) concentration must not exceed 1.8 mg/kg, by total analysis, not analysis of leachate. Cyanide concentrations must be measured by the method specified in 40 CFR 268.40, Note 7.

UTA reported that tests on the untreated lagoon waste demonstrated that it did not exhibit the characteristics of ignitability or corrosivity. Therefore, the petitioned waste would not be considered a hazardous waste for Subtitle C purposes because of these characteristics.

The Agency concluded after reviewing UTA's data on the Multiple Extraction Procedure (MEP, Tables 3 and 10) that the long-term leachability of the petitioned waste is unlikely to have an adverse impact on either human health or the environment. The data for treated, but not fully cured waste, in Table 3, indicate that a relatively small percent of the available cadmium and chromium would leach from this waste, after disposal in a subtitle D landfill, over a period of 1000 years. Furthermore, the data in Table 3 indicate that a period of more than 100 years would be required for the leachate to contain a concentration of cadmium greater than the EPACML-based delisting level for a DAF of 100, in Table 6. EPACML-based-delisting levels, with a DAF of 100 or 34, for chromium are not exceeded in any of the MEP extracts. The MEP pH data in Table 10 indicate that the pH of the treated, but not fully cured waste would remain alkaline for a period of more than 100 years.

Sample calculations which the Agency used to evaluate the MEP data are presented in Table 9.

TABLE 9.—LONG-TERM LEACHABILITY CALCULATIONS FROM MEP DATA FOR STABILIZED, BUT NOT FULLY CURED WASTE

Total chromium (Cr) in MEP extracts (mg) [1]		Total cadmium (Cd) in MEP extracts (mg)		Total Cr available (mg) [2]; % leached after final extract (1000-year estimate) [3]		Total Cd available (mg); % leached after final extract (1000-year estimate)		EPACML-based delisting level, DAF 100; § 261.3 generic delisting level (mg/1, in TCLP leachate)
Sample #32	Sample #36	Sample #32	Sample #36	Sample #32	Sample #36	Sample #32	Sample #36	
0.64	0.74	3.01	2.49	28.9; 2.2% ..	44.9; 1.6% ..	77.7; 3.9% ..	54.3; 4.6% ..	Cr: 10; 0.33. Cd: 0.5; 0.05.

Concentrations of Cd in 6th and 7th extracts of treated Sample #32 (0.80, 0.52) and 6th extract of Sample #36 (0.56) are greater than generic delisting level and EPACML-based DAF of 100 × MCL.

Concentrations of Cd in 8th extract of treated Sample #32 (0.11) and 7th extract of treated Sample #36 (0.46) are greater than generic delisting level, but less than EPACML-based DAF of 100 × MCL.

[1] Milligrams of Cr in all MEP extracts of treated Sample #32, assuming a 100-gram sample is sequentially extracted with 2 liters of extraction fluid/extract = 2 l (.04 + .04 + .04 + .03 + .02 + .03 + .06 + .03 + .03) = 2 (.32) = .64 mg. See Table 3; the SPLP result is used for the concentration in the first of 9 MEP extractions. The same assumptions were used to calculate the values for Cd in Sample #32 and Sample #36 and Cr in Sample #36.

[2] Total concentration Cr in untreated Sample #32 = 289 mg/kg = 28.9 mg/100 g. See Table 3, and with the assumption of a 100-gram sample.

[3] % leached after the last extract, estimated to simulate 1000 years of acid rain (See 47 *FR* 52687, November 22, 1982): (.64 x 100)/28.9 = 2.2%

Similar calculations were made for Cd in treated Sample #32 and for Cr and Cd in treated Sample #36:

Milligrams Cd MEP extracts of treated Sample #32 = 2 l (.005 + .005 + .005 + .005 + .005 + .80 + .52 + .11 + .05) = 2 x 1.505 = 3.01 mg; Total Cd in untreated Sample #32 = 777 mg/kg = 77.7 mg/100 g; % leached in 1000 years = (3.01 x 100)/77.7 = 3.9%.

Milligrams of Cr treated Sample #36 = 2 l x (.07 + .07 + .03 + .03 + .02 + .04 + .05 + .04 + .02) = 2 (.37) = .74 mg; Total Cr in Sample #36 = 449 mg/kg = 44.9 mg/100 g; % leached in 1000 years = (100 x .74)/44.9 = 1.6%.

Milligrams of Cd in treated Sample #36 = 2 l x (.005 + .01 + .005 + .005 + .03 + .56 + .46 + .14 + .03) = 2 x 1.245 = 2.49 mg; Total Cd in Sample #36 = 543 mg/kg = 54.3 mg/100 g; % leached in 1000 years = (100 x 2.49)/54.3 = 4.6%.

TABLE 10.—PH DATA FROM MEP EXTRACTIONS

Sample No.	pH of each MEP extract at beginning and end of extraction (top value is beginning; bottom value is end)								
	Ext. #1	Ext. #2	Ext. #3	Ext. #4	Ext. #5	Ext. #6	Ext. #7	Ext. #8	Ext. #9
32	12.0	11.6	11.3	10.7	10.0	7.90	6.40	4.50	3.00

TABLE 10.—pH DATA FROM MEP EXTRACTIONS—Continued

Sample No.	pH of each MEP extract at beginning and end of extraction (top value is beginning; bottom value is end)								
	Ext. #1	Ext. #2	Ext. #3	Ext. #4	Ext. #5	Ext. #6	Ext. #7	Ext. #8	Ext. #9
	11.6	11.3	10.7	10.0	7.90	6.40	4.50	3.00	3.00
36	11.8	11.6	11.4	10.8	10.6	7.2	6.4	4.0	3.4
	11.6	11.4	10.8	10.6	7.2	6.4	4.0	3.4	3.0

The Agency concluded after reviewing UTA's waste management and waste history information that no other hazardous constituents, other than those tested for, are likely to be present in UTA's petitioned waste. In addition, on the basis of test results and information provided by UTA, pursuant to § 260.22, the Agency concludes that the petitioned waste does not exhibit any of the characteristics of ignitability, corrosivity, or reactivity. See §§ 261.21, 261.22, and 261.23, respectively.

During its evaluation of UTA's petition, the Agency also considered the potential impact of the petitioned waste via nongroundwater routes. With regard to airborne dispersal of waste, the Agency evaluated the potential hazards resulting from airborne exposure to waste contaminants from the petitioned waste using an air dispersion model for releases from a landfill. The results of this evaluation indicated that there is no substantial present or potential hazard to human health from airborne exposure to constituents from UTA's petitioned waste. (A description of the Agency's assessment of the potential impact of airborne dispersal of UTA's waste is presented in the RCRA public docket for today's proposed rule.)

The Agency also considered the potential impact of the petitioned waste via a surface water route. The Agency believes that containment structures at municipal solid waste landfills can effectively control surface water runoff, as the recently promulgated Subtitle D regulations (see 56 *FR* 50978, October 9, 1991) prohibit pollutant discharges into surface waters.

Furthermore, if the waste were to remain on-site, the disposal landfill containing the petitioned waste would be closed in accordance with a closure/post-closure plan approved by the State of Tennessee. Therefore, any significant future releases of contaminants from the petitioned waste at its current location via a surface water route are highly unlikely.

While some contamination of surface water is possible through runoff from a waste disposal area (i.e., storm water), the Agency believes that the dissolved concentrations of any hazardous constituents in the runoff will tend to be lower than the extraction procedure test results reported in today's notice because of the aggressive acidic medium used for extraction in the TCLP.

The Agency also believes that, in general, leachate derived from the waste will not directly enter a surface water body without first traveling through the saturated subsurface where dilution of hazardous constituents may occur.

In addition, any transported contaminants would be further diluted in the receiving water body. Significant releases to surface water due to erosion of undissolved particulates in runoff are also unlikely, due to the controls noted above. Nevertheless, the Agency evaluated the potential hazards resulting from possible releases from Site Lagoon 6, which may become an onsite landfill. The results of these evaluations indicate that UTA's waste would not present a threat to human health or the environment. (See the docket to today's rule for a description of this analysis).

E. Conclusion

The Agency believes that UTA has demonstrated that the petitioned waste is not hazardous for Subtitle C purposes. The Agency believes that the sampling procedures used by UTA were adequate, and that the samples collected from the lagoons are representative of the waste contained in the lagoons, and that the treatability study samples are representative of the petitioned waste, to be generated later.

The Agency, therefore, is proposing that UTA's petitioned waste be delisted as non-hazardous and thus not subject to regulation under RCRA Subtitle C. The Agency proposes to grant a conditional, upfront, one-time exclusion to United Technology Automotive's Detroit, Michigan, facility for the chemically stabilized sludge and soil described in its petition as EPA Hazardous Waste No. F006 and to be generated while conducting a CERCLA removal of untreated sludge and soil from Lagoons 1–6 at the Highway 61 Industrial Site in Memphis, Tennessee (''the Site'').

The Agency's decision to exclude this waste is based on descriptions of waste management and waste history, results from the analysis of samples of a treatability study on the chemical stabilization process which will generate the petitioned waste, results from the analysis of samples of the untreated waste from which the petitioned waste will be generated, and groundwater monitoring data available for untreated waste contained in Site lagoons. The Agency's decision is also contingent upon verification testing conditions. If the proposed rule becomes effective, the exclusion will be valid only if the petitioner demonstrates that the petitioned waste meets the verification testing conditions and delisting levels in the amended Table 1 of Appendix IX of 40 CFR Part 261. If the Agency approves that demonstration, the petitioned waste would not be subject to regulation under 40 CFR Parts 262 through 268 and the permitting standards of 40 CFR Part 270. Although management of the waste covered by this petition would, upon final promulgation, be relieved from Subtitle C jurisdiction, the waste would remain a solid waste under RCRA. As such, the waste must be handled in accordance with all applicable Federal and State solid waste management regulations.

III. Limited Effect of Federal Exclusion

This proposed rule, if promulgated, would be issued under the Federal (RCRA) delisting program. States, however, are allowed to impose their own, non-RCRA regulatory requirements that are more stringent than EPA's, pursuant to section 3009 of RCRA. These more stringent requirements may include a provision which prohibits a Federally issued exclusion from taking effect in the States. Because a petitioner's waste may be regulated under a dual system (i.e., both Federal and State programs), petitioners are urged to contact State regulatory authorities to determine the current status of their wastes under the State laws. Furthermore, some States are authorized to administer a delisting program in lieu of the Federal program, i.e., to make their own delisting decisions. Therefore, this proposed

exclusion, if promulgated, would not apply in those authorized States. If the petitioned waste will be transported to any State with delisting authorization, UTA must obtain delisting authorization from that State before the waste may be managed as nonhazardous in that State.

IV. Effective Date

This rule, if made final, will become effective immediately upon final publication. The Hazardous and Solid Waste Amendments of 1984 amended Section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here, because this rule, if finalized, would reduce the existing requirements for persons generating hazardous wastes. In light of the unnecessary hardship and expense that would be imposed on this petitioner by an effective date six months after publication and the fact that a six-month deadline is not necessary to achieve the purpose of Section 3010, EPA believes that this exclusion should be effective immediately upon final publication. These reasons also provide a basis for making this rule effective immediately, upon final publication, under the Administrative Procedure Act, pursuant to 5 USC 553(d).

V. Regulatory Impact

Under Executive Order 12866, EPA must conduct an ''assessment of the potential costs and benefits'' for all ''significant'' regulatory actions. The effect of this proposed rule would be to reduce the overall costs and economic impact of EPA's hazardous waste management regulations. This reduction would be achieved by excluding waste from EPA's lists of hazardous wastes, thereby enabling this facility to treat its waste as nonhazardous. Therefore, this proposed rule would not be a significant regulatory action under the Executive Order, and no assessment of costs and benefits is necessary. The Office of Management and Budget (OMB) has also exempted this proposed rule from the requirement for OMB review under Section (6) of Executive Order 12866.

VI. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601–612, whenever an agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the impact of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). No regulatory flexibility analysis is required, however, if the Administrator or delegated representative certifies that the rule will not have a significant economic impact on a substantial number of small entities.

This rule, if promulgated, will not have an adverse economic impact on any small entities since its effect would be to reduce the overall costs of EPA's hazardous waste regulations and would be limited to one facility. Accordingly, I hereby certify that this proposed regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities. This regulation, therefore, does not require a regulatory flexibility analysis.

VII. Paperwork Reduction Act

Information collection and record-keeping requirements associated with this proposed rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Pub.L. 96–511, 44 U.S.C 3501 et seq.) and have been assigned OMB Control Number 2050–0053.

VIII. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''UMRA''), Public Law 104–4, which was signed into law on March 22, 1995, EPA generally must prepare a written statement for rules with Federal mandates that may result in estimated costs to State, local, and tribal governments in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is required for EPA rules, under section 205 of the UMRA EPA must identify and consider alternatives, including the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. EPA must select that alternative, unless the Administrator explains in the final rule why it was not selected or it is inconsistent with law. Before EPA establishes regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must develop under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, giving them meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising them on compliance with the regulatory requirements.

The UMRA generally defines a Federal mandate for regulatory purposes as one that imposes an enforceable duty upon State, local, or tribal governments or the private sector. EPA finds that today's proposed delisting decision is deregulatory in nature and does not impose any enforceable duty on any State, local, or tribal governments or the private sector. In addition, the proposed delisting does not establish any regulatory requirements for small governments and so does not require a small government agency plan under UMRA section 203.

List of Subjects in 40 CFR Part 261

Environmental Protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Authority: Sec. 3001(f) RCRA, 42 U.S.C. 6921(f).

Dated: March 20, 1996

James S. Kutzman,

Acting Director, Waste Management Division.

For the reasons set out in the preamble, 40 CFR part 261 is proposed to be amended as follows:

PART 261–IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C 6905, 6912(a), 6921, 6922, and 6938.

2. In Table 1 of Appendix IX, part 261 add the following wastestream in alphabetical order by facility to read as follows:

Appendix IX—Wastes Excluded Under §§ 260.20 and 260.22

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
* *	*	* * * *
United Technologies Automotive	Detroit, Michigan	Chemically stabilized wastewater treatment sludge and soil (CSWWTSS) (EPA Hazardous Waste No. F006) that United Technologies Automotive (UTA) will generate during CERCLA removal of untreated sludge and soil (EPA Hazardous Waste No. F006) from six lagoons at the Highway 61 Industrial Site in Memphis, Tennessee. This is an upfront, one-time exclusion for approximately 11,500 cubic yards of waste that will be disposed of in a Subtitle D landfill or an on-site landfill approved by the State of Tennessee after [insert date of final rule.] UTA must demonstrate that the following conditions are met for the exclusion to be valid: (1) *Verification Testing Requirements:* Sample collection and analyses, including quality control procedures must be performed according to SW–846 methodologies. (A) *Initial Verification Testing:* UTA must collect and analyze a representative sample of every batch, for eight sequential batches of CSWWTSS generated during full-scale operation. A batch is the CSWWTSS generated during one run of the stabilization process. UTA must analyze for the constituents listed in Condition (3). A minimum of four composite samples must be collected as representative of each batch. UTA must report operational and analytical test data, including quality control information, no later than 60 days after the generation of the first batch of CSWWTSS. (B) *Subsequent Verification Testing:* If the initial verification testing in Condition (1)(A) is successful, i.e., delisting levels of condition (3) are met for all of the eight initial batches, UTA must test a minimum of 5% of the remaining batches of CSWWTSS. UTA must collect and analyze at least one composite sample representative of that 5%. The composite must be made up of representative samples collected from each batch included in the 5%. UTA may, at its discretion, analyze composite samples gathered more frequently to demonstrate that smaller batches of waste are non-hazardous. (2) *Waste Holding and Handling:* UTA must store as hazardous all CSWWTSS generated until verification testing as specified in Condition (1)(A) and (1)(B), as appropriate, is completed and valid analyses demonstrate that Condition (3) is satisfied. If the levels of constituents measured in the samples of CSWWTSS do not exceed the levels set forth in Condition (3), then the CSWWTSS is non-hazardous and may be managed in accordance with all applicable solid waste regulations. If constituent levels in a sample exceed any of the delisting levels set forth in Condition (3), the batch of CSWWTSS generated during the time period corresponding to this sample must be retreated until it meets the delisting levels set forth in Condition (3), or managed and disposed of in accordance with Subtitle C of RCRA. (3) *Delisting Levels:* All leachable concentrations for these metals must not exceed the following levels (ppm): Cadmium—0.05; chromium—0.33; lead—0.15; and nickel—1.0. Metal concentrations must be measured in the waste leachate by the method specified in 40 CFR 261.24. The cyanide (total, not amenable) concentration must not exceed 1.8 mg/kg, by total analysis, not analysis of leachate. Cyanide concentrations must be measured by the method specified in 40 CFR 268.40, Note 7. (4) *Changes in Operating Conditions:* UTA must notify the Agency in writing when significant changes in the stabilization process are necessary (e.g., use of new stabilization reagents). Condition (1)(A) must be repeated for significant changes in operating conditions. (5) *Data Submittals:* UTA must notify EPA when the full-scale chemical stabilization process is scheduled to start operating. Data obtained in accordance with Conditions (1)(A) must be submitted to Jeaneanne M. Gettle, Acting Chief, RCRA Compliance Section, Mail Code: 4WD-RCRA, U.S. EPA, Region 4, 345 Courtland Street, N.E., Atlanta, Georgia. 30365. This notification is due no later than 60 days after the first batch of CSWWTSS is generated. Records of operating conditions and analytical data from Condition (1) must be compiled, summarized, and maintained by UTA for a minimum of five years, and must be furnished upon request by EPA or the State of Tennessee, and made available for inspection. Failure to submit the required data within the specified time period or maintain the required records for the specified time will be considered by EPA, at its discretion, sufficient basis to revoke the exclusion to the extent directed by EPA. All data must be accompanied by a signed copy of the following certification statement to attest to the truth and accuracy of the data submitted: Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code, which include, but may not be limited to, 18 U.S.C. 1001 and 42 U.S.C. 6928), I certify that the information contained or accompanying this document is true, accurate and complete.

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate and complete. In the event that any of this information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of waste will be void as if it never had effect or to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's void exclusion.
* * *	* * *	*

[FR Doc. 96–8140 Filed 4–2–96; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 62

RIN 3067–AC26

National Flood Insurance Program; Assistance to Private Sector Property Insurers

AGENCY: Federal Insurance Administration (FEMA).

ACTION: Proposed Rule.

SUMMARY: This proposed rule would amend the National Flood Insurance Program (NFIP) regulations establishing the Financial Assistance/Subsidy Arrangement that may be entered into by and between the Administrator and private sector insurers under the Write Your Own (WYO) program. The proposed amendments would: (1) Simplify the Arrangement by streamlining the format; (2) reflect recent policy changes regarding loss adjustment and financial operation of the private insurers in the WYO program; and (3) delete references to obsolete operating manuals and handbooks. The proposed amendments would also improve the flexibility of the Arrangement and would provide information to permit WYO participants to discharge their responsibilities for underwriting, claims adjustment, and financial control procedures established by the Federal Insurance Administration (FIA).

DATES: All comments received on or before May 20, 1996 will be considered before final action is taken on the proposed rule.

ADDRESSES: Please submit any written comments to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, 500 C Street SW., room 840, Washington, DC 20472, (facsimile) 202–646–4536.

FOR FURTHER INFORMATION CONTACT: Edward T. Pasterick, Federal Emergency Management Agency, Federal Insurance Administration, 500 C Street SW., Washington, DC 20472, (202) 646–3443.

SUPPLEMENTARY INFORMATION: The WYO program has operated for thirteen years. The program's operating documents reflect program experience as well as the FIA's ongoing dialogue with private insurers that have participated in the WYO program, insurance company executives, FEMA's Office of Financial Management, and FEMA's Office of Inspector General. Under the WYO Program, insurers signatory to the Financial Assistance/Subsidy Arrangement may issue in their own names the Standard Flood Insurance Policy, the form and substance of which is approved by the Administrator. Insurers are responsible for all aspects of service, including policy issuance to new policyholders and to their policyholders insured under other lines of property insurance; endorsement and renewals of policies; and the adjustment of claims brought under the policies. The insurers pay losses and loss adjustment expenses, as well as the commissions of agents, out of written premiums. In return for discharging these responsibilities under the Arrangement, insurers retain a set portion of the written premium. The amount of retained written premium by an insurer is based in part on the insurer's performance in achieving marketing goals during the Arrangement year.

The proposed changes to the regulations are intended therefore to simplify the terms and conditions of the WYO Arrangement itself in order to make it easier for private insurers to participate in the WYO program and thereby serve an underlying Congressional intent to carry out the NFIP ''to the maximum extent practicable by the private insurance industry,'' as called for in the Declaration of Purpose for the National Flood Insurance Act of 1968, Pub. L. 90–448, 42 U.S.C. 4001.

The proposed changes would offer a more flexible framework than now for private insurers participating in the WYO program to operate while maintaining the operational and financial controls and standards necessary to preserve program integrity and accountability—both for the Government and for the participating private insurers. For example, the adjuster's fee schedule needs to be revised to reflect program changes prompted by the National Flood Insurance Reform Act (NFIRA) of 1994. Those revisions could be made, more appropriately, in a parallel effort and published in operating manuals rather than encumbering the Arrangement. Operating processes relating to the single adjuster program may be better handled differently from the Arrangement. Also, references to many documents should be deleted so that the Arrangement is not encumbered with details about publications that may be scheduled for revision during the course of the Arrangement year. Consistent with the proposed changes to the WYO Financial Control Plan, Appendix B to 44 CFR Part 62 published in the Federal Register on February 1, 1996, 61 FR 3635–3644, this proposed rule would discontinue the self-audit requirement for private insurers participating in the WYO program.

In sum, the proposed changes to the regulations would produce a WYO Arrangement that would clearly specify the responsibilities and duties of the Government and the private insurers participating in the WYO program without burdening the Arrangement with unnecessary detail or references that may become obsolete before the Arrangement year expires.

National Environmental Policy Act. This proposed rule would be

categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Executive Order 12866, Regulatory Planning and Review. This proposed rule would not be a significant regulatory action as defined under Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735, October 4, 1993. To the extent possible, this rule adheres to the principles of regulation set forth in Executive Order 12866. This rule has not been reviewed by the Office of Management and Budget under the provisions of Executive Order 12866.

Paperwork Reduction Act. This proposed rule would not contain a collection of information and is therefore not subject to the provisions of the Paperwork Reduction Act of 1995.

Executive Order 12612, Federalism. This proposed rule would involve no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule would meet the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 62

Claims, Flood Insurance.

We use certain conventions in this proposed rule to highlight the proposed revisions. New language is shown inside boldfaced arrows >><<, while language that would be deleted is set off with boldfaced brackets **[]**.

Accordingly, 44 CFR part 62 is proposed to be amended as follows:

PART 62—SALE OF INSURANCE AND ADJUSTMENT OF CLAIMS

1. The authority citation for Part 62 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

2. Appendix A of part 62 would be revised to read as follows:

Appendix A to Part 62—Federal Emergency Management Agency, Federal Insurance Administration, Financial Assistance/Subsidy Arrangement

Purpose: To assist the company in underwriting flood insurance using the Standard Flood Insurance Policy.

Accounting Data: Pursuant to Section 1310 of the Act, a Letter of Credit shall be issued for payment as provided for herein from the National Flood Insurance Fund.

Effective Date: **[**October 1, 1995.**]** >> October 1, 1996.<<

Issued By: Federal Emergency Management Agency, Federal Insurance Administration, Washington, DC 20472.

Article I—Findings, Purpose, and Authority

Whereas, the Congress in its ''Finding and Declaration of Purpose'' in the National Flood Insurance Act of 1968, as amended, (''the Act'') recognized the benefit of having the National Flood Insurance Program (the Program) ''carried out to the maximum extent practicable by the private insurance industry''; and

Whereas, the Federal Insurance Administration (FIA) recognizes this Arrangement as coming under the provisions of Section 1345 of the Act; and

Whereas, the goal of the FIA is to develop a program with the insurance industry where, over time, some risk-bearing role for the industry will evolve as intended by the Congress (Section 1304 of the Act); and

Whereas, **[**the Program, as presently constituted and implemented, is subsidized, and**]** the insurer (hereinafter the ''Company'') under this Arrangement shall charge rates established by the FIA; and

Whereas, this Arrangement will subsidize all flood policy losses by the Company; and

Whereas, this Financial Assistance/Subsidy Arrangement has been developed to **[**involve individual Companies in the Program, the initial step of which is to explore ways in which any interested insurer may be able**]** >> enable any interested qualified insurer<< to write flood insurance under its own name; and

Whereas, one of the primary objectives of the Program is to provide coverage to the maximum number of structures at risk and because the insurance industry has marketing access through its existing facilities not directly available to the FIA, it has been concluded that coverage will be extended to those who would not otherwise be insured under the Program; and

Whereas, flood insurance policies issued subject to this Arrangement shall be only that insurance written by the Company in its own name pursuant to the Act; and

Whereas, over time, the Program is designed to increase industry participation, and, accordingly, reduce or eliminate Government as the principal vehicle for delivering flood insurance to the public; and

Whereas, the direct beneficiaries of this Arrangement will be those Company policyholders and applicants for flood insurance who otherwise would not be covered against the peril of flood.

Now, therefore, the parties hereto mutually undertake the following:

Article II—Undertakings of the Company

A. In order to be eligible for assistance under this Arrangement the Company shall be responsible for:

1.0 Policy Administration, including
1.1 Community Eligibility/Rating Criteria
1.2 Policyholder Eligibility Determination
1.3 Policy Issuance
1.4 Policy Endorsements
1.5 Policy Cancellations
1.6 Policy Correspondence
1.7 Payment of Agents' Commissions

The receipt, recording, control, timely deposit and disbursement of funds in connection with all the foregoing, and correspondence relating to the above in accordance with the Financial Control Plan requirements.

2.0 Claims processing in accordance with general Company standards and the Financial Control Plan. **[**The Write Your Own Claims Manual, the Federal Emergency Management Agency Adjuster Manual, the FIA National Flood Insurance Program Policy Issuance Handbook, the Write Your Own Operational Overview, and other instructional material also provide guidance to the Company.**]** >> Other technical and policy material published by FEMA and FIA will also provide guidance to the Company. <<

3.0 Reports

3.1 Monthly Financial Reporting and Statistical Transaction Reporting shall be in accordance with the requirements of National Flood Insurance Program Transaction Record Reporting and Processing Plan for the Write Your Own (WYO) Program and the Financial Control Plan for business written under the WYO Program. These data shall be validated/edited/audited in detail and shall be compared and balanced against Company financial reports.

3.2 Monthly financial reporting shall be prepared in accordance with the WYO Accounting Procedures.

[3.3 The Company shall establish a program of self audit acceptable to the FIA or comply with the self audit program contained in the Financial Control Plan for business written under

the WYO Program. The Company shall report the results of this self-audit to the FIA annually.]

B. The Company shall use the following time standards of performance as a guide:

1.0 Application Processing—15 days (Note: If the policy cannot be mailed due to insufficient or erroneous information or insufficient funds, a request for correction or added monies shall be mailed within 10 days);

1.1 Renewal Processing—7 days;

1.2 Endorsement Processing—[7 days;] >> 15 days; <<

1.3 Cancellation Processing—15 days;

[1.4 Correspondence, Simple and/or Status Inquiries—7 days;]

[1.5 Correspondence, Complex Inquiries—20 days;]

[1.6 Supply, Materials, and Manual Requests—7 days;]

[1.7] >> 1.4 << Claims Draft Processing—7 days from completion of file examination;

[1.8] >> 1.5 << Claims Adjustment—45 days average from receipt of Notice of Loss (or equivalent) through completion of examination.

[1.9] >> 1.6 << For the elements of work enumerated above, the elapsed time shown is from the date of receipt through the date of mail out. Days means working, *not* calendar days.

In addition to the standards for timely performance set forth above, all functions performed by the Company shall be in accordance with the highest reasonably attainable quality standards generally utilized in the insurance and data processing industries.

These standards are for guidance. Although no immediate remedy for failure to meet them is provided under this Arrangement, nevertheless, performance under these standards and the marketing guidelines provided for in Section G. below can be a factor considered by the Federal Insurance Administrator (the Administrator) in requiring corrective action by the Company, in determining the continuing participation of the Company in the Program, or in taking other action, e.g., limiting the Company's authority to write new business.

C. To ensure maximum responsiveness to the National Flood Insurance Program's (NFIP) policyholders following a catastrophic event, e.g., a hurricane, involving insured wind and flood damage to policyholders, the Company shall agree to the adjustment of the combined flood and wind losses utilizing one adjuster under an NFIP-approved Single Adjuster Program in the following cases and under procedures issued by the Administrator:

1.0 Where the flood and wind coverage is provided by the Company;

2.0 Where the flood coverage is provided by the Company and the wind coverage is provided by a participating State Property Insurance Plan, Windpool Association, Beach Plan, Joint Underwriting Association, FAIR Plan, or similar property insurance mechanism;

3.0 Where the flood coverage is provided by the Company and the wind coverage is provided by another WYO Company and the necessary information on the dual coverage is part of the Claims Coordinating Office (CCO) system; and

4.0 Where the flood coverage is provided by the Company and the wind coverage is provided by another property insurer and the State Insurance Regulator has determined that such property insurer shall, in the interest of consumers, facilitate the adjustment of its wind loss by the adjuster engaged to adjust the flood loss of the Company.

[The Government shall provide for the direct business flood losses to be adjusted by a single adjuster where the wind damage coverage is insured by a state market mechanism described in 2.0, above, or by a WYO Company as described in 3.0 above, or by a property insurer, as described in 4.0 above.]

[Except for 1.0, above, the Company shall submit its flood losses that are reasonably believed to involve wind damage to the Single Adjuster Program's Stationary CCO in Lanham, Maryland at the following address:]

[National Flood Insurance Program Stationary Claims Coordinating Office 10115 Senate Drive Lanham, Maryland 20706]

[Such flood losses shall be reported on the ACORD Notice of Loss form, ''ACORD 1 (1/93),'' or a like form calling for the reporting of losses involving both flood and wind damage arising out of a single hurricane event under the following procedures:]

[• Where flood losses reasonably believed to involve wind damage are reported by property insurance agents of brokers, the Company shall instruct its agents or brokers to mail or preferably send by facsimile the ACORD Notice of Loss form, with complete details regarding flood and, if available, wind insurance policies covering the property, to the Single Adjuster Program Stationary CCO for assignment to a single adjuster. The Stationary CCO will also accept loss information directly from the agent by modem in CCO format where the Company has arranged for its agents to provide the information in this fashion.]

[• Where flood losses reasonably believed to involve wind damage are reported directly to the Company by its policyholders or agents, by telephone, the Company shall report the flood loss, with the wind property insurer information, if available, to the Single Adjuster Program Stationary CCO, by modem transfer in CCO format as such flood losses are reported to the Company. Transfer by facsimile from the Company can also be arranged where circumstances warrant it.]

[Upon receipt of the Notice of Loss, the Stationary CCO shall effect immediate entry of all relevant data into the stand-alone CCO System (i.e., not part of the NFIP mainframe computer system) for instantaneous relay to the Catastrophe CCO established in the field. At the Catastrophe CCO, which will be sited and fully operational within 24 hours of landfall, in coordination with the State Insurance Regulator, a qualified loss adjustment organization shall be promptly selected for each loss, and participating insurers shall be promptly advised of the selection for their assignment of the loss to that organization.]

[In respect to the foregoing, the Administrator will continue to implement existing and future CCO Arrangements with State Insurance Regulators and their State Property Insurance Plans, Windpool Associations, Beach Plans, Joint Underwriting Associations, FAIR Plans, or similar property insurance mechanisms, for example, as has been done with the Insurance Department of the State of South Carolina.]

D. Policy Issuance

1.0 The flood insurance subject to this Arrangement shall be only that insurance written by the Company in its own name pursuant to the Act.

2.0 The Company shall issue policies under the regulations prescribed by the Administrator in accordance with the Act;

3.0 All such policies of insurance shall conform to the regulations prescribed by the Administrator pursuant to the Act, and be issued on a form approved by the Administrator;

4.0 All policies shall be issued in consideration of such premiums and upon such terms and conditions and in such States or areas or subdivisions thereof as may be designated by the Administrator and only where the Company is licensed by State law to engage in the property insurance business;

5.0 The Administrator may require the Company to immediately discontinue issuing policies subject to

this Arrangement in the event Congressional authorization or appropriation for the National Flood Insurance Program is withdrawn.

E. The Company shall [establish a bank account,] separate >> Federal flood insurance funds >> [and apart] from all other Company accounts, at a bank >> or banks << of its choosing for the collection, retention and disbursement of >> Federal << funds relating to its obligation under this Arrangement, less the Company's expenses as set forth in Article III, and the operation of the Letter of Credit established pursuant to Article IV. All funds not required to meet current expenditures shall be remitted to the United States Treasury, in accordance with the provisions of the WYO Accounting Procedures Manual.

F. The Company shall investigate, adjust, settle and defend all claims or losses arising from policies issued under this Arrangement. Payment of flood insurance claims by the Company shall be binding upon the FIA.

G. The Company shall market flood insurance policies in a manner consistent with the marketing guidelines established by the Federal Insurance Administration.

Article III—Loss Costs, Expenses, Expense Reimbursement, and Premium Refunds

A. The Company shall be liable for operating, administrative and production expenses, including any >> State premium << taxes, dividends, agent's commissions [or any board, exchange or bureau assessments,] or any other expense of whatever nature incurred by the Company in the performance of its obligations under this Arrangement.

B. The Company shall be entitled to withhold, on a provisional basis, as operating and administrative expenses, including agents' or brokers' commissions, an amount from the Company's written premium on the policies covered by this Arrangement in reimbursement of all of the Company's marketing, operating and administrative expenses, except for allocated and unallocated loss adjustment expenses described in Section C. of this Article, which amount shall be 32.6% of the Company's written premium on the policies covered by this Arrangement. The final amount retained by the Company shall be determined by an increase or decrease depending on the extent to which the Company meets the marketing goals for the [combined 1994–1995 and 1995–1996] 1996–1997 Arrangement year[s] contained in marketing guidelines established pursuant to Article II.G.

The [decrease or increase] >> adjustment << in the amount retained by the Company shall be made after the end of the [1995–1996] >> 1996–1997 << Arrangement year. Any decrease from 32.6% made as a result of a Company not meeting its marketing goals shall be directly related to the extent to which the Company's goal was not achieved, but shall not exceed two (2) percentage points (providing for a minimum of 30.6%). [The amount of any decrease shall be calculated for each month, and each month's decrease shall be subject to interest compounded at rates provided for by 31 U.S.C. 3717(a)(1). Upon notice of the cumulative monthly decreases and interest, the Company agrees to promptly remit to the Government the total amount due.]

The increase, which shall be distributed among the Companies exceeding their marketing goals, shall be drawn from a pool composed of the difference between 32.6% of all WYO Companies' written premium in Arrangement year[s 1994–1995 and 1995–1996,] >> 1996–1997 << and the total amount, prior to the increase, provided to the Companies on the basis of the extent to which they have met their marketing goals. A distribution formula will be developed and distributed to WYO Companies which will consider the extent to which the Company has exceeded its goal and the size of the Company's book of business in relation to the total number of WYO policies. The amount of any increase shall be paid promptly to the Company after the end of the [1995–1996] >> 1996–1997 << Arrangement year.

[If the Company does not enter into the Arrangement for 1995–1996, the extent to which the Company met its goals shall be based upon its Arrangement year 1994–1995 performance, and the final amount retained shall be determined after the end of the 1994–1995 Arrangement year, but the Company shall not be entitled to any increase above the provisional amount.]

[Premium income net of provisional reimbursement (net premium income) and Federal Policy Fee shall be deposited in a special account for the payment of losses and loss adjustment expenses (see Article II, Section E).]

The Company, with the consent of the Administrator as to terms and costs, shall be entitled to utilize the services of a national rating organization, licensed under state law, to assist the FIA in undertaking and carrying out such studies and investigations on a community or individual risk basis, and in determining more equitable and accurate estimates of flood insurance risk premium rates as authorized under the National Flood Insurance Act of 1968, as amended. The Company shall be reimbursed in accordance with the provisions of the WYO Accounting Procedures Manual for the charges or fees for such services.

C. Loss Adjustment Expenses shall be reimbursed as follows:

1. Unallocated loss adjustment shall be an expense reimbursement of 3.3% of the incurred loss (except that it does not include ''incurred but not reported'').

2. Allocated loss adjustment expense shall be reimbursed to the Company pursuant to [Exhibit A, entitled ''Fee Schedule.''] >> a fee schedule established by FIA. <<

3. Special allocated loss expenses shall be reimbursed to the Company [for only those expenses the Company has obtained prior approval of the Administrator to incur.] >> in accordance with guidelines issued by the Administrator. <<

D.1. Loss payments under policies of flood insurance shall be made by the Company from funds retained in the bank account(s) established under Article II, Section E. and, if such funds are depleted, from funds derived by drawing against the Letter of Credit established pursuant to Article IV.

2. Loss payments will include payments as a result of awards or judgments for damages arising under the scope of this Arrangement, policies of flood insurance issued pursuant to this Arrangement, and the claims processing standards and guides set forth at Article II, Section A.,2.0 of this Arrangement. Prompt notice of any claim for damages as to claims processing or other matters arising outside the scope of this Section D.2. shall be sent to the [Assistant Administrator of the FIA's Office of Insurance Policy Analysis and Technical Services (OIPATS),] >> Administrator << along with a copy of any material pertinent to the claim for damages arising outside of the scope of the matters set forth in this Section D.2.

Following receipt of notice of such claim, the General Counsel (OGC), FEMA, shall review the cause and make a recommendation to FIA as to whether the claim is grounded in actions by the Company which are significantly outside the provisions of this Section D.2. After reviewing the General Counsel's recommendation, the Administrator will make her decision and the Company will be notified, in writing, within thirty (30) days of the General Counsel's recommendation, if the decision is that any award or

judgment for damages arising out of such actions will not be recognized under Article III of this Arrangement as a reimbursable loss cost, expense or expense reimbursement. In the event that the Company wishes to petition for reconsideration of the notification that it will not be reimbursed for the award or judgment made under the above circumstances, it may do so by mailing, within thirty days of the notice declining to recognize any such award or judgment as reimbursable under Article III, a written petition to the Chairman of the WYO Standards Committee established under the Financial Control Plan. The WYO Standards Committee will, then, consider the petition at its next regularly scheduled meeting or at a special meeting called for that purpose by the Chairman and issue a written recommendation to the Administrator, within thirty days of the meeting. The Administrator's final determination will be made, in writing, to the Company within thirty days of the recommendation made by the WYO Standards Committee.

E. Premium refunds to applicants and policyholders required pursuant to rules contained in the National Flood Insurance Program (NFIP) ''Flood Insurance Manual'' shall be made by the Company from Federal flood insurance funds referred to in Article II, Section E. and, if such funds are depleted, from funds derived by drawing against the Letter of Credit established pursuant to Article IV.

Article IV—Undertakings of the Government

A. Letter(s) of Credit shall be established by the Federal Emergency Management Agency (FEMA) against which the Company may withdraw funds daily, if needed, pursuant to prescribed procedures implemented by FEMA. The amounts of the authorizations will be increased as necessary to meet the obligations of the Company under Article III, Sections C., D., and E. Request for funds shall be made only when net premium income has been depleted. The timing and amount of cash advances shall be as close as is administratively feasible to the actual disbursements by the recipient organization for allowable Letter of Credit expenses.

Request for payment on Letters of Credit shall not ordinarily be drawn more frequently than daily nor in amounts less than $5,000, and in no case more than $5,000,000 unless so stated on the Letter of Credit. This Letter of Credit may be drawn by the Company for any of the following reasons:

1. Payment of claim as described in Article III, Section D.;

2. Refunds to applicants and policyholders for insurance premium overpayment, or if the application for insurance is rejected or when cancellation or endorsement of a policy results in a premium refund as described in Article III, Section E.; and

3. Allocated and unallocated Loss Adjustment Expenses as described in Article III, Section C.

B. The FIA shall provide technical assistance to the Company as follows:

1. The FIA's policy and history concerning underwriting and claims handling.

2. A mechanism to assist in clarification of coverage and claims questions.

3. Other assistance as needed.

Article V—Commencement and Termination

A. Upon signature of authorized officials for both the Company and the FIA, this Arrangement shall be effective for the period October 1 through September 30. The FIA shall provide financial assistance only for policy applications and endorsements accepted by the Company during this period pursuant to the Program's effective date, underwriting and eligibility rules.

B. By June 1, of each year, the FIA shall publish in the Federal Register and make available to the Company the terms for the re-subscription of this Financial Assistance/Subsidy Arrangement. In the event the Company chooses not to re-subscribe, it shall notify the FIA to that effect by the following July 1.

C. In the event the Company elects not to participate in the Program in any subsequent fiscal year, or the FIA chooses not to renew the Company's participation, the FIA, at its option, may require (1) the continued performance of this entire Arrangement for >> a period not to exceed << one (1) year following the [effective expiration date only for those policies issued during the] original term of this Arrangement, or any renewal thereof, or (2) the transfer to the FIA of:

a. All data received, produced, and maintained through the life of the Company's participation in the Program, including certain data, as determined by FIA, in a standard format and medium; and

b. A plan for the orderly transfer to the FIA of any continuing responsibilities in administering the policies issued by the Company under the Program including provisions for coordination assistance; and

c. All claims and policy files, including those pertaining to receipts and disbursements which have occurred during the life of each policy. In the event of a transfer of the services provided, the Company shall provide the FIA with a report showing, on a policy basis, any amounts due from or payable to insureds, agents, brokers, and others as of the transition date.

D. Financial assistance under this Arrangement may be cancelled by the FIA in its entirety upon 30 days written notice to the Company by certified mail stating one of the following reasons for such cancellation: (1) Fraud or misrepresentation by the Company subsequent to the inception of the contract, or (2) nonpayment to the FIA of any amount due the FIA. Under these very specific conditions, the FIA may require the transfer of data as shown in Section C., above. If transfer is required, the unearned expenses retained by the Company shall be remitted to the FIA. >> In such event the Government will assume all obligations and liabilities owed to policyholders under such policies arising before and after the date of transfer. <<

E. In the event the Act is amended, or repealed, or expires, or if the FIA is otherwise without authority to continue the Program, financial assistance under this Arrangement may be cancelled for any new or renewal business, but the Arrangement shall continue for policies in force which shall be allowed to run their term under the Arrangement.

F. In the event that the Company is unable to, or otherwise fails to, carry out its obligations under this Arrangement by reason of any order or directive duly issued by the Department of Insurance of any Jurisdiction to which the Company is subject, the Company agrees to transfer, and the Government will accept, any and all WYO policies issued by the Company and in force as of the date of such inability or failure to perform. In such event the Government will assume all obligations and liabilities owed to policyholders under such policies arising before and after the date of transfer and the Company will immediately transfer to the Government all funds in its possession with respect to all such policies transferred and the unearned portion of the Company expenses for operating, administrative and loss adjustment on all such policies.

Article VI—Information and Annual Statements

The Company shall furnish to [the FIA] >> FEMA << such summaries and analyses of information >> including claim file information << in its records as may be necessary to carry out the

purposes of the National Flood Insurance Act of 1968, as amended, in such form as the FIA, in cooperation with the Company, shall prescribe. The Company shall be a property/casualty insurer domiciled in a State or territory of the United States. Upon request, the Company shall file with the FIA a true and correct copy of the Company's Fire and Casualty Annual Statement, and Insurance Expense Exhibit or amendments thereof, as filed with the State Insurance Authority of the Company's domiciliary State.

Article VII—Cash Management and Accounting

A. FEMA shall make available to the Company during the entire term of this Arrangement and any continuation period required by FIA pursuant to Article V, Section C., the Letter of Credit provided for in Article IV drawn on a repository bank within the Federal Reserve System upon which the Company may draw for reimbursement of its expenses as set forth in Article IV which exceed net written premiums collected by the Company from the effective date of this Arrangement or continuation period to the date of the draw.

B. The Company shall remit all funds >> including interest, << not required to meet current expenditures to the United States Treasury, in accordance with the provisions of the WYO Accounting Procedures Manual.

C. In the event the Company elects not to participate in the Program in any subsequent fiscal year, the Company and FIA shall make a provisional settlement of all amounts due or owing within three months of the termination of this Arrangement. This settlement shall include net premiums collected, funds drawn on the Letter of Credit, and reserves for outstanding claims. The Company and FIA agree to make a final settlement of accounts for all obligations arising from this Arrangement within 18 months of its expiration or termination, except for contingent liabilities which shall be listed by the Company. At the time of final settlement, the balance, if any, due the FIA or the Company shall be remitted by the other immediately and the operating year under this Arrangement shall be closed.

Article VIII—Arbitration

A. If any misunderstanding or dispute arises between the Company and the FIA with reference to any factual issue under any provisions of this Arrangement or with respect to the FIA's non-renewal of the Company's participation, other than as to legal liability under or interpretation of the standard flood insurance policy, such misunderstanding or dispute may be submitted to arbitration for a determination which shall be binding upon approval by the FIA. The Company and the FIA may agree on and appoint an arbitrator who shall investigate the subject of the misunderstanding or dispute and make a determination. If the Company and the FIA cannot agree on the appointment of an arbitrator, then two arbitrators shall be appointed, one to be chosen by the Company and one by the FIA.

The two arbitrators so chosen, if they are unable to reach an agreement, shall select a third arbitrator who shall act as umpire, and such umpire's determination shall become final only upon approval by the FIA.

The Company and the FIA shall bear in equal shares all expenses of the arbitration. Findings, proposed awards, and determinations resulting from arbitration proceedings carried out under this section, upon objection by FIA or the Company, shall be inadmissible as evidence in any subsequent proceedings in any court of competent jurisdiction.

This Article shall indefinitely succeed the term of this Arrangement.

Article IX—Errors and Omissions

The parties shall not be liable to each other for damages caused by ordinary negligence arising out of any transaction or other performance under this Arrangement, nor for any inadvertent delay, error, or omission made in connection with any transaction under this Arrangement, provided that such delay, error, or omission is rectified by the responsible party as soon as possible after discovery.

However, in the event that the Company has made a claim payment to an insured without including a mortgagee (or trustee) of which the Company had actual notice prior to making payment, and subsequently determines that the mortgagee (or trustee) is also entitled to any part of said claim payment, any additional payment shall not be paid by the Company from any portion of the premium and any funds derived from any Federal Letter of Credit deposited in the bank account described in Article II, section E. In addition, the Company agrees to hold the Federal Government harmless against any claim asserted against the Federal Government by any such mortgagee (or trustee), as described in the preceding sentence, by reason of any claim payment made to any insured under the circumstances described above.

Article X—Officials Not to Benefit

No Member or Delegate to Congress, or Resident Commissioner, shall be admitted to any share or part of this Arrangement, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Arrangement if made with a corporation for its general benefit.

Article XI—Offset

At the settlement of accounts the Company and the FIA shall have, and may exercise, the right to offset any balance or balances, whether on account of premiums, commissions, losses, loss adjustment expenses, salvage, or otherwise due one party to the other, it successors or assigns, hereunder or under any other Arrangements heretofore or hereafter entered into between the Company and the FIA. This right of offset shall not be affected or diminished because of insolvency of the Company.

All debts or credits of the same class, whether liquidated or unliquidated, in favor of or against either party to this Arrangement on the date of entry, or any order of conservation, receivership, or liquidation, shall be deemed to be mutual debts and credits and shall be offset with the balance only to be allowed or paid. No offset shall be allowed where a conservator, receiver, or liquidator has been appointed and where an obligation was purchased by or transferred to a party hereunder to be used as an offset.

Although a claim on the part of either party against the other may be unliquidated or undetermined in amount on the date of the entry of the order, such claim will be regarded as being in existence as of the date of such order and any credits or claims of the same class then in existence and held by the other party may be offset against it.

Article XII—Equal Opportunity

The Company shall not discriminate against any applicant for insurance because of race, color, religion, sex, age, handicap, marital status, or national origin.

Article XIII—Restriction on Other Flood Insurance

As a condition of entering into this Arrangement, the Company agrees that in any area in which the Administrator authorizes the purchase of flood insurance pursuant to the Program, all flood insurance offered and sold by the Company to persons eligible to buy pursuant to the Program for coverages available under the Program shall be written pursuant to this Arrangement.

However, this restriction applies solely to policies providing only flood insurance. It does not apply to policies provided by the Company of which flood is one of the several perils covered, or where the flood insurance coverage amount is over and above the limits of liability available to the insured under the Program.

Article XIV—Access to Books and Records

The FIA and the Comptroller General of The United States, or their duly authorized representatives, for the purpose of investigation, audit, and examination shall have access to any books, documents, papers and records of the Company that are pertinent to this Arrangement. The Company shall keep records which fully disclose all matters pertinent to this Arrangement, including premiums and claims paid or payable under policies issued pursuant to this Arrangement. Records of accounts and records relating to financial assistance shall be retained and available for three (3) years after final settlement of accounts, and to financial assistance, three (3) years after final adjustment of such claims. The FIA shall have access to policyholder and claim records at all times for purposes of the review, defense, examination, adjustment, or investigation of any claim under a flood insurance policy subject to this Arrangement.

Article XV—Compliance With Act and Regulations

This Arrangement and all policies of insurance issued pursuant thereto shall be subject to the provisions of the National Flood Insurance Act of 1968, as amended, the Flood Disaster Protection Act of 1973, as amended, **>>** the National Flood Insurance Reform Act of 1994, **<<** and Regulations issued pursuant thereto and all Regulations affecting the work that are issued pursuant thereto, during the term hereof.

Article XVI—Relationship Between the Parties (Federal Government and Company) and the Insured

Inasmuch as the Federal Government is a guarantor hereunder, the primary relationship between the Company and the Federal Government is one of a fiduciary nature, i.e., to assure that any taxpayer funds are accounted for and appropriately expended.

The Company is not the agent of the Federal Government. The Company is solely responsible for its obligations to its insured under any flood policy issued pursuant hereto.

[In witness whereof, the parties hereto have accepted this Arrangement on this _____ day of _____, 1993.]

_____

[Company]

[by _____]

[(Title) _____]

[The United States of America]

[Federal Emergency Management Agency]

[by _____]

[(Title) _____]

[EXHIBIT A]

[FEE SCHEDULE]

[Range (by covered loss)	Fee]
[Erroneous Assignment	$40.00]
[Closed Without Payment	125.00]
[Minimum for Upton-Jones Claims	800.00]
[$0.01 to $600.00	150.00]
[$600.01 to $1,000.00	175.00]
[$1,000.01 to $2,000.00	225.00]
[$2,000.01 to $3,500.00	275.00]
[$3,500.01 to $5,000.00	350.00]
[$5,000.01 to $7,000.00	425.00]
[$7,000.01 to $10,000.00	500.00]
[$10,000.01 to $15,000.00	550.00]
[$15,000.01 to $25,000.00	600.00]
[$25,000.01 to $35,000.00	675.00]
[$35,000.01 to $50,000.00	750.00]
[$50,000.01 to $100,000.00	1,000.00]
[$100,000.01 to $150,000.00	1,300.00]
[$150,000.01 to $200,000.00	1,600.00]
[$200,000.01 to limits	2,000.00]

[Allocated fee schedule entry value is the covered loss under the policy based on the standard deductibles ($500 and $500) and limited to the amount of insurance purchased.]

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: March 26, 1996.

Harvey G. Ryland,

Deputy Director.

[FR Doc. 96–8127 Filed 4–2–96; 8:45 am]

BILLING CODE 6718–03–P

44 CFR Part 67

[Docket No. FEMA–7177]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed base (1% annual chance) flood elevations and proposed base flood elevation modifications for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street, SW, Washington, DC 20472, (202) 646–2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency proposes to make determinations of base flood elevations and modified base flood elevations for each community listed below, in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified base flood elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Acting Associate Director, Mitigation Directorate, certifies that this proposed rule is exempt from the requirements of the Regulatory Flexibility Act because proposed or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to

establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This proposed rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. Elevation in feet. (NGVD)	
				Existing	Modified
California	Orange (County) Unincorporated Areas.	Arroyo Salada	At confluence with Salt Creek	*122	None
			Just upstream of East Nine Drive	*186	*206
			Approximately 400 feet upstream of East Nine Drive.	*200	*208
			Approximately 800 feet upstream of East Nine Drive.	*210	*212
			Approximately 1,200 feet upstream of East Nine Drive.	*219	224
			Approximately 1,600 feet upstream of East Nine Drive.	*229	*232
			Approximately 2,000 feet upstream of East Nine Drive.	*236	*238
			Approximately 2,400 feet upstream of East Nine Drive.	*244	*244
			Approximately 2,800 feet upstream of East Nine Drive.	*250	*251
			Approximately 3,200 feet upstream of East Nine Drive.	*258	*261
			Approximately 3,600 feet upstream of East Nine Drive.	*269	271
			Approximately 3,900 feet upstream of East Nine Drive.	*274	*276

Maps are available for inspection at Orange County Flood Programs, EMA, 400 Civic Center, Santa Ana, California.

Send comments to The Honorable Gaddi Vasquez, Chairman, Orange County Board of Supervisors, P.O. Box 687, Santa Ana, California 92702–0687.

California	Williams (City) Colusa County.	Salt Creek	At Freshwater Road	None	*72
			At Interstate 5	None	*73
			At Business Route 5	None	*77
			Approximately 350 feet upstream of Business Route 5.	None	*77
		Salt Creek—Overflow Area 1.	At Freshwater Road	None	*69
			Approximately 3,250 feet upstream of Freshwater Road.	None	*72
		Salt Creek—Overflow Area 2.	Southwest of intersection of Interstate 5 and State Route 20.	None	*77
			At Business Route 5	None	*78
			Approximately 950 feet upstream of Worth Street.	None	*83
			West of intersection of State Route 20 and E Street.	None	*86
			South of intersection of State Route 20 and E Street.	None	*90
		Salt Creek—Overflow Area 3.	At Husted Road	None	*68
			Approximately 5,100 feet upstream of Husted Road.	None	*73

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. Elevation in feet. (NGVD)	
				Existing	Modified
Maps are available for inspection at the City Building Department, City Hall, 810 E Street, Williams, California.					
Send comments to The Honorable Donald Burnett, Mayor, City of Williams, P.O. Box 310, Williams, California 95987.					
Missouri	Lawson (City) Clay and Ray Counties.	Brushy Creek	Approximately 3,950 feet downstream of the Atchison, Topeka, and Santa Fe Railroad bridge.	None	*996
			Approximately 2,600 feet downstream of the Atchison, Topeka, and Sante Fe Railroad bridge.	None	*1,000
			Approximately 1,000 feet downstream of the Atchison, Topeka, and Santa Fe Railroad bridge.	None	*1,005
			Approximately 900 feet upstream of confluence with Brushy Creek Tributary II.	None	*1,010
		Brush Creek Tributary II	At confluence with Brushy Creek	None	*1,008
			At County Highway D	None	*1,013
			Approximately 2,500 feet upstream of County Highway D.	None	*1,020
			Approximately 1,500 feet downstream of Salem Road.	None	*1,030
			Just downstream of Salem Road	None	*1,043
Maps are available for inspection at the City of Lawson, City Hall, City Administrator's Office, 3rd and Pennsylvania, Lawson, Missouri.					
Send comments to The Honorable Robert Gill, Mayor, City of Lawson, P.O. Box 185, Lawson, Missouri 64062.					
Texas	Montgomery County (Unincorporated Areas).	Sam Bell Gully	Approximately 300 feet downstream of Maplewood Drive.	*121	*121
			Approximately 1,100 feet just upstream of Maplewood Drive.	*122	*123
			Just upstream of Maplewood Drive	*124	*124
Maps are available for inspection at the County Administration Building, 301 North Thompson, Suite 208, Conroe, Texas.					
Send comments to The Honorable Alan Sadler, Montgomery County Judge, County Administration Building, 301 North Thompson, Suite 208, Conroe, Texas 77301.					

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: March 25, 1996.

Richard W. Krimm,

Acting Associate Director for Mitigation.

[FR Doc. 96–8128 Filed 4–2–96; 8:45 am]

BILLING CODE 6718–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[CC Docket No. 96–61, FCC 96–123]

Interstate, Interexchange Marketplace; and Implementation of Section 254(g) of the Communications Act of 1934, as Amended

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In the light of the passage of the 1996 Act, changes in the interexchange market over the past decade, and the recent reclassification of AT&T as a non-dominant carrier, the Commission is issuing this Notice of Proposed Rulemaking (''Notice'' or ''NPRM'') seeking comment on possible changes in the regulatory treatment of interstate, interexchange telecommunications service providers. Specifically, the Notice tentatively concludes that, as required by the forbearance provision in Section 10 of the Communications Act, as amended, the Commission must forbear from applying Section 203 tariff filing requirements to non-dominant interexchange carriers for domestic services. The Notice tentatively concludes that the Commission's proposed detariffing policy should be implemented on a mandatory basis. The Notice seeks comment on whether the Commission should forbear, with respect to non-dominant carriers that file bundled domestic and international tariffs, from requiring such carriers to file tariffs for the international portions of their service offerings as well.

DATES: Comments on Section IV of the NPRM (related to market definition), Section V (related to separation requirements) and Section VI (related to the implementation of Section 254(g) of the Communications Act of 1934, as amended) must be submitted on or before April 19, 1996. Reply comments for these sections must be filed on or before May 3, 1996. Comments on all other sections of the NPRM must be submitted on or before April 25, 1996. Reply comments for these sections must be submitted on or before May 24, 1996. Written comments on the Initial Regulatory Flexibility Analysis must be filed in accordance with the same filing deadlines set for comments on the other issues (other than Sections IV, V, and VI) in the NPRM, but they must have a separate and distinct heading designating them as responses to the Regulatory Flexibility Analysis. Written comments by the public on the proposed and/or modified information collections are due on or before April 19, 1996. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed and/or modified information collections on or before June 3, 1996.

ADDRESSES: Comments and reply comments should be sent to Office of

the Secretary, Federal Communications Commission, 1919 M Street, N.W., Room 222, Washington, D.C. 20554, with a copy to Janice Myles of the Common Carrier Bureau, 1919 M Street, N.W., Room 544, Washington, D.C. 20554. Parties should also file one copy of any documents filed in this docket with the Commission's copy contractor, International Transcription Services, Inc., 2100 M Street, N.W., Suite 140, Washington, D.C. 20037. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, 1919 M Street, N.W., Room 239, Washington, D.C. 20554. In order to facilitate review of comments and reply comments, both by parties and by Commission staff, we require that comments on Section IV of the NPRM (related to market definition), Section V (related to separation requirements), and Section VI (related to Implementation of Section 254(g) of the Communications Act, as amended) be no longer than forty-five (45) pages and reply comments be no longer than twenty-five (25) pages. We require that comments on the remaining sections of the NPRM be no longer than forty-five (45) pages and reply comments on the remaining sections be no longer than twenty-five (25) pages. Comments and reply comments must include a short and concise summary of the substantive arguments raised in the pleading. Parties are also asked to submit comments and reply comments on diskette. Such diskette submissions would be in addition to and not a substitute for the formal filing requirements addressed above. Parties submitting diskettes should submit them to Janice Myles of the Common Carrier Bureau, 1919 M Street, N.W., Room 544, Washington, D.C. 20554. Such a submission should be on a 3.5 inch diskette formatted in an IBM compatible form using MS DOS 5.0 and WordPerfect 5.1 software. The diskette should be submitted in ''read only'' mode. The diskette should be clearly labelled with the party's name, proceeding, type of pleading (comment or reply comments) and date of submission. The diskette should be accompanied by a cover letter. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Dorothy Conway, Federal Communications Commission, Room 234, 1919 M Street, N.W., Washington, DC 20554 or via the Internet to dconway@fcc.gov, and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725 - 17th Street, N.W., Washington, DC 20503 or via the Internet to fain__t@al.eop.gov.

FOR FURTHER INFORMATION CONTACT: Melissa Waksman or Donald Stockdale at (202) 418–1580, Common Carrier Bureau, Policy and Program Planning Division. For additional information concerning the information collections contained in this NPRM, contact Dorothy Conway at 202–418–0217, or via the Internet at dconway@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking (FCC 96–123) adopted on March 21, 1996 and released on March 25, 1996. The full text of this Notice of Proposed Rulemaking is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M St., N.W., Washington, DC. The complete text also may be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M St., NW., Suite 140, Washington, DC 20037.

Background

The Notice reserves for another day, in a separate proceeding, the broader question of whether the Commission should consider generally forbearing from requiring tariffs for international service provided by a non-dominant carrier, given the current market conditions in the international market. The Notice also invites parties to comment on whether, with respect to existing regulations examined in this Notice, the Commission should forbear from applying such regulations to some or all interexchange carriers or services, in particular areas or regions. The Notice also considers whether the Commission should reexamine the geographic and product market definitions that the Commission adopted in the *Competitive Carrier* proceeding. The Notice tentatively concludes that the Commission should follow the approach taken in the U.S. Department of Justice/Federal Trade Commission 1992 Merger Guidelines for defining relevant markets. The Notice interprets the Guidelines' approach as suggesting that the Commission should define as a relevant product market an interstate, interexchange service for which there are no close substitutes or group of services that are close substitutes for each other but for which there are no other close substitutes. The Notice tentatively concludes, however, that the Commission need not address the issue of delineating the boundaries of specific product markets, except where there is credible evidence suggesting that there is or could be a lack of competitive performance with respect to a particular service or group of services. The Notice also tentatively concludes that the Commission should define a relevant geographic market for interstate, interexchange services as all calls between two particular points. The Notice states, however, that geographic rate averaging and other factors imply that a carrier or group of carriers cannot change interexchange rates for calls between two particular points without changing rates nationwide for calls of that distance. The Notice, therefore, tentatively concludes that the Commission should treat interstate, interexchange calling as generally one national market. Where, however, there is credible evidence suggesting that there is or could be a lack of competition in a particular point-to-point market or group of markets, and that geographic rate averaging will not sufficiently mitigate the exercise of market power, the Notice proposes that the Commission will examine individually that market (or group of markets) for the presence of market power. In the *BOC Out-of-Region NPRM*, 60 FR 6607 (February 21, 1996) the Commission stated its intent to consider whether it may be appropriate to modify or eliminate separation requirements that are currently imposed upon independent LECs, and that we tentatively concluded in the *BOC Out-of-Region NPRM* should be imposed on BOCs, in order to qualify for non-dominant treatment in the provision of out-of-region interstate, interexchange services. The Notice thus seeks comment on whether the Commission should modify or eliminate the separation requirements independent LECs must satisfy if they are to be treated as non-dominant carriers in the provision of interstate, interexchange services outside their local exchange areas. The Notice seeks comment on whether, if the Commission modifies or eliminates these requirements for independent LECs, it should apply the same requirements to BOCs that provide out-of-region interstate, interexchange services. Section 254(g) of the Communications Act of 1934, as amended by the 1996 Act, requires the Commission to adopt rules to implement the requirements that rates for interexchange services be geographically averaged and be integrated. The Notice proposes to adopt a rule requiring that the rates charged by all providers of interexchange telecommunications services to subscribers in rural and high cost areas shall be no higher than the rates charged by each such provider to subscribers in

urban areas. The Notice states that Section 254(g) requires the Commission to adopt rules to require geographic averaging for intrastate and interstate telecommunications services. The Notice states the Commission believes that Section 254(g) preempts state laws or regulations requiring geographic rate averaging only to the extent such laws or regulations are inconsistent with the Commission's rules and policies. The Notice also proposes to adopt a rule to require rate integration for services between the contiguous forty-eight states and Alaska, Hawaii, U.S. territories and possessions. The Notice tentatively concludes that providers of interexchange services must file certifications stating they are in compliance with their statutory geographic rate averaging obligations and that providers of interstate, interexchange services must file certifications stating that they are in compliance with their statutory rate integration obligations. The Notice also seeks comment on: (1) the extent to which interexchange carriers do not offer discount plans throughout their service areas, and whether such carriers' failure to do so constitutes geographic deaveraging; (2) the appropriate mechanism for implementing rate integration for U.S. territories and possessions that are not currently subject to the Commission's domestic rate integration policy; and (3) whether there may be competitive conditions or other circumstances that could justify Commission forbearance from enforcing the proposed geographic rate averaging requirement with respect to particular interexchange telecommunications carries or services. Changes in the structure of the interexchange marketplace over the past decade have raised certain issues relating to the pricing of interexchange telecommunications services. The Notice seeks comment on certain of these issues. Based on the Commission's prior findings regarding competition in both the customer premises equipment (CPE) and interstate, interexchange markets, the Notice tentatively concludes that the Commission should amend Section 64.702(e) of the Commission's rules to allow non-dominant interexchange carriers to bundle CPE with interstate, interexchange services. The Notice notes that the Commission intends to initiate a comprehensive proceeding to address payphone issues, and therefore any amendment to Section 64.702(e) of the Commission's rules adopted in this proceeding will not apply to payphone bundling. Concerns about the application of the substantial cause test and other issues related to contract tariffs raised in the *AT&T Reclassification* proceeding by resellers and large business subscribers remain relevant if the Commission decides not to adopt a mandatory detariffing policy or implements permissive detariffing. Accordingly, the Notice seeks comment on such tariff-related issues. This NPRM contains proposed or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA). It has been submitted to the Office of Management and Budget (OMB) for review under the PRA. OMB, the general public, and other Federal agencies are invited to comment on the proposed or modified information collections contained in this proceeding.

Paperwork Reduction Act: This NPRM contains either a proposed or modified information collection. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collections contained in this NPRM, as required by the Paperwork Reduction Act of 1995, Pub. L. No. 104–13. Public and agency comments are due at the same time as comments on Section IV of the NPRM (related to market definition), Section V (related to separation requirements), and Section VI (related to Implementation of Section 254(g) of the Communications Act, as amended); OMB notification of action is due June 3, 1996. Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

OMB Approval Number: None.

Title: Policy and Rules Concerning the Interstate, Interexchange Marketplace; and Implementation of Section 254(g) of the Communications Act of 1934, as amended, CC Docket No. 96–61.

Form No.: N/A.

Type of Review: New Collection.

Respondents: Businesses or other for-profit, including small businesses.

Proposed requirement	No. of respondents	Estimated time per response
Detariffing*	0	0
Recordkeeping	519	1
Certification	519	2
Advertising	519	2

*The Commission proposes to eliminate the tariffing requirement now imposed on non-dominant interexchange carriers for domestic services.

Total Annual Burden: 2595.

Estimated Costs Per Respondent: $0.

Needs and Uses: The information collected under the proposed recordkeeping and certification requirements would be used by the Common Carrier Bureau of the Commission to ensure that affected interexchange carriers fulfill their obligations under the Communications Act, as amended. The information collected under the advertising requirement, if adopted, would be used to ensure that consumers have information regarding carriers' rate plans.

Synopsis of Notice of Proposed Rulemaking

I. Introduction

1. On February 8, 1996, the Telecommunications Act of 1996 (1996 Act) became law. The 1996 Act seeks ''to provide for a pro-competitive, de-regulatory national policy framework'' designed to make available to all Americans advanced telecommunications and information technologies and services ''by opening all telecommunications markets to competition.'' Integral to achieving this goal, the 1996 Act requires the Commission to forbear from applying any provision of the Communications Act of 1934, as amended (Communications Act), or our regulations, to a telecommunications carrier or telecommunications service, or class thereof, if the Commission makes certain specified findings with respect to such provisions or regulations. In addition, the 1996 Act provides for the entry of the Bell Operating Companies (BOCs) and their affiliates into the interstate, interexchange market, after certain preconditions are satisfied. 1996 Act at § 151 (adding § 271). This entry can be expected to intensify competition in the interstate, domestic, interexchange market. For purposes of this proceeding, we generally use the term ''BOCs'' as that term is defined in Section 3(a)(35) of the Communications Act of 1934, as amended. In a few instances, however,

we use the term ''BOCs'' also to encompass BOC affiliates, such as are contemplated by Section 272 of the Communications Act of 1934, as amended. The preconditions specified in the 1996 Act apply to a BOC's provision of interLATA services originating in any of its in-region states. 1996 Act at § 151 (adding § 271).

2. Consistent with the thrust of the 1996 Act, the Commission has long pursued policies designed to facilitate the growth of competition in the domestic long-distance market. In 1979, the Commission commenced the *Competitive Carrier* proceeding in which it considered how its regulations should be modified to reflect and promote competition in this market. In succeeding years, in part as a result of reforms adopted in the *Competitive Carrier* proceeding, the interstate, domestic, interexchange market has evolved from a market of fledgling competitors overshadowed by a single, dominant service provider to a market characterized by substantial competition. The Commission explicitly acknowledged these dramatic changes when, in October 1995, we concluded that AT&T Corporation (AT&T) no longer possessed individual market power in the domestic long-distance market taken as a whole and, accordingly, reclassified AT&T as a non-dominant carrier for interstate, domestic, interexchange services.

3. The 1996 Act builds upon the progress made to date in facilitating competition in the domestic long-distance market, and provides a framework for raising competition to a higher plane. In light of the passage of the 1996 Act, changes in the interexchange market over the past decade, and our recent reclassification of AT&T as a non-dominant carrier, we believe it is timely to review our regulatory regime for interstate, domestic, interexchange telecommunications services. In this proceeding, we therefore examine whether and how our policies and rules should be changed, consistent with the intent of the 1996 Act.

4. Specifically, we propose, pursuant to the forbearance authority provided in the 1996 Act, to adopt a mandatory detariffing policy for domestic services of non-dominant, interexchange carriers. We also propose to eliminate the prohibition against bundling customer premises equipment with the provision of interstate, interexchange services by non-dominant interexchange carriers. In addition, we consider whether to reduce or eliminate the separation requirements for non-dominant treatment of local exchange carriers in their provision of certain interstate, interexchange services. By these proposals, we seek to promote competition by reducing or eliminating existing regulations that may no longer be in the public interest in the increasingly competitive interexchange marketplace.

5. We also reexamine other aspects of our oversight of the interstate, interexchange market. In this respect, we consider whether we should more narrowly focus our definitions of relevant product and geographic markets for interexchange services to reflect current and future market conditions. We also address issues related to residential services pricing, including allegations of tacit price coordination in the interexchange market, and inquire how additional facilities-based competition pursuant to the 1996 Act affects this issue. We also consider other issues, including tariff-related issues that would remain relevant if we determine not to forbear from requiring non-dominant interexchange carriers to file tariffs, or if we decide to adopt a permissive detariffing policy. Finally, as required by the 1996 Act, we propose rules to implement the 1996 Act's provisions relating to geographic rate averaging and rate integration.

II. Background

A. The Telecommunications Act of 1996

6. The 1996 Act significantly alters the legal framework governing the interstate, interexchange market. The new statutory provisions should generally promote facilities-based competition in the interexchange market and open the door for new entrants to compete with existing service providers. For example, the 1996 Act, inter alia, permits the BOCs immediately to provide interLATA telecommunications services originating outside their in-region states, as well as ''incidental'' interLATA services. More significantly, after fulfilling specified preconditions, BOCs may provide interLATA telecommunications services originating inside their in-region states. In addition, the 1996 Act provides regulatory flexibility by requiring the Commission to forbear from applying any regulation or any provision of the Communications Act to telecommunications carriers or telecommunications services, or classes thereof, if the Commission determines that certain specified conditions are satisfied. The forbearance authority applies to all provisions of the Communications Act, except the provisions added by the 1996 Act relating to interconnection and BOC entry into long-distance services.

B. The Competitive Carrier Proceeding

7. The Commission, since 1979, has pursued, in the *Competitive Carrier* proceeding, pro-competitive and deregulatory goals similar to those now underlying the 1996 Act. The Commission there examined how its regulations should be adapted to reflect and promote increasing competition in interexchange telecommunications markets, and sought to reduce or eliminate the application of economic regulation to new competitive entrants. In these efforts, the Commission pursued a forbearance policy, encompassing both permissive and mandatory detariffing. Upon judicial review, however, the Court found that the Communications Act, at that time, did not provide the Commission with the requisite authority to do so.

8. In its *Competitive Carrier* orders, the Commission distinguished two kinds of carriers—those with market power (dominant carriers) and those without market power (non-dominant carriers). In determining whether a firm possessed market power, the Commission focused on certain ''clearly identifiable market features,'' including the number and size distribution of competing firms, the nature of barriers to entry, the availability of reasonably substitutable services, and whether the firm controlled bottleneck facilities. The Commission relaxed its tariff filing and facilities authorization requirements for non-dominant carriers, and focused its regulatory efforts on constraining the ability of dominant firms to act contrary to consumer welfare.

C. The Interexchange Competition Proceeding

9. In 1990, the Commission commenced the *Interexchange Competition* proceeding to examine the state of competition in the interstate, long-distance marketplace, and to assess the efficacy of existing regulation in light of this competition. In the *First Interexchange Competition Order*, 56 FR 66602 (December 24, 1991), the Commission found that business services (except analog private line services) had become ''substantially competitive.'' The Commission accordingly streamlined its regulation of those AT&T services. For services subject to ''streamlined'' regulation, AT&T was allowed to file tariffs on 14 days' notice, without cost support, and such tariffs were presumed lawful. In addition, price cap ceilings, bands and rate floors did not apply to streamlined services. Later, the Commission, after

ordering 800 number portability, found that 800 services (except 800 directory assistance services) were also subject to substantial competition, and streamlined regulation of those AT&T services as well.

10. In the *First Interexchange Competition Order*, 56 FR 55235 (October 25, 1991) the Commission also authorized all interexchange carriers to offer services pursuant to individually negotiated, contract-based tariffs, provided they make such rates generally available to similarly situated customers. The Commission found such arrangements would allow customers to negotiate service arrangements that best addressed their particular needs and would unleash competition by allowing AT&T to offer the same type of contract arrangements its competitors were already offering.

D. The AT&T Reclassification Order

11. On October 23, 1995, we issued an order granting AT&T's motion to be reclassified as a non-dominant carrier, based upon our finding that AT&T no longer possessed individual market power in the interstate, domestic, interexchange market taken as a whole. As a result, AT&T is now generally subject to the same regulations as its long-distance competitors. Like other non-dominant carriers, AT&T is still subject to regulation under Title II of the Communications Act. Thus, it is required to do the following: offer interstate services under rates, terms and conditions that are just, reasonable and not unduly discriminatory; file tariffs; and give notice prior to any discontinuance, reduction or impairment of service. Moreover, like other non-dominant carriers, AT&T continues to be subject to the Commission's complaint process.

12. In the *AT&T Reclassification* proceeding, AT&T made certain voluntary commitments, which AT&T stated were intended to serve as transitional arrangements to address concerns expressed by parties about possible adverse effects of reclassifying AT&T. These commitments concerned: service to low-income and other customers; analog private line and 800 directory assistance services; service to and from the State of Alaska and other regions subject to our rate integration policy; geographic rate averaging; changes to contract tariffs that adversely affect existing customers; and dispute resolution procedures for reseller customers. In the *AT&T Reclassification Order*, we accepted AT&T's commitments and ordered AT&T to comply with those commitments.

13. In the *AT&T Reclassification Order*, we stated that we would consider the following issues relevant to the interstate, domestic, interexchange market as a whole in this proceeding: (1) whether there is tacit price coordination in the interexchange market; (2) how changes in the interexchange market affect our rate integration and geographic averaging policies; (3) reseller and large user concerns regarding contract tariffs; and (4) the application of the filed rate doctrine to contract tariff arrangements.

E. Need for Review of Commission Regulation of the Interexchange Market

14. The Commission's obligation to be responsive to the dynamic nature of the communications industry has long been recognized. The passage of the 1996 Act, the dramatic changes in the interstate, domestic, interexchange telecommunications services market since the *Interexchange Competition* proceeding, and our reclassification of AT&T as a non-dominant carrier in the overall interstate, domestic, interexchange market, make it timely for us to reexamine our policies and rules in light of the goals of the 1996 Act. In pursuing the pro-competitive policy established by the 1996 Act, we intend to examine existing regulations to see whether they can be reduced or eliminated consistent with our public interest responsibilities.

III. Regulatory Forbearance

A. Introduction

15. The 1996 Act amends the Communications Act to require the Commission to:

[F]orbear from applying any regulation or any provision of this Act to a telecommunications carrier or telecommunications service, or class of telecommunications carriers or telecommunications services, in any or some of its or their geographic markets, if the Commission determines that—

(1) enforcement of such regulation or provision is not necessary to ensure that the charges, practices, classifications or regulations by, for, or in connection with that telecommunications carrier or telecommunications service are just and reasonable, and are not unjustly or unreasonably discriminatory;

(2) enforcement of such regulation or provision is not necessary for the protection of consumers; and

(3) forbearance from applying such provision or regulation is consistent with the public interest.

In addition, in determining whether forbearance from enforcing a particular provision or regulation is in the public interest, the Commission is specifically required to consider whether forbearance will promote competitive market conditions, including the extent to which forbearance will enhance competition among providers of telecommunications services. New Section 10(b) also provides that, ''[i]f the Commission determines that such forbearance will promote competition among providers of telecommunications services, that determination may be the basis for a Commission finding that forbearance is in the public interest.'' Section 401 of 1996 Act also provides that the Commission may not forbear from applying the requirements of the provisions of new Section 251 related to interconnection (except as provided in Section 251(f)) and of new Section 271 related to BOC provision of interLATA services until the Commission determines that those requirements have been fully implemented.

16. Accordingly, with respect to each of the existing regulations examined in this proceeding, we invite parties to comment on whether we should forbear from applying such regulations to some or all interexchange carriers or services, in particular geographic areas or regions. With respect to each issue, parties should specify the bases on which they believe we can make the findings required to meet the statutory criteria for forbearance.

17. We address below whether, given the current domestic, interstate, interexchange market, the 1996 Act requires the Commission to forbear from requiring non-dominant interexchange carriers to file tariffs for domestic services. Based on the Commission's analyses and findings in prior proceedings, we tentatively conclude that we are required by the 1996 Act to forbear from applying the Section 203 tariff filing requirements to non-dominant interexchange carriers for domestic interexchange services.

18. We note that we do not address here the issue of forbearance from applying Section 226 of the Act, which requires operator service providers to file informational tariffs. That issue will be addressed in a separate upcoming proceeding.

B. Forbearance From Tariff Filing Requirements for Non-Dominant Interexchange Carriers

1. Background

19. In the *Competitive Carrier* proceeding, the Commission explored the cost of imposing Title II regulation on entities lacking market power. In the *Competitive Carrier Further NPRM*, 46 FR 10924 (February 5, 1981), the

Commission suggested that tariff filing requirements for non-dominant carriers could harm consumers by slowing ''the introduction of new services, dampening competitive responses and ultimately encouraging price collusion through the forced publication of charges.'' The Commission accordingly, in a series of orders, established a permissive tariff forbearance policy for non-dominant carriers. In the *Sixth Report and Order*, 50 FR 1215 (January 10, 1985), the Commission established a mandatory detariffing policy for non-dominant carriers. The Commission concluded that tariff filings were not essential to its ability to ensure that non-dominant carriers do not unjustly discriminate in their rates, and that other means were available to ensure that the Commission fulfilled its mandate under the Communications Act.

20. The *Sixth Report and Order* subsequently was vacated and remanded by the U.S. Court of Appeals for the D.C. Circuit. The court held that the Commission lacked statutory authority to prohibit carriers from filing tariffs. The court, however, did not reach the issue of whether the Commission's earlier permissive detariffing orders were valid. The Commission, accordingly, continued to apply permissive detariffing for non-dominant carriers. The Commission's permissive detariffing regime subsequently was invalidated by the U.S. Court of Appeals for the D.C. Circuit in 1992. The court, in reviewing and disposing of a complaint filed by AT&T against MCI, vacated the Commission's *Fourth Report and Order*, 48 FR 52452 (November 18, 1983), thereby invalidating the Commission's tariff filing forbearance policy for non-dominant carriers. While stating that it had no ''quarrel with the Commission's policy objectives,'' the court found that the Communications Act did not give the Commission authority to adopt such a policy.

21. Prior to the U.S. Court of Appeals' vacation of the *Fourth Report and Order*, the Commission adopted a Report and Order in a rulemaking proceeding commenced in response to AT&T's complaint. The Commission again determined that permissive detariffing was within its authority under the Communications Act. The U.S. Court of Appeals for the D.C. Circuit granted summary reversal of the Commission's order based on the court's earlier ruling. In affirming the U.S. Court of Appeal's ruling, the Supreme Court found that Section 203(b)(2) of the Communications Act gave the Commission authority to modify the Act's tariff filing requirement, but not to eliminate it entirely. The Commission thereafter established a one-day tariff notice period for all non-dominant carriers after again concluding that traditional tariff regulation of non-dominant carriers is not necessary to ensure just and reasonable rates.

22. Against this background, Congress enacted Section 401 of the 1996 Act, adding Section 10(a) to the Communications Act, to grant the Commission authority to forbear from applying the provisions of Title II, subject to certain, limited exceptions.

2. Discussion

23. As noted above, the 1996 Act requires the Commission to forbear from applying to a telecommunications carrier or telecommunications service any regulation or any provision of the Communications Act, if the Commission makes the three specified determinations.

24. We believe, based on the Commission's prior analyses and findings, that we can make the determinations necessary in order to forbear from enforcing Section 203's tariffing requirements with respect to the domestic services offered by non-dominant, interexchange carriers. Specifically, we tentatively find that enforcement of the Section 203 tariffing requirements with respect to non-dominant interexchange carriers: (1) is not necessary to ensure that non-dominant interexchange carriers' charges, practices, or classifications are just and reasonable, and are not unjustly or unreasonably discriminatory; and (2) is not necessary for the protection of consumers. We also tentatively find that forbearing from enforcing Section 203 tariffing requirements with respect to non-dominant interexchange carriers is consistent with the public interest. Accordingly, we tentatively conclude that we must forbear from applying Section 203 tariff filing requirements to non-dominant interexchange carriers for domestic services. Each of these tentative determinations is discussed below.

25. We tentatively conclude that tariff filings for non-dominant interexchange carriers are not necessary to ensure that the charges, and practices of a telecommunications carrier or telecommunications service are just and reasonable and are not unjustly or unreasonably discriminatory. As the Commission stated in the *First Report and Order*, 45 FR 76148 (November 18, 1980):

> The economic underpinning of our proposal to streamline the regulatory procedures for non-dominant carriers flows from the fact that firms lacking market power simply cannot rationally price their services in ways which, or impose terms and conditions which, contravene Sections 201(b) and 202(a) of the Act.

Two years ago, in adopting a mandatory detariffing policy for providers of domestic commercial mobile radio service (CMRS), the Commission reiterated its conclusion that ''non-dominant carriers are unlikely to behave anticompetitively, in violation of Sections 201(b) and 202(a) of the Act, because they recognize that such behavior would result in a loss of customers.'' Based on the Commission's experience under its prior tariff forbearance policy for non-dominant interexchange carriers, as well as the Commission's findings in the *Regulatory Treatment of Mobile Services* proceeding, we continue to believe that non-dominant carriers are unlikely to price their services in ways which, or to impose terms and conditions which, violate Section 201(b) and Section 202(a) of the Act. Similarly, we continue to believe that the Communications Act's objectives of just, reasonable, and not unjustly or unreasonably discriminatory rates can be achieved effectively through market forces and the administration of the complaint process.

26. We also tentatively conclude that requiring non-dominant interexchange carriers to file tariffs for domestic offerings is not necessary for the protection of consumers of interexchange services. To the contrary, we believe a tariff filing requirement harms consumers by undermining the development of vigorous competition. The Commission previously has found, in the *Second Report and Order*, 47 FR 37899 (August 27, 1982), that applying tariff requirements to competitive entities is superfluous as a consumer protection device, since competition circumscribes the prices and practices of these companies. Moreover, beginning with the *Second Report and Order*, and as recently as the 1994 *Regulatory Treatment of Mobile Services Order*, 59 FR 18493 (April 19, 1994), the Commission has consistently found that the imposition of tariff obligations in these circumstances stifles price competition and service and marketing innovations. We tentatively find that these conclusions remain valid in today's more competitive domestic, interexchange market.

27. Finally, we tentatively conclude that forbearing from imposing tariff filing requirements on non-dominant interexchange carriers is consistent with the public interest. As part of the determination of whether forbearance is

consistent with public interest, the 1996 Act requires the Commission to consider ''whether forbearance from enforcing the provision or regulation will promote competitive market conditions, including the extent to which forbearance will enhance competition among providers of telecommunications services.'' We believe that forbearance from requiring tariff filings for non-dominant carriers will promote competition and deter price coordination. In the *Sixth Report and Order*, the Commission found that requiring non-dominant carriers to file tariffs can: (1) take away carriers' ability to make rapid, efficient responses to changes in demand and cost; (2) impede and remove incentives for competitive price discounting; and (3) impose costs on carriers that attempt to make new offerings. The Commission also concluded that continuing to require non-dominant carriers to file tariffs presents an opportunity for collusive pricing by competing carriers because carriers can ascertain their competitors' existing rates and keep track of any changes by reviewing filed tariffs. The Commission indicated that this may encourage carriers to maintain rates at artificially high levels.

28. The Commission recently reiterated, in the *Regulatory Treatment of Mobile Services Order*, its findings in the *Sixth Report and Order*. We believe that forbearance from tariff filing requirements will promote competition by enabling non-dominant carriers to respond quickly to changes in the market, and reducing administrative costs on carriers making new offerings. We also believe that, without pricing and other material information available from the public tariffs of their rivals, non-dominant interexchange carriers are more likely to initiate price reductions and other competitive programs. Accordingly, we tentatively conclude that forbearing from requiring non-dominant carriers to file tariffs for interexchange services promotes competitive market conditions, and therefore is in the public interest.

29. Based on the foregoing tentative determinations, we tentatively conclude that we are required by Section 10 of the Communications Act, as amended, to forbear from requiring non-dominant interexchange carriers to file tariffs for domestic services. We invite comment on all of these tentative conclusions.

30. We note that many carriers currently file bundled tariffs that include both domestic and international services. We therefore seek comment as to whether the Commission should forbear from requiring these non-dominant firms to file tariffs for the international portions of their offerings as well. We reserve for another day, in a separate proceeding, the broader question of whether the Commission should consider generally forbearing from requiring tariffs for international service provided by a non-dominant carrier, given current market conditions in the international market. As stated in an order adopted earlier this month, we ''anticipate review of our international Section 214 authorization and tariffing procedures to identify new areas where additional streamlining may be appropriate. . . . [S]uch steps should be taken in the context of a new proceeding where we can make additional determinations about the state of competition in the international market and receive more public input.'' *Streamlining the International Section 214 Authorization Process and Tariff Requirements*, IB Docket No. 95–118, Report and Order, at ¶ 86 (rel. Mar. 13, 1996).

31. We also tentatively conclude that forbearance from tariff filing requirements for domestic services of non-dominant interexchange carriers should be implemented on a mandatory basis. Permitting non-dominant interexchange carriers to file tariffs in this context does not appear to be in the public interest. We believe that a regime without non-dominant interexchange carrier tariffs is the most pro-competitive, deregulatory regime. The risk of anticompetitive conduct inherent in, and the costs associated with, tariff filings by non-dominant interexchange carriers, discussed above, would persist if carriers were permitted to file tariffs voluntarily. In addition, the absence of tariffs would eliminate possible invocation by carriers of the filed rate doctrine, which allows carriers certain rights unilaterally to change rates, terms, and conditions of contract tariffs and other long-term service arrangements, and to limit their liability for damages. Absent filed tariffs, the legal relationship between carriers and customers will much more closely resemble the legal relationship between service providers and customers in an unregulated environment. Therefore, to establish a more market-based environment that will help prevent these possible anti-competitive practices and better protect consumers, we tentatively conclude that it would be in the public interest to prohibit non-dominant interexchange carriers from filing tariffs with respect to domestic interstate, interexchange services.

32. Our proposal to adopt a mandatory tariff forbearance policy for non-dominant interexchange carriers is supported by the Commission's adoption of a mandatory tariff forbearance policy for domestic CMRS, in response to a similar grant of forbearance authority with respect to CMRS providers and services in Section 6002(b) of the Omnibus Budget Reconciliation Act of 1993 (OBRA). In *Regulatory Treatment of Mobile Services*, the Commission concluded that, in a competitive environment, voluntary tariff filings would create a risk that competitors would use tariff filings ''merely to send price signals and thereby manipulate prices.'' It also found that forbearance would promote competition by enabling providers of CMRS to respond quickly to competitors' price packages and reducing administrative costs. To prevent collusive pricing practices, and to protect consumers and the public interest, the Commission determined that it would ''forbear from requiring or permitting tariffs for interstate service offered directly by CMRS providers to their customers.''

33. We seek comment on our tentative conclusion that we should adopt a mandatory detariffing policy for the domestic services offered by non-dominant interexchange carriers. We also seek comment on whether the Commission has the authority pursuant to the Communications Act, as amended, to prohibit carriers from filing tariffs. We tentatively conclude that, if we adopt a mandatory or a permissive detariffing policy, non-dominant carriers should be required to maintain at their premises price and service information regarding all of their interstate, interexchange offerings, that they can submit to the Commission upon request. We seek comment on this tentative conclusion.

34. We recognize that the Commission gradually relaxed its regulation of non-dominant carriers in the *Competitive Carrier* proceeding in part because it concluded that the availability of service from a nationwide dominant carrier subject to close regulation would effectively constrain the rates that could be charged by non-dominant carriers. Given the recent reclassification of AT&T, there currently are no nationwide dominant interstate, domestic, interexchange carriers. While we still believe that non-dominant carriers lacking market power cannot rationally price services anticompetitively, we seek comment on whether the absence of a nationwide dominant carrier should affect our tentative conclusion to forbear from requiring non-dominant interexchange carriers to file tariffs, and if so, how.

35. We note that market conditions or other circumstances may change in the

future. In the event of changed circumstances, such that the statutory prerequisites for forbearance are no longer present, the Commission can revisit tariff forbearance to consider whether it continues to meet the statutory criteria.

36. Finally, in the *AT&T Reclassification* proceeding, AT&T made certain voluntary commitments regarding its provision of interstate analog private line and 800 directory assistance services. Specifically, AT&T committed, for a period of three years, to limit any price increases for these services to a maximum increase in any year of no more than the increase in the consumer price index. AT&T also committed, for a period of three years, to file tariff changes increasing the prices of these services on not less than five business days' notice, and to identify clearly such tariff transmittals as affecting the provisions of this commitment. We believe that it would be consistent with AT&T's intent that its commitments act as a transitional mechanism for AT&T to continue to tariff these services in accordance with its commitments. Accordingly, we tentatively conclude that, even if we decide to forbear from requiring non-dominant interexchange carriers to file tariffs, AT&T should remain subject to its prior commitments, and our corresponding order, that AT&T file tariffs with respect to these services for the specified term of the commitments. We seek comment on these tentative conclusions.

IV. Definition of Relevant Product and Geographic Markets

37. In the *Competitive Carrier* proceeding, the Commission found, for purposes of assessing the market power of interexchange carriers covered by that proceeding, that: ''(1) interstate, domestic, interexchange telecommunications services comprise the relevant product market, and (2) the United States (including Alaska, Hawaii, Puerto Rico, U.S. Virgin Islands, and other U.S. offshore points) comprises the relevant geographic market for this product, with no relevant submarkets.'' In this section, we consider whether we should reexamine the geographic and product market definitions that the Commission adopted in the *Competitive Carrier* proceeding. We believe more sharply focused market definitions will aid us in evaluating whether the BOCs possess market power with respect to the provision of interLATA services in areas where they provide local access service. Moreover, evidence in the recent *AT&T Reclassification* proceeding suggests that the market definitions adopted in the *Competitive Carrier* proceeding might be more narrowly drawn to provide us with a more refined analytical tool for evaluating whether a carrier or group of carriers has market power. For example, there was evidence that suggested that AT&T might possess the ability to raise and sustain prices for 800 directory assistance and analog private line services above competitive levels without making the price increase unprofitable, which may imply that these services might constitute separate relevant product markets.

38. We invite comment on whether we should retain the relevant product and geographic market definitions adopted in the *Competitive Carrier* proceeding. We tentatively conclude that we should follow the approach taken in the U.S. Department of Justice/ Federal Trade Commission 1992 Merger Guidelines (the ''Guidelines'') for defining relevant markets. 1992 U.S. Department of Justice/Federal Trade Commission Merger Guidelines, 4 Trade Reg. Rep. (CCH) ¶ 13,104, at p. 20,569. ''In many respects the . . . Guidelines and the scholarship on which they are based offer important insights and substantially improved formulations of relevant market issues.'' Moreover, courts have increasingly relied on the Guidelines' approach in defining relevant markets. We believe the Guidelines' approach suggests that we should define as a relevant product market an interstate, interexchange service for which there are no close substitutes or a group of services that are close substitutes for each other but for which there are no other close substitutes. We tentatively conclude, however, that we need not address the issue of delineating the boundaries of specific product markets, except where there is credible evidence suggesting that there is or could be a lack of competitive performance with respect to a particular service or group of services.

39. With respect to the relevant geographic market, we tentatively conclude that we should define a relevant geographic market for interstate, interexchange services as all calls (in the relevant product market) between two particular points. However, geographic rate averaging and other factors imply that a carrier or group of carriers cannot change interexchange rates for calls between two particular points without changing rates nationwide for calls of that distance. For purposes of market power analysis, we tentatively conclude to treat interstate, interexchange calling generally as one national market, as the Commission did in the *Competitive Carrier* proceeding. If there is credible evidence suggesting that there is or could be a lack of competition in a particular point-to-point market (or group of markets), and there is a showing that geographic rate averaging will not sufficiently mitigate the exercise of market power (if it exists); however, we propose to examine individually that market (or group of markets) for the presence of market power.

40. We note that comments and reply comments on this section are due April 19, 1996; reply comments are due May 3, 1996.

A. Relevant Product Market

41. For the reasons discussed above, we tentatively conclude that we should follow the Guidelines' approach for defining the relevant product market. In the *Competitive Carrier* proceeding, the Commission defined the relevant product market as ''all interstate, domestic, interexchange telecommunications services'' and concluded that there were no relevant submarkets. Although we recently used this product market definition to reclassify AT&T as non-dominant, we question whether a narrower product market definition might provide us with a more refined analytical tool for evaluating whether a carrier or group of carriers together are exerting market power. For example, our finding that the prices of 800 directory assistance and analog private line services could profitably be raised above competitive levels may imply these services constitute distinct relevant product markets.

42. The Guidelines define the relevant product market as ''the product or group of products such that a hypothetical profit maximizing firm that was the only present and future seller of those products ('monopolist') would impose at least a 'small but significant and nontransitory' increase in price.'' Accordingly, in defining the relevant product market, one must examine whether a ''small but significant and nontransitory'' increase in the price of the relevant product would cause enough buyers to shift their purchases to a second product, so as to make the price increase unprofitable. If so, the two products should be considered to be in the same product market.

43. Under the Guidelines, ''[m]arket definition focuses solely on demand substitution factors—i.e., possible consumer responses.'' Consideration of substitutability of demand supports the use of narrower relevant product markets than the ''all services'' product market defined in the *Competitive*

Carrier proceeding. It appears unlikely, for example, that a substantial number of residential customers would switch from residential service to 800 service in response to a small but significant nontransitory increase in the price of residential service. Thus, these two services may fall in different product markets. On the other hand, it appears that defining each interexchange service as a separate relevant product market would result in relevant markets that are too narrow. Business customers, in particular, may view certain interexchange services as sufficiently close substitutes that, if an interexchange carrier raised the price of one of the services, customers would switch to one of the substitute services. Based on this analysis, we believe that we should define as a relevant product market an interstate, interexchange service for which there are no close substitutes or a group of services that are close substitutes for each other, but for which there are no other close substitutes.

44. We believe that it would be administratively burdensome to delineate all relevant product markets for interstate, interexchange services. The fact that we have previously found that there is substantial competition with respect to most interstate, domestic, interexchange service offerings suggests that we do not need to do so at this time. Accordingly, we tentatively conclude that we should address the question whether a specific interstate, interexchange service (or group of services) constitutes a separate product market only if there is credible evidence suggesting that there is or could be a lack of competitive performance with respect to that service (or group of services). We seek comment on this approach and invite parties to suggest other approaches. Interested parties should provide support for the position they advocate. Parties recommending that services be grouped in relevant product markets should identify the services that should be grouped together, as well as providing evidence that there is or could be a lack of competitive performance with respect to those services. We also seek comment on what factors we should consider in defining relevant product markets, as well as what obstacles, problems, or administrative burdens we are likely to face in adopting narrower market definitions.

B. Relevant Geographic Market

45. The Merger Guidelines define the relevant geographic market as the ''region such that a hypothetical monopolist that was the only present or future producer of the relevant product at locations in that region would profitably impose at least a 'small but significant and nontransitory' increase in price, holding constant the terms of sale for all products produced elsewhere.'' This definition focuses on whether products in one region are good substitutes for products in other regions. Accordingly, in defining the relevant geographic market, one must examine whether a ''small but significant and nontransitory'' increase in the price of the relevant product at a particular location would cause a buyer to shift his purchase to a second location, so as to make the price increase unprofitable. If so, the two locations should be considered to be in the same geographic market.

46. In applying the principles in the Guidelines, we note that, at its most fundamental level, interexchange calling involves a customer making a connection from a specific location to another specific location. We believe that most telephone customers do not view interexchange calls originating in different locations to be close substitutes for each other. For example, it is unlikely that a person living in Chicago who wishes to make a telephone call to San Francisco will be willing to travel to another location to make the call for a lower price. Similarly, a customer will not view a call that terminates in a place other than the location of the person to whom he or she is calling to be a good substitute for a call to that person. Thus, applying the Merger Guidelines principles, we tentatively conclude that the relevant geographic market for interstate, interexchange services should be defined as all calls from one particular location to another particular location. We note that defining a relevant geographic market as transport between two specific points is well established in other contexts. For example, the Department of Justice has used city pairs as the relevant geographic market for evaluating mergers in the airline industry. Similarly, in the *International Competitive Carrier* proceeding, the Commission found that each country pair constitutes a separate geographic market. *See International Competitive Carrier Policies,* 50 FR 48191 (November 22, 1985). Thus, one geographic market consists of calls between the U.S. and France, and another consists of calls between the U.S. and Great Britain.

47. We recognize that it would be impracticable to conduct a market power analysis in each individual market implied by a point-to-point market definition for interstate, interexchange services. We believe that, in the majority of cases, economic factors and the realities of the marketplace will cause these markets to behave in a sufficiently similar manner to allow us to aggregate them into broader, more manageable groups of markets for purposes of market power analysis. For example, residential interexchange service can be thought of as a bundle of all possible interexchange calls originating from a single point and terminating anywhere, and 800 service as a bundle of interstate, interexchange calls originating from a certain geographic region and terminating at a specific point. Similarly, the ''single nationwide geographic market'' the Commission adopted in the Competitive Carrier proceeding can be viewed as an aggregate of the point-to-point markets encompassing all points in the United States.

48. We tentatively conclude for the following reasons that, in most cases, we should continue to treat interstate, interexchange services as a single national market when examining whether a carrier or group of carriers acting together has market power. First, geographic rate averaging reduces the likelihood that a carrier could exercise market power in a single point-to-point market. Because the prices a carrier can charge in a particular market are linked to the prices it charges in all other markets, it generally would not be profitable for a carrier to raise its prices throughout the nation (with a resulting loss of market share in some areas) to take advantage of market power between two particular cities. Second, customers typically purchase ubiquitous calling that enables them to make calls to all domestic locations. Thus, because of geographic rate averaging, a price change in one point-to-point market would require such price changes to be extended to all residential customers.

49. Another reason we can treat the relevant geographic market as a national market is that price regulation of access services and excess capacity in interstate transport further reduce the likelihood that an interexchange carrier could exercise market power in most point-to-point markets. In making this determination, we recognize that an interstate, interexchange call from point A to point B requires three separate inputs, each of which is sold in a separate input market: (1) originating access from point A; (2) interstate transport from point A to point B; and (3) terminating access to point B. The ability to raise the price for any of the inputs above the competitive level or to prevent competitors from assembling inputs to provide retail service would enable a firm unilaterally to raise the

retail price of and thereby exercise market power with respect to interexchange calls between points A and B. We note, however, that all originating and terminating access services are currently subject to some form of price regulation, which constrains a LEC's ability to raise access prices to monopoly levels. We also note that there are ways in which a LEC could exercise market power without raising the price of interstate, interexchange services. For example, a LEC could raise its interexchange rivals' costs by providing poorer interconnection to the LEC's network facilities than the LEC provides to itself or its affiliate, or by delaying fulfillment of its rivals' requests to connect to the LEC's network. We will be addressing these issues in upcoming proceedings that address implementation of new Sections 251 and 272 of the Communications Act, as amended. While interstate transport service is not subject to price regulation, we concluded in the *AT&T Reclassification Order* that, between most points, excess transport capacity undermines the ability of any carrier to raise and maintain the price of interstate transport above the competitive level. Thus, because the prices of access and transport services are similarly constrained in all point-to-point markets, we believe we can generally examine simply whether a carrier has market power in the group of point-to-point markets that comprise the ''nationwide geographic market.''

50. Nevertheless, we believe there may be special circumstances in which treating interexchange services as a national market will not be sufficient for purposes of market power analysis. For example, the BOCs' control of access facilities in their local service regions may require us to examine those regions individually in determining whether the BOCs have market power with respect to in-region interexchange services. If market power were found to exist in such a large region, there is no guarantee that geographic rate averaging would provide a credible check on the exercise of such power. For instance, if a BOC's interexchange customers and traffic are concentrated in one region, the BOC might find it profitable to raise prices above competitive levels, even if geographic rate averaging might cause it to lose market share outside that region. We therefore propose to examine a particular point-to-point market (or group of markets) for the presence of market power if there is credible evidence suggesting that there is or could be a lack of competition in that market (or group of markets) and there is a showing that geographic rate averaging will not sufficiently mitigate the exercise of market power (if it exists) in that market (or group of markets). We are not addressing in this proceeding the circumstances, if any, in which a BOC or independent LEC should be classified as a dominant carrier with respect to the provision of interstate, interexchange services in areas where it provides local access services. We intend to address these questions in an upcoming proceeding.

51. We seek comment on the proposed approach. We also seek comment on how narrowly we would need to define points of origination and termination if we adopt this approach. Because it would be administratively infeasible to conduct a market power analysis that defines separate geographic markets between each pair of individual locations (such as homes), we need to adopt somewhat broader definitions for this situation. One possibility is to define geographic markets between two local exchange areas. An alternative approach might be to use geographic areas currently used by the Commission, such as Major Trading Areas (MTAs), Basic Trading Areas (BTAs), or Metropolitan Statistical Areas (MSAs). Commenters should explain why the geographic market definition they recommend is appropriate and should address the administrative benefits or burdens of their proposed definition. We note that Rand McNally & Company is the copyright owner of the Basic Trading Area and Major Trading Area Listings, which list the counties contained in each BTA, as embodied in Rand McNally's Trading Area System Diskette and Atlas & Marketing Guide. Rand McNally has licensed the use of its copyrighted MTA/BTA listings and maps for certain wireless telecommunications services.

52. We also invite parties to suggest alternative approaches they believe better characterize the relevant geographic market for interstate, interexchange services, than the point-to-point market definition we have proposed. Parties should explain how the market definition they recommend reflects the market for interexchange services and should describe the likely administrative benefits or burdens of their proposal. Finally, parties should discuss the factors that we should consider in defining the relevant geographic market for interstate, domestic, interexchange services.

V. Separation Requirements for Independent Local Exchange Carrier and Bell Operating Company Provision of ''Out-of-Region'' Interstate, Interexchange Services

53. The 1996 Act authorizes the BOCs, upon enactment, to provide interLATA services originating outside their in-region states. In a recent Notice of Proposed Rulemaking, we considered what regulatory regime we should apply to BOC provision of such ''out-of-region'' interstate, interexchange services. Specifically, we considered whether such services should be subject to dominant carrier or non-dominant carrier regulation. The *BOC Out-of-Region NPRM*, 60 FR 6607 (February 21, 1996) addresses only BOC provision of out-of-region interstate, interexchange services; BOC provision of in-region interstate, interexchange services will be considered in a separate proceeding. In that Notice, we tentatively concluded that the separation requirements imposed for non-dominant treatment of independent LEC provision of interexchange services, presented a useful model upon which to base, on an interim basis, oversight of BOC provision of out-of-region interstate, interexchange services.

54. The separation requirements imposed on independent LECs were established by the Commission in the *Competitive Carrier* proceeding. The Commission there determined that interexchange carriers affiliated with independent LECs would be regulated as non-dominant carriers. In the *Fifth Report and Order*, 49 FR 34824 (September 4, 1984), the Commission specified that an ''affiliate'' of an independent LEC was ''a carrier that is owned (in whole or in part) or controlled by, or under common ownership (in whole or in part) or control with, an exchange telephone company.'' The Commission further clarified that, to qualify for non-dominant treatment, the affiliate providing interstate, interexchange services must: (1) maintain separate books of account; (2) not jointly own transmission or switching facilities with its affiliated exchange telephone company; and (3) acquire any services from its affiliated exchange telephone company at tariffed rates, terms and conditions. The Commission also stated that any interstate service offered directly by an independent LEC, rather than through a separate affiliate, would be regulated as dominant.

55. The Commission observed that the separation requirements would provide some ''protection against cost-shifting and anticompetitive conduct'' by an

independent LEC that could result from using its control of local bottleneck facilities. Noting that the requirements it had specified were less stringent than those established in the *Second Computer Inquiry,* the Commission concluded that the separation requirements would not impose excessive burdens on independent LECs.

56. The Commission stated in the *Fifth Report and Order* that the non-dominant treatment accorded to interexchange carriers affiliated with independent LECs did not apply to the BOCs, which, the Commission noted, were then prohibited from offering interLATA services. The Commission added that, ''if this bar is lifted in the future, we would regulate the BOCs' interstate, interLATA services as dominant until we determined what degree of separation, if any, would be necessary for the BOCs or their affiliates to qualify for nondominant regulation.''

57. As noted, in the *BOC Out-of-Region NPRM* we tentatively concluded that the separation requirements imposed upon independent LECs providing interexchange services, presented a useful model upon which to base, on an interim basis, oversight of BOC provision of out-of-region interstate, interexchange services. Accordingly, we tentatively concluded that, if a BOC provides out-of-region interstate, interexchange services through an affiliate that satisfies the separation requirements established in the *Competitive Carrier Fifth Report and Order,* the BOC affiliate should be regulated as a non-dominant carrier. We also tentatively concluded that, if a BOC provides out-of-region interstate, interexchange services directly, or through an affiliate that does not meet the separation requirements, those services should be regulated as dominant carrier offerings.

58. We stated in that Notice, however, our intent to consider in this proceeding whether it may be appropriate at some future date to modify or eliminate the separation requirements that are currently imposed upon independent LECs, and that we tentatively concluded should be imposed on BOCs, in order to qualify for non-dominant treatment in the provision of out-of-region interstate, interexchange services. Accordingly, we now seek comment on whether we should modify or eliminate these separation requirements as a condition for non-dominant treatment of independent LEC provision of interstate, interexchange services outside their local exchange areas. We also seek comment on whether, if we modify or eliminate these separation requirements for non-dominant treatment of independent LEC provision of interstate, interexchange services outside their local exchange areas, we should apply the same requirements to BOC provision of out-of-region interstate, interexchange services. We defer to another proceeding consideration of the appropriate regulatory treatment of BOCs that provide in-region interstate, interexchange services and independent LECs that provide interstate, interexchange services within the area in which they also provide local exchange service.

59. Parties should identify the requirement or requirements that they believe should be modified or eliminated, and offer support for their positions. Parties should comment on whether complying with the separation requirements would create an unnecessary burden for LECs subject to those requirements. Parties should also comment on whether there is a possibility of cost-shifting or other anti-competitive conduct that could result if the separation requirements are modified or eliminated, and if so, how we can or should address such conduct.

60. We note that comments and reply comments on this section are due April 19, 1996; reply comments are due May 3, 1996. *See also* Section X.D. infra regarding requirements for all pleadings.

VI. Rate Averaging and Integration Requirements of 1996 Act

61. Section 254(g) of the Communications Act, as amended by the 1996 Act, provides that the Commission, within six months after the date of enactment, must:

> [A]dopt rules to require that the rates charged by providers of interexchange telecommunications services to subscribers in rural and high cost areas shall be no higher than the rates charged by each such provider to its subscribers in urban areas. Such rules shall also require that a provider of interstate interexchange telecommunications services shall provide such services to its subscribers in each State at rates no higher than the rates charged to subscribers in any other State.

Accordingly, we propose and address here the rules necessary to implement these requirements.

62. We note that comments and reply comments on this section implementing Section 254(g) of the Communications Act, as amended, are due April 19, 1996; reply comments are due May 3, 1996. *See also* Section X.C. *infra* regarding requirements for all pleadings.

A. Geographic Rate Averaging

63. We first address the statutory requirement that the rates charged by providers of interexchange telecommunications services to subscribers in rural and high cost areas not be higher than the rates charged to subscribers in the interexchange carrier's urban areas (*i.e.*, that rates be geographically averaged). The Commission has long supported a policy of geographic rate averaging for interstate, domestic, interexchange services. As the Commission stated in 1989:

> This Commission has repeatedly voiced our support for rate averaging. . . . Geographic rate averaging redounds to the benefit of rural ratepayers, and customers of high cost local exchange carriers. First, geographic rate averaging ensures that interexchange rates for rural areas, or areas served by high cost companies, will not reflect the disproportionate burdens that may be associated with common line cost recovery in these areas. Thus, geographic rate averaging furthers our goal of providing a universal nationwide telecommunications network. Second, geographic rate averaging ensures that ratepayers share in the benefits of nationwide interexchange competition. If prices are falling due to competition in the corridors carrying the most traffic, prices will also fall for rural Americans. An additional benefit of rate averaging has been its contribution to the simplicity of [message toll service] rates. Customers seeking to compare rates charged by various interexchange carriers have been substantially benefited by the relative simplicity of the existing rate structure.

As recently as the *AT&T Reclassification Order,* we reaffirmed our commitment to maintain our geographic rate averaging policy.

64. While the Commission has consistently endorsed a policy of geographic rate averaging, the Commission has not formally promulgated a requirement that rates be geographically averaged. As required by the 1996 Act, we propose to adopt a rule requiring that the rates charged by all providers of interexchange telecommunications services to subscribers in rural and high cost areas shall be no higher than the rates charged by each such provider to its subscribers in urban areas. As established by the 1996 Act, this requirement would apply to all providers of interexchange telecommunications services. We seek comment generally on this proposed rule.

65. Section 254(g) of the Communications Act, as amended by the 1996 Act, states in part:

> the Commission shall adopt rules to require that the rates charged by providers of interexchange telecommunications services to subscribers in rural and high cost areas shall be no higher than the rates charged by each such provider to its subscribers in urban areas.

Thus, the statute requires the Commission to adopt rules to require geographic rate averaging for intrastate and interstate, interexchange telecommunications services. We note that the legislative history states:

> [n]ew section 254(g) is intended to incorporate the policies of geographic rate averaging . . . of interexchange services in order to ensure that subscribers in rural and high cost areas throughout the Nation are able to continue to receive both intrastate and interstate interexchange services at rates no higher than those paid by urban subscribers.

We also believe, however, that Section 254(g) preempts state laws or regulations requiring intrastate geographic rate averaging only to the extent such laws or regulations are inconsistent with the rules we adopt with respect to geographic rate averaging. Preemption may occur even when Congress has not fully foreclosed state regulation in a specific area if state law conflicts with federal law. *See Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142–143 (1963) (conflict when ''compliance with both federal and state regulations is a physical impossibility''); *Hines* v. *Davidowitz,* 312 U.S. 52, 67 (1941) (conflict when state law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress''). Although the statute makes clear that the Commission is to establish the rules requiring geographic averaging, it does not appear to foreclose consistent state action in this area. Indeed, the Senate Report statement included in the Joint Explanatory Statement provides:

> States shall continue to be responsible for enforcing this [geographic averaging provision] with respect to intrastate interexchange services, so long as the State rules are not inconsistent with Commission rules and policies on rate averaging.

The Joint Explanatory Statement indicates that the House receded to the Senate with modifications with respect to new Communications Act Section 254. We note that the geographic rate averaging provision of Section 254(g) contains only minor modifications from the Senate Bill geographic rate averaging provision, Section 253(h). *See* S. 652 104th Cong., 1st Sess. § 253(h) (1995). Thus, we invite comment on these views.

66. In addition to seeking comment on preemption, we seek comment on whether there may be competitive conditions or other circumstances that could justify Commission forbearance from enforcing the proposed geographic rate averaging requirement with respect to particular interexchange telecommunications carriers or services.

67. In light of our proposal in this Notice to forbear from requiring non-dominant interexchange carriers to file tariffs, we tentatively conclude that it would not be in the public interest to attempt to enforce geographic rate averaging through the tariff process. Rather, we believe that we can ensure compliance with the proposed rate averaging requirements by requiring providers of interexchange telecommunications services to file certifications stating that they are in compliance with their statutory geographic rate averaging obligations. Such a requirement would not impose a significant burden on such providers. Accordingly, we tentatively conclude that we should require providers of interexchange telecommunications services to file such certifications. We also tentatively conclude that we should rely on the complaint process under Section 208 to bring violations to our attention. We seek comment on these tentative conclusions. Parties challenging these tentative conclusions should suggest possible alternative enforcement mechanisms.

68. Enforcement issues similarly arise in the absence of tariff forbearance. Because non-dominant carriers currently are permitted to file tariffs on one day's notice, we seek comment on whether, in the absence of tariff forbearance, we should adopt any requirements in order to facilitate enforcement of the proposed rule that requires, *inter alia,* that the rates of non-dominant providers of interexchange telecommunications services be geographically averaged. Parties supporting such requirements should propose specific examples of regulatory mechanisms that could be adopted.

69. Parties in the *AT&T Reclassification* proceeding asserted that carriers often do not offer discount rate plans ubiquitously, and that, as a result, interexchange customers in some rural and high cost areas are forced to pay the carriers' higher basic rates, while customers in other geographic areas can take advantage of the carriers' discount plans. These parties further asserted that this disparity amounts to geographic rate deaveraging. We seek comment on the extent to which providers of interexchange telecommunications services do not offer optional discount plans to subscribers in rural and high cost areas and, if so, the reasons for this practice. We also seek comment on whether an interexchange carrier's failure to make a promotional plan available in the entirety of its service area constitutes geographic deaveraging, and if so, whether we should require that discount rate plans be made available and advertised in the entirety of an interexchange telecommunications service provider's service area.

70. Finally, as noted above, in the *AT&T Reclassification* proceeding, AT&T made voluntary commitments related to geographic rate averaging. Specifically, AT&T committed to file any new geographically specific tariffs that depart from its traditional approach to geographic averaging for interstate residential direct dial services on five business days' notice. AT&T committed that such tariff transmittals will be clearly identified as affecting the provisions of the commitment. AT&T committed that ''[t]his will continue for three years unless the Commission adopts rules addressing this issue for all carriers or there is a change in federal law addressing this issue.'' We tentatively conclude that, given the specific limitation of AT&T's commitment on this issue, upon adoption of the foregoing proposed rules relating to geographic rate averaging, AT&T would be subject to those adopted rules, and would not be bound to the specific commitments it made with respect to geographic rate averaging. We seek comment on this tentative conclusion.

B. Rate Integration

71. As noted above, the 1996 Act also requires that the Commission adopt rules to require that providers of interstate, interexchange telecommunications services provide such services to their subscribers in each State at rates no higher than the rates charged to their subscribers in any other State (*i.e.*, that rates be integrated). As with geographic rate averaging, the Commission has long maintained a rate integration policy for interexchange rates between the forty-eight contiguous states and various non-contiguous United States regions, including Alaska, Hawaii, Puerto Rico and the U.S. Virgin Islands.

72. As required by the 1996 Act, and guided by the Conference Committee's statement to incorporate the policies contained in our *1976 Integration of Rates and Services Order,* we propose to adopt a rule requiring that ''a provider of interstate interexchange telecommunications services shall provide such services to its subscribers in each State at rates no higher than the rates charged to its subscribers in any other State.'' The Joint Explanatory Statement provides: ''[t]he conferees intend the Commission's rules to require geographic rate averaging and rate integration, and to incorporate the policies contained in the Commission's

proceeding entitled 'Integration of Rates and Services for the Provision of Communications by Authorized Common Carriers between the United States Mainland and the Offshore Points of Hawaii, Alaska and Puerto Rico/ Virgin Islands' (61 FCC 2d 380 (1976)).'' We seek comment on this proposed rule.

73. We note that the Communications Act, as amended, defines the term ''State'' as including ''the District of Columbia and the Territories and possessions.'' Accordingly, the 1996 Act extends rate integration to U.S. Territories and possessions, such as Guam and the Northern Mariana Islands, that currently are not subject to the Commission's domestic rate integration policy. The U.S. Virgin Islands and Puerto Rico are the only territories or possessions subject to the Commission's domestic rate integration policy at the present time. We seek comment on appropriate mechanisms to implement rate integration for U.S. territories and possessions that currently are not subject to the Commission's domestic rate integration policies. We note that currently pending before the Commission are three petitions to establish rulemakings to implement domestic rate integration policies for the Territory of Guam and the Commonwealth of the Northern Mariana Islands. *See* Governor's Office of the Territory of Guam Petition for Rulemaking to Integrate Rates, filed May 12, 1995, Public Notice, AAD 95–84 (rel. June 16, 1995); JAMA Corporation Petition for Rulemaking to Implement Domestic Rate Integration Policies for Guam, filed May 1, 1995, Public Notice, AAD 95–85 (rel. June 16, 1995); Commonwealth of the Northern Mariana Islands Petition for Rulemaking to Implement Domestic Rate Integration for the Commonwealth of the Northern Mariana Islands, filed June 7, 1995, Public Notice, AAD 95–86 (rel. June 16, 1995). We believe these petitions would become moot when we adopt the rules implementing new Section 254(g).

74. We tentatively conclude, in light of our proposal in this Notice to forbear from requiring non-dominant interexchange carriers to file tariffs, that it would not be in the public interest to attempt to enforce rate integration through the tariff process. Rather, we believe that we can ensure compliance with the proposed rate integration requirements by requiring providers of interstate, interexchange telecommunications services to file certifications stating that they are in compliance with their statutory rate integration obligations. Such a requirement would not impose a significant burden on such providers. Accordingly, we tentatively conclude that we should require providers of interstate, interexchange telecommunications services to file such certifications. We also tentatively conclude that we should rely on the complaint process under Section 208 to bring violations to our attention. We seek comment on these tentative conclusions. Parties challenging these tentative conclusions should suggest possible alternative enforcement mechanisms.

75. Finally, in the *AT&T Reclassification* proceeding, AT&T made voluntary commitments relating to service to and from the State of Alaska and other regions subject to our rate integration policy. Specifically, AT&T committed that it ''will continue to comply with all conditions and obligations contained in the various Commission orders regarding rate integration between the contiguous forty-eight states and the states of Alaska, Hawaii, Puerto Rico and the Virgin Islands, until or unless those orders are superseded by Congressional or Commission action.'' We tentatively conclude that, given the specific limitation of AT&T's commitment on this issue, upon adoption of the foregoing proposed rule relating to rate integration, AT&T would be subject to that rule, and would not be bound to the specific commitment it made with respect to rate integration. We seek comment on this tentative conclusion. We note that this tentative conclusion does not apply to AT&T's separate commitment to ''comply with all the conditions and obligations contained in the Commission orders associated with AT&T's purchase of Alascom, Inc.'' as that commitment is not limited in duration.

VII. Pricing Issues

76. Changes in the structure of the interexchange marketplace over the past decade have raised certain issues relating to the pricing of interexchange telecommunications services. In the *AT&T Reclassification* proceeding, a number of parties alleged that the interexchange market is characterized by oligopolistic price coordination, and that the reclassification of AT&T would lead to an increase in basic rates for domestic residential service. We address these issues in this section.

A. Allegations of Tacit Price Coordination

77. In the *AT&T Reclassification Order*, we found inconclusive and conflicting evidence in the record regarding the existence of alleged tacit price coordination among interexchange carriers for basic residential services, or residential services generally. We concluded that, if there were tacit price coordination in the interexchange market, the problem was generic to the industry and would be better addressed by removing regulatory requirements that may have facilitated such conduct. Our reclassification of AT&T as non-dominant removed one such regulatory requirement—the longer advance notice period applicable only to AT&T tariff filings. In addition, we believe that the 1996 Act provides the best solution to any problem of tacit price coordination, to the extent that it exists currently, by allowing for competitive entry in the interstate interexchange market by the facilities-based BOCs and others. Increasing the number of facilities-based carriers should make tacit price coordination more difficult. Moreover, we believe that the mandatory detariffing regime we propose in this Notice similarly will discourage price coordination by eliminating carriers' ability to ascertain their competitors' interstate rates and service offerings from publicly available tariffs filed with the Commission. We seek comment on these issues.

B. Residential Services Rate Plans

78. In order to alleviate concerns expressed in the *AT&T Reclassification* proceeding that rates for residential services would increase if AT&T were reclassified as non-dominant, AT&T voluntarily committed, for a period of three years, to offer two optional calling plans designed to mitigate the impact of future increases in basic schedule or residential rates. The first plan is targeted to low-income customers, and the second is targeted to low-volume consumers, but is generally available to all residential customers.

79. With respect to low-income customers, in our recent Notice of Proposed Rulemaking regarding implementation of the 1996 Act's universal service directives, we solicited comment ''on whether and how we should encourage domestic interstate interexchange carriers to provide optional calling plans for low-income consumers to promote the statutory [universal service] principles enumerated [in the 1996 Act].'' We anticipate resolving this issue in the Universal Service proceeding, but because the service is interstate in nature, we retain concurrent jurisdiction.

VIII. Bundling of Customer Premises Equipment

80. In 1980, the Commission adopted a rule prohibiting common carriers from bundling the provision of customer premises equipment (CPE) with the provision of common carrier telecommunications services. Carriers previously offered CPE as part of a package of services to subscribers. Changes in the industry, in particular the advent of competitive CPE vendors, led the Commission to conclude that carriers' continued bundling of telecommunications services with CPE could force customers to purchase unwanted CPE in order to obtain necessary transmission services, thus restricting customer choice and retarding the development of a competitive CPE market. It therefore required carriers to separate the provision of CPE from the provision of transmission services. Section 64.702(e) of our rules provides: ''Except as otherwise ordered by the Commission, after March 1, 1982, the carrier provision of customer-premises equipment used in conjunction with the interstate telecommunications network shall be separate and distinct from provision of common carrier communications services and not offered on a tariffed basis.''

81. The Commission recognized, however, that ''[i]f the markets for components of [a] commodity bundle are workably competitive, bundling may present no major societal problems so long as the consumer is not deceived concerning the content and quality of the bundle.'' It further acknowledged that some consumers may believe that bundled offerings can reduce transaction costs to customers. Bundling can also enable market participants to compete more effectively by offering attractive sales packages.

82. Since the adoption of the rule prohibiting CPE bundling in 1980, significant changes have occurred in the markets for CPE and interstate long-distance services. The CPE market is now widely recognized to be fully competitive. In the *AT&T Reclassification Order,* we found that AT&T no longer possesses market power in the overall interstate, domestic, interexchange market. Moreover, in the *Interexchange Competition Proceeding,* we concluded that the business services market was ''substantially competitive.''

83. The Supreme Court has stated that the essential characteristic of an illegal tying or bundling arrangement ''lies in the seller's exploitation of its control over [one] product to force the buyer into the purchase of a [second] product that the buyer either did not want at all or might have preferred to purchase elsewhere on different terms.'' Under the ''leverage theory'' of tying, ''tying provides a mechanism whereby a firm with monopoly power in one market can use the leverage provided by this power to foreclose sales in, and thereby monopolize, a second market.''

84. Based on our earlier findings regarding competition in both the CPE and interstate, interexchange services markets, we tentatively conclude that it is unlikely that non-dominant interexchange carriers can engage in the type of anticompetitive conduct that led the Commission to prohibit the bundling of CPE with the provision, *inter alia,* of interstate, interexchange services. We also tentatively conclude that allowing non-dominant interexchange carriers to bundle CPE with interstate, interexchange services would promote competition by allowing such carriers to create attractive service/equipment packages for customers. Accordingly, we tentatively conclude that we should amend Section 64.702(e) of the Commission's rules to allow non-dominant interexchange carriers to bundle CPE with interstate, interexchange services. We seek comment on these tentative conclusions.

85. Parties that believe we should amend Section 64.702(e) should also comment on whether we should require interexchange carriers offering bundled packages of CPE and interstate, interexchange services to continue to offer separately, unbundled interstate, interexchange services on a nondiscriminatory basis. We note that the U.S. Government has committed in the Uruguay Round Agreements of the General Agreement on Tariffs and Trade, to ensure, among other things, that ''service suppliers'' are permitted ''to purchase or lease and attach terminal or other equipment which interfaces with the [public telecommunications transport] network and which is necessary to supply a supplier's service. . . .'' *See* Uruguay Round Agreements Act of 1994, Pub. L. No. 103–465, Section 801, 108 Stat. 4809 (1994) (to be codified at 47 U.S.C. § 309(j)(13)). ''Service supplier'' is defined to mean a supplier of any service in any sector except services supplied in the exercise of governmental authority. We seek comment on whether this commitment implies that interexchange carriers should be required to offer separately, unbundled interstate, interexchange services on a nondiscriminatory basis if they are permitted to bundle CPE with the provision of interstate, interexchange services.

86. Parties that believe that we should not amend Section 64.702(e) as proposed should set forth specific reasons in support of their position. We also seek comment on the effect that the proposed amendment of Section 64.702(e) would have on our other policies or rules. We believe that our tentative conclusions regarding CPE bundling are consistent with our nation's foreign trade policy that seeks to promote, in trade negotiations with other countries, the unbundling of telecommunications services and CPE in certain international markets where monopoly providers may exist in either the services or CPE market. As described above, our domestic CPE and interstate, domestic, interexchange markets are both subject to competition, thus we believe that the potential for anticompetitive bundling behavior is highly unlikely in the U.S. market. Finally, we seek comment on whether and how the anticipated entry of local exchange carriers, in particular the BOCs, into the market for interstate, interexchange services should affect our analysis.

87. We note that we intend to initiate a comprehensive proceeding to address payphone issues, and to implement the sections of the 1996 Act relating to the provision of payphone service. In that proceeding, we intend to consider the issue of bundling of pay telephone equipment with underlying transmission capacity. Accordingly, any amendment to Section 64.702(e) of our rules adopted in this proceeding will not apply to payphone bundling.

IX. Other Issues

88. For reasons set forth above, we have tentatively concluded that we are required to forbear from requiring non-dominant interexchange carriers to file tariffs, and that such detariffing should be mandatory. In the *AT&T Reclassification* proceeding, commenters raised certain issues regarding contract tariffs. We deferred consideration of those issues to this proceeding because we found those issues were unrelated to the determination of whether AT&T possessed market power. We note that these issues will largely be mooted if, as proposed above, we adopt a mandatory detariffing policy. We examine those and other tariff-related issues here, however, because such issues will remain relevant if we determine not to forbear from requiring non-dominant interexchange carriers to file tariffs. In addition, if we determine to adopt a policy of permissive detariffing, it is possible that some carriers will choose

to continue to file tariffs, including contract tariffs.

89. In the *First Interexchange Competition Order,* the Commission established its contract carriage regime under which interexchange carriers are permitted to offer services pursuant to individually negotiated contracts. The Commission further found that, as long as all contracts were made generally available to similarly situated customers under substantially similar circumstances, the offering of individually-negotiated contracts for interexchange services under the contract carriage regime would comply with the nondiscrimination provisions of the Communications Act. The Commission later found that the ''contract carriage policy serves the public interest by enabling users to purchase services that match their needs in particular ways and by facilitating user and interexchange carrier planning by increasing the availability of long-term commitments and price protection.''

90. The Title II statutory scheme permits carriers to make changes to their tariffs. Moreover, it is well established that, pursuant to the ''filed rate doctrine,'' in a situation where a filed tariff rate differs from a rate set in a non-tariffed carrier-customer contract, the carrier is required to assess the tariff rate. Consequently, if a carrier unilaterally changes a rate by filing a tariff revision, the newly filed rate becomes the applicable rate unless the revised rate is found to be unjust, unreasonable, or unlawful under the Communications Act.

91. In the *RCA Americom Decisions,* the Commission recognized that a dominant carrier's proposal ''to modify extensively a long term service tariff may present significant issues of reasonableness under Section 201(b) that are not ordinarily raised in other tariff filings.'' Accordingly, the Commission held that a dominant carrier's unilateral tariff revisions that alter material terms and conditions of a long-term service tariff will be considered reasonable only if the carrier can make a showing of ''substantial cause'' for the revision. The Commission has stated that the substantial cause test would apply to unilateral changes by dominant carriers to long-term contract tariffs. In the *February 1995 Interexchange Reconsideration Order,* 60 FR 13637 (March 14, 1995), the Commission indicated that the substantial cause test would also apply to unilateral tariff modifications made by non-dominant carriers.

92. In the *February 1995 Interexchange Reconsideration Order,* we indicated that commercial contract law was highly relevant in assessing the reasonableness of a unilateral tariff revision, but we declined to declare that contract law principles constituted the sole and dispositive basis for a substantial cause showing. We seek comment on whether commercial contract law principles should be the sole criterion in applying the substantial cause test. If not, parties should suggest other factors that the Commission should consider in evaluating whether a carrier has shown substantial cause for unilaterally changing a contract tariff. We also seek comment on whether the substantial cause test should apply only to the carrier and the customer with whom it negotiated the original contract, or whether it also should apply to subsequent customers who take service under the contract tariff. We note that, in the *February 1995 Interexchange Reconsideration Order,* we stated that in applying the substantial cause test, we would consider whether the original tariff terms were the product of negotiation and mutual agreement. Commenters arguing that the substantial cause test should apply only to the initial customer, should explain how this position is consistent with the nondiscrimination requirements of Section 202 of the Communications Act. In addition, in cases in which the Commission determines that a carrier has established substantial cause for a unilateral change to a contract tariff, we seek comment on whether the modified contract tariff should be treated as a new contract tariff and should be made available to other similarly situated customers.

93. The *Mobile-Sierra* doctrine established a strict ''public interest'' standard that a carrier must meet before a regulatory agency can accept a superseding tariff that modifies the terms of a negotiated carrier-to-carrier contract. *See United Gas Pipe Line Co. v. Mobile Gas Service Corp.*, 350 U.S. 332 (1956) (*Mobile*); *FPC v. Sierra Pacific Power Co.,* 350 U.S. 348 (1956) (*Sierra*). In *Bell Telephone Company of Pennsylvania v. FCC,* 503 F.2d 1250 (3rd Cir. 1974), *cert. denied,* 422 U.S. 1026 (1975), *rehearing denied,* 423 U.S. 886 (1975), the U.S. Court of Appeals for the Third Circuit, applying the *Mobile-Sierra* doctrine, held that a common carrier could not abrogate a contract with another carrier simply by filing superseding tariffs. We seek comment on the relationship between the substantial cause test and the *Mobile-Sierra* doctrine in cases where a carrier attempts through a tariff revision to abrogate an underlying carrier-to-carrier contract.

94. In the *AT&T Reclassification* proceeding, resellers raised various issues concerning contract tariffs. Several commenters argued that resellers and other large customers need protection from the ability of carriers to revise unilaterally contract-based service arrangements. AT&T made certain transitional voluntary commitments, for a period of twelve months, in order to alleviate those concerns on an interim basis. Commenters proposed, among other things, that the Commission require carriers to: give customers advance notice of any tariff filing that materially alters negotiated agreements; obtain the consent of all affected customers before making such a filing; treat the lack of consent to a proposed tariff change as *prima facie* evidence of its unlawfulness; allow any non-consenting customer either to terminate its service arrangement without liability or to enforce the unchanged term; and provide a reasonable period of rate stability to permit service migration if the customer chooses to terminate its service agreement. We seek comment on the above proposals. In addition, we tentatively conclude that AT&T should remain subject to its voluntary commitments concerning unilateral changes to contract tariffs, regardless of what action we take in this proceeding with respect to the foregoing proposals. We seek comment on this tentative conclusion.

95. Parties in the *AT&T Reclassification* proceeding also argued that the ability of non-dominant carriers to file unilateral tariff modifications on one day's notice effectively precludes customers from challenging such revisions before they become effective. We seek comment on whether we should require a longer notice period for tariff filings that materially revise long-term service or contract tariffs, and if so, what notice period should be established. We also seek comment on whether a carrier should be required to identify clearly tariff filings that unilaterally alter existing long-term service or contract tariffs.

96. Resellers have also complained that ordering procedures are used to prevent them from subscribing to contract tariffs. Accordingly, we seek comment on whether specific ordering procedures should be allowed to be incorporated in contract tariffs (*i.e.,* when is an order placed, what documents must a customer file, when must a customer identify locations that

it will include in the plan). Resellers also complain that carriers use narrowly circumscribed customer descriptions in order to prevent resellers from taking service under contract-based tariffs. We seek comment on what is an appropriate level of specificity for customer descriptions that are used by carriers to determine eligibility under a contract tariff. We also seek comment on whether there are certain terms that should be prohibited as unreasonable (*e.g.*, extremely large upfront deposits from the customer).

97. Finally, in the *AT&T Reclassification* proceeding, we indicated that we would in the future ''initiate a new proceeding to identify specific areas of the interstate, domestic, interexchange market that may raise policy concerns, and if there are any, to seek comment on possible remedies.'' Further, we noted that we would monitor closely the areas in which AT&T had made voluntary commitments in order to protect consumers. Should parties wish to raise issues in this proceeding with regard to these issues, we encourage parties to comment.

X. Procedural Issues

A. Ex Parte Presentations

98. This is a non-restricted notice-and-comment rulemaking proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided that they are disclosed as provided in the Commission's rules. *See generally* 47 CFR §§ 1.1202, 1.1203, 1.1206.

B. Initial Regulatory Flexibility Analysis

99. Pursuant to the Regulatory Flexibility Act of 1980, 5 U.S.C. §§ 601–612, the Commission's Initial Regulatory Flexibility Analysis with respect to the Notice of Proposed Rulemaking is as follows:

100. *Reason for Action:* The Commission is issuing this Notice of Proposed Rulemaking to review our regulatory regime for interstate, domestic, interexchange telecommunications services, and to implement certain provisions of the 1996 Act.

101. *Objectives:* The objective of the Notice of Proposed Rulemaking is to provide an opportunity for public comment and to provide a record for a Commission decision on the issues stated above.

102. *Legal basis:* The Notice of Proposed Rulemaking is adopted pursuant to Sections 1, 2, 4, 201–205, 215, 218 and 220 of the Communications Act of 1934, as amended, 47 U.S.C. §§ 151, 152, 154, 201–205, 215, 218 and 220.

103. *Description, potential impact, and number of small entities affected:* Any rule changes that might occur as a result of this proceeding could impact entities which are small business entities, as defined in Section 601(3) of the Regulatory Flexibility Act. After evaluating the comments in this proceeding, the Commission will further examine the impact of any rule changes on small entities and set forth findings in the Final Regulatory Flexibility Analysis. The Secretary shall send a copy of this Notice of Proposed Rulemaking to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 603(a) of the Regulatory Flexibility Act, Pub. L. No. 96–354, 94 Stat. 1164, 5 U.S.C. § 601, *et seq.* (1981).

014. *Reporting, recordkeeping and other compliance requirement:* The proposed rules would require non-dominant interexchange carriers to retain business records containing price and service information regarding their interstate, domestic, interexchange offerings. The proposed rules also would require providers of interexchange services to certify their compliance with their statutory geographic rate averaging obligations, and providers of interstate, interexchange services to certify their compliance with their statutory rate integration obligations.

105. *Federal rules which overlap, duplicate or conflict with the Commission's proposal:* None.

106. *Any significant alternatives minimizing impact on small entities and consistent with stated objectives:* The Notice of Proposed Rulemaking solicits comments on alternatives.

107. *Comments are solicited:* Written comments are requested on this Initial Regulatory Flexibility Analysis. These comments must be filed in accordance with the same filing deadlines set for comments on the other issues (other than those in Sections IV, V, and VI) in this Notice of Proposed Rulemaking but they must have a separate and distinct heading designating them as responses to the Regulatory Flexibility Analysis. The Secretary shall send a copy of the Notice to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 603(a) of the Regulatory Flexibility Act, 5 U.S.C. § 601, *et seq.*

C. Initial Paperwork Reduction Act of 1995 Analysis

108. This Notice contains either a proposed or modified information collection. As part of its continuing effort to reduce paperwork burdens, we invite the general public and the Office of Management and Budget (OMB) to take this opportunity to comment on the information collections contained in this Notice, as required by the Paperwork Reduction Act of 1995, Pub. L. No. 104–13. Public and agency comments are due April 19, 1996; OMB comments are due June 3, 1996. Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

D. Comment Filing Procedures

109. Pursuant to applicable procedures set forth in Sections 1.415 and 1.419 of the Commission's rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments on Sections IV, V, and VI, on or before April 19, 1996, and reply comments on Sections IV, V, and VI on or before May 3, 1996. Interested parties may file comments on all other sections of this Notice on or before April 25, 1996, and reply comments on or before May 24, 1996.

110. To file formally in this proceeding, parties must file an original and six copies of all comments, reply comments, and supporting comments. Parties wanting each Commissioner to receive a personal copy of their comments, must file an original and eleven copies. Comments and reply comments should be sent to Office of the Secretary, Federal Communications Commission, 1919 M Street, N.W., Room 222, Washington, D.C. 20554, with a copy to Janice Myles of the Common Carrier Bureau, 1919 M Street, N.W., Room 544, Washington, D.C. 20554. Parties should also file one copy of any documents filed in this docket with the Commission's copy contractor, International Transcription Services, Inc., 2100 M Street, N.W., Suite 140, Washington, D.C. 20037. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, 1919 M Street, N.W., Room 239, Washington, D.C. 20554.

111. In order to facilitate review of comments and reply comments, both by parties and by Commission staff, we require that comments submitted on Sections IV, V, and VI, be no longer than

45 pages and reply comments on those sections be no longer than 25 pages. We require that comments on the remaining sections of this Notice be no longer than 45 pages and reply comments on the remaining sections be no longer than 25 pages.

112. Comments and reply comments on *all* sections of this Notice must include a short and concise summary of the substantive arguments raised in the pleading. Comments and reply comments must also comply with Section 1.49 and all other applicable sections of the Commissions Rules. *See* 47 CFR § 1.49. However, we require here that a summary be included with all comments and reply comments, regardless of length. The summary may be paginated separately from the rest of the pleading (*e.g.*, as ''i, ii''). *See* 47 CFR § 1.49.

113. Parties are also asked to submit comments and reply comments on diskette. Such diskette submissions would be in addition to and not a substitute for the formal filing requirements addressed above. Parties submitting diskettes should submit them to Janice Myles of the Common Carrier Bureau, 1919 M Street, N.W., Room 544, Washington, D.C. 20554. Such a submission should be on a 3.5 inch diskette formatted in an IBM compatible form using MS DOS 5.0 and WordPerfect 5.1 software. The diskette should be submitted in ''read only'' mode. The diskette should be clearly labelled with the party's name, proceeding, type of pleading (comment or reply comments) and date of submission. The diskette should be accompanied by a cover letter.

114. Written comments by the public on the proposed and/or modified information collections are due April 19, 1996. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed and/or modified information collections on or before 60 days after date of publication in the Federal Register. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Dorothy Conway, Federal Communications Commission, Room 234, 1919 M Street, N.W., Washington, DC 20554, or via the Internet to dconway@fcc.gov and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725—17th Street, N.W., Washington, DC 20503 or via the Internet to fain—t@al.eop.gov.

E. Ordering Clauses

115. Accordingly, it is ordered that pursuant to Sections 1, 4, 10, 201–205, 214(e), 215, 218, 220 and 254 of the Communications Act of 1934, as amended, 47 U.S.C. §§ 151, 154, 201–205, 214(e), 215, 218 and 220 a notice of proposed rulemaking is hereby adopted.

116. It is further ordered that, the Secretary shall send a copy of this notice of proposed rulemaking, including the regulatory flexibility certification, to the Chief Counsel for Advocacy of the Small Business Administration, in accordance with paragraph 603(a) of the Regulatory Flexibility Act, 5 U.S.C. §§ 601 *et seq.* (1981).

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96–8116 Filed 4–2–96; 8:45 am]

BILLING CODE 6712–01–P

47 CFR Part 73

[MM Docket No. 96–65; RM–8773]

Radio Broadcasting Services; Kiowa, KS

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Kiowa Broadcasters requesting the allotment of Channel 252C1 to Kiowa, Kansas. Channel 252C1 can be allotted to Kiowa in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 252C1 at Kiowa are 37–01–00 and 98–29–12.

DATES: Comments must be filed on or before May 21, 1996, and reply comments on or before June 5, 1996.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Leonard Johnson, III, Kiowa Broadcasters, 218 Carriage Place Court, Decatur, Georgia 30033 (Petitioner).

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MM Docket No. 96–65, adopted March 14, 1996, and released March 29, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC'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 contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 96–8122 Filed 4–2–96; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR PART 393

[FHWA Docket No. MC–96–5]

RIN 2125–AD76

Parts and Accessories Necessary for Safe Operation: Television Receivers and Data Display Units

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA is proposing to rescind restrictions on the locations at which television viewers or screens may be positioned within commercial motor vehicles (CMVs). Under the President's Regulatory Reinvention Initiative, the FHWA has reviewed the Federal Motor Carrier Safety Regulations (FMCSRs) and believes the restrictions to be obsolete and redundant. The unsafe behavior that the regulation is intended to discourage is more effectively deterred through State traffic laws concerning driver inattentiveness. Further, the current regulation may have the unintended effect of discouraging the use of certain Intelligent Transportation Systems (ITS)-related

technologies such as collision-avoidance and traveler information systems which could be used to improve safety and efficiency of CMV operations.

DATES: Written comments must be received on or before June 3, 1996.

ADDRESSES: Submit written, signed comments to FHWA Docket No. MC–96–5, Room 4232, HCC–10, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Larry W. Minor, Office of Motor Carrier Research and Standards, HCS–10, (202) 366–4009; or Mr. Charles E. Medalen, Office of the Chief Counsel, HCC–20, (202) 366–1354, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

On January 3, 1951, after conferences with representatives of the motor carrier industry to discuss the need for revisions to the Federal Motor Carrier Safety Regulations (FMCSRs) and consultations with Federal and State agencies, technical societies and other experts, the Interstate Commerce Commission (ICC) published a comprehensive notice of proposed rulemaking (NPRM) (16 FR 23).

The NPRM included a section on television receivers. The ICC proposed that any commercial motor vehicle equipped with a television viewer, screen or other means of visually receiving a television broadcast be required to have the viewer or screen located at a point to the rear of the driver's seat if the device is in the driver's compartment. Further, the viewer or screen could not be visible to the driver while the vehicle is being operated. The television controls would have to be located so they could not be operated from the driver's seat. The NPRM did not discuss this section, but the proposal was apparently intended to prevent a potential problem from becoming a reality. It is unlikely that any significant number of television receivers had been installed in trucks by the early 1950's.

On May 15, 1952, the ICC published a final rule adopting the proposed restrictions on television receivers, along with many other new or revised regulations (17 FR 4422). The ICC report on the final rule amounted to a preamble, but, like the NPRM, it failed to explain why the television provision was necessary (54 M.C.C. 337, April 14, 1952). The regulation has not been amended since 1952.

Regulatory Reinvention

As part of the President's Regulatory Reinvention Initiative, the FHWA has reviewed the FMCSRs and believes that § 393.88 is obsolete and redundant. At the time is was adopted, the ICC apparently believed that the absence of a Federal requirement would tempt drivers or motor carriers to install receivers that operators could watch while driving. This concern has not been borne out, and was probably unrealistic even in 1952. Television broadcasts are designed to be visually attractive and therefore have an enormous potential to distract the driver. For that very reason, however, motor carriers recognize the inherent safety risks of allowing drivers to watch television while driving, which would make them far more susceptible to accidents that could be avoided by watching the road and other vehicles. There is no reason to believe that § 393.88 has any beneficial effect on the behavior of drivers or motor carriers.

The behavior that § 393.88 is intended to address, driver inattentiveness, is effectively covered by State laws. Accidents attributed to driver inattentiveness are generally cited by State officials as a failure to maintain control of the vehicle, with a brief description of the activity with which the driver was preoccupied. Therefore, State's have a legal means to cite commercial motor vehicle drivers for failing to pay attention to their driving tasks.

In addition to being obsolete, the regulation may have the unintended effect of discouraging the use of certain ITS-related technologies such as collision-avoidance and traveler information systems which could be used to improve the safety and efficiency of CMV operations. These systems may include the use of in-vehicle display screens which provide real-time displays of areas of traffic congestion, construction, and accidents on maps which may be viewed by the driver while the vehicle is being operated. Some satellite communications systems enable motor carriers to track CMVs en route to a destination and to transmit written messages to drivers that appear on video terminals in the cab. Also, some collision avoidance/warning systems display video images of traffic around the CMV.

On November 17, 1993 (58 FR 60734, 60757), the FHWA published regulatory guidance on the applicability of § 393.88 to closed circuit monitoring devices used as safety viewing systems to prevent certain types of accidents between passenger cars and CMVs. The regulatory guidance indicated that § 393.88 is not applicable if the system cannot receive television broadcasts or be used for the viewing of video tapes.

More recently the FHWA has received a number of requests for regulatory guidance on the applicability of § 393.88 to other configurations of display units that may be viewed by the driver while the vehicle is being operated. Some of these systems have functions which could be considered inconsistent with the intent of § 393.88 in that the systems may be capable of displaying information or video images that are not associated with collision avoidance or other ITS concepts.

The FHWA believes that case-by-case regulatory guidance on the many different configurations of in-cab video display systems would be burdensome, confusing, and ineffective at ensuring safety. It would not be in the best interest of the manufacturers of these systems, the motor carrier industry, or the agency. Further, the regulatory guidance process, if applied to each make and model of in-cab displays, would become a *de facto* design approval program. Equipment manufacturers, motor carriers, and CMV drivers are capable of working together to design and develop in-cab information systems using the most cost-effective technology and resources to facilitate improvements in the safety and efficiency of CMV operations. The effectiveness of this approach would be greatly enhanced by the removal of § 393.88.

This rulemaking is not intended to encourage motor carriers to install display screens for entertainment purposes or otherwise reduce the safety of operation of commercial motor vehicles. Rather, it is the intent of this rulemaking to eliminate a Federal regulation that does not ensure a level of safety greater than that provided by State laws, and to remove regulatory obstacles to the use of ITS-related technologies.

Rulemaking Analyses and Notices

All comments received before the close of business on the comment closing date indicated above will be

considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable, but the FHWA may issue a final rule at any time after the close of the comment period. In addition to late comments, the FHWA will also continue to file in the docket relevant information that becomes available after the comment closing date, and interested persons should continue to examine the docket for new material.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has considered the impacts of this document and has determined that it is neither a significant rulemaking action within the meaning of Executive Order 12866 nor a significant rulemaking under the regulatory policies and procedures of the Department of Transportation. The rulemaking would amend part 393 of the FMCSRs by removing an obsolete regulation. It is anticipated that the economic impact of this rulemaking will be minimal. Therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this rule on small entities. Based upon this evaluation, and for the reasons set forth in the preceding paragraph, the FHWA certifies that this rule would not have a significant economic impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This document does not contain information collection requirements for the purposes of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq*).

National Environmental Policy Act

The agency has analyzed this rulemaking for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 393

Highway safety, Highways and roads, Motor carriers, Motor vehicle safety.

Issued on: March 26, 1996.

Rodney E. Slater,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA proposes to amend title 49, Code of Federal Regulations, subchapter B, chapter III, as follows:

PART 393—[AMENDED]

1. The authority citation for part 393 continues to read as follows:

Authority: Section 1041(b) of Pub. L. 102–240, 105 Stat. 1914, 1993 (1991); 49 U.S.C. 31136 and 31502; 49 CFR 1.48.

§ 393.88 [Removed and Reserved]

2. Section 393.88 is removed and reserved.

[FR Doc. 96–8179 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–22–P

Surface Transportation Board

49 CFR Parts 1100 through 1149

[STB Ex Parte No. 527]

Expedited Procedures for Processing Rail Rate Reasonableness, Exemption and Revocation Proceedings; Correction

AGENCY: Surface Transportation Board.

ACTION: Advance notice of proposed rulemaking; correction.

SUMMARY: This document contains corrections to the advance notice of proposed rulemaking that was published Friday, March 22, 1996, at 61 FR 11799. In that notice the Board solicited comments on how existing regulations could be modified to expedite the handling of rail rate reasonableness and exemption/revocation proceedings.

FOR FURTHER INFORMATION CONTACT: Thomas J. Stilling, (202) 927–7312. [TDD for the hearing impaired: (202) 927–5721.]

Accordingly, the publication on March 22, 1996 of the advance notice of proposed rulemaking [STB Ex Parte No. 527] which was the subject of FR Doc. 96–6986, is corrected as follows:

1. On page 11799, 3rd column, in the heading of the document, the CFR citation should read as set forth above.

2. On page 11799, 3rd column, in the **SUMMARY,** lines 14–15, the reference to ''49 CFR Parts 1000 through 1149'' should read ''49 CFR Parts 1100 through 1149''.

3. On page 11800, 2nd column, 5th paragraph of **SUPPLEMENTARY INFORMATION,** lines 5–6, the reference to ''49 CFR 1000 through 1129'' should read ''49 CFR 1100 through 1129''.

Vernon A. Williams,

Secretary.

[FR Doc. 96–8014 Filed 4–2–96; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 646

[I.D. 032596D]

Snapper Grouper Fishery of the South Atlantic; Public Scoping Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Public scoping meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) is holding a public scoping meeting to solicit comments on the sale of fish (all species) caught under the recreational bag limits established by the Council's fishery management plans (FMPs). The public scoping meeting will be held in conjunction with the Council's public meetings to be held April 8–12, 1996.

DATES: The public scoping meeting is scheduled to begin at 6:30 p.m. on Tuesday, April 9, 1996, and will end when all business is completed.

ADDRESSES: The public scoping meetings will be held at the Comfort Inn Island Suites, 711 Beachview Drive, Jekyll Island, GA; telephone: (912) 635-2211.

Requests for copies of the public scoping document should be sent to the Council at the following address: South Atlantic Fishery Management Council; One Southpark Circle, Suite 306; Charleston, SC 29407-4699.

FOR FURTHER INFORMATION CONTACT: Susan Buchanan, Public Information Officer; telephone: (803) 571-4366; fax (803) 769-4520.

SUPPLEMENTARY INFORMATION: At the scoping meeting, comments will be solicited on the sale of fish caught under the recreational bag limits for all species as established by the Council's FMPs. The Council has considered this issue on numerous occasions over the past several years, and both commercial and recreational fishermen have expressed concern about this matter. Currently, all of the Council's FMPs allow for the sale of fish taken in a legal bag limit. The issue regarding the sale of fish caught under bag limits involves several considerations including: (1) The definitions of recreational and commercial fisherman; (2) the ethical question of a ''recreational'' fisherman selling his catch; and (3) the impacts of selling fish caught under a recreational bag limit on an established commercial quota for the same species. The Council will consider prohibiting the sale of fish caught by recreational fishermen. The Council is inviting, and will consider, the views of recreational and commercial fishermen and other interested persons on this matter prior to taking any formal and final action. The Council is particularly interested in hearing about the possible impacts of prohibiting the sale of recreationally caught fish.

Written public comments on the subject of the scoping meeting, as well as on any Council scoping documents made available to the public, may be submitted to the Council from the time of the scoping meeting until such time as the Council has prepared appropriate public hearing documents that are available for public comment. For copies of the public scoping documents, see **ADDRESSES**.

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office by April 3, 1996, (see **ADDRESSES**).

Authority: 16 U.S.C. 1801 *et. seq.*

Dated: March 28, 1996.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96–8178 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 61, No. 65
Wednesday, April 3, 1996

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ASSASSINATION RECORDS REVIEW BOARD

Sunshine Act Meeting

DATE: April 16–17, 1996.
PLACE: ARRB, 600 E Street, NW., Washington, DC.
STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Review and Accept Minutes of Closed Meeting
2. Review of Assassination Records
3. Other Business

CONTACT PERSON FOR MORE INFORMATION: Thomas Samoluk, Associate Director for Communications, 600 E Street, NW., Second Floor, Washington, DC 20530. Telephone: (202) 724–0088; Fax: (202) 724–0457.

David G. Marwell,
Executive Director.
[FR Doc. 96–8394 Filed 4–1–96; 4:10 pm]
BILLING CODE 6118–01–M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Ohio 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 Ohio Advisory Committee to the Commission will convene at 9:00 a.m. and adjourn at 5:00 p.m. on Tuesday, April 30, 1996, at the Courtyard Marriott, 35 W. Spring Street, Columbus, Ohio 43215. The purpose of the meeting is to hold an Ohio Consultation: Focus on Affirmative Action.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Grace Ramos, 614–466–6715, or Constance M. Davis, Director of the Midwestern Regional Office, 312–353–8311 (TDD 312–353–8362). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) 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, March 26, 1996.
Carol-Lee Hurley,
Chief, Regional Programs Coordination Unit.
[FR Doc. 96–8060 Filed 4–2–96; 8:45 am]
BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted the following collection requirement to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. An emergency clearance is being requested with a response date of April 4, 1996, from OMB.

Agency: National Oceanic and Atmospheric Administration (NOAA).
Title: Notice for Filing Statement of Claims and Recommendations Under Public Law 104–91.
Agency Number: None.
OMB Number: None.
Type of Request: New Collection—EMERGENCY PROCESSING REQUESTED.
Burden: 328 hours.
Number of Respondents: 50.
Avg. Hours Per Response: Ranges between 2 and 40 hours.
Needs and Uses: On January 6, 1996, President Clinton signed Public Law 104–91. This legislation directs the Secretary of Commerce to prepare a report for Congress which proposes necessary actions to resolve all federal responsibilities on the Pribilof Islands. In order to include the claims and recommendations of local entities and residents, NOAA needs to collect certain information directly from them. The information will be used to prepare the report and identify the types of claims against the U.S. Government.
Affected Public: Individuals, businesses or other for-profit institutions, not-for-profit institutions, federal government, state, local or tribal government.
Frequency: One-time.
Respondent's Obligation: Required to obtain a benefit.
OMB Desk Officer: Victoria Wassmer, (202) 395–7340.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC's Acting Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent to Victoria Wassmer, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, D.C. 20503.

Dated: March 28, 1996.
Linda Engelmeier,
Acting Departmental Forms Clearance Officer, Office of Management and Organization.
[FR Doc. 96–8075 Filed 4–2–96; 8:45 am]
BILLING CODE 3510–12–P

Bureau of the Census

Current Industrial Reports Surveys—WAVE III (Voluntary and Mandatory Submissions)

ACTION: Proposed agency information collection activity; 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 June 3, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting 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:

Food, Textiles & Apparel and Wood and Chemical Products—Michael

Zampogna, (301) 457–4810, Bureau of Census, Manufacturing & Construction Division, Room 2212, Building 4, Washington, DC 20233.

Electrical & Transportation and Metals and Industrial Machinery—Kenneth Hansen, (301) 457–4755, Bureau of Census, Manufacturing & Construction Division, Room 2207, Building 4, Washington, DC 20233.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau conducts a series of monthly, quarterly, and annual surveys as part of the Current Industrial Reports (CIR) program. The CIR program includes both mandatory and voluntary surveys. Typically the monthly and quarterly surveys are conducted on a voluntary basis. Those companies that choose not to respond to the voluntary surveys are required to submit a mandatory annual counterpart. The annual counterpart collects annual data from those firms not participating in the more frequent collection. These surveys provide continuing and timely national statistical data on manufacturing. The results of these surveys are used extensively by individual firms, trade associations, and market analysts in planning or recommending marketing and legislative strategies. The CIR's deal mainly with the quantity and value of shipments of particular products and occasionally with data on production and inventories; unfilled orders, receipts, stocks and consumption; and comparative data on domestic production, exports, and imports of the products they cover.

Due to the large number of surveys in the CIR program, for clearance purposes we group the surveys into three Waves. The mandatory and voluntary surveys in each Wave are separately submitted. Thus, a total of six clearances cover all of the surveys in the CIR program. One Wave is submitted for reclearance each year. This year the Census Bureau plans to submit mandatory and voluntary surveys of Wave III for clearance. The surveys in Wave III are as follows:

Mandatory Surveys

MA23D—Gloves and Mittens
MA32E—Consumer, Scientific, Technical, and Industrial Glassware
MA35A—Farm Machinery and Lawn and Garden Equipment
MA35D—Construction Machinery
MA35F—Mining Machinery MA35J—Selected Pollution Control Equipment MA35M—Air Conditioning and Refrigeration Equipment
MQ22T—Broadwoven Fabrics (Gray)

Voluntary Surveys

M33D—Aluminum Ingot and Mill Products MA20D—Confectionery MA35U—Vending Machines

II. Method of Collection

The Census Bureau will use mail out/mail back survey forms to collect data. We ask respondents to return monthly report forms within 10 days, quarterly report forms within 15 days, and annual report forms within 30 days of the initial mailing. Telephone calls and/or letters encouraging participation will be mailed to respondents that have not responded by the designated time.

III. Data

OMB Number: 0607–0476—Mandatory Surveys; 0607–0776—Voluntary Surveys.

Form Number: M33D, MQ22T, MA20D, MA23D, MA32E, MA35A, MA35D, MA35F, MA35J, MA35M and MA35U.

Type of Review: Regular Review.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: Mandatory Surveys—3,207; Voluntary Surveys—904.

Estimated Time Per Response: Mandatory Surveys—1.33 hrs; Voluntary Surveys—2.96 hrs.

Estimated Total Annual Burden Hours: Mandatory Surveys—4,253; Voluntary Surveys—2,679.

Estimated Total Annual Cost: The estimated cost of the CIR program for fiscal year 1996 is $4.2 million.

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: March 26, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 96–7781 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–07–P

Current Population Survey (CPS) Basic Demographic Survey

ACTION: Proposed agency information collection activity; 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: Submit written comments on or before June 3, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting 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 Julia Williams, Bureau of the Census, FOB 3, Room 3340, Washington, DC 20233–8400, (301) 457–3806.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau is requesting clearance for the monthly collection of demographic data through the CPS. The current clearance expires December 31, 1996. Title 13, United States Code, Section 182 authorizes collection of selected demographic data in the CPS. In accordance with the Office of Management and Budget's (OMB) request, the Census Bureau and Bureau of Labor Statistics (BLS) divide the clearance request in order to reflect the joint sponsorship and funding of the CPS program. This proposal covers the collection of the CPS demographic information. BLS will submit a separate proposal to cover the collection of labor-force information in the CPS.

The demographic information provides a unique set of data on selected characteristics for the civilian noninstitutional population. Some of the demographic information we collect are: age, marital status, sex Armed

Forces status, education, race, origin, and family income. We use these data in conjunction with other data, particularly the monthly labor-force data, as well as periodic supplement data. We use these data also independently for internal analytic research and for evaluation of other surveys.

II. Method of Collection

The demographic information will be collected by both personal visit and telephone interviews in conjunction with the regular monthly CPS interviewing. All interviews are conducted using computer-assisted interviewing.

III. Data

OMB Number: 0607–0049.
Form Number: There are no forms. We conduct all interviewing on computers.
Type of Review: Regular submission.
Affected Public: Households.
Estimated Number of Respondents: 48,000 per month.
Estimated Time Per Response: 1.58 minutes.
Estimated Total Annual Burden Hours: 15,168.

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: March 26, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 96–7782 Filed 4–2–96; 8:45 a.m.]

BILLING CODE 3510–07–P

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Opportunity to Request Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation.

BACKGROUND: Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended, may request, in accordance with section 353.22 or 355.22 of the Department of Commerce (the Department) Regulations (19 CFR 353.22/355.22 (1993)), that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

OPPORTUNITY TO REQUEST A REVIEW: Not later than April 31, 1996, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in April for the following periods:

	Period
Antidumping Duty Proceedings	
CANADA: Sugar and Syrups (A–122–085)	04/01/95–03/31/96
FRANCE: Sorbitol (A–427–001)	04/01/95–03/31/96
GREECE: Electrolytic Manganese Dioxide (A–484–801)	04/01/95–03/31/96
JAPAN: Calcium Hypochlorite (A–588–401)	04/01/95–03/31/96
JAPAN: Electrolytic Manganese Dioxide (A–588–806)	04/01/95–03/31/96
JAPAN: Lenses (A–588–819)	04/01/95–03/31/96
JAPAN: 3.5″ Microdisks and Media (A–588–802)	04/01/95–03/31/96
JAPAN: Roller Chain Other Than Bicycles (A–588–028)	04/01/95–03/31/96
KAZAKHSTAN: Ferrosilicon (A–834–804)	04/01/95–03/31/96
KENYA: Standard Carnations (A–779–602)	04/01/95–03/31/96
MEXICO: Fresh Cut Flowers (A–201–601)	04/01/95–03/31/96
NORWAY: Fresh and Chilled Salmon (A–403–801)	04/01/95–03/31/96
REPUBLIC OF KOREA: Color Television Receivers (A–580–008)	04/01/95–03/31/96
TAIWAN: Color Television Receivers (A–583–009)	04/01/95–03/31/96
UKRAINE: Ferrosilicon (A–823–804)	04/01/95–03/31/96
Countervailing Duty Proceedings	
ARGENTINA: Wool (C–357–002)	01/01/95–12/31/95
BRAZIL: Pig Iron (C–351–062)	01/01/95–12/31/95
NORWAY: Fresh and Chilled Atlantic Salmon (C–403–802)	01/01/95–12/31/95
PERU: Pompon Chrysanthemums (C–333–601)	01/01/95–12/31/95

In accordance with sections 353.22(a) and 355.22(a) of the regulations, an interested party as defined by section 353.2(k) may request in writing that the Secretary conduct an administrative review. The Department has changed its requirements for requesting reviews for countervailing duty orders. Pursuant to 19 CFR 355.22(a) of the Department's Interim Regulations (60 FR 25137 (May 11, 1995)), an interested party must specify the individual producers or exporters covered by the order for which they are requesting a review. Therefore, for both antidumping and

countervailing duty reviews, the interested party must specify for which individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin, and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request if intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, Washington, D.C. 20230. The Department also asks parties to send a copy of their requests to the Office of Antidumping Compliance, Attention: Pamela Woods, in room 3065 of the Main Commerce Building. Further, in accordance with section 353.31(g) or 355.31(g) of the regulations, a copy of each request must be sent to every party on the Department's service list.

The Department will publish in the Federal Register a notice of ''Initiation of Antidumping (Countervailing) Duty Administrative Review,'' for requests received by April 31, 1996. If the Department does not receive, by April 31, 1996, a request for review of entries covered by an order or finding listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute, but is published as a service to the international trading community.

Dated: March 28, 1996.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 96–8024 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–DS–M

[A–570–845, A–570–846]

Initiation of Antidumping Duty Investigations: Certain Brake Drums and Certain Brake Rotors From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 3, 1996.

FOR FURTHER INFORMATION CONTACT: Katherine Johnson at (202) 482–4929 or James Terpstra at (202) 482–3965, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, DC 20230.

Initiation of Investigations

The Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (''the Act'') by the Uruguay Round Agreements Act (''URAA'').

The Petition

On March 7, 1996, the Department of Commerce (''the Department'') received a petition filed in proper form by The Coalition for the Preservation of American Brake Drum and Rotor Aftermarket Manufacturers (''petitioner''), whose members consist of Brake Parts, Inc., Iroquois Tool Systems, Inc., and Wagner Brake Corporation, a Division of Wagner Electric Corp. (domestic producers of both brake drums and rotors) and Kinetic Parts Manufacturing, Inc. (domestic producer of brake rotors).

In accordance with section 732(b) of the Act, the petitioner alleges that imports of both brake drums and brake rotors from the People's Republic of China (PRC) are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, respective U.S. industries.

The petitioner is a coalition, the majority of whose members are producers of both domestic like products as defined in the petition. Therefore, it has standing to file the petition because it is an interested party, as defined under section 771(9)(E) of the Act, with respect to both products.

Determination of Industry Support for the Petition

Section 732(c)(4)(A) of the Act requires the Department to determine, prior to the initiation of an investigation, that a minimum percentage of the domestic industry supports an antidumping petition. A petition meets these minimum requirements if the domestic producers or workers who support the petition account for (1) at least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

A review of the production data provided in the petition and other information readily available to the Department indicates that the petitioner accounts for more than 50 percent of the total production of each of the domestic like products. The Department received no expressions of opposition to the petition from any domestic producer or workers. Accordingly, the Department determines that the petition is supported by the respective domestic industries.

Scope of the Investigations

The products covered by these two investigations are 1) certain brake drums and 2) certain brake rotors.

Brake Drums

Brake drums are made of gray cast iron, whether finished, semifinished, or unfinished, ranging in diameter from 8 to 16 inches (20.32 to 40.64 centimeters) and in weight from 8 to 45 pounds (3.63 to 20.41 kilograms). The size parameters (weight and dimension) of the brake drums limit their use to the following types of motor vehicles: automobiles, all-terrain vehicles, vans and recreational vehicles under ''one ton and a half,'' and light trucks designated as ''one ton and a half.''

Finished brake drums are those that are ready for sale and installation without any further operations. Semi-finished drums are those on which the surface is not entirely smooth, and has undergone some drilling. Unfinished drums are those which have undergone some grinding or turning.

These brake drums are for motor vehicles, and do not contain in the casting a logo of an original equipment manufacturer (OEM) which produces vehicles sold in the United States (*e.g.*, General Motors, Ford, Chrysler, Honda, Toyota, Volvo). Brake drums covered in this investigation are not certified by OEM producers of vehicles sold in the

United States. The scope also includes composite brake drums that are made of gray cast iron, which contain a steel plate, but otherwise meet the above criteria.

Brake drums are classifiable under subheading 8708.39.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and Customs purposes, our written description of the scope of this investigation is dispositive.

Brake Rotors

Brake rotors are made of gray cast iron, whether finished, semifinished, or unfinished, ranging in diameter from 8 to 16 inches (20.32 to 40.64 centimeters) and in weight from 8 to 45 pounds (3.63 to 20.41 kilograms). The size parameters (weight and dimension) of the brake rotors limit their use to the following types of motor vehicles: automobiles, all-terrain vehicles, vans and recreational vehicles under ''one ton and a half,'' and light trucks designated as ''one ton and a half.''

Finished brake rotors are those that are ready for sale and installation without any further operations. Semi-finished rotors are those on which the surface is not entirely smooth, and has undergone some drilling. Unfinished rotors are those which have undergone some grinding or turning.

These brake rotors are for motor vehicles, and do not contain in the casting a logo of an original equipment manufacturer (OEM) which produces vehicles sold in the United States (*e.g.*, General Motors, Ford, Chrysler, Honda, Toyota, Volvo). Brake rotors covered in this investigation are not certified by OEM producers of vehicles sold in the United States. The scope also includes composite brake rotors that are made of gray cast iron, which contain a steel plate, but otherwise meet the above criteria.

Brake rotors are classifiable under subheading 8708.39.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and Customs purposes, our written description of the scope of this investigation is dispositive.

Export Price and Normal Value

The following are descriptions of the allegations of sales at less than fair value upon which our decisions to initiate are based. Petitioners have provided separate margin calculations for brake drums and brake rotors. Should the need arise to use any of this information in our preliminary or final determinations, we will re-examine the information and may revise the margin calculations, if appropriate.

Export Price

The petitioner based export price on prices charged by U.S. distributors of Chinese brake drums and brake rotors, and deducted from these prices a distributor mark-up. In addition, the petitioner deducted an amount for freight, insurance and duties based on the percentage difference between the c.i.f. price and the Customs value price of PRC imports of like products during the POI.

Normal Value

The petitioner asserts that the PRC is a nonmarket economy country (NME) within the meaning of section 771(18) of the Act. Thus, pursuant to section 773(c) of the Act and in accordance with the Department's usual practice with respect to NMEs, the normal value of the products should be based on the producer's factors of production, valued in a surrogate market economy country. In previous investigations, the Department has determined that the PRC is an NME, and the presumption of NME status continues for the initiation of these investigations. *See, e.g., Final Determination of Sales at Less Than Fair Value: Pure Magnesium and Alloy Magnesium from the People's Republic of China,* 60 FR 16437 (March 30, 1995).

It is our practice in NME cases to calculate normal value based on the factors of production of those factories that produced subject merchandise sold to the United States during the period of investigation.

In the course of these investigations, all parties will have the opportunity to provide relevant information related to the NME status of the PRC and the assignment of separate rates to individual exporters. *See, e.g., Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the PRC,* 59 FR 22585 (May 2, 1994).

The petitioner based the factors of production (*i.e.*, raw materials, labor, and energy) for brake drums and brake rotors on its own experience, claiming that its production process is similar to that of the Chinese producers. These factors were valued by the petitioner, where possible, using publicly available published Indian data. India is an acceptable surrogate country because its level of economic development is comparable to that of the PRC and it is a producer of both brake drums and brake rotors.

Where Indian data were unavailable, the petitioner valued the factor of production on the basis of its own costs. Except as noted below for the ferromanganese input, we disregarded factor values where the inputs were based on prices in the United States because the petitioner (1) failed to follow the Department's established hierarchy regarding selection of surrogate countries for the PRC with respect to factor valuation by failing to examine possible values in other appropriate surrogate countries, and (2) provided no basis for determining that United States values are representative of the appropriate surrogate country values. *See Initiation of Antidumping Duty Investigations: Furfuryl Alcohol from the People's Republic of China, the Republic of South Africa, and Thailand,* 59 FR 32953, 32954, June 27, 1994.

Because of the similarity in production processes, the petitioner valued factory overhead, selling general, and administrative expenses and profit using data from a State Department cable contained in the public record of the *Final Results of the Antidumping Administrative Review: Certain Iron Construction Castings from the People's Republic of China,* 57 FR 10644 (March 27, 1992.)

To value the ferromanganese input, the petitioner used its own costs. Although the petitioner was able to identify an Indian value for this input material, it rejected this value claiming that it was not representative of the true price of ferromanganese. The petitioner claimed that the use of its own cost of ferromanganese was not only conservative, but comparable to world prices for this commodity product.

We excluded from our petition analysis the margin calculation of a particular model for which the petitioner was unable to provide a surrogate value for purchased castings.

Based on comparisons of export price to the factors of production, the calculated dumping margins, as revised by the Department, ranged from 46.76 percent to 105.56 percent for brake drums and from 52.08 percent to 62.55 percent for brake rotors.

Fair Value Comparisons

Based on the data provided by the petitioner, there is reason to believe that imports of brake drums and brake rotors from the PRC are being, or are likely to be, sold at less than fair value.

Initiation of Investigations

We have examined the petition on brake drums and brake rotors and have found that it meets the requirements of section 732 of the Act, including the requirements concerning allegations of the material injury or threat of material injury to the domestic producers of domestic like products by reason of the

complained-of imports, allegedly sold at less than fair value. Therefore, we are initiating antidumping duty investigations to determine whether imports of brake drums and brake rotors from the PRC are being, or are likely to be, sold in the United States at less than fair value. Unless the investigations are extended, we will make our preliminary determinations by August 14, 1996.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of the petition has been provided to the representatives of the government of the PRC.

International Trade Commission (ITC) Notification

We have notified the ITC of our initiations, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will determine by April 22, 1996, whether there is a reasonable indication that imports of brake drums and brake rotors from the PRC are causing material injury, or threatening to cause material injury, to a U.S. industry. A negative ITC determination in either of the investigations will result in that investigation being terminated; otherwise, the investigations will proceed according to statutory and regulatory time limits.

Dated: March 27, 1996.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 96–8022 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–DS–P

A–583–816

Certain Welded Stainless Steel Butt-Weld Pipe Fittings From Taiwan, Antidumping Duty Administrative Review; Time Limits

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Extension of Time Limits.

SUMMARY: The Department of Commerce (the Department) is extending the time limits of the preliminary and final results of the second antidumping duty administrative review of stainless steel butt-weld pipe fittings from Taiwan. The review covers one manufacturer/exporter of the subject merchandise to the United States and the period June 1, 1994 through May 31, 1995.

EFFECTIVE DATE: April 3, 1996.

FOR FURTHER INFORMATION CONTACT: Robert M. James at (202) 482–5222 or John Kugelman at (202) 482–5253, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: Because it is not practicable to complete this review within the time limits mandated by Section 751(a)(3)(A) of the Tariff Act of 1930, as amended by the Uruguay Round Agreements Act of 1994, the Department is extending the time limits for completion of the preliminary results until July 16, 1996. *See* Memorandum from Joseph A. Spetrini to Susan G. Esserman, March 22, 1996, on file in Room B–099 of the Main Commerce Building. We will issue our final results for this review by January 16, 1996.

These extensions are in accordance with Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)(3)(A)).

Dated: March 28, 1996.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 96–8023 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–DS–P

National Institute of Standards and Technology

[Docket No. 960227052–6052–01]

RIN: 0693–ZA06

Continuation of Fire Research Grants Program—Availability of Funds

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Announcing NIST continuation of fire research grants program.

SUMMARY: The purpose of this notice is to inform potential applicants that the Fire Research Program, National Institute of Standards and Technology, is continuing its Fire Research Grants Program.

DATES FOR APPLICATION: September 30, 1996.

ADDRESSES: Applicants must submit one signed original and two (2) copies of the proposal along with the Application for Federal Assistance, Standard Form 424, (Rev. 4–92), as referenced under the provisions of OMB Circular A–110 to: Building and Fire Research Laboratory, Attention: Sonya Parham, Building 226, Room B206, National Institute of Standards and Technology, Gaithersburg, Maryland 20899–0001.

FOR FURTHER INFORMATION CONTACT: Technical questions concerning the NIST Fire Research Grants Program should be directed to Sonya Parham, (301) 975–6854. Administrative questions concerning the NIST Fire Research Grants Program may be directed to the NIST Grants Office at (301) 975–6329.

SUPPLEMENTARY INFORMATION:

Catalog of Federal Domestic Assistance Name and Number: Measurement and Engineering Research Standards; 11.609.

Authority: As authorized by section 16 of the Act of March 3, 1901, as amended (15 U.S.C.; 278f), the NIST Building and Fire Research Laboratory conducts directly and through grants and cooperative agreements, a basic and applied fire research program. The annual budget for the Fire Research Program is approximately $1.4 million. Because of commitments for the support of multi-year programs, only a portion of the budget is available to initiate new programs, only a portion of the budget is available to initiate new programs in any one year. Most grants and cooperative agreements are in the $10,000 to $100,000 per year range. The Fire Research Program is limited to innovative ideas which are generated by the proposal writer on what research to carry out and how to carry it out. The issuance of awards is contingent upon the availability of funding.

All grant proposals submitted must be in accordance with the programs and objectives listed below.

Program Objectives

A. Fire Modeling and Applications: To perform research, develop, and demonstrate the application of analytical models for the quantitative prediction of the consequences of fires and the means to assess the accuracy of those models. This includes: Developing methods to assess fire hazard and risk; creating advanced, usable models for the calculation of the effluent from building fires; modeling the ignition and burning of furniture, contents, and building elements such as walls; developing methods of evaluating and predicting the performance of building safety design features; developing a protocol for determining the accuracy of algorithms and comprehensive models; and developing data bases to facilitate use of fire models.

B. Large Fire Research: To perform research on and develop techniques to measure, predict the behavior of, and mitigate large fire events. This includes: Understanding the mechanisms of large fires that control gas phase combustion, burning rate, thermal and chemical emissions, transport processes; developing field measurement

techniques to assess the near- and far-field impact of large fires and their plumes; performing research on the use of combustion for environmental cleanup; predicting the performance and environmental impact of fire protection measures and fire fighting systems and techniques; and developing and operating the Fire Research Program large-scale experimental facility.

C. Smoke Dynamics Research: To produce scientifically sound principles, metrology, data, and predictive methods for the formation/evolution of smoke components in flames for use in understanding and predicting general fire phenomena. This includes research on the effects of within-flame and post-flame fluid mechanics on the formation and emission of smoke, including particulates, aerosols, and combustion gases; understanding the mechanistic pathway for soot from chemical inception to post-flame agglomerates; and developing calculation methods for the prediction of the yields of CO (and eventually other toxicants) as a function of fuel type, availability of air, and fire scale.

D. Materials Fire Research: To perform research to understand fundamentally the mechanisms that control the ignition, flame spread, and burning rate of materials and the chemical and physical characteristics that affect these aspects of flammability. This involves developing methods of measuring and predicting the response of a material to a fire, including characterizing the burning rates of charring and non-charring polymers and composites; delineating and modeling the enthalpy and mass transfer mechanisms of materials combustion; and developing computational molecular dynamics and other mechanistic approaches to understand the relationships between polymer structure and flammability.

E. Fire Sensing and Extinguishment: To develop understanding, metrology, and predictive methods to enable high-performance fire sensing and extinguishment systems. This involves devising new approaches to minimizing the impact of unwanted fires and the suppression process, including research for the identification and *in-situ* measurements of the symptoms of pending and nascent fires or explosions, and the consequences of suppression; devising or adapting monitors for these variables and creating the intelligence for timely interpretation of the data; determining mechanisms for deflagration and detonation suppression by advanced agents and principles for their optimal use; modeling the extinguishment process; and developing performance measures for the effectiveness of suppression system design.

Award Period: Proposals will be considered for research projects from one to three years. When a proposal for a multi-year grant is approved, funding will be provided for only the first year of the program. If an application is selected for funding, DoC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DoC.

Matching Requirements: The Fire Research Grants Program does not involve the payment of any matching funds and does not directly affect any state or local government.

Eligibility: Academic institutions, non-Federal agencies, and independent and industrial laboratories.

Proposal Review Process: All proposals are assigned to the appropriate group leader of the five programs listed above. Both technical value of the proposal and the relationship of the work proposed to the needs of the specific program are taken into consideration in the group leader's recommendation to the Deputy Director. Applicants should allow up to 90 days processing time. Proposals are evaluated for technical merit by at least three reviewers chosen from NIST professionals, technical experts from other interested government agencies and experts from the fire research community at large.

Evaluation Criteria:

a. Intrinsic value of the research—0–40.

b. Qualifications—0–20.

c. Utility of the research—0–20.

d. Balance and financial feasibility—0–20.

Selection Procedure: The results of these evaluations are transmitted to the group leader of the appropriate research unit in the Building and Fire Research Laboratory who prepares an analysis of comments and makes a recommendation.

Paperwork Reduction Act: The Standard Forms 424, 424A, 424B, and LLL mentioned in this notice are subject to the requirements of the Paperwork Reduction Act and have been approved by the Office of Management and Budget, (OMB), under Control Numbers 0348–0043, 0348–0044, 0348–0040, and 0348–0006.

Application Kit: An application kit, containing all required application forms and certifications is available by calling Sonya Parham, NIST Fire Research Grants Program (301) 975–6854. An application kit includes the following:

SF–424 (Rev. 4/92)—Application for Federal Assistance.

SF–424A (Rev. 4/92)—Budget Information-Non-Construction Programs.

SF–424B (Rev. 4/92)—Assurances-Non-Construction Programs.

CD–511 (7/91)—Certification Regarding Debarment, Suspension, and Other Responsibility Matters: Drug-Free Workplace Requirements and Lobbying.

CD–512 (7/91)—Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusions-Lower Tier Covered Transactions and Lobbying.

SF–LLL—Disclosure of Lobbying Activities.

Additional Requirements

Past Performance: Unsatisfactory performance under prior Federal awards may result in an application not being considered for funding.

Preaward Activities: Applicants that incur any costs prior to an award being made do so solely at their own risk of not being reimbursed by the Federal Government. Applicants are also hereby notified that notwithstanding any verbal assurance that they may have received, there is no obligation on the part of DoC to cover preaward costs.

Primary Application Certification: All primary applicants must submit a completed Form CD–511, ''Certification Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying,'' and the following explanations are hereby provided:

1. Nonprocurement Debarment and Suspension. Prospective participants (as defined at 15 CRF Part 26, Section 605) are subject to 15 CFR Part 26, Subpart F., ''Nonprocurement Debarment and Suspension'' and the related section of the certification form prescribed above applies;

2. Drug-Free Workplace. Grantees (as defined at 15 CFR Part 26, Section 605) are subject to 15 CFR Part 26, Subpart F., ''Governmentwide Requirements for Drug-Free Workplace (Grants)'' and the related section of the certification form prescribed above applies;

3. Anti-Lobbying. Persons (as defined at 15 CFR Part 28, Section 105) are subject to the lobbying provisions of 31 U.S.C. 1352, ''Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions,'' and the lobbying section of the certification form prescribed above applies to application/bids for grants, cooperative agreements , and contracts for more than $100,000, and

loans and loan guarantees for more than $150,000, or the single family maximum mortgage limit for affected programs, whichever is greater, and;

4. Anti-Lobbying Disclosure. Any applicant that has been paid or will pay for lobbying using any funds must submit an SF-LLL, ''Disclosure of Lobbying Activities,'' as required under 15 CFR Part 28, Appendix B.

5. Lower Tier Certifications. Recipients shall require applicants/bidders for subgrants, contracts, subcontracts, or other lower tier covered transactions at any tier under the award to submit, if applicable, a completed Form CD–512, ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions and Lobbying'' and disclosure form, SF-LLL, ''Disclosure of Lobbying Activities.'' Form CD–512 is intended for the use of recipients and should not be transmitted to NIST. SF-LLL submitted by an tier recipients or subrecipient should be submitted to NIST in accordance with the instructions contained in the award document.

Name Check Reviews: All for-profit and non-profit applicants will be subject to a name check review process. Name checks are intended to reveal if any key individuals associated with the applicant have been convicted of or are presently facing, criminal charges such as fraud, theft, perjury, or other matters which significantly reflect on the applicant's management honesty or financial integrity.

False Statements: Applicants are reminded that a false statement may be grounds for denial or termination of funds and grounds for possible punishment by fine or imprisonment.

Delinquent Federal Debts: No award of Federal funds shall be made to an applicant who has an outstanding delinquent Federal debt until either:

1. The delinquent account is paid in full;

2. A negotiated repayment schedule is established and at least one payment is received, or,

3. Other arrangements satisfactorily to DoC are made.

No Obligation for Future Funding: If an application is accepted for funding, DoC has no obligation to provide any additional future funding in connection with that award. Renewal of an award, increased funding, or extending the period of performance is at the total discretion of NIST.

Federal Policies & Procedures: Recipients and subrecipients under the Fire Research Grants Program are subject to all applicable Federal laws and Federal and Department policies, regulations, and procedures applicable to Federal financial assistance awards. The Fire Research Grant Program does not directly affect any state or local government. Applications under this program are not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.''

Purchase of American-Made Equipment and Products: Applicants are hereby notified that they are encouraged, to the greatest extent practicable, to purchase American-made equipment and products with funding provided under this program.

Indirect Costs: The total dollar amount of the indirect costs proposed in an application under this program must not exceed the indirect cost rate negotiated and approved by a cognizant Federal agency prior to the proposed effective date of the award or 100 percent of the total proposed direct cost dollar amount in the application, whichever is less.

Executive Order 12866: This funding notice has been determined to be ''not significant'' for purposes of E.O. 12866.

Dated: March 27, 1996.

Samuel Kramer,

Associate Director.

[FR Doc. 96–8139 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–13–M

National Oceanic and Atmospheric Administration

[Docket No. 960322090–6090–01; I.D. 032696A]

Weakfish; Interstate Fishery Management Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of determination of compliance; cancellation of moratorium.

SUMMARY: In accordance with the Atlantic Coastal Fisheries Cooperative Management Act of 1993 (Act), NOAA announces the cancellation of the planned Federal moratorium on weakfish in the coastal waters of Maryland that would have become effective on April 15, 1996. The intent to impose the moratorium was cancelled upon notification to the Secretary of Commerce (Secretary) by the Atlantic States Marine Fisheries Commission (Commission) that Maryland is in compliance with the provisions of the Commission's Interstate Fishery Management Plan (FMP) for weakfish, and after NOAA determined that the State of Maryland is now in compliance.

EFFECTIVE DATE: The determination to impose the moratorium is cancelled on March 29, 1996.

FOR FURTHER INFORMATION CONTACT: Richard H. Schaefer, Director, Office of Fisheries Conservation and Management, NMFS, 301–713–2334.

SUPPLEMENTARY INFORMATION:

Background

On February 20, 1996, the Secretary published a notice in the Federal Register (61 FR 6351) that the State of Maryland was not in compliance with the Commission's FMP for weakfish. The notice document declared a moratorium on fishing for this species in the State waters of Maryland, effective April 15, 1996, if the State of Maryland was not in compliance by April 1, 1996. Details were provided in the February 20, 1996, Federal Register notice and are not repeated here.

The Act specifies that, if, after a moratorium is declared, the Secretary is notified by the Commission that it is withdrawing the determination of noncompliance, the Secretary shall immediately determine whether the State is in compliance with the applicable plan(s). If the State is in compliance, the moratorium shall be cancelled.

Activities Pursuant to the Act

On March 6, 1996, the Secretary received a letter (dated March 5, 1996) from the Commission stating that the State of Maryland had now implemented regulations for the weakfish fishery which meet the provisions of the Commission's FMP, and, therefore, the Commission was withdrawing its determination of noncompliance.

Cancellation of Moratorium

Based on the Commission's March 5, 1996, letter, and information received from the State of Maryland and the U.S. Fish and Wildlife Service, Department of the Interior, NOAA has determined that Maryland is now in compliance with the Commission's FMP for weakfish. Accordingly, the declaration of a moratorium on Maryland is cancelled.

Dated: March 29, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

[FR Doc. 96–8150 Filed 3–29–96; 3:47 pm]

BILLING CODE 3510–22–F

[I.D. 032296B]

Gulf of Mexico Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene a public meeting.

DATES: The meeting will be held from April 22–25, 1996, beginning at 1:00 p.m. on April 22 and concluding at 12:00 noon on April 25.

ADDRESSES: This meeting will be held at the Tampa Airport Hilton at MetroCenter, 2225 North Lois Avenue, Tampa, FL; 813–877–6688.

Council address: Gulf of Mexico Fishery Management Council, 5401 West Kennedy Boulevard, Suite 331, Tampa, FL 33609.

FOR FURTHER INFORMATION CONTACT: Antonio B. Lamberte, Economist, Gulf of Mexico Fishery Management Council; telephone: 813–228–2815.

SUPPLEMENTARY INFORMATION:

The Socioeconomic Assessment Panel (SEP) will review available social and economic data on Gulf of Mexico fisheries of king and Spanish mackerels and cobia, to determine the social and economic implications of the levels of acceptable biological catch recommended by the Council's Mackerel Stock Assessment Panel. The SEP will then recommend to the Council levels of total allowable catch for the 1996–1997 fishing year. In addition, the SEP will review Amendment 14 to the Reef Fish Fishery Management Plan, with particular emphasis on the social and economic implications of the proposed license limitation system for the fish trap fishery.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by April 15, 1996.

Dated: March 28, 1996.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96–8176 Filed 4–2–96; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0010]

Proposed Collection; Comment Request Entitled Progress Payments

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 (9000–0010).

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 Progress Payments. This OMB clearance currently expires on August 31, 1996.

DATES: *Comment Due Date:* June 3, 1996.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, or obtaining a copy of the justification, should be submitted to: General Services Administration, FAR Secretariat (MVRS), 18th & F Streets, NW, Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000–0010, Progress Payments, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy F. Olson, Federal Acquisition Policy Division, GSA (202) 501–3221.

SUPPLEMENTARY INFORMATION:

A. Purpose

Certain Federal contracts provide for progress payments to be made to the contractor during performance of the contract. The requirement for certification and supporting information are necessary for the administration of statutory and regulatory limitation on the amount of progress payments under a contract. The submission of supporting cost schedules is an optional procedure that, when the contractor elects to have a group of individual orders treated as a single contract for progress payments purposes, is necessary for the administration of statutory and regulatory requirements concerning progress payments.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *.55* 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.

The annual reporting burden is estimated as follows: Respondents, *27,000*; responses per respondent, *32*; total annual responses, *864,000*; preparation hours per response, *.55*; and total response burden hours, *475,200*.

Dated: March 26, 1996.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 96–7939 Filed 4–2–96; 8:45 am]

BILLING CODE 6820–EP–M

[OMB Control No. 9000–0080]

Proposed Collection; Comment Request Entitled Integrity of Unit Prices

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 (9000–0080.

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 Integrity of Unit Prices. This OMB clearance currently expires on August 31, 1996.

DATES: *Comment Due Date:* June 3, 1996.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, or obtaining a copy of the justification, should be submitted to: General Services Administration, FAR Secretariat (MVRS), 18th & F Streets NW., Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000–0080, Integrity of Unit Prices, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy F. Olson, Federal Acquisition Policy Division, GSA (202) 501–3221.

SUPPLEMENTARY INFORMATION:

A. Purpose

FAR 15.812–1(c) and the clause at FAR 52.215–26, Integrity of Unit Prices, require offerors and contractors under Federal contracts to identify in their proposals those supplies which they will not manufacture or to which they will not contribute significant value. The policies included in the FAR are required by section 501 of Public Law 98–577 (for the civilian agencies) and section 927 of Public Law 99–500 (for DOD and NASA). The rule eliminates reporting requirements on contracts with civilian agencies for commercial items.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *5* minutes per line item, 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, *7,822*; responses per respondent, *95*; total annual responses, *743,090*; preparation hours per response, *.084*; and total response burden hours, *62,420*.

Dated: March 26, 1996.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 96–7940 Filed 4–2–96; 8:45 am]

BILLING CODE 6820–EP–M

[OMB Control No. 9000–0082]

Proposed Collection; Comment Request Entitled Economic Purchase Quantities—Supplies

AGENCY: 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 (9000–0082).

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 Economic Purchase Quantities—Supplies. This OMB clearance currently expires on August 31, 1996.

DATES: *Comment Due Date* June 3, 1996.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, or obtaining a copy of the justification, should be submitted to: General Services Administration, FAR Secretariat (MVRS), 18th & F Streets, NW, Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000–0082, Economic Purchase Quantities—Supplies, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy F. Olson, Federal Acquisition Policy Division, GSA (202) 501–3221.

SUPPLEMENTARY INFORMATION:

A. Purpose

The provisions at 52.207–4, Economic Purchase Quantities—Supplies, invites offerors to state an opinion on whether the quantity of supplies on which bids, proposals, or quotes are requested in solicitations is economically advantageous to the Government. Each offeror who believes that acquisitions in different quantities would be more advantageous is invited to (1) recommend an economic purchase quantity, showing a recommended unit and total price, and (2) identify the different quantity points where significant price breaks occur. This information is required by Public Law 98–577 and Public Law 98–525.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *50* 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, *2,252*; responses per respondent, *35*; total annual responses, *78,820*; preparation hours per response, *.83*; and total response burden hours, *65,421*.

Dated: March 26, 1996.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 96–7941 Filed 4–2–96; 8:45 am]

BILLING CODE 6820–EP–M

[OMB Control No. 9000–0083]

Proposed Collection; Comment Request Entitled Qualification Requirements

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 (9000–0083).

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 Qualification Requirements. This OMB clearance currently expires on August 31, 1996.

DATES: *Comment Due Date:* June 3, 1996.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, or obtaining a copy of the justification, should be submitted to: General Services Administration, FAR Secretariat (MVRS), 18th & F Streets, NW, Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000–0083, Qualification Requirements, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph De Stefano, Federal Acquisition Policy Division, GSA (202) 501–1758.

SUPPLEMENTARY INFORMATION:

A. Purpose

Under the Qualified Products Program, an end item, or a component thereof, may be required to be prequalified. The solicitation at FAR 52.209–1, Qualification Requirements, requires offerors who have met the qualification requirements to identify the offeror's name, the manufacturer's name, source's name, the item name, service identification, and test number (to the extent known).

The contracting officer uses the information to determine eligibility for award when the clause at 52.209–1 is included in the solicitation. The offeror must insert the offeror's name, the manufacturer's name, source's name, the item name, service identification, and test number (to the extent known). Alternatively, items not yet listed may be considered for award upon the submission of evidence of qualification with the offer.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *15* 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, *7,882;* responses per respondent, *100;* total annual responses, *788,200;* preparation hours per response, *.25;* and total response burden hours, *197,050.*

Dated: March 26, 1996.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 96–7942 Filed 4–2–96; 8:45 am]

BILLING CODE 6820–EP–M

DEPARTMENT OF DEFENSE

Department of the Army

Reengineering the Personal Property Program—Synopsis of Comments Received

AGENCY: Military Traffic Management Command (MTMC), DOD.

ACTION: Notice.

SUMMARY: As part of the reengineering of the Department of Defense (DOD) personal property program on June 30, 1995, MTMC released the draft requirements document over MTMC's EasyLink Bulletin Board. The initial draft of the requirements document outlined the anticipated requirements to participate in the movement of personal property under MTMC's reengineered concept. More importantly, the initial draft of the requirements document was provided with the intent to give industry the opportunity to comment on the feasibility of the proposal. A request for comments from industry concerning the draft requirements document was published in the Federal Register, Thursday, July 13, 1995, Vol 60, No. 134. In conjunction with the draft requirements document, MTMC released on August 1, 1995, the proposed acquisition strategy over the EasyLink Bulletin Board. In the proposed acquisition strategy, MTMC informed industry that we were considering the use of the Federal Acquisition Regulation (FAR) to procure services for the movement of personal property.

An additional request for industry's comments, this time concerning the proposed acquisition strategy, was published in the Federal Register, Thursday, August 10, 1995, Vol 60, No. 154. In this Federal Register notice, we requested industry consider the draft requirement document and proposed acquisition strategy as one package, and that comments be provided to MTMC by September 20, 1995.

ADDRESSES: Headquarters, Military Traffic Management Command, ATTN: MTOP–Q, 5611 Columbia Pike, Falls Church, Virginia 22041–5050.

FOR FURTHER INFORMATION CONTACT: Mr. Lee Strong or Shelly Johnson, MTOP–Q, (703) 681–6393.

SUPPLEMENTARY INFORMATION: As a result of the Federal Register requests for comments, MTMC received 297 letters from industry. The 297 letters included 102 individual letters, 152 National Moving and Storage Association endorsement letters, and 43 Washington Movers Conference endorsement letters. The following provides a summary of many of the questions posed by industry concerning the draft requirements document and proposed acquisition strategy, as well as, MTMC's current position regarding these industry questions.

Summary of Industry Comments Concerning the Draft Requirements Document and Proposed Acquisition Strategy

In response to a request for comments concerning MTMC's reengineering draft requirements document and proposed acquisition strategy, we received 297 letters, including 102 individual letters, 152 National Moving and Storage Association endorsement letters, and 43 Washington Movers Conference endorsement letters. The following summarizes and consolidates the questions posed in those letters and provides a MTMC response.

Comments Regarding the Acquisition Strategy

(1) *Industry:* The use of proposed FAR to award contracts for personal property movements is unacceptable and will adversely impact the DOD Personal Property Program by imposing detailed, complex, and burdensome regulations, including the provisions of the Service Contract Act and Small Business Act. The use of the FAR is more onerous and complex than the current system and fails to achieve the stated goal of simplification.

Response: The Federal Acquisition Regulation (FAR) is an instrument the Federal Government routinely utilizes to acquire and administer the vast majority of its contracts for goods and services. It may be as simple or as complex as the requirement being procured. It may require minimal to detailed documentation depending upon the requirement and the dollar threshold involved. Currently the FAR is geared toward streamlining the acquisition process as much as possible while maintaining the proper expenditure of public funds. The language in the FAR is to the mutual benefit of private industry and the Federal Government. The Service Contract Act (SCA) requirements are administered and implemented by the Department of Labor (DOL). The FAR simply implements the procedures and regulations published by DOL. While compliance with the SCA provisions may require changes in carrier business practices, these changes are not insurmountable. Likewise, the FAR implementation of the Small Business Act, where applicable, will not necessarily make the acquisition process unduly burdensome. While many members of the industry may not be familiar with these provisions, we are confident that this industry has the capability to learn, adjust and master new procedures just as it has done in the past when we made changes to the current program. MTMC is available to assist industry in understanding these provisons.

(2) *Industry:* The ongoing regulatory requirements of the Service Contract Act (SCA) would impose a significant burden and subject industry to varying interpretations, continuous review of the contract award procedures, and significantly increase costs due to mandatory wage levels. The burden of imposing wage determinations and benefit guidelines on full-service worldwide moves will fall directly upon the small businesses, the agents and owner operators who actually perform the services for the member. The detailed accounting infrastructure does not exist to handle such a complex process.

Response: The Service Contract Act (SCA) does not require a detailed accounting system, nor does it require continuous review of the contract award procedures. MTMC intends to work with the Department of Labor to attempt to lessen the impact on the industry, as

much as possible. Again, while compliance with the SCA provisions may require changes in carrier business practices, carriers will be able to factor into their rates any increased costs in the operations caused by their compliance with the SCA. Once established, the specific burdens/interpretations imposed by the SCA will have to be addressed between the industry and the Department of Labor.

(3) *Industry:* The provisions of the Small Business Act mandate maximum business opportunity for small and small disadvantaged businesses. In addition, large businesses with annual gross receipts of $18.5 million, or more, must submit a subcontracting plan outlining the minimum goals for subcontracting and specifying how the plan will be executed. These requirements are an administrative burden, and are difficult to understand and enforce. Small businesses have an equal opportunity to compete in the current program and the requirements of the FAR will prevent them from competing in the new program.

Response: The FAR does not prevent small and small disadvantaged business from bidding/proposing on any requirement that has full and open competition. Small businesses will be given an equal opportunity to compete among small businesses and among their larger competitors. The provisions of the Act apply to both the current program and the proposed reengineered program. The broad policies of the Act are to ensure that a fair proportion of acquisitions are placed with small business concerns and small disadvantaged business concerns. The FAR regulations implement this policy. The regulations will not prevent competition by these concerns. Rather, the regulations promote competition by mandating that such concerns have the maximum practicable opportunity to compete. For information on how to submit a subcontracting plan, which is only applicable to large businesses for awards over a certain threshold, it is recommended that companies review the guidance in FAR Subpart 19.7. It is apparent that many of the large firms currently have an operating procedure with many small businesses; therefore, they should review actions that they currently have in place to determine whether they would satisfy the requirement. The FAR approach may be more or less labor intensive depending upon the type of solicitation and the type of contract awarded. Part of its advantage, however, is that it is a competitive process for the award of contracts which allows technical and price factors to be considered; it is not simply a system for filing rates.

(4) *Industry:* The FAR is a very complex bidding process and requires a very large amount of work for potential contractors who wish to bid on the program. The decision to file rates from each area of responsibility to each rate area will result in 17,425 contract awards. If 50 carriers should file rates for all channels, MTMC would be required to evaluate 871,250 offers. Under the current program, all rates are submitted electronically and require only a few number of personnel to manage the process. The FAR evaluation process is labor intensive and will not reduce the manpower required to administer and manage the program.

Response: MTMC agrees that awarding a best value FAR contract under the Area of Responsibility (AOR) to rate area/channel concept would be labor intensive and difficult to administer because of the large number of potential offers and awards to be evaluated and administered. Although a low cost FAR-exempt concept would provide simplicity in administration, we believe FAR contracts, which are awarded based on price and non price factors and which would allow the contracting officer to exercise business judgment in selecting an awardee, would result in an overall better value to the Government than the present distribution scheme which awards to the carrier with the low rate. Since quality of service is a major goal in the reengineering effort, MTMC has been considering alternatives which allow us to achieve greater value while being administratively manageable.

Consequently, MTMC is considering an approach which encompasses six origin regions which include four CONUS and two OCONUS regions. We anticipate the four CONUS regions being divided into the states within the four Regional Storage Management Offices (RSMO) areas currently in existence. The two OCONUS regions would be divided into countries under the current responsibility of the Military Traffic Management Command, Europe and the Military Traffic Management Command, Pacific. We envision three categories of service out of each origin region and contractors may choose to bid as follows:

CONUS Origin Regions

a. *Intra-Region Destination.* Contractor must provide service from all areas of responsibility (AOR) of personal property shipping offices (PPSOs) located within a region to all AORs located within states in that same region. (Example: The Atlanta Region encompasses North Carolina, South Carolina, Kentucky, Tennessee, Mississippi, Alabama, Georgia, and Florida. The contractor must provide service from North Carolina to any other state within the Atlanta Region.) Locals and intra-state moves will not be included for the pilot acquisition.

b. *Inter-CONUS Destination.* Contractor must provide service from all AORs of PPSOs located within a region to all AORs located within states outside that region. (Example: From Atlanta Region to California, Kansas, New Jersey, etc.)

c. *OCONUS Destination.* Contractor must provide service from all AORs or PPSOs located within a CONUS region to all OCONUS AORs. (Example: From Atlanta Region to Germany, Japan, Italy, etc.)

OCONUS Origin Regions

(Moves originating from these regions will not be included in the pilot acquisition.)

a. *Intra-Region Destination.* Contractor must provide service from all AORs of PPSOs located within a region to AORs located within countries in that same region. (Example: From MTMCEUR Region (Germany) to United Kingdom, Italy, Turkey, etc.)

b. *Inter-OCONUS Destination.* Contractor must provide service from all AORs of PPSOs located within a region to all AORs located within countries outside that region. (Example: From MTMCEUR Region (Germany) to Japan, Korea, Hawaii, etc.)

CONUS Destination. Contractor must provide service from all AORs of PPSOs located within a OCONUS region to all CONUS AORs. (Example: From MTMCEUR Region (Germany) to South Carolina, California, New Jersey, etc.)

We anticipate making multiple awards on DOD's needs and the contractor's capacity set out in responsive proposals. In addition, we envision awarding an indefinite delivery/indefinite quantity (IDIQ) fixed price contract for one (1) year, with four (4) priced one (1) year option periods. The contract will specify the minimum tonnage the contractor is guaranteed for the base period and the maximum tonnage the contractor is obligated to move during each year of performance and for the life of the contract. Further, the contractor will specify his maximum daily tonnage capacity for each installation within the region.

Contractors may be authorized to submit a separate daily maximum for peak season. The maximum daily tonnage capacities will be a negotiable element in determining contract awards.

A contractor may choose to submit a proposal for any or all of the categories of service. Each awardee is obligated to provide service from all areas of responsibility of PPSOs located within a region to all destination AORs encompassed within each category of service.

(5) *Industry:* MTMC's repeated statements indicate the technical area elements of an offeror's proposal will have priority over cost. It is very difficult for those who have been in business with the military for any length of time to believe cost will not be the primary factor. This element of the reengineering proposal is critical to providing premium services for the military customer.

Response: One of the main differences between the current personal property program and the reengineered concept, is that the current program awards traffic to the low rate carrier. The reengineered concept, on the other hand, will emphasize the selection of carriers that provide quality service, even if this results in the payment of commensurably higher rates. Thus, the reengineered source selection process will place weight on the carriers' capability to provide quality service and not just focus on low rates. The relative importance of the technical factors the Government will evaluate during the source selection process will be specifically stated in the solicitation.

(6) *Industry:* Technical issues can only be evaluated subjectively. Awards based on subjective evaluation factors and the offerors writing ability rather than the carriers ability to competitively meet MTMC's established service requirements will result in litigation.

Response: We are aware that changing the present system may result in litigation. However, if we adopt a FAR-based system, we plan to develop a streamlined acquisition process that will help us achieve two main objectives: facilitate the source selection process for both the carriers and MTMC, and minimize the potential for litigation. We plan to develop a source selection process which de-emphasizes proposal writing skills and emphasizes the contractors' capability and past performance. Again, if we adopt the FAR-based approach, we will seek industry assistance with the draft solicitation and the streamlined acquisition method.

(7) *Industry:* Industry is not familiar with the terms, conditions, and requirements of the FAR. This will lead to inconsistent interpretations, appeals and protests.

Response: Industry has indicted repeatedly that it understands the terms and conditions of the services we want to procure. Additionally, industry has indicated that it can provide most of the required services under the current program. The main difference lies on the source selection methods and standardized clauses which the FAR provides. Thus, whether we procure those services using the FAR, or using FAR-exempt procedures, does not appear to increase the potential for inconsistent service. The statement of work will be essentially the same under either method. With regard to appeals and protests, please note that the right to appeal or protest procurement decisions is based on statute, not the FAR. If the FAR is chosen, MTMC is dedicated to work with industry in facilitating the transition to a FAR-based system and, together, avoid any conditions which may lead to unnecessary appeals or protests.

(8) *Industry:* A FAR based contract has indefinite and various terms and conditions which are subject to legislative change and new interpretations by parties with no knowledge of the moving industry. This will adversely impact the ability of the contractor to comply and provide the services required.

Response: No government contract, be it FAR or FAR-exempt, has ''indefinite and variable terms and conditions.'' The FAR contains rules, terms, and conditions which generally govern the formation and administration of government contracts. The work requirements are established by the requiring activity and are set forth in the contract. While the FAR is often revised to implement new ideas, court decisions and legislative changes, those changes are always prospectively applied. In those unusual cases where a contract needs to be modified to implement a new court decision or statute, the contractor is compensated for any increased cost of performance.

(9) *Industry:* Subcontracting requires discussions prior to bid submission between the parties involved. These discussions will involve the exchange of price information, as well as consideration of whether a potential bidder will agree not to submit its own independent bid. This raises serious anti-trust implications. The moving industry has in the past been subject to Justice Department grand jury investigations and threatened indictments on the basis of alleged joint actions by bidders and agents in connection with the submission of bids on military traffic.

Response: Carriers concerned about whether their discussions regarding potential subcontracting arrangements with other carriers or contractors might have antitrust implications should consult their legal counsel. Hundreds of contractors in other industries routinely enter into subcontracting arrangements without violating antitrust laws. We are unaware of any statutory provision which would prevent the household goods industry from entering into similar subcontracting or other types of teaming arrangements. Please refer to FAR Subpart 9.6 for the Federal Government's policy on teaming arrangements and joint ventures.

(10) *Industry:* Subcontracting is developed based on business relationships and established on the basis of mutual integrity and reputation for performance and prompt payment. In addition, subcontractors will have no protection against slow payment or nonpayment by the Government selected contractor.

Response: Any acquisition concept we adopt will place significant emphasis on past performance. This will include the contractor's financial performance. Since a carrier's failure to comply with its financial obligations to its subcontractors is likely to negatively impact its performance, we anticipate that the carrier receiving awards under such a reengineered proposal will be motivated to maintain excellent working relationships with its subcontractors. As far as protection against slow payment, or nonpayment by a Government selected contractor, we believe that this responsibility rests with industry. As a general rule, the Government's obligation is to the prime contractor. It is the responsibility of subcontractors to assure that they are involved in a business relationship with a reliable and responsible prime contractor. The same holds true for the prime contractor.

(11) *Industry:* MTMC's concept of contractors and subcontractors will put the agent/van line relationship seriously at risk. No large van line, with appointed and dependent and financially supported agents, will make its resources available to those agents working as subcontractors for a competing van line, on a contract that the carrier itself bid on and lost.

Response: The objectives of the reengineering process include the design of a procurement process that maximizes competition, selects quality carriers, and is administratively manageable for MTMC and the PPSOs. We recognize that any acquisition method we adopt which satisfies these objectives may require some modification of industry's current business practices. We do not wish to dictate what specific changes the carrier industry should make to its business

practices. We trust that the household goods industry has the capability to make those business decisions independently. Hundreds of other government contractors have been able to adjust to changing market conditions. The freight industry, for example, is successfully adjusting to deregulation. We are confident that those household goods carriers that are committed to providing quality transportation services to DOD at competitive rates will find ways to successfully compete for these contracts.

(12) *Industry:* Large van lines have the resources to provide the services required and can satisfy the subcontracting requirements within their own system of agents and owner operators without utilizing the services of other carriers and agents. Capacity will only be an issue during peak period of times. Many smaller carriers or agents will not be able to survive on peak business alone. As a result, the agent infrastructure will be severely damaged. Warehouse and van capacity will be reduced resulting in serious deterioration of service and competition on subsequent bids will be significantly reduced since many unsuccessful bidders, who have been deprived military shipments will go out of business. Service quality will ultimately deteriorate.

Response: If we adopt a FAR-based approach we anticipate making multiple awards. The decision on how many awards we need to make will depend on the minimum transportation needs of DOD shippers and the capacity of the competing carriers. The solicitation will provide data showing DOD's minimum transportation needs for each performance period, including peak periods. It is possible that some carriers will base their capacity on the agent infrastructure they already have in place. Others may choose to expand their capacity by entering into additional subcontracting arrangements. Carriers will retain absolute discretion on how they wish to structure their proposals for these requirements. At this point, it would be speculative to assert with a high degree of certainty the potential impact the reengineered acquisition will have on the agents infrastructure, as well as warehouse and van capacity. We anticipate that the pilot acquisition we plan to conduct will provide factual information about the potential impact of the reengineered concept on the industry's infrastructure.

(13) *Industry:* The FAR contains many stringent reporting requirements. These reports may be required simply because the contract is subject to the terms and conditions of the FAR.

Response: The only known reporting requirement required by the FAR relates to subcontracting and is only required of large businesses. The report reflects the contractor's progress on meeting his/her subcontracting goals as proposed and incorporated into any resultant contracts. Any other required reports will not result from the FAR, but will be generated as a requirement under the particular contract for purposes of providing specific management information to the Government.

(14) *Industry:* The FAR contains strict penalty provisions for contractors that are not able to meet all of the terms of the contract. Given the lack of familiarity with the detailed requirements of the FAR, the number of violations can be expected to be very high and the amount of potential penalties could be crippling to the entire industry. There is no need for these penalties because they only serve to enforce meaningless and unnecessary rules. This requirement is another reason to exempt this contract from the FAR.

Response: The FAR provides guidance to Federal agencies on how to conduct its acquisition. It provides standardized clauses which Federal agencies must use for certain types of acquisition. It does not contain penalties; rather, it outlines remedies available to both contractors and government agencies in place of contract changes or disputes. These remedies are incorporated into the contract through standardized contract clauses. See FAR Subpart 33.2, for guidance on disputes and appeals, and FAR Part 43, for guidance on contract modifications. Contractors are only required to comply with the terms and conditions of the contract. These terms and conditions initially are stated in the request for proposals. Thus, carriers will know, even before they submit a bid in response to the request for proposals (RFP), the terms and conditions of the proposed acquisition. Those carriers that believe they cannot comply with the terms of the RFP has essentially two options. First, they can inform the procuring agency of the fact which in their opinion prevent them from complying with the requirements, and request the agency to amend the RFP. Second, carriers can enter into teaming or joint venture agreements with other companies in order to enhance their capability to perform the requirements. Of course, while we understand this is not a desirable option, a carrier can always choose not to bid. Finally, it should be noted that, like any other private citizen, contractors also have to comply with Federal statutes. Most of these statutes would apply regardless of whether we are dealing with FAR or FAR-exempt contracts.

(15) *Industry:* The FAR contains provisions regarding default terms and conditions. It also stipulates procedures regarding contractor liability for procurement costs. The clauses pertaining to default are not mandatory and the reasonableness of these terms should be dependent upon the type of contract awarded. Specific information is required regarding default provisions and punitive actions.

Response: The use of contract termination clauses for convenience and default are mandated as specified in FAR Subpart 49.5. The standardized clauses to be used are listed in that subpart. General guidance regarding the policies and procedures for the complete or partial termination of contracts is provided in FAR Part 49. We will be glad to answer any specific questions industry may have about these clauses. The specific clauses applicable to any contract will be included in its appropriate RFP.

(16) *Industry:* All of MTMC's service requirements, with a single exception (full replacement liability), can be achieved by modifying the current program and without incurring the problems resulting from the proposed ''winner take all'' FAR contract concept. The draft Requirements Package and Acquisition Strategy reveals a program that is far more bureaucratic and complex than the existing program and it contradicts standard commercial business practices in most aspects.

Response: One of the primary reengineering goals it to move away from the current rate driven system, to one that encompasses a quality/greater value approach. MTMC has discovered several factors that argue decisively against merely modifying the current program. First, the existing system itself is a product of the process of making many isolated changes without considering the total impact. It seems inappropriate to fix a program by the same process that brought it to its present form. Additionally, it is often difficult to adjust single elements of the program because of vested interests and the interconnected nature of various provisions. Frequently, good ideas are lost in the negotiation or compromise process. Also, achieving a system that awards traffic on other than cow cost cannot be attained by modifying the existing program. The FAR provides an established and proven procurement method to achieve the desired approach. In addition, MTMC is considering a multiple award regional approach in place of the ''winner take all'' concept.

Thus, there will be adequate opportunities for several contractors to receive contract distribution system and ''me-too'' bidding, on the other hand, effectively emasculates the benefits that competition can provide.

Comments Regarding the Draft Requirements Document; Industry Comments and MTMC Responses are Keyed to the Paragraph Number of the Requirement Document

1. Requirements

1.1 Channel Concept

(17) *Industry:* Commercial accounts are national, not regional or point-to-point in scope. The moving industry, even at its inception, was concerned about return loads. Trucks must be kept filled and this cannot be done in a point-to-point environment, especially if it is not known who will be awarded the contract from the other end. Not knowing which routes will be awarded to an offeror further complicates the bidding strategy. A traffic lane concept will minimize the opportunity to fully utilize equipment and will increase costs.

Response: MTMC agrees the majority of commercial accounts are national in scope; however, due to significant concerns from industry regarding a national/worldwide approach and the effect it might have on small and medium carriers, local moving and storage companies, and freight forwarders, the approach was changed. MTMC considered awarding traffic on a ''winner take all'' basis out of an area of responsibility (AOR) to a rate area. It became clear through industry comments and MTMC's analysis that the channel approach created many administrative complexities. Consequently, MTMC is considering use of a regional approach with multiple awards. The proposed regional concept provides an opportunity for all carriers, local agents, and freight forwarders to submit offers. Subcontracting provides an opportunity for carriers to participate in those channels in which they were not awarded contracts.

(18) *Industry:* The proposed traffic channel concept is no different than those in use today. This concept offers no program simplification for MTMC or industry.

Response: MTMC agrees. Analysis of the AOR/channel concept confirmed this approach would not simplify the program for the Government or industry. We feel the regional approach will simplify evaluation, execution and administration.

1.1 Winner Take All

(19) *Industry:* The ''winner take all'' approach will have a devastating impact on small corporations within the industry. It would create a monopoly of large van lines, thus forcing small carriers, agents, and forwarders out of business.

Response: The regional/multiple award concept should eliminate concerns regarding ''winner take all.''

(20) *Industry:* No one carrier or any one agent in a military market is able or willing to provide for 100 percent of all traffic in any given channel. Every year during peak season there are problems somewhere in the country acquiring the necessary capacity. It should be abundantly clear from this that no one contractor is capable of handling all of the shipments, whether worldwide, at an installation, or in a single traffic channel. The volume is too large.

Response: Concerns over available capacity during peak season was an important factor for MTMC in deciding upon multiple award options. Multiple awards, in conjunction with contractor stated maximum daily capacity and PPSO discretion in awarding traffic, will ensure sufficient capability for movement requirements.

2.1 Expansion Capability

2.1.1

(21) *Industry:* A carrier and its agent cannot be expected to maintain additional capacity and personnel to cover seasonal surges which may or may not materialize. Steps should be taken to minimize such surges by encouraging movements during the winter months. Additionally, no prudent bidder can provide a viable rate without knowing the parameters of the daily workload requirement. The Government's estimated daily requirements and minimum acceptable daily requirements must be provided for each channel.

Response: One of the ways that a contractor can expand capacity during seasonal surges is through an effective subcontracting plan. The revised concept allows for the contractor to specify their maximum daily capacity. In addition, we are considering separate daily maximums for peak season movement requirements. Multiple awards and subcontracting will ensure the capability is available to support seasonal surges. Contractor established daily maximums and the right of refusal once daily maximums have been met, afford the contractor an opportunity to effectively manage his/her company's operations. Although MTMC and the services would like to see the volume of moves evened out over the entire year, realistically there is not much that can be done to accomplish this. Often, even when military members with families are ordered to a new duty station during the winter months, the spouse and children will stay behind until the school year is completed. Although the DOD can control when a service member must report for a new duty assignment, we can not mandate when he/she chooses to move household goods and family. Just like the commercial world, a move is a quality of life issue and most people with families prefer to move in the summer to minimize the adverse impact on their children's education.

(22) *Industry:* The Contractor should be compensated overtime labor charges when services are requested and performed during other than normal working hours. It is not realistic to require the contractor to extend work hours without any additional compensation. The provisions of the Service Contract Act would require the contractor to pay its employees overtime wages and the Government should like be willing to pay the contractor.

Response: Since confirmed pack, pickup, and delivery dates are established between the contractor and customer, MTMC does not envision the payment of overtime charges as a separate charge item. We would expect contractors to factor anticipated costs into their rates.

(23) *Industry:* The expansion capability requirement is restrictive on small business. The alternative to the unlimited expansion capability requirements is to use the FAR-exempt tender system of procurement. It has agent and carrier expansion capability built in by using the Me-Too rate filing system. The available capability provided by the Me-Too carriers will not be available under the FAR contract concept.

Response: MTMC wants to move from the current rate driven system, to one that considers the value of services provided. Although price will continue to be one of the factors evaluated, it will not be the driving factor in determining which proposal is awarded the traffic. The Government will make cost-technical tradeoffs, and determine which proposal offers greatest value based on sound business judgment and the evaluation criteria stated in the solicitation. The current Me-Too rate filing system does not lend itself to an approach that evaluates factors other than cost. Although it allows for a carrier to match or Me-Too the rate of the low cost carrier, it does not provide a vehicle for the carrier to match the other factors encompassed in an

evaluated procurement. Therefore, under Me-Toos, the rate becomes the driving factor once again. The alternative for expansion capability, is for the contractor to assemble an effective and efficient subcontracting plan.

2.1.2

(24) *Industry:* The Contractor may be asked to support unforecasted contingencies, but should not be required to do so. The Contractor should be compensated for all additional cost incurred in supporting such an effort.

Response: Because of the potential severity of unforecasted emergencies such as military contingencies, natural disasters, etc., MTMC believes it is imperative that the contractor be required to support these unforeseen events. A provision does exist for HQMTMC and the contractor to negotiate, when applicable, rate adjustments necessitated by such unforecasted conditions that exceed contract requirements. However, if such requirements are within the daily maximum capacity established in the initial contract, they should not entitle the contractor to additional compensation.

2.2 Movement Via Air Mobility Command (AMC)/Military Sealift Command (MSC)

(25) *Industry:* Movement via AMC/MSC is not a commercial business practice. MTMC is taking away the Contractors traffic management responsibility for through movement. The PPSO's right to direct movement via AMC/MSC will deny the Contractor the ability to negotiate the most cost effective rates based on volume.

Response: DOD policy mandates use, under certain circumstances, of AMC and MSC lift capability. This policy serves to maintain DOD's transportation assets in operation during peacetime so they are available during contingencies. In addition, there always is not ample American flag service to accommodate the volume of DOD Unaccompanied Baggage moving between CONUS and certain OCONUS destination (*i.e.*, Korea), and there are some OCONUS areas where AMC/MSC assets provide the only service available. Any directed use will be separately addressed in any ensuing solicitation.

2.3 Compliance With DOD Policies

(26) *Industry:* Compliance with regulations, publications, directives, MTMC advisories, and changes thereto are not commercial business practices. The contract should be all inclusive and the contract should not be revised without consultation and agreement from the Contractor.

Response: The contract will specify which conditions the contractor must comply with. Once the contract is signed and awarded, any change must be discussed with the contractor. There is no way it can be revised without the knowledge of the contractor.

2.5 Automation Interface

(27) *Industry:* Automation interface systems must be readily available in the commercial marketplace and not out of the technical or financial reach of contractors. Interface capability of the local agents may be cost prohibitive and the requirement may preclude small businesses from participating. MTMC should consider assisting small businesses in acquiring this capability by providing sufficient notice of the details of the electronic capability being requested.

Response: Definitive automation requirements will be included in the Request for Proposal. MTMC envisions many benefits associated with electronic capability such as intransit visibility of shipments, electronic billing, and payments, etc. However, MTMC is also sensitive to demands upon small and medium size businesses that provide quality service. Consequently, MTMC will look to implement electronic capability requirements that are efficient, cost effective and reasonably avilable to the industry. We will also consider capabilities of DFAS, the PPSOs, the military services, the customers, and MTMC.

3. Key Personnel

3.1/3.2 Contract Manager/Operations Manager

(28) *Industry:* It is not commercial practice to dictate the experience levels of the contractor or subcontractor personnel. Key personnel requirements should not be micromanaged by MTMC. The 10 years experience requirement for the Contract Manager, and the 5 year requirement for the alternate and Site Manager is unreasonable. Recommend reducing or eliminating this requirement since the quality feedback of the market place will drive the parties providing service to employ the best personnel available to ensure high quality rankings.

Response: MTMC partially agrees and has eliminated the requirement for years of experience for all key personnel except the Contract Manager. MTMC believes that a minimum number of years of experience is a necessary requirement to assure that the Contract Manager has the knowledge and background to be responsible for the performance and operation of the contract. However, as recommended by industry, MTMC will relook the minimum experience requirement for the Contract Manager. The specific requirement will be stated in the RFP.

3.3

(29) *Industry:* The prohibition against a contractor removing key personnel constitutes interference with the internal management of the contractor's company. This requirement should be deleted.

Response: MTMC has eliminated the requirement that the contractor must notify and receive concurrence by HQMTMC of the replacement of key personnel, with the exception of the Contract Manager whose replacement must be with the concurrence of HQMTMC. HQMTMC is only concerned with the replacement's qualifications. It is necessary that the contractor verify to HQMTMC the qualifications of the potential replacement of the Contract Manager to assure that the quality of contract performance is not placed at risk by the employment of an inexperienced contract manager.

4. Personnel

4.3

(30) *Industry:* Imposing requirements for uniforms with company name or logo and Contractor issued identification cards are an excessive regulatory requirement which provides no service quality benefit. These requirements disrupt commercial industry practices and impact subcontractors, small businesses, and carriers employing casual labor. An alternative would be to require employees performing services at the customers residence to dress in appropriate attire and be in presentable clean condition. If identification is sought by the customer, require the driver or lead foreman to present commercial drivers license or possibly a Contractor issued identification card.

Response: MTMC has modified the requirement. All employees performing moving services at the customer's residence shall be in uniform shirt with company name or logo and maintain a professional demeanor. The team leader shall have some type of contractor issued identification. The uniform shirt and team leader's identification card provide a method for the customer to verify who the individuals are before allowing entry to their home. The identification card provides a quick and accurate way for the customer to identify the team leader who is in

charge of the work group and who the customer can go to if a problem arises. MTMC feels that these requirements are simple as well as inexpensive methods to reassure the service members that the individuals handling their personal belongings are professionals. Although these requirements may not have a direct impact on the quality of service being provided, we believe that they are reasonable methods to relieve some of the anxiety associated with moving.

5. Quality Control

5.2 Intransit Visibility Service

(31) *Industry:* MTMC requiring tracing within 2 hours is not realistic and not the prevailing commercial practice.

Response: MTMC realizes that at the time of a tracing request, the shipment may be in route and it may be difficult for a contractor to provide an exact status on that particular shipment. Upon a request of a shipment trace by the customer or the government, an initial response from the contractor that provides the most current status available within 2 hours from the time of the request will be required. Once the initial response is made, a more updated and exact status can then be provided at a later time. Technology available and currently in use by many carriers today allows for the capability to trace, monitor, and report movement progress of any shipment instantaneously. As our members may also be traveling at the time of the request, we feel that a 2 hour response time reasonably meets their needs while placing a reasonable demand on the contractor.

(32) *Industry:* The requirement for the contractor to provide a weekly report to the destination PPSO listing all anticipated late shipments is excessive.

Response: MTMC understands industry's concerns with the volume and frequency of reports currently proposed. Consequently, MTMC is currently reviewing all the report requirements to determine which ones can be streamlined or eliminated.

5.3 Access to Contractor Facilities

(33) *Industry:* Access to contractor's facilities should be limited to normal working hours, by appointment only, and should not include access to personnel files.

Response: Access to contractor records is often required to substantiate compliance with statutory or contractual requirements. When such efforts are necessary, the Government will coordinate with the affected contractor to minimize disruptions as much as feasible.

5.4 Contractor Meeting With PPSO

(34) *Industry:* Contractor meetings with the PPSO should follow the commercial practice that a meeting occur on an as needed basis based upon common sense, problem resolution and the judgment of the manager involved. It is not necessary to hold these meeting on a weekly, biweekly, or monthly basis.

Response: MTMC agrees. The intent of this requirement is to let the PPSO schedule the meetings at his discretion.

5.5 Contractor Operational Problems

(35) *Industry:* Agree that the contractor should keep MTMC/PPSO informed about serious problems that arise, but disagree with being required to advise the PPSO of the loss of a subcontractor. If a subcontractor goes out of business or the relationship to the contractor is terminated for any reason, neither MTMC nor the PPSO should be involved as long as the contractor is still able to fulfill its duties.

Response: MTMC agrees and will modify the requirement accordingly. MTMC has no privity of contract with subcontractors; however, prime contractors will be expected to fulfill their contractual obligations. However, should a subcontracting plan become part of any ensuing contract, any substantial variance from its terms must be reported.

5.6 Customery Survey

(36) *Industry:* Agrees with replacing TQAP with a customer survey form.

Response: MTMC agrees and TQAP will be replaced with the customer survey form.

(37) *Industry:* MTMC should not prescribe the questions on the customer survey to be asked.

Response: MTMC believes that there are some core questions that must be mandatory on the customer survey form to evaluate contractor performance. However, MTMC does not intend to otherwise limit the questions that the carrier believes it needs to retain quality service.

(38) *Industry:* There should be a mandatory return policy on the customer survey form for the military service member, and if after a predetermined time no reply is received then the move should be considered satisfactory with the contractor receiving credit accordingly.

Response: MTMC cannot mandate that the military member return the customer survey form. We would expect carriers to institute reasonable efforts to obtain representational answers. PPSOs will conduct a sufficient number of random surveys to assure the sample size for each contractor per region/contract provides a minimum 95 percent confidence level. However, PPSO efforts will not remove carrier responsibility to take all reasonable efforts to obtain survey results.

6. Quality Assurance

6.2 Contractor Performance

(39) *Industry:* The required standards of 99% for on-time pickups, 95% for on-time delivery, and 95% for using the contractor again are higher than most corporate accounts and should be lowered.

Response: MTMC does not concur and has retained the requirement for these standards. MTMC has benchmarked this requirement with corporate customers and found numerous examples of standards equal to or higher than these, and believes that the DOD, as this industry's largest single customer, deserves equal service. Consequently, MTMC believes that these standards are appropriate and reasonable.

(40) *Industry:* In addition to measuring loss/damage, claims frequency and loss/damage claims exceeding a certain dollar amount, the contractor's performance should be measured on the basis of claims cost per hundredweight. Furthermore, loss/damage should not count against a carrier as long as the member was made whole and is satisfied with the move.

Response: MTMC disagrees that loss/damage should not count against a carrier as long as the member was made whole and is satisfied with the move. We believe that loss/damage is a critical element of a contractor's overall performance and should be compiled and evaluated. MTMC is considering claims' cost per hundredweight, as well as other alternatives.

7. Specific Tasks

7.1 Customer Service

7.1.1 Toll Free Telephone Numbers

(41) *Industry:* It is simple to provide for toll free numbers in the United States, but toll free numbers are not available all over the world internationally. Also, the toll free number should only be required to be manned during normal business hours which is 5 days a week and 8 hours a day. Recommend that after hours be covered by a mechanical message collection device with follow up during the next official business day.

Response: MTMC recognizes that in some instances toll free numbers may not be available internationally. MTMC

has modified the requirements document to read that if toll free capability is not available, the contractor shall accept collect calls. MTMC has also modified the requirement of the toll free number being manned 24 hours a day, 7 days a week, to it being operational 24 hours a day, 7 days a week. Thus, a type of recorder, beeper, or other electronic device may be used provided someone knowledgeable will promptly respond to the customer's concern. The goal is to allow customer's located in different time zones, to contact the contractor without being restricted by the contractors routine office hours.

(42) *Industry:* It is redundant and unnecessary for the contractor's origin and destination agents to have toll free numbers. The service member should be dealing with the contractor; thus, only one toll free number is necessary.

Response: MTMC agrees and has eliminated the requirement for origin and destination agent toll free numbers. However, the requirement for the contractor to establish and maintain a toll free number for their service areas has been retained in the requirements document. We believe it is necessary that the customer have at least one toll free number where his/hers inquiries/ problems can be dealt with in a timely manner.

7.1.2 Movement Counseling

7.1.2.1

(43) *Industry:* Imposing a minimum transit time schedule for the RDD is micro management, and instead MTMC should allow the contractor to work with the customer to reach a mutually agreed upon RDD. MTMC should also allow the use of spread dates for pickup and delivery because it is a commercial practice, allows for the greatest flexibility, and the maximum use of a carrier's capability.

Response: MTMC agrees that the transit time guide should not be a mandatory regulation for determining the RDD, and the contractor and the customer should be allowed to come to a mutually agreed upon delivery date. However, a transit time guide will be made available to be used as a tool to assist in determining the RDD. In those instances when a mutually agreed RDD cannot be reached between the Contractor and the customer, the transit time guide will be used to establish the RDD. MTMC will not require the customer to agree to the use spread dates. However, if the contractor and the customer mutually agree to the use of spread dates for pack, pickup, or delivery, then spread dates may be used. However, if the customer does not agree to spread dates, then the contractor must agree to a specified date for these services.

(44) *Industry:* MTMC needs to clarify the requirement that the contractor must notify the customer within 2 work days after notification by the PPSO that the contractor has been awarded the traffic.

Response: MTMC has eliminated the 2 work day minimum for notification, and modified the requirement so that upon notification of shipment award, the contractor shall contact the customer to confirm the pack, pickup, and tentative required delivery dates established during the PPSO entitlement counseling or establish mutually agreed upon dates. The contractor shall provide each customer and the PPSO a schedule of all confirmed dates prior to the pickup date. The PPSO will then issue a service order based on these confirmed dates.

(45) *Industry:* Agrees with move counseling being done by the carrier. However, MTMC/PPSO must continue to provide entitlement counseling because of the variation in policy among each of the military services.

Response: MTMC agrees and the PPSOs will continue to provide entitlement counseling to the service members while the contractor will now be responsible for movement counseling.

7.2 Pre-move Survey

(46) *Industry:* It is unnecessary to require an on site pre-move survey on all shipments regardless of weight or type. Telephone surveys should suffice for small shipments and shipments more than a specified number of miles away.

Response: MTMC wants the contractor to perform a pre-move survey on all shipments. However, MTMC agrees that in many instances a pre-move survey conducted by telephone would be effective and appropriate. Consequently, the requirement has been modified so that a residence pre-move survey shall be conducted on all shipments estimated at 3000 pounds or more, at origin points within a 50 mile radius of contractor's nearest agent facility, unless specifically waived by the customer and annotated on the service order. A telephone contact pre-move survey shall be made, as a minimum, for all other shipments.

7.3 Customer Inconvenience Payment

7.3.1

(47) *Industry:* There should exist a minimum weight and miles standard in determining inconvenience claims, as is the prevailing commercial practice. The contractor should not be responsible to pay 100% of the costs of meals, clothing, or other purchased items that retain a residual value. Inconvenience payments should not be tied to the government per diem rate.

Response: MTMC does not concur and has retained the requirement that the contractor shall pay the customer an inconvenience claim when a missed pickup, missed RDD, or missed confirmed delivery date from SIT causes inconvenience to the customer and the expenditure of personal funds for the reasonable costs for lodging meals, and rental/purchase of household necessities. MTMC has also retained the requirement that the contractor's maximum liability, excluding costs for rental/purchase of reasonable household necessities, shall not exceed the local DOD per diem rate. MTMC believes that the customer should be reimbursed for reasonable out of pocket expenses incurred as a result of these type of situations. MTMC further believes that the DOD per diem rate provides an established and effective tool to determine the cost for lodging and food expenses associated with the various cost of living rates in different areas of the world.

7.3.2

(48) *Response:* The contractor being required to acknowledge receipt of the inconvenience claim is unnecessary. Also, the contractor will require more than 15 work days from the time of the customer's request for reimbursement to make payment of the inconvenience claim.

Response: MTMC partially agrees, and has eliminated the requirement for the contractor to acknowledge receipt of the claim to the customer within 5 days of the date of the customer's request. However, MTMC believes that 15 work days from the time of the customer's request is a reasonable period of time for the contractor to make payment on an inconvenience claim, and has retained this requirement. This requirement is designed to reimburse the customer for unexpected expenses that he/she may not be reasonably able to personally underwrite.

8. Transportation Services at Origin

8.3 Advance Notice of Pack/Pickup Dates

(49) *Industry:* Do not agree with short notice shipments being done at no additional cost to the government. Additional services of this type should be compensated because it goes beyond the level of normal service.

Response: MTMC has retained the requirement that short notice shipments, such as disciplinary actions, compassionate reassignments, movements pertaining to deceased members and their families and short notice assignments, shall be moved at no additional cost to the Government. The contractor should account for these possible type situations up front in the contractor's single factor rate, and exercise sound business practices that permit the him/her to be responsive to the government's needs. On the other hand, unforeseen emergencies such as natural disasters, are subject to negotiation under the expansion capability paragraphs of the draft requirements document.

8.4 Acceptance of Shipments

8.4.1

(50) *Industry:* It makes no sense to force the contractor to take shipments with dates that cannot be met. There must be a minimum daily work load established.

Response: MTMC is considering allowing contractors to establish their maximum daily capacity at each AOR within a region. Each contractor would be required to accept all shipments offered until they reach their established maximum daily capacity. Contractors may refuse shipments once they reach their maximum daily capacity. We will provide specific details in the draft solicitation.

8.4.3

(51) *Industry:* Forcing the contractor to provide the PPSO a daily report of all shipments scheduled for pack and pickup for the next work day is an administrative burden with no clear value added.

Response: MTMC agrees and has eliminated the requirements that the contractor provide this daily report.

8.6 Expedited Service

(52) *Industry:* Currently, the draft requirements document provides that expedited service charges apply only if the RDD is less than 25% of the published transit line. This language must be changed to require an expedited service charge whenever the PPSO requires the RDD to be less than the transit time. The requirement that expedited service be provided without additional cost is unreasonable.

Response: MTMC has modified the requirements document to state that if the required delivery date is less than 50% of the transit time then expedited service charges will apply. MTMC believes that with the contractor and the customer working together to set up a mutually agreed upon delivery date, this will allow the flexibility and the opportunity for the contractor to meet most expedited deliveries necessitated by member needs. In those cases when the PPSO deems it necessary for the required delivery date to be less than 50% of the published transit time when the expedited service charge will apply. Otherwise, we expect potential contractors to include this requirement in their single factor rate.

11. Shipment Diversion

(53) *Industry:* Diversions of shipments up to 100 miles at no additional cost is an excessive requirement.

Response: MTMC agrees that requiring the contractor to be responsible for shipments diverted to a new destination up to 100 miles at no additional cost is excessive. Consequently, the requirements has been modified to 50 miles. However, when necessary to meet the needs of the Government, the PPSO may order the contractor to divert a shipment to a new destination that is more than 50 miles from the original destination. In such case, a new single factor rate that includes all charges from original origin to new destination will be negotiated between the PPSO, in coordination with MTMC, and the contractor.

14. Transportation Services at Destination

14.8 Destination Shipment Report

14.8.1

(54) *Industry:* Destination shipment reports are excessive and unnecessary micro management by MTMC.

Response: MTMC understands industry's concerns with the volume and frequency of reports currently proposed. Consequently, MTMC is currently reviewing all the reporting requirements to determine which ones can be streamlined and/or eliminated.

14.9 Conversion of Storage in Transit (SIT) to Commercial Storage

(55) *Industry:* There must be a defined end point to government paid SIT, not just an undefined specified date by the PPSO.

Response: SIT is authorized in increments of 90 days with extensions up to 360 days. Consequently, SIT does have a defined end point. In addition, a storage extension forms reflecting the expiration date will be provided to the Contractor.

15. Liability

15.1

(56) *Industry:* The contractor should have the prerogative of repairing a damaged item or replacing the item whichever they deem more cost effective.

Response: MTMC agrees and has added the option of allowing the contractor to negotiate with the member to repair damaged item(s) are repaired to the same condition as received by the contractor from the member at the time of pickup. If however, the contractor chooses to replace the lost or damaged item(s), then replacement will be determined by current market value without depreciation.

15.2

(57) *Industry:* Need to add statement that any item replaced becomes the property of the contractor.

Response: MTMC agrees and has modified the requirements document to read that all items which are replaced or for which the full current market value has been paid become the property of the contractor. The contractor shall pick up the salvage within 30 calendar days after settling the claim with the customer unless provisions for a later pick up date are made with the customer. Failure to pick up salvaged property within the prescribed time results in forfeiture of the property, loss of any deduction of funds for salvage value, and the customer may then dispose of the property.

15.3

(58) *Industry:* Full value protection of $100,000 per shipment is excessive and should be modified to apply a released value on a per pound basis. Coverage should be depreciated; however, the member could choose to purchase additional coverage at an additional cost if desired. The contractor should be allowed to use a high-value inventory in which the member must identify articles with a value of greater than $100.00 per pound.

Response: MTMC partially agrees and has reduced the maximum liability from $100,000 per shipment to $75,000 unless the customer purchases additional insurance. MTMC is aware that additional up front costs may be associated with full value protection; however, it is a service that is desirable for our military members. We believe that in the long run, these up front costs will be offset by better service and a reduced claims ratio per move. This notwithstanding use of a high-value inventory being considered.

16. Loss and Damage Claims

16.1

(59) *Industry:* Agrees with service members filing their claims directly with the contractor.

Response: MTMC also agrees with direct claim settlement between the contractor and the customer, and has provided for this option in the draft requirements document.

16.3

(60) *Industry:* Commercial practice requires that exceptions (damage to property) be noted at the time of delivery. At a minimum, the customer should be required to notify the contractor of loss or damage within a minimum number of specified days following delivery.

Response: The contractor will provide the customer a notice document at time of delivery, and the customer will provide the contractor at time of delivery with written notice of discovered lost and damage. MTMC agrees that the service member should notify the contractor in a timely manner of later discovered loss or damage. Consequently, the requirement has been modified to read that the customer will have 90 days to notify the contractor in writing of later discovered lost or damaged items. For lost and damaged items identified by the customer within the 90 day notice period, the notice document overcomes the presumption of the correctness of the delivery receipt.

16.4

(61) *Industry:* The service member should only have up to nine months to file a claim as is the current commercial practice.

Response: MTMC disagrees. Current commercial practice is no less than 9 months. We feel that a 1 year limit for the service member to file their claim directly with the contractor is fair, due to the uniqueness of military constraints.

16.7

(62) *Industry:* Need to add a clause allowing the contractor to inspect the damaged item(s).

Response: MTMC agrees, and has added the statement that the contractor shall have the right to inspect the damaged property within 45 calendar days of delivery or dispatch of the customer's written notice document, whichever is later. The contractor shall notify the customer prior to any inspection to arrange a mutually agreeable time.

16.8

(63) *Industry:* The contractor will need more than 30 days to gather documentation, determine the validity of a claim, make investigation, conduct inspections, arrange for repairs and make cash settlement to the service member.

Response: MTMC agrees that in certain cases the contractor may require more than 30 days to settle the claims as was required in the original draft requirements document. It has been changed to read that the contractor shall pay, decline, or make a firm compromise settlement offer in writing to the customer within 60 calendar days after receipt of the claim by the contractor. However, if the contractor fails to respond within 60 calendar days of receipt of the claim, or the contractor declines to pay the claim, the customer may file a claim with the appropriate military claim service. Such claim to the military claim service may address all items which are not covered by an agreeable resolution between the contractor and the customer.

16.11

(64) *Industry:* The service member should be precluded from filing a claim directly with the government. Also, the government should not have the power to offset on disputed claims between the contractor and the customer.

Response: We cannot change the member's statutory right to file a claim directly with the government. However, we prefer that the member file directly with the contractor, and we plan to encourage it by not making full replacement coverage available if the member decides to settle directly with the military, without first seeking reimbursement from the carrier. As for the government not having the right to offset on disputed claims, we disagree and believe that the government should have the right to enforce contract requirements and be the service members' advocate. In any event, it is a remedy available under the terms of government contracts. Consequently, as a minimum, the contractor will be subject to set aside by the government on those items that the military pays for and which the contractor improperly denied.

16.13

(65) *Industry:* A monthly claims activity report provided by the contractor to the PPSO is unnecessary and should be reduced to a quarterly basis.

Response: MTMC disagrees. This monthly report is necessary to assist in evaluating carriers' overall performance.

17. Billing and Payment Procedures

17.1

(66) *Industry:* The requirement to have all invoices certified by the PPSO, that show that all services have been performed, is unnecessary, encourages lost billing, and is counter productive to the prompt payment act. Instead the contractor should bill the finance center directly.

Response: The invoice certification requirement is being reevaluated as part of the effort to implement EDI procedures.

Attachment 3—Single Factor Rate/ Accessorial Information

1. Single Factor Rate (SFR)

(67) *Industry:* Single factor rates reduce the direct compensation to service providers for extra services rendered, which are time and labor intensive. The SFR is too inclusive. Prevailing commercial practice is that accessorial services are separately identified and payable when requested and performed.

Response: MTMC disagrees and will retain the SFR pricing structure. Carriers currently participating in the international through Government bill of lading program submit SFRs for household goods and unaccompanied baggage shipments. Additionally, MTMC feels the SFR should encompass the majority of the accessorial services which may affect a shipment. Service providers should ensure costs for accessorial services are negotiated and agreed upon prior to contract award. MTMC has identified those accessorial services which will be outside the SFR pricing structure. These services are not routinely ordered, are labor intensive, and costly to perform. Separate rates will be submitted by the Contractor for these services. This should ensure the Contractor's service providers are equitably compensated for services rendered.

2. SFR Solicitation/Submission

(68) *Industry:* Single factor rates are not prevailing commercial practice for domestic shipments and are used on a very small percentage of commercial corporate accounts. SFR pricing does not provide the means or the structure needed for fair pricing and payment of moving services. Domestic movements and the majority of commercial accounts use a discount from a common industry baseline tariff and a segmented rate. Corporate accounts which do use single factor pricing predicate rates on a weight and mileage matrix.

Response: MTMC recognizes that SFRs are not the prevailing commercial practice for domestic shipments. However use of SFRs will standardize, simplify, and reduce administrative workload associated with rate

submissions/evaluation, accessorial services, billing and payment, and program management. Major goals for the reengineering effort are program simplification and reduction of administrative processing. The volume associated with the personal property program warrants attaining such goals.

2.1, 2.3.1 Domestic Service

(69) *Industry:* The underlying services and transportation methods for unaccompanied baggage (UB) differ significantly from those for household goods (HHG) shipments. Bundling of HHGs and UB together to move on the same SFR is not supportable. Factors for fixed costs also have a larger impact on smaller shipments and domestic baggage cannot be moved at the same rate as a large HHG shipment. It would be unrealistic for the same rate to apply for UB as it does for HHG shipments regardless of size. UB shipments are more expensive due to initial acquisition costs, inventory control measures, and labor costs for containerization. Pricing shipments at the same rate per hundredweight regardless of size and distance will result in significant over-payment for some shipments and under-payment for others. An alternative procedure for domestic service would be to establish domestic baggage service and have separate baggage rates.

Response: MTMC is reevaluating movement of unaccompanied baggage/personal effects within CONUS to determine if a different pricing structure is appropriate.

(70) *Industry:* By combining domestic UB with HHG rates, the small business set-aside used for the Direct Procurement Method (DPM) pack & crate service is eliminated. This will adversely impact many small businesses who specialize in the service for DOD.

Response: MTMC believes that the multiple contract aspects of its proposed system, along with inherent opportunities to form consortiums and use subcontracts will provide meaningful small business opportunities.

(71) *Industry:* Carriers and forwarders do not typically perform local move services. Local moves are provided by local agents within the AOR and contracts for these services are awarded by the installation contracting offices. Prevailing commercial practice is to bill local moves at an hourly rate. Local moves should be solicited and awarded separately.

Response: Local moves will be excluded from the pilot program. MTMC is currently evaluating how local moves will be incorporated into the regional concept.

(72) *Industry:* UB needs to be better defined. The types of items which will be included in a typical baggage shipment and whether it must be shipped via air or surface must be known. If UB can be more accurately defined, an SFR could possibly be used since fewer accessorials apply. In addition, some type of mileage factors need to be included.

Response: UB is defined as that portion of the customer's prescribed weight allowance of personal property, including professional books, papers, and equipment, normally shipped separately from the bulk of the personal property. UB is usually shipped via an expedited mode because it is needed immediately, or soon after, the customer's arrival at destination for interim housekeeping pending the arrival of the major portion of the customer's property. The entitlement for a UB shipment normally only exists when a member has a permanent change of station to/from an OCONUS location. The term ''UB'' will not be used for shipments moving within CONUS under the reengineered program. Small shipments moving with CONUS will be classified as a personal property shipment and normally are not shipped via an expedited method. However, if the PPSO determines the need to expedite a personal property shipment, the expedited service paragraph of the draft requirements document will control carrier compensation.

2.2 International Service

2.3.2

(73) *Industry:* Requiring the contractor to file rates for all four international types of service restricts competition and constitutes bundling. Bundling of HHG and UB in the international program restricts competition and ''administrative convenience'' is not sufficient justification for bundling. The contractor should be allowed to bid on HHG and UB separately. This alternative would provide all required HHG and UB services for each AOR and will increase competition by permitting more carriers to independently file rates for each channel.

Response: MTMC does not agree. Under the regional concept all potential contractors will be required to submit both HHG and UB rates for every rate area within an origin region to all destination rate areas for a category of service (e.g., a CONUS origin region to all OCONUS destinations, and OCONUS origin region to all CONUS destinations, or an OCONUS origin region to all OCONUS destinations). MTMC recognizes certain carriers participating in the present program have specialized in UB service; however, we believe that requiring the same contractor to provide HHG and UB services simplifies the acquisition process for DOD, enhances competition, and simplifies accountability by allowing DOD and the customer to deal with one contractor per move. Bench marking surveys with corporate accounts and commercial business practices disclose that commercial customers are not usually required to consult with different carriers to acquire movement services for HHG and UB. This requirement does not constitute improper bundling or restrict competition because the regional/multiple award concept increases business opportunities for industry. In addition, potential contractors may subcontract with any carrier for specialized services.

(74) *Industry:* American carriers who file inter- and intra-theater rates would not normally have operating authority and expertise to transport local and in-country overseas moves. Historically, in-country and local moves have been separated and performed by the local small business movers located with the AOR. Rates for these shipments are procured by overseas Contracting Officers who have the experience with the local conditions and requirements. Combining these types of moves in one channel is not cost efficient and does not simplify the process. The procurement for these moves should remain with the overseas contracting offices.

Response: MTMC is evaluating the unique requirements and factors which may affect these movements to determine how they can be incorporated into the regional concept. OCONUS local and in-country moves will be excluded from the pilot program.

2.4

(75) *Industry:* Separate accessorial service charges are needed for each origin AOR.

Response: MTMC agrees and recognizes costs vary significantly by geographic area. Therefore, Schedule A of the requirements document has been modified to allow contractors to submit separate accessorial charges for SIT services, Flat Service, and special crating for each origin rate area within a region.

2.5

(76) *Industry:* It is unreasonable to have 100 net pounds as the minimum weight for all SFRs. The prevailing commercial practice is generally a

minimum weight of 1,000 pounds for HHG and 100 pounds gross for UB. The use of the net weight in lieu of gross weight for UB will create additional work. Gross weight is used for UB because obtaining the tare weight of small cartons and boxes is costly and labor intensive. Further the ITGBL program has always moved UB on a gross weight basis. Recommend using prevailing commercial practice or a 500 pound minimum,

Response: MTMC agrees and has modified the Requirements Document to state the SFR and all accessorial service charges, computed on weight, are subject to a 500 pound net minimum.

3. Accessorial Service

3.1

(77) *Industry:* An accessorial statement being sent to the PPSO for signature is redundant and unnecessary. The contractor's billing, supported by the member signed accessorial should suffice. Allowing 10 days to return the certified accessorial statement to the contractor will unreasonably delay carrier billings.

Response: MTMC disagrees. The contractor will be required to prepare and submit to the PPSO for certification an accessorial statement authorizing accessorial services. The service member is often unable to verify all accessorial services that are performed. For example, the service member may be unaware of possible charges such as an attempted pickup, waiting time, number of days in SIT, etc. Consequently, it is a necessary requirement for the PPSO to certify the accessorial services.

(78) *Industry:* Auxiliary services are costly, labor intensive, and time consuming. The frequency of this service cannot be determined and therefore should not be part of the SFR.

Response: MTMC agrees and Attachment 3 has been modified to include auxiliary service. The Flat Service charge will be used for computing the cost for auxiliary service. Auxiliary service must be authorized by the PPSO prior to commencement of service.

3.4.1 Storage-in-Transit (SIT) Services

(79) *Industry:* The criteria established for commencement of SIT charges is not acceptable or prevailing commercial practice. This requirement will either force an increase in SIT charges to cover days that are no longer billable or it will have a negative impact on local agent's revenue. MTMC would like to reduce the amount paid for SIT, so it is attempting to limit its application by not paying for SIT prior to the required delivery date. This application may apply if commercial shipments were involved and commercial practices and commercial rate levels were used. Prevailing commercial practice is to use spread of dates for delivery. If the shipment arrives within the spread, SIT begins on date of arrival. If the shipment arrives ahead of the spread, SIT commences on the first day of the spread.

Position. MTMC does not agree and will retain the requirement that SIT charges at destination will not commence prior to the first work day following the agreed upon RDD or the offered delivery date when later than the RDD. The RDD will be established and mutually agreed to between the contractor and customer during the movement counseling. This direct personal interface between the contractor and customer will encourage open communication and realistic RDDs can be established. This will also allow the contractor to more efficiently utilize his resources. MTMC realizes spread dates are a commercial business practice; however, we believe the use of spread dates should be at the discretion of the customer. MTMC does not object to use of spread dates if agreed to by the customer. If the shipment arrives within the spread and delivery cannot be coordinated, SIT begins from expiration of the time provided for transportation services at destination. If the shipment arrives ahead of the spread, then SIT will start on the first day of the spread. Our desire to limit SIT is not based on considerations associated with the cost of SIT. Rather, we hope to limit unnecessary handling of the HHGs and thereby reduce the incidence of damage.

(80) *Industry:* A single daily SIT charge, based on a 100 pound minimum, which includes warehouse handling, storage, and drayage to/from the SIT facility is not appropriate and not prevailing commercial practice. When a shipment is placed into storage, a large percentage of the charges are incurred from unloading the truck and handling the shipment. That is why the tariff contains a warehouse handling charge and a higher first-day SIT charge. The charges for additional days are lower because the costs involved with actual storage are much lower than the first day. The Government would save money by continuing this practice. Other alternatives include minimum 30-day storage period with separate warehouse handling and delivery charges or separating the SIT charge from the warehouse handling/drayage charge. These alternatives would ensure sufficient revenue is generated to pay for administrative and operational costs.

Response: MTMC partially agrees and has modified Attachment 3 to read ''Charges for this service will be based on the net weight of property stored in transit, subject to a 500# minimum.'' MTMC recognizes charges associated with warehouse handling and drayage differ from those associated with the actual storage of the property. Accordingly, a modification also has been made which allows the Contractor to submit a SIT charge which applies for each 15-day period of storage or fraction thereof and a warehouse handling/ drayage charge. These two charges will be submitted separately and considered in the price area during the source selection evaluation process.

(81) *Industry:* A 100 mile radius for delivery out of SIT at no additional charge is not a commercial practice as well as an excessive requirement.

Response: MTMC agrees and has reduced the requirement. The requirement has been reduced to the contractor being responsible for direct deliveries and deliveries from SIT within a 50 mile radius of the original destination at no additional charge. The contractor will be compensated for direct deliveries and deliveries from SIT within the AOR that are more than 50 miles from the original destination. Attachment 3, of the draft solicitation, will specify these provisions.

3.4.2 Flat Service Charge

(82) *Industry:* The Flat Service Charge is not a commercial business practice. The charge is stated on a per hour basis and the per hour amount includes all labor, mileage, and vehicle use. Accessorial services involving labor are billed in the commercial marketplace on a per man, per hour basis. The number of personnel required to perform a service varies depending on the size of a shipment. Therefore, it is difficult to construct a rate which would compensate the service provider equitably. Recommend changing this service to include billing on a per hour, per man, basis. In addition, a separate flat service charge should be solicited for HHG and UB because the equipment and manpower for each is vastly different.

Response: MTMC does not agree. The per man approach complicates the verification and billing process. MTMC believes industry can construct a rate based on the average number of personnel required to perform the services specified.

3.4.2.3 Extra Pickup and/or Delivery

(83) *Industry:* Extra pickup and/or delivery requirements are not commercial business practices. The contractor should be compensated for any extra pickup or delivery, not just more than one. The 75-mile radius is excessive and should be changed to 50 miles.

Response: MTMC recognizes requiring the contractor to perform the first extra pickup or delivery outside a 75-mile radius from the first pickup point may be excessive. Accordingly, the 75-mile radius has been changed to 50 miles. MTMC believes those accessorials services which are routinely ordered should be included in the SFR. This will ease the program administration and execution.

3.4.2.6 Partial Withdrawal From Sit

(84) *Industry:* Application of the flat service charge is not realistic. The definition of this charge includes the use of trucks and mileage. Removal of a shipment from storage in a warehouse and sorting items is completely different in nature. A charge based on labor per hour, per man should apply to ensure service providers are equitably compensated.

Response: The Flat service charge is a labor charge which includes the sorting of items.

(85) *Industry:* Customer presence in the warehouse during sorting may pose insurance problems.

Response: Should such presence require additional cost to the carrier, MTMC would expect that to be addressed in the carrier's SFR. The option which allows the customer or PPSO to be present at the contractor's facility during sorting and removal of the partial withdrawal from SIT has been retained. The customer or PPSO presence will minimize claims disputes because of the actual observation and should therefore protect the contractor and the customer by eliminating speculation over mishandling.

3.4.2.7 Waiting Time

(86) *Industry:* Free waiting time should be limited to 2 hours for both domestic and international.

Response: MTMC agrees that 4 hours free waiting on domestic shipment is excessive, and has reduced the requirement to 2 hours. However, do not agree on reducing free waiting time on international shipments from the 24 hours initially established in the draft requirements document. The majority of international shipments go into agent facilities first. Consequently, driver time will typically not be lost as a result of the 24 hours of free waiting time on international shipments because the shipment will most likely already be stationed in an agent's facilities.

3.4.5 Third Party Service

(87) *Industry:* Commercial practice allows the contractor to add a percentage to the cost incurred for the process of handling and funding the transaction. Normal add-ons are in the 10 percent range and this provision should be incorporated into this item.

Response: MTMC disagrees and retains the requirement that the contractor will be reimbursed actual charges. Historically, a third party invoice which sets both the services rendered, charges and basis thereof must accompany the contractor billing. We do not intend to change that practice from the commercial practice in effect throughout the U.S.

Schedule A—Rate Sample

(88) *Industry:* The sample needs to be expanded to include the charges at both origin and destination for all services. Because of the requirement that prevailing wage scales be utilized in all areas, there will be vast differences in the charges.

Response: MTMC agrees and recognizes costs vary significantly by geographic area. Therefore, Schedule A has been modified to allow contractors to submit separate accessorial charges for SIT services, Flat Service, and special crating for each origin rate area within a region.

(89) *Industry:* The proposed rate sample contemplates only one rate for commercial/military air for HHG and UB. The same SFR cannot apply to those shipments moving either commercial or military air.

Response: MTMC did not contemplate the same SFR applying for HHG and UB movement via commercial and military air. The contractor will be asked to submit a separate rate for commercial air—HHG and UB; and military air—HHG and UB. However, the contractor will be required to accept all commodities for movement upon contract award.

Attachment 9—Weight Additives

1.

(90) *Industry:* The only item that the draft requirements document provides additional compensation for are boats. A weight additives charges should apply for other commonly shipped bulky articles such as satellite dishes, hot tubs, etc., as spelled out in the current tariff item.

Response: MTMC does not agree. The costs associated with bulky articles should be included in the SFR. In the current ITGBL program, costs for this service are included in the SFR.

1.3 Boats and Sailboats

(91) *Industry:* It is unreasonable to expect contractors to transport boats and/or similar items 14 feet and less at no additional cost. Boat charges should follow the commercial tariff. Also, the proposed provisions for boats over 14 feet but less than 25 feet presents serious problems for international shipments. Boats of this size will not fit in lift vans and must go inside the ocean container. The proposed weight additive factor for boats will not provide adequate revenues to cover significant expenses incurred in accommodating boats of this size. If boats are too wide to fit inside a ocean container they must be accommodated on racks. Ocean charges increase significantly if the boat extends beyond the sides of the rack since the boat occupies three ocean container spaces. Recommend boats 14 feet and over in length remain in the OTO program for international shipments.

Response: MTMC has modified the requirements document by adding a weight additive of 700 pounds for boats and sailboats less than 14 feet in length. Boat trailers less than 14 feet will have a weight additive of 1000 pounds. Boats, sailboats, and boat trailers 14 feet and over will be moved under the one time only (OTO) program. Canoes, skiffs, rowboats, dinghies, sculls, and kayaks 14 feet and over in length will have a weight additive of 700 pounds, while those less than 14 feet will be moved under a single factor rate with no weight additive. Other specifics of the requirements concerning boats will be released in the upcoming draft solicitation.

Attachment 10—Weigh/reweigh Procedures

(92) *Industry:* Current commercial practice is that there is no specific charge for a reweigh but the second weight is the billing weight, regardless of whether it is above or below the first weight. Since DOD shipments have a very high reweigh request rate, then the contractor should be compensated for reweighs.

Response: MTMC will require the contractor to incorporate reweighs in their single factor rate. Also, MTMC feels that the DOD as the single largest shipper should benefit from the best commercial practices available. Since the commercial practice is that no specific charge is associated with reweighs, then reweighs ordered by the government should also be conducted at

no additional cost to the Government. Further, MTMC, by requiring the lower of the two weights to be used as the transportation charge, is not modifying the program as it currently operates today. Finally, changing reweigh procedures so that the second weight is also the billing weight may adversely effect the members' entitlement to request reweighs.

7. Observation of Weighing

(93) *Industry:* Unless specifically requested by the PPSO or the customer, the contractor should not have to advise the PPSO or the customer of the time and specific location of every shipment weighing. This is an unnecessary administrative burden on the PPSO, the customer, and the contractor.

Response: MTMC agrees and has changed the language to read that ''upon request'' the contractor will, prior to weighing, advise the PPSO or the customer of the time and specific location of every shipment weighing. Also the PPSO or the customer will have the right to observe all weighing upon request and will be entitled to notice of the time and location of the weighing with sufficient time to exercise that right.

Gregory D. Showalter,

Army Federal Register, Liaison Officer.

[FR Doc. 96–8093 Filed 4–2–96; 8:45 am]

BILLING CODE 3710–08–M

Tender Filing Instructions for the Movement of Foreign Military Sales (FMS) Materiel

AGENCY: Military Traffic Management Command (MTMC), DOD.

ACTION: Notice.

SUMMARY: The Military Traffic Management Command's (MTMC) guidance to the carrier industry on how to submit unsolicited transportation rates (voluntary tenders) for the movement of FMS materiel is as follows:

Carriers who voluntarily agree to participate in FMS movements must submit a Standard Tender(s) of Freight Services MT Form 364–R numbered in the 300,000 series (300,000 to 399,999 inclusive) to apply to movement of FMS materiel only; numbered in the 400,000 series (400,000 to 499,000 inclusive) to apply to movement of both FMS and Department of Defense (DOD) materiel; and, numbered according to instructions contained in MTMC Standard Tender Instruction Publication No. 364 to apply to movement of DOD material only. Tender numbers must be consecutively numbered.

DATES: These instructions are effective April 3, 1996.

ADDRESSES: Headquarters, Military Traffic Management Command, ATTN: MTOP–T–SR, Room 629 5611 Columbia Pike, Falls Church, VA 22041–5050.

FOR FURTHER INFORMATION CONTACT: Ms. Teresa Schoppert, MTOP–T–SR, (703) 681–3440 or e-mail schoppet@baileys-emh5.army.mil.

SUPPLEMENTARY INFORMATION: Historically, shipments of FMS have moved using public tariff rates only. The Interstate Commerce Commission Termination Act of 1995 (Public Law 104–88) abolished the Interstate Commerce Commission, and the Trucking Industry Regulatory Reform Act of 1994 (Public Law 103–311) repealed the requirement that motor carriers (other than carriers of household goods) publish and file a tariff and access rates contained in that tariff. As a result, tariffs are no longer filed by carriers with a regulatory agency, and there is, accordingly, no legal requirement that carries apply a tariff rate to FMS traffic. MTMC will now accomplish movement of FMS materiel by the use of tenders (MT Form 364–R). Carriers wishing to voluntarily offer rates for these movements should follow the guidelines published herein.

Gregory D. Showalter,

Army Federal Register, Liaison Officer.

[FR Doc. 96–8056 Filed 4–2–96; 8:45 am]

BILLING CODE 3710–08–M

Corps of Engineers

Intent To Prepare a Draft Supplemental Environmental Impact Statement (SEIS), Operation and Maintenance, Arkabutla Lake, Enid Lake, Grenada Lake, and Sardis Lake, MS; Addressing Yalobusha River, Above Grenada Lake

AGENCY: U.S. Army Corps of Engineers, Vicksburg District, DOD.

ACTION: Notice of Intent.

SUMMARY: The purpose of the proposed action is to reduce flood damage potential, sedimentation, and erosion of the Yalobusha River by restoring channel capacity upstream of the Grenada Lake flood control reservoir. The project includes the Yalobusha River within the U.S. Army Corps of Engineers Grenada Lake project boundary, near Calhoun City, Mississippi.

FOR FURTHER INFORMATION CONTACT: Mr. Stuart C. McLean (601) 631–5965, CELMK–PD–Q, 2101 North Frontage Road, Vicksburg, Mississippi 39180–5191.

SUPPLEMENTARY INFORMATION:

1. Authority for the work is contained in the Flood Control Act of 1936, as amended by the Flood Control Act of 1946 and subsequent Acts. Specific authorization for Yalobusha River channel maintenance is contained in the SR 104–120, 29 July 1995.

2. The range of alternatives to be considered include no action, acquisition of lands subject to flooding, and various options for restoring channel capacity.

3. a. Significant issues tentatively identified include bottom-land hardwood/wetlands, waterfowl, fisheries, water quality, cultural resources, and socioeconomic conditions. Additional environmental requirements may be identified during the scoping process.

b. The Environmental Protection Agency; U.S. Fish and Wildlife Service; Mississippi Department of Wildlife, Fisheries and Parks; Mississippi Department of Environmental Quality; and Natural Resource Conservation Service will be invited to participate as cooperating agencies.

c. The scoping process is scheduled to begin in March 1996. Public notices, containing a description of the proposed project, will solicit input as to the scope of issues to be addressed in the Draft SEIS. All affected Federal, state, and local agencies and other interested private organizations and parties will be invited to participate.

4. A Draft SEIS will be available for review by the public during FY 97.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 96–8052 Filed 4–2–96; 8:45 am]

BILLING CODE 3710–PU–M

Department of the Navy

Notice of Proposed Information Collection; Naval Sea Systems Command

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Naval Sea Systems Command announces the proposed reinstatement of a previously approved public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and

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

DATES: Consideration will be given to all comments received by June 3, 1996.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to Commander, Naval Sea Systems Command, Code SEA–071, 2531 Jefferson Davis Highway, Arlington, VA 22242–5160.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call Mr. Leonard Thompson at (703) 602–4170, extension 139.

Title, Associated Form, and OMB Number: Facilities Available for the Construction or Repair of Ships; Standard Form 17; OMB Control Number 0703–0006.

Needs and Uses: The information collection requirement is necessary to provide Commander, Naval Sea Systems Command and the Maritime Administration with a list of facilities available for the construction or repair of ships and a database for assessing the production capability of the individual shipyards.

Affected Public: Businesses or other for profit institutions.

Annual Burden Hours: 700.

Number of Respondents: 175.

Responses Per Respondent: 1.

Average Burden Per Response: 4 hours.

Frequency: Annually and as requested.

SUPPLEMENTARY INFORMATION: Data collection of the Standard Form 17 is used for determining and assessing capabilities for ship construction, ship repair, and services rendered to Maritime and Navy ships. No other information source provides a comprehensive listing of private sector ship repair firms' physical capabilities and limitations including launching ways drydocks, piers, shops, cranes, work force, etc. among other items.

Dated: March 22, 1996.

M.D. Schetzsle,

LT, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 96–8061 Filed 4–2–96; 8:45 am]

BILLING CODE 3810–FF–P

Notice of Proposed Information Collection for Headquarters, Navy and Marine Corps MARS

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Headquarters, Navy and Marine Corps Military Affiliate Radio System (MARS) announces the proposed reinstatement of a previously approved public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 3, 1996.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to Chief, Navy and Marine Corps MARS, Building 13, Naval Communication Detachment, Cheltenham (NCDC), Washington, DC 20397–5161.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call Mr. D. Vittum at (301) 394–0267.

Title, Associated Form, and OMB Number: Application for Membership in Navy-Marine Corps Military Affiliate Radio System (MARS); DD 630; OMB Control Number 0704–0013.

Needs and Uses: The information collection requirement is necessary to collect data to make a determination as to the applicant's eligibility for membership into Navy-Marine Corps MARS.

Affected Public: Individuals or households.

Annual Burden Hours: 150.

Number of Respondents: 500.

Responses per Respondent: 1.

Average Burden Per Response: 18 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION: The information collected on the DD 630 is necessary to assess the applicant's qualifications to meet membership criteria. Information is provided by amateur radio operators interested in joining Navy-Marine Corps MARS. The information gathered is used by MARS officials to certify eligibility for membership.

Dated: March 22, 1996.

M.D. Schetzsle,

LT, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 96–8062 Filed 4–2–96; 8:45 am]

BILLING CODE 3810–FF–P

Notice of Proposed Information Collection for Chief of Naval Education and Training

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Chief of Naval Education and Training announces the extension of a currently approved public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 3, 1996.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to LT Jackson at the Chief of Naval Education and Training, CNET N211, 250 Dallas Street, Pensacola, FL 32508.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call LT Jackson at (904) 452–4941 or 1–800–NAV–ROTC.

Title, Associated Form, and OMB Number: Application Forms. Booklet; CNET 1533/74, 1533/91, 1533/87, 1533/92, 1533/88, 1533/93, 1533/89; OMB Control Number 0703–0026.

Needs and Uses: The information collection requirement is necessary to make a determination of applicant's academic and/or leadership potential and eligibility for an NROTC Scholarship.

Affected Public: Individuals or Households.

Annual Burden Hours: 56,000.

Number of Respondents: 14,000.

Responses per Respondent: 1.

Average Burden per Response: 4 hours.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION: The NROTC Four-Year Scholarship Booklet (CNET Forms 1533/74/91/87/92/88/93/89) is the collection instrument of information which is used to make a determination of an applicant's academic and/or leadership potential and eligibility for an NROTC Scholarship.

Dated: March 22, 1996.

M.D. Schetzsle,

LT, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 96–8063 Filed 4–2–96; 8:45 am]

BILLING CODE 3810–FF–P

Naval Research Advisory Committee; Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), notice is hereby given that the Naval Research Advisory Committee Panel on Damage Control/Maintenance will meet on April 10 and 11, 1996. The meeting will be held at the Office of Naval Research, 800 North Quincy Street, Room 915, Arlington, Virginia. The first session will commence at 9:00 a.m. and terminate at 5:00 p.m. on April 10; the second session will commence at 9:00 a.m. and terminate at 12:00 Noon on April 11, 1996. All sessions of the meeting will be open to the public.

The purpose of the meeting is to provide the Navy with an assessment of current science and technology opportunities, as well as policy and process improvements, to reduce onboard manning for damage control and maintenance of at-sea platforms.

The meeting will include briefings and discussions relating to the study tasking, previous studies, task force assignments, briefings from the Office of Naval Research on current technology challenges and issues, and a status report on the Smart Ship.

For further information concerning this meeting contact:Ms. Diane Mason-Muir, Office of Naval Research, 800 North Quincy Street, Arlington, VA 22217-5660, Telephone Number: (703) 696-4870.

Dated: March 25, 1996

M.D. Schetzsle,

LT, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 96-8065 Filed 4-2-96; 8:45 am]

BILLING CODE 3810-FF-P

Report on Navy Ship Garbage Discharges in MARPOL Annex V Special Areas

SUMMARY: Under section 1003 of the National Defense Authorization Act for Fiscal Year 1994, Public Law 103–160, the Secretary of Defense must report annually in years 1994 through 2000 on the amount and nature of garbage discharges from Navy ships operating in special areas, when such discharges are not otherwise authorized under Annex V of the International Convention on the Prevention of Pollution from Ships (MARPOL). This notice is the second annual report.

FOR FURTHER INFORMATION CONTACT: Mr. Louis Maiuri, Office of the Chief of Naval Operations Environmental Protection, Safety and Occupational Health Division, Crystal Plaza #4, Room 654, 2211 South Clark Place, Arlington, Virginia, 22244–5108; 703–602–2602.

SUPPLEMENTARY INFORMATION: The International Convention on the Prevention of Pollution from ships (MARPOL) as amended by the MARPOL Protocol of 1978, protects the ocean environment by prohibiting some discharges altogether, restricting other discharges to particular distances from land, and establishing ''special areas'' within which additional discharge limitations apply. Special areas are particular bodies of water which, because of their oceanographic characteristics and ecological significance, require protective measures more strict than other areas of the ocean. Within special areas that are in effect internationally, except under emergency circumstances the only authorized garbage discharge from vessels in food waste. At present, three special areas are in effect: the North Sea, the Baltic Sea, and the Antarctic Region. Section 1003 of the National Defense Authorization Act for Fiscal Year 1994, Pub. L. 103–160, 107 Stat. 1745, established deadlines for compliance by U.S. Navy ships with the Annex V special area requirements. Surface ships must comply with the special area requirements by December 31st of the year 2000. Submarines must comply with the special area requirements by December 31st of the year 2008. The Act further requires the Secretary of Defense to report in the Federal Register the amount and nature of Navy ship discharges in special areas, not otherwise authorized under MARPOL Annex V. This Federal Register notice is the second of the required annual reports. This report covers the period between 1 August 1994 and 31 July 1995. The end date of July 31st is necessary to allow time for data collection and report preparation. During the period 1 August 1994 through 31 July 1995 there were no garbage discharges from Navy ships into MARPOL Annex V special areas that were not authorized under MARPOL Annex V.

Dated: March 22, 1996.

M.D. Schetzsle,

LT, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 96–8059 Filed 4–2–96; 8:45 am]

BILLING CODE 3810–FF–P

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: Uniformed Services University of the Health Sciences.

TIME AND DATE: 1:00–4:00 p.m., May 17, 1996.

PLACE: Uniformed Services University of the Health Sciences, Board of Regents Conference Room (D3001), 4301 Jones Bridge Road, Bethesda, MD 20814–4799.

STATUS: Open—under ''Government in the Sunshine Act'' (5 U.S.C. 552b(e)(3)).

MATTERS TO BE CONSIDERED:

1:00 p.m. Meeting—Board of Regents

(1) Approval of Minutes—February 5, 1996

(2) Faculty Matters

(3) Granting of Degrees

(4) Departmental Reports

(5) Financial Report

(6) Report—President, USUHS

(7) Report—Dean, School of Medicine

(8) Comments—Chairman, Board of Regents

(9) New Business

CONTACT PERSON FOR MORE INFORMATION: Mr. Bobby D. Anderson, Executive Secretary of the Board of Regents, (301) 295–3116.

Dated: April 1, 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–8381 Filed 4–1–96; 3:22 pm]

BILLING CODE 5800–04–M

DEPARTMENT OF ENERGY

Contractor Litigation Cost Policies; Policies, Terms of Law Firm Engagement, and Allowability of Costs

AGENCY: Department of Energy.

ACTION: Notice of final policy statement.

SUMMARY: The Department of Energy today publishes a final policy statement that was issued in interim form in an internal Acquisition Letter giving policy guidance to contracting officers. This policy statement sets forth policies regarding two contract clauses that are prescribed by the Department of Energy Acquisition Regulation (DEAR). The policy statement sets forth a statement of policy regarding the terms of engagement that should be a condition of any contracting officer's authorizing a current or former management and operating (M&O) contractor to engage a law firm to defend a lawsuit. The policy statement also sets forth policies for a contracting officer's consideration in determining whether particular litigation costs are reasonable and allowable.

EFFECTIVE DATE: May 3, 1996.

FOR FURTHER INFORMATION CONTACT: Lisa Schiavo Blatt, Assistant General Counsel for Contractor Litigation Reform, U.S. Department of Energy, Washington, DC 20585 (202) 586–5281.

SUPPLEMENTARY INFORMATION: The Department of Energy (Department) owns facilities in various locations in the United States which have been operated by former and current M&O contractors. In connection with these facilities, there is a substantial amount of litigation against which the Department may elect to defend the contractor or authorize the contractor to defend. The standard provisions of M&O contracts allow contracting officers to authorize contractors to engage lawyers to defend lawsuits, subject to such conditions as the contracting officers deem appropriate. See 48 CFR 970.5204–31. The standard provisions of M&O contracts also authorize contracting officers to determine whether the costs charged are reasonable and allowable. See 48 CFR 970.5204–13.

In recent years, the Department experienced unacceptably high litigation costs from M&O contractors in connection with the defense of lawsuits where the Department elected to have the contractor engage lawyers to conduct the litigation. Moreover, contracting officers dealing with these costs differed in their approaches to determining whether a litigation cost was reasonable. The Department had an urgent need to promote a more uniform approach by contracting officers to such costs and to stem payment of unreasonable expenses. This need was and will continue to be particularly compelling in light of the substantial dollar amounts at stake and the Department's budgetary situation.

As a result, on August 31, 1994, the Department published an interim Acquisition Letter as an interim policy in the Federal Register (59 FR 44981). The interim Acquisition Letter was issued to contracting officers responsible for administering M&O contracts and set forth the Department's policies for contracting officer's consideration regarding the interpretation and application of two clauses prescribed by the DEAR. The interim Acquisition Letter established the Department's policy that should prove to be reasonable in most circumstances regarding the terms of engagement that should be a condition of any authorization to a current or former M&O contractor (or any contractor who may have or had a Department of Energy contract containing a ''Litigation and Claims'' clause) to engage a law firm for purposes of litigation. The interim Acquisition Letter also established policies for a contracting officer's consideration in determining whether particular litigation costs are reasonable and allowable.

The provisions of this policy statement are largely self-explanatory. They are based on past experience of the contractors, the Department, and other federal agencies (including the Federal Deposit Insurance Corporation and Resolution Trust Corporation) in managing and controlling litigation costs throughout the Nation, and should provide a reasonable decisionmaking framework for contracting officers without being unnecessarily constraining. If any of the provisions of this policy statement would be unreasonable as applied, contracting officers have the discretion to depart from the policy based upon particular facts and circumstances.

The Department sought public comment on the interim Acquisition Letter in order to give the public, including those persons who are affected by the policies, an opportunity to comment on the interim Acquisition Letter before it was finalized. Comments on the notice of interim policy were required to be received on or before September 30, 1994. The Department received comments from only one commenter. The Department reviewed the comments and has determined to finalize the interim policy in the August 31, 1994, Acquisition Letter with some minor modifications as described below.

The commenter suggested that the Department combine the guidance provided in the interim Acquisition Letter with earlier guidance issued by the Department entitled ''Litigation Management Procedures'' (referred to by the commenter as ''Management of Litigation Activities'') and publish the combined procedures for review and comment. The commenter claimed that there were significant differences between the two documents and argued that the existence of two documents on the subject of contractor litigation makes it unclear which terms of engagement are binding on M&O contractors.

While there may be some merit to having one comprehensive document addressing contractor litigation procedures, the Department does not believe that the guidance provided in the two documents is conflicting or confusing because they address different topical areas. The earlier document on litigation management provides guidance to the Department's contracting officers and M&O contractors on the development of contractor litigation procedures such as a Staffing and Resource Plan. The interim Acquisition Letter provided guidance to the Department's contracting officers in determining the reasonableness of contractor litigation expenses and related terms of engagement. However, the Department will continue to review the effectiveness of its litigation management policies and cost guidelines and will work to consolidate and streamline procedures if warranted.

The commenter questioned whether the policy on contractor litigation costs could be implemented by the issuance of an Acquisition Letter. The commenter pointed out that the Department does not have the right to modify a contract unilaterally.

The Department disagrees with the commenter's position that a bilateral contract modification is necessary to implement or modify the provisions of the interim Acquisition Letter or this policy statement. The interim Acquisition Letter, now finalized as a policy statement, does not constitute a unilateral contract modification, but rather a set of non-binding uniform and consistent guidelines to assist contracting officers in determining the reasonableness of litigation costs, which they are required to do under 48 CFR 970.3101–3. Contracting officers may authorize exceptions to the policies set forth in the policy statement based upon ''economy, the interests of the Government, or other good cause.'' If a

contractor were to contest a contracting officer's adverse determination on allowability of costs or terms of engagement consistent with the policy statement, the Department would have to defend those determinations on the merits under the terms of applicable contract clauses.

The commenter suggested that the Department should not require contracting officer approval on a case-by-case basis of the terms of engagement between the contractor and an outside firm. Instead, once a contractor's litigation management policies have been approved by the Department, all costs incurred consistent with the approved system should be allowable.

The Department believes that case-by-case review of contractor agreements with outside law firms is necessary to ensure effective control of contractor litigation costs. This need is particularly compelling in light of the substantial dollar amounts at stake and the Department's budgetary constraints.

The commenter recommended that the Department modify 48 CFR 970.71, ''Management and Operating Contractor Purchasing,'' to incorporate provisions governing the terms of engagement with outside law firms, since these are, in effect, contracts for services. However, the Department is disinclined at this time to codify this policy statement in the Department of Energy Acquisition Regulation. As the Department gains experience with the guidance provided in this policy statement and with the implementation of its Litigation Management Procedures, it will consider whether and to what extent the provisions of these documents should be codified in the DEAR.

Finally, the commenter characterized as ''confusing'' the statement in section III.A. of the interim Acquisition Letter that failure to specify or describe a particular category of costs does not imply that such category of costs is either allowable or unallowable. However, the commenter did not provide any example to illustrate why the statement was ''confusing.'' The statement in Section III.A. is essentially a quotation from the Department's standard allowable cost clause. See 48 CFR 970.5204–13(c). The purpose of the statement, also contained in this policy statement, is to reiterate to contractors that costs not identified as specifically allowable or unallowable are still subject to the general rules of allowability, reasonableness, and allocability. Since the statement points out to contractors that an existing standard clause applies to litigation costs and procedures, the Department believes no further clarification is necessary.

Issued in Washington, D.C. on March 22, 1995.

Richard H. Hopf,

Deputy Assistant Secretary for Procurement and Assistance Management.

Final Policy Statement:

Management and Operating Contractor Litigation Costs

I. Purpose

The purpose of this policy statement is to establish final policies on the reasonableness of management and operating (M&O) contractor litigation costs.

II. Background

Under the allowable costs clause of the Department's M&O contracts, attorneys' fees and other litigation costs are allowable only if reasonable and incurred in accordance with the Litigation and Claims clause. The policies set forth below are a prospective reference to aid in Contracting Officers' determinations as to whether contractor litigation costs under M&O contracts are reasonable.

The Department recognizes that these policies can be most effectively achieved for pending cases through the cooperation of the contractors and the law firms involved. The Department intends to work closely with the contractors to ensure a smooth implementation that will not compromise the defense of pending matters.

III. Guidance

These policies apply to reimbursement of present and former M&O contractors for amounts paid to outside law firms and consultants (''outside firms'') in connection with litigation to which the contractor is a party, except to the extent the contractor's own litigation procedures or current retainer agreements contain more cost-restrictive provisions. The Contracting Officer, or his or her designated representative (hereinafter ''Contracting Officer''), may, after consultation with Department counsel, authorize an exception to the policies described below based upon economy, the interests of the Government, or other good cause. These policies may be modified, from time to time, as the Department determines appropriate. The Contracting Officer has authority to exclude from these policies cases whose expected costs of defense are less than $25,000 and/or routine matters handled by outside counsel retained and supervised by an insurance carrier.

A. Final Policies

Contracting Officers shall refer to and consider the following policies in determining the reasonableness of contractor litigation costs. The failure to specify or describe a particular category of cost in paragraphs III.A.1. through III.A.10. does not imply that such category of cost is either allowable or unallowable.

1. Terms of Engagement

In order for costs incurred by an M&O contractor for an outside firm to be considered reasonable, they shall be incurred in accordance with the terms of engagement between the contractor and the outside firm which have been approved by the Contracting Officer. The terms of engagement between the contractor and the outside firm shall incorporate and include the policies included in paragraphs III.A.1. through III.A.10. of this policy statement. The terms of engagement shall also provide that the outside firm will comply with the Department's Litigation Management Procedures, which, among other things, require a Staffing and Resource Plan (for significant cases), periodic case assessments and budgets, adequate audit provisions, and notification to the Department and the contractor of any significant change in the Staffing and Resource Plan.

a. Bills and invoices. All bills and invoices shall reflect the information and contents set forth in the model format of Attachment A. Any bill or invoice shall also contain a certification signed by a representative of the outside law firm to the effect that:

''Under penalty of law, [the representative] acknowledges the expectation that the bill will be paid by the contractor and that the contractor will be reimbursed by the Federal Government through the U.S. Department of Energy, and, based on personal knowledge and a good faith belief, certifies that the bill is truthful and accurate, and that the services and charges set forth herein comply with the terms of engagement and the policies set forth in the Department of Energy policy statement on contractor litigation, and that the costs and charges set forth herein are necessary for the litigation.''

b. Audit. All terms of engagement must contain a provision for auditing expenditures under the terms of engagement to determine and ensure compliance with the terms of engagement and the provisions of the prime contract, and to determine the accuracy of any bill or invoice for the services of the outside firm. The provision shall include a statement that:

- [The outside firm] expects that the costs of the services rendered under the terms of engagement will be paid by the contractor and that the contractor will be reimbursed by the Federal Government through the U.S. Department of Energy.
- [The contractor] and the Department of Energy, its designated representative, and the General Accounting Office, have the right upon request, at reasonable times and at reasonable locations, to inspect, copy, and audit all records documenting billable fees and costs under the terms of engagement, the systems employed by [the outside firm] to capture, record, and bill the fees and costs, and any other records relevant to the representation by the outside firm under the terms of engagement.
- [The outside firm] will retain all such records for a period of three (3) years after the final payment under the terms of engagement.
- The provision does not constitute a waiver of any applicable legal privilege, protection, or immunity with respect to disclosure of these records to third parties.

2. Fees

In determining whether fees or rates charged by an outside firm are reasonable for purposes of approving a contractor's terms of engagement with an outside firm, the Contracting Officer shall consider whether the contractor sought the lowest reasonably achievable fees or rates (including any currently available or possibly negotiable discounts) from the outside firm, whether the contractor considered rates available from other firms providing comparable services, and whether the contractor considered alternative rate structures such as flat, contingent, and other innovative proposals.

3. Profit and Overhead

The rate and fee structure shall include all outside firm ''overhead'' and ''profit,'' and, therefore, any additional overhead or profit charged by the outside firm shall be considered unreasonable. Similarly, any markups by the outside firm for supplies or services procured from third parties would be unreasonable. For instance, only the actual costs of messenger services shall be allowed, whether the service was performed by the outside firm or a third party. Additionally, any interest the contractor incurred on any outstanding (unpaid) bills from outside firms is not reimbursable under the Department of Energy Acquisition Regulation.

4. Travel and Related Expenses

Charges for air travel shall be the actual cost, not to exceed the coach class fare. Charges for local ground travel shall be the actual cost of the taxi service, or the existing Internal Revenue Service's mileage deduction allowance if the person drives his or her own automobile. Charges billed for meals, lodging and rental cars must be moderate. The rates set forth in the Federal Travel Regulations will be deemed presumptively reasonable. See 41 CFR ch. 301. Charges for luxury hotels, cars, or services such as movies and fitness facilities are neither necessary nor reasonable.

Travel by more than one person from an outside law or consulting firm to attend a deposition, court hearing, interview, or meeting outside the person's home office shall not be considered reasonable except when authorized by contractor counsel in accordance with procedures agreed upon with Department counsel.

Any travel time may be reimbursed at a full rate for the portion of time during which the outside firm performs work for the contractor. For air travel, any remaining travel time during normal working hours shall be reimbursed at 50 percent. In no event is travel time for time during which work was performed for other clients reimbursable.

5. Copying

Copying charges shall not exceed ten cents a page, unless supported by a cost study and approved in advance by the Contracting Officer. Copying projects where volume would generate substantial savings should be sent to outside vendors when practicable and cheaper. As with costs for all supplies and services, the Contracting Officer should look to local commercial rates as a benchmark.

6. Telephone Charges and Faxes

Charges billed for toll or long distance calls, including facsimile/telecopier transmissions, shall not exceed the actual charge for each call, with no overhead or surcharge adjustment.

7. Computer Time

Charges for computer-assisted research shall not exceed the actual cost, with no overhead or surcharge adjustments.

8. Overtime and Certain Temporary Employees

Secretarial and clerical overtime or costs of temporary support personnel billed by the outside firm shall not be charged, unless the Contracting Officer approves such overtime or temporary support personnel or the cost is caused or required by an emergency situation not of the contractor or outside attorney's making. Time charged by summer associates should be scrutinized for its efficiency and consistency with the Staffing and Resource Plan.

9. Experts Employed by Department of Energy Contractors

If the contractor or outside counsel wishes to retain as a consultant in a matter an employee of another contractor of the Department of Energy, the requesting contractor must receive prior approval from the Department of Energy, which will attempt to furnish the expert directly through the contractor that currently employs the potential consultant. This policy does not alter any applicable provisions of the prime contract with either the requesting or the employing contractor.

10. Specific Non-reimbursable Costs

The contracting officer shall not consider for reimbursement any proposed costs by the contractor for any direct costs incurred by outside firms for the following items: entertainment; alcoholic beverages; secretarial or clerical support time (except as provided under paragraph 8, above); word processing; computers or general application software; client development and related activities; trade publications, books, treatises, background materials, and other similar documents; professional/educational seminars and conferences; preparation of bills; parking fines or any other fines or penalties for illegal conduct; and food, beverages and the like when the attorney or consultant is not on travel status and away from the home office. An exception may be made, however, for reasonable expenses for working meals during an in-house meeting not in excess of $10 per person. No outside firm's bills are to contain any items representing disbursements made for the benefit of the contractor's employees, such as meals or lodging for contractor's current personnel (other than conference meals at which contractor personnel are present under this paragraph).

IV. Effective Dates

These policies are effective with respect to determinations of reasonableness and allowability of costs for services rendered and expenses incurred:

1. on or after October 1, 1994, for all class actions;

2. on or after November 1, 1994, for all non-class actions commenced on or after October 1, 1994; and

3. on or after February 1, 1995, for all non-class-action litigation commenced before October 1, 1994.

Attachment A. — U.S. Department of Energy, Office of General Counsel, Contractor Litigation Costs, Model Bill Format and Contents

I. FOR FEES

Date of service	Description of service	Name or initials of attorney	Approved rate	Time charged	Amount (rate x time)
.....	(See Note 1 below).	.....	.....	.....	

II. FOR DISBURSEMENTS

Date	Description of disbursement	Amount
.....	(See Note 2 below).	

Note 1.—Description of Service: All fees must be itemized and described in sufficient detail and specificity to reflect the purpose and nature of the work performed (e.g., subject matter researched or discussed; names of participants of calls/meetings; type of documents reviewed).

Note 2.—Description of Disbursement: Description should be in sufficient detail to determine that the disbursement expense was in accordance with all applicable DOE policies on contractor litigation costs and the terms of engagement between the contractor and the law firm (e.g., if copying charges, include number of pages copied and cost per page).

[FR Doc. 96–8171 Filed 4–2–96; 8:45 am]
BILLING CODE 6450–01–P

Notice of Conference on Freedom of Information Act Policies and Procedures

AGENCY: U.S. Department of Energy.

ACTION: Notice of conference.

SUMMARY: The Department of Energy (DOE) is announcing that it will hold a conference to discuss DOE Freedom of Information Act policies and procedures. This conference is being held to further the goals of the Secretary's Openness Initiative.

DATES AND ADDRESSES: The meeting will be held on April 23, 1996, from 10 a.m. to 12 noon beginning in the Main Auditorium of the Forrestal Building, U.S. Department of Energy Headquarters, 1000 Independence Avenue, S.W., Washington, D.C. 20585. Break-out sessions will follow in both the Main and Small Auditoriums.

FOR FURTHER INFORMATION CONTACT: Ed McGinnis, FOIA/Privacy Act Division, U.S. Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585 or call (202) 586–1310.

SUPPLEMENTARY INFORMATION: President Clinton, in an October 4, 1993, memorandum, called on all Federal departments and agencies to renew their commitment to the underlying principles and sound administration of the Freedom of Information Act (FOIA). On that same day, Attorney General Janet Reno asked all Federal departments and agencies to ensure that the principle of openness in government be applied in every disclosure and nondisclosure decision made pursuant to the FOIA.

The Department of Energy is fully committed to the goals and principles articulated in President Clinton's and Attorney General Reno's memoranda. As part of the Department's efforts to comply with both the letter and spirit of the FOIA, a FOIA Users Conference is being convened to discuss how the Department can better meet the needs of FOIA requesters. All interested parties are encouraged to attend this Conference and contribute to the discussion.

AGENDA: The agenda for the meeting is as follows:

(1) Welcome and introductory remarks;

(2) Concurrent panel discussions (Panelist will be DOE program officials who will discuss their programs record systems and FOIA procedures);

(3) Open discussion and question and answer period.

PUBLIC PARTICIPATION: The meeting will be open to the public. However, seating is limited and will be available on a first-come, first-served basis. Individuals who need further assistance or wish to provide special remarks at the conference should contact Ed McGinnis at (202) 586–1310 by April 16, 1996.

Signed March 26, 1996.

Archer L. Durham,

Assistant Secretary for Human Resources and Administration.

[FR Doc. 96–8132 Filed 4–2–96; 8:45 am]
BILLING CODE 6450–01–P

Energy Information Administration

Agency Information Collection Activities

AGENCY: Energy Information Administration, Department of Energy.

ACTION: Agency information collection activities: Proposed collection; comment request.

SUMMARY: The Energy Information Administration (EIA) is soliciting comments concerning the revisions to the Form EIA–411, ''Coordinated Bulk Power Supply Program Report.''

DATES: Written comments must be submitted on or before June 3, 1996. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below of your intention to do so as soon as possible.

ADDRESSES: Send comments to Mr. John W. Makens, EI–523, Office of Coal, Nuclear, Electric and Alternate Fuels, Energy Information Administration, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585. Phone—(202) 426–1165. FAX—(202) 426–1308. E:mail: JMAKENS@EIA.DOE.GOV

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Mr. John W. Makens at the address listed above.

SUPPLEMENTARY INFORMATION:

I. Background.
II. Current Actions.
III. Request for Comments.

I. Background

In order to fulfill its responsibilities under the Federal Energy Administration Act of 1974 (Pub. L. No. 93–275) and the Department of Energy Organization Act (Public Law 95–91), the Energy Information Administration is obliged to carry out a central, comprehensive, and unified energy data and information program. As part of this program, EIA collects, evaluates, assembles, analyzes, and disseminates data and information related to energy resource reserves, production, demand, and technology, and related economic and statistical information relevant to the adequacy of energy resources to meet demands in the near and longer term future for the Nation's economic and social needs.

The Energy Information Administration, as part of its continuing effort to reduce paperwork and respondent burden (required by the Paperwork Reduction Act of 1995 (Public Law 104–13)), conducts a presurvey consultation program to provide the general public and other Federal agencies with an opportunity to comment on proposed and/or continuing reporting forms. This program helps to ensure that requested data can be provided in the desired format, reporting burden is minimized, reporting forms are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

The Form EIA–411 is filed annually as a voluntary report. The information reported includes: (1) Actual energy and peak demand for the preceding year and 10 additional years; (2) existing and future generating capacity; (3) scheduled capacity transfers; (4) projections of capacity, demand, purchases, sales, and scheduled maintenance; and (5) bulk power system maps. These data support queries from the executive branch, Congress, other public agencies, and the general public. The data present various council aggregate totals for their member electric utilities, with some nonmember information included. The *1994 Electric Power Annual, Volume II* published selected information, while the *1994 Inventory of Power Plants in the United States* published capacity information. These publications and other EIA publications may be purchased from the Superintendent of Documents, U.S. Government Printing Office. Telephone orders may be directed to: Mail Order Desk, (202) 512–1800 or by FAX at (202) 512–2250.

II. Current Actions

EIA is requesting a 3 year clearance to an existing collection that has been changed. The following schedules were dropped when the form (previously the OE–411, ''Coordinated Regional Bulk Power Supply Program Report) was transferred to EIA: Item 3–B, Assessment of Adequacy; Item 3–C, Generating Capacity Unavailability; Item 5–A, Near Term Transmission Adequacy; Item 5–B, Future Critical Bulk Power Facilities That Will Not Be in Service When Required; Item 5–C, System Evaluation Criteria; Item 6–A, Coordination of Operations; Item 6–B, Load Preservation Program; and Item 7, Additional Information. Comments, if any, about these deletions from the new form will be considered. In addition, the information from Item 1, Actual Energy and Peak Demand for the Preceding Year and 10 Additional Years, will not be available in 1996; however, Item 1 is under consideration to be kept on the new form via this clearance review. Information found in Item 1 includes, by North American Electric Reliability Council Region (NERC), the 12 monthly peak and energy demand data elements for the prior year, estimated values for the reporting year, and 10-year projections. The information provided shows all monthly peak loads and energy, thereby allowing the examination of seasonal patterns by NERC regions and for any region having sub-regions.

The Form EIA–411 will be filed in a unified, electronic format in which the national and individual council aggregates will be provided for all items. There will be no individual council reports produced on paper.

III. Request for Comments

Prospective respondents and other interested parties should comment on the actions discussed in item II. The following guidelines are provided to assist in the preparation of responses.

General Issues

EIA is interested in receiving comments from persons regarding:

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. Practical utility is the actual usefulness of information to or for an agency, taking into account its accuracy, adequacy, reliability, timeliness, and the agency's ability to process the information it collects.

B. What enhancements can EIA make to the quality, utility, and clarity of the information to be collected?

As a Potential Respondent

A. Are the instructions and definitions clear and sufficient? If not, which instructions require clarification?

B. Can data be submitted in accordance with the due date specified in the instructions?

C. Public reporting burden for this collection is estimated to average 13 hours per utility providing information to the NERC regional councils and average of 650 hours for each of the regional councils to provide consolidated information to NERC. It is then estimated that it will take NERC 240 hours to file 1 report covering all council regions with the EIA. Burden includes the total time, effort, or financial resources expended to generate, maintain, retain, or disclose or provide the information including: (1) Reviewing instructions; (2) developing, acquiring, installing, and utilizing technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

Please comment on (1) the accuracy of our estimate, and (2) how the agency could minimize the burden of the collection of information, including, through the use of automated collection techniques or other forms of information technology.

D. What are the estimated (1) total dollar amount annualized for capital and start-up costs, and (2) recurring annual dollar amount of operation and maintenance and purchase of services costs associated with this data collection? The estimates should take into account the costs associated with generating, maintaining, and disclosing or providing the information. Estimates should not include purchases of equipment or services made as part of customary and usual business practices, or the cost of any burden hours for completing the form. EIA estimates that there are no additional costs other than those that the respondent incurs in keeping the information for its own uses.

E. Do you know of any other Federal, State, or local agency that collects similar data? If you do, specify the agency, the data element(s), and the methods of collection.

As a Potential User

A. Can you use data at the levels of detail indicated on the form?

B. For what purpose would you use the data? Be specific.

C. Are there alternate sources of data and do you use them? If so, what are their deficiencies and/or strengths?

D. For the most part, information is published by EIA in U.S. customary units, e.g., cubic feet of natural gas, short tons of coal, and barrels of oil. Would you prefer to see EIA publish more information in metric units, e.g., cubic meters, metric tons, and kilograms? If yes, please specify what information (e.g., coal production, natural gas consumption, and crude oil imports), the metric unit(s) of measurement preferred, and in which EIA publication(s) you would like to see such information.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the form. They also will become a matter of public record.

Statutory Authority: Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 (Public Law No. 104–13).

Issued in Washington, DC March 27, 1996.

Yvonne M. Bishop,

Director, Office of Statistical Standards Energy Information Administration.

[FR Doc. 96–8133 Filed 4–2–96; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. RP96–178–000]

Cove Point LNG Limited Partnership; Notice of Filing

March 28, 1996.

Take notice that on March 15, 1996, pursuant to Section 1.27 of the General Terms and Condition (GT&C) of Cove Point LNG Limited Partnership (Cove Point) FERC Gas Tariff, First Revised Volume No. 1, filed with the Commission its revised retainage schedule and tariff to be effective April 16.

Cove Point states that the retainage for Cove Point's three peaking services was in excess of the 20.5 percent retainage cap for peaking services provided in GT&C section 1.27. Cove Point states the schedule attached to the filing shows that retainage levels for transportation services for the effective point were 2.86 percent. Cove Point states that the later figures is known to be inaccurate in that Cove Point experienced a significant problem with the meters at the Washington Gas (Cove Point's primary transportation customer) delivery points off of the Cove Point pipeline. Cove Point further states that instead of increasing the existing transportation retainage based on the currently available data, Cove Point proposes to defer any adjustment in the transportation retainage percentage until the inaccuracies are rectified.

Cove Point states that (i) there is no change in the filed retainage levels to be made effective April 16, 1996; and (ii) at such time as Cove Point has ascertained more accurate meter readings regarding transportation volumes it will, to the extent a variance in actual versus collected retainage exists, file a revised retainage schedule.

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, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before April 4, 1996. 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. 96–8066 Filed 4–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–374–004]

Gas Research Institute; Notice of Petition To Amend GRI's 1996 RD&D Program

March 28, 1996.

Take notice that on March 22, 1996, the Gas Research Institute (GRI) filed a petition requesting expedited approval of its proposal to amend its approved 1996 RD&D Program. In its petition, GRI states that it now anticipates an approximately 20 percent reduction in 1996 revenues due to decontracting and greater than anticipated discounting and, therefore, proposes to reduce its RD&D Program Obligations Budget from the approved 1996 level of $218.8 million to $174.8 million. GRI also requests approval of one-time staff severance and restructuring costs of $2.0 million, associated with an approximately 20 percent cut in GRI staffing.

GRI requests approval to utilize its proposed amended 1996 Program Obligations Budget of $174.8 million to fund R&D obligations of $151.0 million and general operating expenses of $23.8 million. GRI states that it expects to be able to fund this reduced budget with the currently effective GRI surcharges.

GRI proposes to maintain the overall balance of the approved 1996 program in the amended 1996 program, and therefore proposes to allocate reduced budgets for contract R&D and directly associated R&D management costs on a roughly *pro rata* basis across the overall objectives of GRI's RD&D program.

A detailed description of GRI's proposed revision of its approved 1996 R&D Program budget, including its plan to eliminate 1996 funding for seventeen approved new projects, and to fund eight additional projects that were not previously included in its 1996 R&D Program, is set forth in the text of GRI's petition and its attachments.

In a supplemental letter to its filing, GRI clarifies that it is not seeking Commission approval to fund the eight additional projects. According to GRI, these programs are being implemented using existing authority under Stipulation No. 6 and are only included in the revised budget request filing to give the Commission, all intervenors and other interested parties a complete picture of GRI's current funding plans and priorities.

Any person desiring to be heard or to make any protest with reference to said petition should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214) and the Regulations under the NGA (18 CFR 157.10). All such petition or protests must be filed on or before April 4, 1996. All protests filed with the Commission will be considered by it 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 to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Lois D. Cashell,

Secretary.

[FR Doc. 96–8067 Filed 4–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG96–9–000]

KO Transmission Co.; Notice of Filing

March 28, 1996.

Take notice that on March 19, 1996, KO Transmission Company (KO) filed standards of conduct under section 161.3 of the Commission's regulations, 18 CFR 161.3, and to comply with the Commission's February 5, 1996 order in Docket No. CP95–149–000. 74 FERC ¶ 61,101.

Any person desiring to be heard or to protect said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 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 April 15, 1996. 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. 96–8069 Filed 4–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–49–005]

Paiute Pipeline Company; Notice of Report of Billings and Refunds

March 28, 1996.

Take notice that on March 18, 1996, Paiute Pipeline Company (Paiute) tendered for filing a Report of Billings and Refunds detailing the amounts billed and refunded to each customer as of February 15, 1996, in accordance with the Offer of Settlement filed on November 9, 1995, and approved by the Commission's order issued January 22, 1996, in Docket Nos. RP93–49–000 and RP93–49–003.

Paiute states that this filing is being made to comply with Section 3.1 of the Settlement. The Settlement offer resolves the allocation among Paiute's customers of the direct-billed take-or-pay buyout and buydown costs charged to Paiute by its upstream supplier, Northwest Pipeline Corporation.

Paiute states that copies of the report are being served upon all of Paiute's customers and interested state regulatory commissions, as well as upon all parties in Docket No. RP93–49–000, *et al.*

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before April 4, 1996. 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. 96–8068 Filed 4–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG96–2–001]

Sea Robin Pipeline Company; Notice of Filing

March 28, 1996.

Take notice that on March 21, 1996, Sea Robin Pipeline Company (Sea Robin) submitted revised standards of conduct under Orders Nos. 566 *et seq.*[1] Sea Robin states that it is revising its standards of conduct to incorporate the changes required by the Commission's February 20, 1996 Order On Standards of Conduct.[2]

Sea Robin states that it has mailed copies of this filing to all of its shippers 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, DC, 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 April 15, 1996. 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. 96–8070 Filed 4–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP94–753–002]

United Cities Gas Company; Notice of Petition To Amend

March 28, 1996.

Take notice that on March 19, 1996, United Cities Gas Company (United Cities), 5300 Maryland Way, Brentwood, Tennessee 37027, filed in Docket No. CP94–753–002 a petition pursuant to Section 7(c) of the Natural Gas Act to amend its certificate issued in Docket No. CP94–753–000,[1] to add additional fields to its certificated storage facilities, all as more fully set forth in the petition on file with the Commission and open to public inspection.

United Cities proposes to add to its certificated storage facilities the following four storage fields: the Liberty North and Liberty South Fields in Montgomery County, Kansas, and the Buffalo and Fredonia Fields in Wilson County, Kansas. United Cities states that, like Barnsley, these fields are owned by United Cities Storage Company, a subsidiary of United Cities, which leases all of the capacity in these fields to United Cities. United Cities advises that, to date, it has operated these four fields solely in support of its local distribution function in Kansas.

United Cities states that Woodward Marketing, L.L.C. (Woodward) would now like to lease part of the capacity in the Kansas storage facilities and use it for its system management in the same way it uses the capacity in Barnsley.[2] United Cities further states that with the exception of the location of the leased storage capacity, all other aspects of the certificated operations would remain unchanged and still limited to one party: Woodward. It is further stated that Woodward intends to use the leased capacity solely for its own benefit (1) to balance its gas supply portfolio, (2) to enhance its operational capabilities, and (3) to enable it to

[1] Standards of Conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27, 1994), III FERC Stats. & Regs. ¶30,997 (June 17, 1994); Order No. 566–A, *order on rehearing*, 59 FR 52896 (October 20, 1994), 69 FERC ¶61,044 (October 14, 1994); Order No. 566–B, *order on rehearing*, 59 FR 65707 (December 21, 1994); 69 FERC ¶61,334 (December 14, 1994).

[2] 74 FERC ¶61,173 (1996).

[1] By order issued September 20, 1994, United Cities was granted a limited-jurisdiction certificate authorizing the transportation of natural gas in interstate commerce limited to operations involving the Barnsley Storage Field (Barnsley) in Hopkins County, Kentucky (68 FERC ¶61,334 (1994)).

[2] On June 28, 1995, an order was issued in Docket No. CP94–753–001 authorizing the substitution of Woodward for Sonat Marketing Company as the lessee of storage capacity in Barnsley (71 FERC ¶62,220 (1995)).

provide more flexible firm sales services to potential customers.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before April 8, 1996, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 384.214 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 be taken but will not serve to make the protestants parties to the proceeding. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 96–8071 Filed 4–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. EG96–51–000, et al.]

NCP Houston Power Incorporated, et al.; Electric Rate and Corporate Regulation Filings

March 27, 1996.

Take notice that the following filings have been made with the Commission:

1. NCP Houston Power Incorporated

[Docket No. EG96–51–000]

On March 18, 1996, NCP Houston Power Incorporated (Applicant) filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to 18 CFR Part 365.

Applicant states that it is a Delaware corporation formed to acquire a general partnership interest in Mid-Georgia Cogen L.P., a Delaware limited partnership formed to develop, own and operate a nominal 300 MW natural gas and oil fired cogeneration facility to be located in Kathleen, Georgia.

Comment date: April 19, 1996, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. San Diego Gas & Electric Company v. Public Service Company of New Mexico

[Docket No. EL96–40–000]

Take notice that on March 18, 1996, San Diego Gas & Electric Company (SDG&E) tendered for filing a complaint with the Commission against Public Service Company of New Mexico (PNM). In the complaint, SG&E states that the demand rate charged SDG&E by PNM under a long-term 100-megawatt system power sale is unjust, unreasonable, and unduly discriminatory. SDG&E asks the Commission to initiate a proceeding under Section 206(b) of the Federal Power Act to investigate the rate and establish a refund effective date of May 17, 1996.

Comment date: April 26, 1996, in accordance with Standard Paragraph E at the end of this notice. Answers to the complaint shall be due on or before April 26, 1996.

3. Public Service Electric & Gas Company

[Docket No. ER96–1070–000]

Take notice that on March 13, 1996, Public Service Electric & Gas Company tendered for filing an amendment in the above-referenced docket.

Comment date: April 10, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. Portland General Electric Company

[Docket No. ER96–1197–000]

Take notice that on March 15, 1996, El Paso Electric Company tendered for filing a Certificate of Concurrence in the above-referenced docket.

Comment date: April 10, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Florida Power Corporation

[Docket No. ER96–1255–000]

Take notice that on March 11, 1996, Florida Power Corporation tendered for filing a correction to the moratorium provision filed for service to Seminole Electric Cooperative in this docket. The Company requests that the correction be allowed to become effective on March 5, 1996, when the original filing was made.

Comment date: April 10, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Wisconsin Public Service Corporation

[Docket No. ER96–1292–000]

Take notice that on March 11, 1996, Wisconsin Public Service Corporation (WPSC), tendered for filing an executed Transmission Service Agreement between WPSC and Manitowoc Public Utilities. The Agreement provides for transmission service under the Comparable Transmission Service Tariff, FERC Original Volume No. 7.

WPSC asks that the agreement become effective retroactively to February 29, 1996.

Common date: April 10, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Southern Company Services, Inc.

[Docket No. ER96–1293–000]

Take notice that on March 12, 1996, 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 ''Southern Companies) filed a service agreement between SCS, as agent of the Southern Companies, and KN Marketing, Inc. for non-firm transmission service under the Point-to-Point Transmission Service Tariff of Southern Companies.

Common date: April 10, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Entergy Power, Inc.

[Docket No. ER96–1300–000]

Take notice that on March 13, 1996, Entergy Power, Inc. (EPI) tendered for filing a Base Agreement for the Purchase and Sale of Wholesale Power and Energy Service with Houston Lighting & Power Company.

Common date: April 10, 1996, in accordance with Standard Paragraph E at the end of this notice.

9. Louisville Gas and Electric Company

[Docket No. ER96–1333–000]

Take notice that on March 18, 1996, Louisville Gas and Electric Company (LG&E), tendered for filing a service agreement between LG&E and PECO Energy Company under Rate PSS—Power Sales Service.

A copy of the filing has been mailed to the Kentucky Public Service Commission.

Common date: April 10, 1996, 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. 96–8184 Filed 4–2–96; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–00182; FRL–5360–1]

Agency Information Collection Activities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this notice announces that EPA is planning to submit the following continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB). Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the information collection as described below. The ICR is a continuing ICR entitled ''TSCA Section 4 Test Rules, Consent Orders and Test Rule Exemptions,'' EPA ICR No. 1139, OMB No. 2070–0033. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9.

DATES: Written comments must be submitted on or before June 3, 1996.

ADDRESSES: Submit three copies of all written comments to: TSCA Document Receipts (7407), Rm. NE-G99, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone 202-260-7099. All comments should reference administrative record number AR–155. This ICR is available for public review at, and copies may be requested from, the docket address and phone number listed above.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the administrative record number ''AR–155'' and ICR number ''1139.'' No CBI should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit III. of this document.

FOR FURTHER INFORMATION CONTACT: For general information contact: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: 202-554-1404, TDD: 202-554-0551, e-mail: TSCA-Hotline@epamail.epa.gov. For technical information contact: Keith Cronin, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: 202-260-8157, Fax: 202-260-1096, e-mail: cronin.keith@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Entities potentially affected by this action are those companies that manufacture, process, use, distribute or dispose of chemicals. For the collection of information addressed in this notice, EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

(iii) Enhance the quality, utility, and clarity of the information to be collected.

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

II. Information Collection

EPA is seeking comments on the following Information Collection Request.

Title: TSCA Section 4 Test Rules, Consent Orders and Test Rule Exemptions, EPA ICR No. 1139, OMB No. 2070-0033, expires August 31, 1996.

Abstract: Section 4 of the Toxic Substances Control Act (TSCA) is designed to assure that chemicals that may pose serious risks to human health or the environment undergo testing by manufacturers or processors, and that the results of such testing is made available to EPA. EPA uses the information collected under the authority of TSCA section 4 activity to assess risks associated with the manufacture, processing, distribution, use or disposal of a chemical, and to support any necessary regulatory action with respect to that chemical.

EPA must assure that appropriate tests are performed on a chemical if it decides: (1) That a chemical being considered under TSCA section 4(a) may pose an ''unreasonable risk'' or is produced in ''substantial'' quantities that may result in substantial or significant human exposure or substantial environmental release of the chemical; (2) that additional data are needed to determine or predict the impacts of the chemical's manufacture, processing, distribution, use or disposal; and (3) that testing is needed to develop such data. Rules and consent orders under TSCA section 4 require that one manufacturer or processor of a subject chemical perform the specified testing and report the results of that testing to EPA. TSCA section 4 also allows a manufacturer or processor of a subject chemical to apply for an exemption from the testing requirement if that testing will be or has been performed by another party.

Responses to the collection of information are mandatory (see 40 CFR part 790). Respondents may claim all or part of a notice confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden Statement: The burden to respondents for complying with this ICR is estimated to total 95,728 hours per year, with an annual cost of $3,865,600. These totals are based on an average burden of approximately 486 hours per test rule and consent order response for an estimated 152 respondents, submitting one or more reports of information annually. There are also recordkeeping requirements associated with this collection. This estimate includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating and verifying information, processing and maintaining information, and

disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

III. Public Record

A record has been established for this action under docket number ''OPPTS–00182'' (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to EPA at:

ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this action, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Lists of Subjects

Environmental protection and Information collection requests.

Dated: March 27, 1996.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 96–8141 Filed 4–2–96; 8:45 am]

BILLING CODE 6560–50–F

[PF–647; FRL–5358–4]

Pesticide Tolerance Petition; Notice of Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces that EPA has received a request to amend pesticide petition (PP) 9F3714 by proposing to amend 40 CFR 180.430 to extend the time-limited tolerances for residues of the herbicide Fenoxyprop-ethyl.

DATES: Comments, identified by the docket number [PF–647], must be received on or before May 3, 1996.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF–647]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM 23), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 703–305–7830, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

PP 9F3714. EPA has received a request to amend pesticide petition (PP) 9F3714 to extend the interim tolerances under the regulation 40 CFR 180.430(b) from April 12, l996 to November 1, l997. The request was made by AgrEvo USA Company, Little Falls Centre One, 2711 Centerville Road, Wilmington, DE 19808. The extension of the interim (time-limited) tolerances is based on the need to coordinate these tolerances with an extension of time granted by EPA for submitting a required repeat mouse oncogenicity study, the data gap that triggered the tolerance to being time-limited. The new date granted for submitting the repeat mouse oncogenicity study is November 1, l996. In order to allow the shipping of fenoxyprop-ethyl pesticide products for the use-site involving raw agricultural commodities used for domestic animal food, these time-limited tolerances are needed for conditional registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended.

A record has been established for this notice of filing under docket number [PF–647] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: March 22, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96–8143 Filed 4–3–96; 8:45 am]

BILLING CODE 6560–50–F02

[PF–648; FRL–5359–6]

Withdrawal of Feed Additive Petition for Dacthal W75

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is withdrawing a feed additive petition from ISK Biotech Corp., 5966 Heisley Rd., P.O. Box 8000, Mentor, OH 44061-8000 for residues of (Dacthal W75) in or on bean cannery waste, tomato pomace and potato peels.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller, Product Manager (23) Registration Division (7505C), Office of Pesticide Programs. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, 703–305–6224.

SUPPLEMENTARY INFORMATION:

Withdrawn Petition

FAP 4H5688. Notice of the petition requested by ISK Biotech Corp., 5966 Heisley Rd., P.O. Box 8000, Mentor, OH 44061-8000 was filed by EPA November 2, l994 (59 FR 54907). The Notice stated that ISK Biotech Corp. had proposed to amend 40 CFR part 186 by establishing a feed additive regulation to permit the residues of DCPA (Dacthal W75) in or on bean cannery waste, tomato pomace and potato peels. The Agency's Subdivision O Guidelines were revised June, l994. Bean cannery waste was removed from Table II of that guideline, therefore a feed additive tolerance is no longer required. Tomato pomace is no longer considered to be a significant animal feed, therefore a feed additive tolerance is no longer required. The need for feed additive tolerances on processed potato waste is based on the maximum concentration factor observed for residues in or on wet peel. Concentration was only observed in the dry peel fraction, therefore a feed additive tolerance for dried potato waste is not required. The Agency has withdrawn the subject FAP.

List of Subjects

Environmental protection, Animal feeds, Pesticides and pest.

Dated: March 22, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96–8144 Filed 4–2–96; 8:45 am]

BILLING CODE 6560–50–F

[OPPTS–42186A; FRL–5359–3]

Request for Proposals for Enforceable Consent Agreements; Dermal Absorption Rate Testing of Eighty OSHA Chemicals; Solicitation of Interested Parties; Text of Test Protocol

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice addresses all manufacturers and processors of eighty chemical substances of interest to the Occupational Safety and Health Administration of the Department of Labor (OSHA) which were designated for dermal absorption testing in the 31st, 32nd and 35th Reports of the TSCA section 4 Interagency Testing Committee (ITC). These persons are invited to submit to EPA proposals for enforceable consent agreement (ECA) consideration for dermal absorption rate testing of the 80 chemicals. The protocol set forth in this notice is recommended as the test protocol for these proposals. In addition, EPA is soliciting ''interested parties'' to participate in or monitor any ECA negotiations initiated in response to this solicitation.

DATES: Written proposals for ECAs and written requests to be designated an interested party must be received by July 2, 1996. EPA may extend the deadline for receipt of testing proposals upon request and a showing of good faith efforts on the part of potential submitters to develop testing proposals by the deadline.

ADDRESSEES: Send written submissions, identified by the document control number (OPPTS–42186A) (FRL–5359–3), in triplicate to: TSCA Document Control Office (7407), Rm. ET–G099, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Attn: TSCA section 4. The public record supporting this action, including comments, is available for public inspection from Noon to 4 p.m., Mondays through Fridays, except legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Persons submitting information any portion of which they believe is entitled to treatment as confidential business information (CBI) by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this waiver of any confidentiality claim, and the information may be made available to the public by EPA without further notice to the submitter.

Proposals may be submitted electronically by sending electronic mail (e-mail) to: ncic@epamail.epa.gov. Proposals in electronic form must be submitted as ASCII files and must avoid the use of special characters and any form of encryption. Proposals will also be accepted on disks in WordPerfect 5.1 (DOS) file format or ASCII file format. All proposals in electronic form must be identified by docket number OPPTS–42186A (FRL–5359–3). Information claimed as CBI should not be submitted via e-mail. Proposals in electronic form may be filed on-line at many Federal depository libraries. Additional information on submissions in electronic form may be found in Unit VI of this notice.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. ET–543B, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 554–1404; TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov. For specific information regarding this solicitation or related matters, contact Roger A. Nelson, Project Manager, Chemical Testing and Information Branch (7405), Rm. ET–729A, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 260–8163; e-mail: nelson.roger@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The ITC has reviewed 658 chemical substances that were presented to the ITC by OSHA in 1991 (58 FR 26898, 26900, May 5, 1993 and 58 FR 38490,

38492–38493, July 16, 1993). OSHA requested the ITC to assess the availability of dermal absorption data for these chemical substances and to determine the need for further testing. (See 58 FR 26898, 26900, May 5, 1993.) The ITC indicated that OSHA needs quantitative measures of dermal absorption in order to evaluate the potential hazard of these chemicals to workers (58 FR 38490, 38492, July 16, 1993).

In its 31st, 32nd, and 35th Reports to the EPA Administrator (published at 58 FR 26898, May 5, 1993; 58 FR 38490, July 16, 1993; and 59 FR 67596, December 29, 1994, respectively) (FRL–4583–4, FRL–4630–2, and FRL–4923–2, respectively), the ITC designated for dermal absorption testing a total of 83 of the chemical substances nominated by OSHA. These chemicals are listed in Table 1.—''Chemicals Designated by the ITC for Dermal Absorption Testing'' in Unit II of this notice. After reviewing additional information, in its 34th and 36th Reports (published at 59 FR 35720, July 13, 1994 and 60 FR 42982, August 17, 1995, respectively) (FRL–4870–4 and FRL–4965–6, respectively), the ITC withdrew the designation for three of the chemicals (noted in table 1 in Unit II of this notice). Eighty of the chemical substances nominated by OSHA are thus currently designated by the ITC for dermal absorption testing.

In the Federal Register notices containing the 31st, 32nd and 35th ITC Reports, EPA solicited proposals for ECAs for dermal absorption testing of the subject chemical substances. In the notices of the 31st, 32nd and 35th Reports, EPA referenced a proposed dermal absorption test protocol for review by potential submitters in developing their submissions (Ref. 1). Public comments on the protocol were received by EPA and were entered into the docket for the 31st, 32nd, or 35th ITC Report, as appropriate (docket nos. OPPTS–41038, OPPTS–41039, and OPPTS–41042, respectively). In addition, the Chemical Manufacturers Association (CMA) submitted a proposal outlining an alternative protocol (Ref. 2). Scientists from EPA and a number of agencies represented on the ITC (including OSHA) reviewed the public comments and the CMA proposal. Based on this review, a protocol entitled ''Recommended Protocol for *In Vitro* Percutaneous Absorption Rate Studies'' was developed, and is set forth in Unit V of this notice.

EPA received no proposals for ECAs for dermal absorption testing of any of the subject chemical substances in response to the above-mentioned solicitations. In today's notice, EPA is soliciting proposals for ECAs which address the chemical substances listed in table 1 in Unit II of this notice and through which dermal absorption rate data would be developed to meet OSHA's needs.

II. Response to Submissions to EPA

A. Response to Public Comments on the ITC Reports

Comments were received on the 31st, 32nd and 35th ITC Reports and were entered into the docket for the corresponding ITC Report. Comments received on these ITC Reports addressing the proposed test protocol were reviewed as part of the protocol development process, as discussed in Unit I of this notice. EPA and the ITC have reviewed all other comments received on these ITC Reports. The analysis of these comments by EPA and the ITC follows.

In its comments on the 31st ITC Report, Mobil (Ref. 3) asserted that acute dermal toxicity studies would be cheaper and faster than skin penetration studies. EPA and the ITC believe that acute dermal toxicity studies would not meet OSHA's needs since such studies would not provide data on absorption rates.

BASF (Ref. 4) stated that it has been established that tetrahydrofuran (32nd ITC Report) can be rapidly absorbed in lethal amounts through the skin of rats and rabbits. OSHA needs data related to the real measured rate of the absorption of tetrahydrofuran by the skin. The needed data are not provided in the comment.

Aristech (Ref. 5) commented that there is no specific need to test diphenylamine (32nd ITC Report) since this chemical is no different from other regulated substances for which dermal penetration data are not available. EPA and the ITC believe that such data are needed to make determinations concerning the need to alert industrial hygienists, employers, and workers to the potential adverse health effects of dermal exposure to diphenylamine, as explained in Unit III of this notice.

DuPont (32nd ITC Report) and the CMA Propylene Glycol Ethers Panel (35th ITC Report) (Refs. 6 and 7, respectively) questioned how OSHA planned to use these data. The uses to which the data will be put are explained in Unit III of this notice. Dow (31st ITC Report) (Ref. 8) questioned the appropriateness of the grouping of the subject chemical substances for testing purposes. EPA believes that the identity of testing needs (dermal absorption rate) for these eighty chemicals is sufficient reason for grouping them together in one notice.

The CMA Ketones Panel (Ref. 9) commented on the request contained in the Federal Register notice announcing the 31st ITC Report for a testing consortium to develop ECAs for all designated chemicals. The Panel expressed its belief that such a consortium would not be feasible in light of the number of chemicals designated and the number of companies that would have to participate in ECA negotiations. EPA acknowledges that multiple ECAs may present a feasible approach. (See Unit III of this notice).

Angus Chemicals submitted two dermal absorption studies (Refs. 10 and 11)—one on 1-nitropropane (31st ITC Report) and the other on 2-nitropropane (32nd ITC Report). These studies were submitted by Angus to support its claims that additional testing of these chemicals is not needed. EPA and the ITC have ascertained that the submitted studies are deficient because the recovered amounts (0.5%) of test material rendered the studies inadequate to determine dermal absorption rates for these chemicals.

DuPont (Ref. 6) submitted comments on 14 chemical substances in the 32nd ITC Report claiming that dermal toxicity data for these chemicals (referenced in the comments) are available. EPA and the ITC have determined that the references cited by DuPont do not address the issue of dermal absorption rate.

The CMA Dinitrotoluenes Panel (32nd ITC Report) (Ref. 12) submitted comments on 2,4-dinitrotoluene (2,4-DNT), including literature describing studies of 2,6-DNT and technical grade DNT, a mixture of 2,4-DNT and 2,6-DNT. (The literature on 2,6-DNT was offered on the basis that 2,6-DNT was an acceptable surrogate for 2,4-DNT.) The Panel claimed that existing dermal absorption data are adequate for 2,4-DNT. EPA and the ITC reviewed the literature and determined that since it does not address dermal absorption rates, the literature is not adequate to meet OSHA's data needs.

The CMA Propylene Glycol Ethers Panel (Ref. 13) commented that dermal toxicity data already exist on dipropylene glycol methyl ether (DPGME) (35th ITC Report). EPA and the ITC ascertained that no dermal absorption rate studies were cited by CMA.

SOCMA (Ref. 14) questioned the designation of biphenyl (35th ITC Report), stating that dermal exposure to biphenyl is limited and animal studies indicate that biphenyl does not produce

adverse health effects following dermal application. EPA and the ITC determined that none of the studies cited by SOCMA relate to dermal absorption rate.

Union Carbide (Ref. 15) asserted that the ITC should not have designated isophorone (35th ITC Report) for dermal absorption testing. OSHA needs data related to the dermal absorption rate of isophorone. These needed data are not provided in the comment.

B. Response to TSCA Section 8(d) Studies

EPA has screened the health and safety studies on the subject chemical substances that have been submitted to the Agency pursuant to section 8(d) of the Toxic Substances Control Act (TSCA). None of these submitted studies was determined to be relevant to dermal absorption rate.

TABLE 1.—CHEMICALS DESIGNATED BY THE ITC FOR DERMAL ABSORPTION TESTING

CAS No.	Chemical Name
31st ITC Report:	
60-29-7	Ethyl ether
75-65-0	*tert*-Butyl alcohol
76-22-2	Camphor
78-92-2	*sec*-Butyl alcohol
79-20-9	Methyl acetate
97-77-8	Disulfiram
100-25-4	*p*-Dinitrobenzene
105-46-4	*sec*-Butyl acetate
106-42-3	*p*-Xylene
107-31-3	Methyl formate
107-66-4	Dibutyl phosphate
108-03-2	1-Nitropropane
108-87-2	Methylcyclohexane
109-66-0	Pentane
110-83-8	Cyclohexene
111-84-2	Nonane
123-92-2	Isoamyl acetate
142-82-5	*n*-Heptane
287-92-3	Cyclopentane
532-27-4	*a*-Chloroaceto-phenone
540-88-5	*tert*-Butyl acetate
628-63-7	*n*-Amyl acetate
7631-90-5	Sodium bisulfite
7681-57-4	Sodium metabisulfite
32nd ITC Report:	
61-82-5	Amitrole
74-96-4	Ethyl bromide
75-15-0	Carbon disulfide
75-25-2	Bromoform
75-34-3	1,1-Dichloroethane
77-78-1	Dimethyl sulfate
79-46-9	2-Nitropropane
80-62-6	Methyl methacrylate[1]
84-66-2	Diethyl phthalate[1]
88-72-2	*o*-Nitrotoluene
89-72-5	*o*-*sec*-Butylphenol
90-04-0	*o*-Anisidine
95-13-6	Indene
95-49-8	*o*-Chlorotoluene
99-65-0	*m*-Dinitrobenzene
100-00-5	*p*-Nitrochlorobenzene
100-01-6	*p*-Nitroaniline
100-44-7	Benzyl chloride
100-63-0	Phenylhydrazine
106-49-0	*p*-Toluidine
108-44-1	*m*-Toluidine
108-90-7	Chlorobenzene
109-99-9	Tetrahydrofuran
121-14-2	2,4-Dinitrotoluene
122-39-4	Diphenylamine
126-99-8	*beta*-Chloroprene
150-76-5	*p*-Methoxyphenol
528-29-0	*o*-Dinitrobenzene
540-59-0	1,2-Dichloroethylene
626-17-5	*m*-Phthalodinitrile
768-52-5	N-Isopropylaniline
1300-73-8	Xylidine
6423-43-4	Propylene glycol dinitrate
25013-15-4	Vinyl toluene
35th ITC Report:	
75-05-8	Acetonitrile
75-12-7	Formamide
75-35-4	Vinylidene chloride
77-73-6	Dicyclopentadiene
78-59-1	Isophorone
78-83-1	Isobutyl alcohol
78-87-5	Propylene dichloride
91-20-3	Naphthalene
92-52-4	Biphenyl
95-50-1	*o*-Dichlorobenzene
96-18-4	1,2,3-trichloropropane
98-29-3	*t*-Butylcatechol
99-08-1	*m*-Nitrotoluene
99-99-0	*p*-Nitrotoluene
106-46-7	*p*-Dichlorobenzene
107-06-2	Ethylene dichloride
108-93-0	Cyclohexanol
108-94-1	Cyclohexanone[2]
110-12-3	Methyl isoamyl ketone
120-80-9	Catechol
121-69-7	Dimethylaniline
123-42-2	Diacetone alcohol
127-19-5	Dimethyl acetamide
542-92-7	Cyclopentadiene
34590-94-8	Dipropylene glycol methyl ether

[1] Removed by the ITC in its 34th Report.

[2] Removed by the ITC in its 36th Report.

III. Request for Proposals

No proposals for ECAs for dermal absorption testing of any of the subject chemical substances were received by EPA as a result of the solicitations in the Federal Register notices containing the 31st, 32nd and 35th ITC Reports. EPA has revised the test protocol and is now seeking proposals that will provide for the development of dermal absorption rate data on the eighty chemical substances listed in table 1 in Unit II of this notice. EPA has reason to believe that industry now has an interest in proposing dermal absorption rate testing schemes for at least some of these chemical substances.

EPA encourages submitters to work together to develop proposals for ECAs that address all eighty subject chemical substances or significant subsets thereof. The Agency, however, will also accept proposals for ECAs providing for the testing of individual chemicals. All proposals should set forth offers to test specific chemicals for the endpoint of interest (dermal absorption rate); expressions of interest in ECA negotiations do not, in and of themselves, constitute proposals.

The dermal absorption rate data obtained under this testing program will be used to support development of OSHA's ''skin designations'' for the subject chemical substances. Skin designations for specific chemicals alert industrial hygienists, employers, and workers to potential adverse health effects resulting from dermal exposure to these chemicals in the workplace. OSHA assigns a skin designation to a chemical if it determines that cutaneous exposure (through the skin, eyes, and mucous membranes) to that chemical in the workplace represents a potential significant contribution to overall workplace exposure. Cutaneous exposure is a function of, among other things, the rate of absorption of the chemical substance. One methodology under consideration for developing and assigning skin designations is discussed in Walker et al. (Ref. 17).

EPA has developed a protocol, set forth in Unit V of this notice, that is recommended as the test protocol for all proposals for ECAs. The Agency believes that testing conducted in accordance with the protocol will provide data of use to OSHA, is consistent with EPA and OSHA testing policies, and provides the most economical approach to address a large number of diverse chemical substances. If a submitter chooses not to use the recommended protocol but instead submits an alternative protocol, an explanation should be given as to how this alternative protocol will provide comparable data and achieve the same goals as the recommended protocol.

IV. Solicitation of Interested Parties

Negotiations on ECAs for dermal absorption rate testing of the subject chemical substances will be conducted pursuant to the procedures described in 40 CFR 790.22. All persons who respond to this notice on or before July 2, 1996 will be given the status of interested parties and will be afforded an opportunity to monitor or participate

in the negotiations. All such persons should indicate the chemical substance(s), by name and CAS number, in which they are interested. Those persons who have already given notice in their response(s) to the 31st, 32nd, or 35th ITC Report that they wish to be designated interested parties with regard to ECA negotiations on specific chemical substances will be considered automatically to be interested parties on such chemicals. Interested parties do not incur any obligation by being so designated.

Upon making the appropriate findings under section 4 of the Toxic Substances Control Act (TSCA), EPA has the authority to require dermal absorption rate testing of some or all of these chemical substances through formal rulemaking. If an ECA-based approach does not prove viable, EPA will proceed with rulemaking to require industry to conduct the needed testing.

V. Recommended Protocol for In Vitro Percutaneous Absorption Rate Studies

A. Introduction

This recommended protocol was developed to provide percutaneous absorption rate data for the Occupational Safety and Health Administration (OSHA) chemicals designated in the 31st, 32nd and 35th Reports (published at 58 FR 26898, May 5, 1993; 58 FR 38490, July 16, 1993; and 59 FR 67596, December 29, 1994, respectively) of the TSCA section 4 Interagency Testing Committee (ITC), as modified by the 34th and 36th ITC Reports (published at 59 FR 35720, July 13, 1994 and 60 FR 42982, August 17, 1995, respectively). The protocol was developed by a group of scientists from agencies represented on the ITC (the Consumer Product Safety Commission, the Department of Defense, EPA, the Food and Drug Administration, the National Institute for Occupational Safety and Health, and OSHA) based on the methods of Bronaugh and Collier (Ref. 16), and modified in response to comments.

The protocol outlines procedures for measuring a permeability constant (Kp) and a short-term absorption rate for chemicals in liquid form. Measurement of short-term absorption rates is only required when a Kp cannot be obtained using the protocol described. For most chemicals, a Kp is most useful in estimating skin permeation. However, for harsh chemicals that may damage the skin more severely with prolonged contact, a short-term absorption rate is more relevant. The permeability constants and short-term absorption rates measured will be used by OSHA to give more specific guidance to employers on whether a chemical used in a particular process warrants changes in engineering controls or use of personal protective equipment to reduce the hazard of systemic toxicity after dermal absorption of the chemical.

OSHA expects that this would be accomplished by using a semi-quantitative procedure such as estimating time required to absorb a toxic dose compared to the inhalation permissible exposure limits (Ref. 17). It is not contemplated that the values developed using this protocol would be used for quantitative risk assessment because of the limitations of the methods used to collect the data and the variability of individual exposure scenarios present in workplaces.

The protocol utilizes established *in vitro* diffusion cell techniques which allow absorption studies to be conducted with human skin. The *in vitro* method is chosen for practical considerations. It is efficient in terms of labor and materials and can be easily performed using a standard method by different laboratories. *In vitro* diffusion cell studies are necessary for measuring a Kp.

Although maintaining the viability of skin more closely simulates *in vivo* conditions, this protocol allows use of static diffusion cells and cadaver skin. This protocol also requires the use of radiolabeled chemicals unless it can be demonstrated that alternative, non-radiolabeled methods provide sufficient sensitivity to detect the parent chemical (and its major skin metabolites in those cases where skin viability is maintained). The first five protocol parameters that are discussed (choice of membrane, preparation of membrane, diffusion cell design, testing hydrophobic chemicals and vehicle) are similar for determination of either of the two percutaneous absorption values. In contrast, the remaining two protocol parameters (i.e., dose and study duration) are different for the two percutaneous absorption values.

B. Conduct of Test

1. Choice of Membrane

i. *Skin selection.* The most accurate absorption data for regulatory concerns related to human health would be obtained with human skin. Since this protocol allows use of the static cell, maintenance of viability of skin is not necessary. Human cadaver skin is required for these studies.

ii. *Number of subjects.* Data from a total of at least six samples obtained from at least three human subjects should be averaged to allow for biological variation between subjects. Replicates are not required. The variability can be up to 5-fold in different samples of normal human skin.

iii. *Regional variability.* Variability in skin permeation is well known to occur in different anatomical regions. The trunk and the extremities have reasonably similar barrier properties (less than 2-fold differences). Enhanced absorption can be observed in regions of the face (4-fold) and the scrotum (20-fold). Small differences in regional absorption may not be significant compared to intersubject variability. However, to minimize the variability in skin absorption measurements, for these tests all samples of human skin shall be obtained from the abdominal region of human subjects of known source and disease state. The time elapsed between death and harvest of tissue shall be reported.

iv. *Validation of human skin barrier.* Barrier properties of human skin shall be pretested with a standard compound such as tritiated water prior to conducting an experiment with the test chemical because barrier alteration can result from surgery or topical scrubbing (Ref. 18).

2. Preparation of Membrane

Full thickness skin should not be used. Since absorbed chemicals are taken up by blood vessels directly beneath the epidermis *in vivo*, an *in vitro* study should use a membrane with most of the dermis removed. This is particularly important for hydrophobic chemicals that would diffuse slowly through the dermis. A suitable membrane shall be prepared from fresh skin with a dermatome at a thickness of 200 to 500 mm. The microtomed skin samples can be stored frozen for up to two weeks, if necessary, if they are frozen quickly and the barrier properties of the samples are confirmed.

3. Diffusion Cell Design

Flow cells or static diffusion cells shall be used in these studies. Flow cells are useful for maintaining the viability of the skin (in the case that live skin is used) because nutrient media must be continually replaced. Also, these cells are preferable for studies requiring round-the-clock sampling since samples can be collected automatically in a fraction collector. Flow cells of adequate design will have only small exposed areas of skin for applying test chemicals because the receptor volume must be small so that the cell contents can be rapidly exchanged (Ref. 19). If flow cells are used, the draft ITC protocol describing their use shall be followed. The draft

ITC protocol was first made publicly available with the 31st ITC Report.

If static cells are used, the testing laboratory must verify that there is not an increase in concentration of the test compound in the receptor fluid that would change the penetration rate. Specifically, the concentration difference across the membrane must not decrease by more than 10% during the experiment. Concentration of the neat liquid should be taken as the density of the compound.

4. Temperature

Skin shall be maintained at a physiological temperature which is about 32°C.

5. Testing Hydrophobic Test Chemicals

Chemicals with water solubility less than about 10 mg/L do not freely partition from skin into aqueous receptor fluid. To increase the water solubility of such hydrophobic chemicals, polyethoxyoleate (PEG 20 oleyl ether) shall be added to the receptor fluid at a concentration of 6 percent. To ensure that an increase in concentration of the chemical in the receptor fluid does not alter the penetration rate, the concentration difference across the membrane must not decrease by more than 10% during the experiment.

6. Vehicle

If the test chemical is a liquid at room temperature and does not damage the skin during the determination of Kp, it shall be applied neat. If the chemical cannot be applied neat because it is a solid at room temperature or because it damages the skin when applied neat, it should be dissolved in water. If the concentration of a hydrophobic chemical in water is not high enough so that a steady-state absorption can be obtained, the chemical shall be dissolved in isopropyl myristate. *In vitro* percutaneous absorption experiments with other vehicles of interest may be required for selected test chemicals in order to meet the data needs of individual Federal agencies. A sufficient volume of liquid shall be used to completely cover the skin and provide the amount of test chemical needed as described in section B.7. ''Dose'' of this protocol below. The volume should be sufficient so that the skin surface remains covered by the vehicle during the determination of Kp.

7. Dose

i. *Permeability constant.* An ''infinite dose'' of the test chemical shall be applied to the skin to achieve the steady-state rate of absorption necessary for calculation of a Kp. The actual concentration required to give an undepletable reservoir on the surface of the skin depends on the rate of penetration of the test chemical. Preliminary studies may be necessary to determine this concentration. If necessary to generate a reliable Kp, the diffusion cell tops should be covered with a stopper or with Parafilm7 to prevent evaporation of the vehicle or test chemical. If damage to the skin is likely due to the nature of the test chemical, the skin barrier integrity shall be verified at the end of the experiment by measuring the absorption of a standard compound such as tritiated water (Ref. 18).

ii. *Short-term absorption rates.* Short-term absorption rates shall be determined for those chemicals for which a Kp cannot be measured. The dose of test chemical applied to the skin shall be sufficient to completely cover the exposed skin surface. Four to six diffusion cells shall be set up using skin from a single subject and two to three of these will be terminated at 10 minutes and at 60 minutes. Skin absorption at each sampling time is the sum of the receptor fluid levels and the absorbed chemical that remains in the skin (Ref. 20). Unabsorbed chemical is removed from the skin surface by washing gently with soap and water. This experiment shall be repeated with skin from two additional subjects. If necessary to generate reliable short-term absorption rates, the diffusion cell tops should be covered with a stopper or with Parafilm7 to prevent evaporation of the test chemical.

8. Study Duration

i. *Permeability constant.* The percutaneous absorption study shall be performed until at least four absorption measurements are obtained during the steady state absorption portion of the experiment. A preliminary study may be useful to establish time points for sampling. The required absorption measurements can be accomplished in an hour or two with fast penetrating chemicals but can require 24 hours or longer for slow-penetrating chemicals. Unabsorbed material need not be removed from the surface of the skin.

ii. *Short-term exposure rate.* The test chemical shall be applied to skin for at least durations of 10 and 60 minutes. At the end of the study, the unabsorbed material shall be removed from the surface of the skin with soap and water and the amount absorbed into the skin and receptor fluid shall be determined (Ref. 20).

C. Expression of Results

1. Permeability Constant

The Kp shall be calculated by dividing the steady-state rate of penetration (measured in $\mu g \times hr^{-1} \times cm^{-2}$) by the concentration of test chemical (measured in $\mu g \times cm^{-3}$) applied to the skin. For example, if the steady-state rate is $1\ \mu g \times hr^{-1} \times cm^{-2}$ and the concentration applied to the skin is $1000\ \mu g \times cm^{-3}$, then the Kp value is calculated to be $0.001\ cm \times hr^{-1}$.

2. Short-Term Exposure Rate

The rates of penetration ($\mu g \times hr^{-1} \times cm^{-2}$) shall be determined from the total amount of test chemical found in the receptor fluid and skin after the 10- and 60-minute exposures.

D. Recordkeeping and Reporting Requirements

In addition to compliance with TSCA Good Laboratory Practice (GLP) Standards at 40 CFR part 792, the following specific information shall be collected and reported:

1. Description of Test Systems and Test Methods

The report shall include where and when the test was performed, who performed it, a good laboratory practice statement, and where the records of the test are stored. All of this must be certified by the signatures of the individuals performing the work and their supervisors.

The source, identity and purity of the test chemical shall be reported. The source, identity and handling of the test skin shall be described. There shall be a detailed description of the test procedure and all materials, devices used and doses tested. There shall be a detailed description and illustration of flow cell design. There shall be a description of the skin preparation method including measurements of the skin membrane thickness.

The analytical techniques to be used including their accuracy, precision and detection limits (in particular for non-radiolabelled tests) shall be described and if a radiolabel is used, there shall be a description of the radiolabel (e.g., type, location of and radiochemical purity of the label).

All data collected in the course of the experiment must clearly be identified as to dose and specimen. Derived values (means, permeability coefficient, graphs, charts, etc.) are not sufficient.

2. Conduct of Study

Data shall be collected and reported on the following:

1. Monitoring of testing parameters.

2. Temperature of chamber.
3. Receptor fluid pH.
4. Barrier property validation.
5. Maintenance of glucose utilization (if using viable skin).
6. Analysis of receptor fluid for radioactivity or test chemical and metabolites (if using viable skin).

3. Results

The permeability constant (Kp) or short-term absorption rate shall be presented. In addition, all raw data from each individual diffusion cell shall be maintained to support the calculations of permeability constants and short-term exposure rates. When radiolabelled compounds are used, a full balance of the radioactivity shall be presented, including cell rinsings and stability of the test substance in the donor compartment.

VI. Public Docket

A. Materials Contained in the Docket

EPA has established a docket for this action (to include paper versions of comments in electronic form) under docket control number OPPTS-42186A (FRL–5359–3). The public record is available for inspection from Noon to 4 p.m., Mondays through Fridays, except legal holidays, in the TSCA Nonconfidential Information Center, Rm. NE–B607, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Information claimed as CBI, while part of the record, is not available for public review. The docket includes the following:

1. USEPA. Proposed Protocol for *In Vitro* Percutaneous Absorption Studies. (May 5, 1993).

2. Chemical Manufacturers Association (CMA). Letter to Charles M. Auer, USEPA. (October 21, 1994).

3. Mobil Oil Corporation. Comments on the 31st TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (July 6, 1993).

4. BASF Corporation. Comments on the 32nd TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (September 13, 1993).

5. Aristech Chemical Corporation. Comments on the 32nd TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (September 29, 1993).

6. DuPont. Comments on the 32nd TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (September 15, 1993).

7. The CMA Propylene Glycol Ethers Panel. Comments on the 35th TSCA Interagency Testing Committee Report. Submitted to the TSCA Nonconfidential Information Center, USEPA. (February 27, 1995).

8. The Dow Chemical Company. Comments on the 31st TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (June 3, 1993).

9. The CMA Ketones Panel. Comments on the 31st TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (July 2, 1993).

10. Angus Chemical Company. Letter from Allen F. Bollmeier, Jr. to Roger Nelson, USEPA, enclosing study entitled: ''Skin Absorption and Metabolism/Toxicokinetic Study of ^{14}C-1-Nitropropane in Female Rhesus Monkeys''. (June 16, 1993).

11. Angus Chemical Company. Letter from Allen F. Bollmeier, Jr. to John D. Walker, ITC, enclosing study entitled: ''Skin Absorption and Metabolism/Toxicokinetic Study of ^{14}C-2-Nitropropane in Female Rhesus Monkeys''. (June 21, 1993).

12. The CMA Dintrotoluenes Panel. Comments on the 32nd TSCA Interagency Testing Committee Report. Submitted to the TSCA Docket Receipts Office, USEPA. (September 30, 1993).

13. The CMA Propylene Glycol Ethers Panel. Comment letter on the 35th TSCA Interagency Testing Committee Report from Langley Spurlock to Charles M. Auer, USEPA. (March 31, 1995).

14. Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA). Comments on the 35th TSCA Interagency Testing Committee Report. Submitted to the TSCA Nonconfidential Information Center, USEPA. (January 30, 1995).

15. Union Carbide Corp. Comments on the 35th TSCA Interagency Testing Committee Report. Submitted to the TSCA Nonconfidential Information Center, USEPA. (February 24, 1995).

16. Bronaugh, R.L. and Collier, S.W. Protocol for *In Vitro* Percutaneous Absorption Studies, in *In Vitro Percutaneous Absorption: Principles, Fundamentals, and Applications*, (R.L. Bronaugh and H.I. Maibach, Eds.), CRC Press, Boca Raton, 1991, pp. 237–241.

17. Walker, J.D., Whittaker, C. and McDougal, J.N. Role of the TSCA Interagency Testing Committee in Meeting the U.S. Government's Data Needs: Designating Chemicals for Percutaneous Absorption Testing. In: F. Marzulli and H. Maibach (eds.) *Dermatotoxicology*. Taylor Francis, Washington, DC. (In press).

18. Bronaugh, R.L., Stewart, R.F., and Simon, M. Methods for *In Vitro* Percutaneous Absorption VII: Use of Excised Human Skin, *J. Pharm. Sci.*, vol. 75, pp. 1094–1097, 1986.

19. Bronaugh, R.L. and Stewart, R.F. Methods for *In Vitro* Percutaneous Absorption Studies IV: The Flow-Through Diffusion Cell, *J. Pharm. Sci.*, vol. 74, pp. 64–67, 1985.

20. Bronaugh, R.L., Stewart, R.F., and Storm, J.E. Extent of Cutaneous Metabolism during Percutaneous Absorption of Xenobiotics, *Toxicol. Appl. Pharmacol.*, vol. 99, pp. 534–543, 1989.

B. Submissions to the Docket in Electronic Form

Proposals in electronic form may be sent directly to EPA at:
ncic@epamail.epa.gov
Proposals in electronic form must be submitted as ASCII files and must avoid the use of special characters and any form of encryption.

The official record of this action, as well as the public version, will be maintained in paper form. Accordingly, EPA will transfer all proposals received electronically into paper form as they are received and will place the paper copies in the official record which will also include all proposals submitted directly in writing. The official record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Authority: 15 U.S.C. 2603.

Dated: March 26, 1996.

Charles M. Auer,
Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 96-8008 Filed 4–2–96; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

BACKGROUND: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number. A proposed renewal of the following currently approved collection of information is hereby published for comment. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the

estimate of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarify of the information to be collected; and (d) ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before June 3, 1996.

ADDRESSES: Interested parties are invited to submit written comments to Steven F. Hanft, FDIC Clearance Officer, (202) 898–3907, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street N.W., Washington, D.C. 20429. All comments should refer to the OMB control number 3064–0027. Comments may be hand-delivered to Room F–400, 1776 F Street, N.W., Washington, D.C. 20429, on business days between 8:30 a.m. and 5:00 p.m. [FAX number (202) 898–3838; Internet address: comments@fdic.gov].

A copy of the comments may also be submitted to the OMB desk officer for the agencies: Milo Sunderhauf, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Steven F. Hanft, at the address identified above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently Approved Collection of Information

Title: Deregistration Form for Registered Transfer Agents.

Form Number: Unnumbered form.

OMB Number: 3064–0027.

Frequency of Response: On occasion.

Affected Public: Insured nonmember banks.

Estimated Number of Respondents: 22.

Estimated Time per Response: 0.042 hours.

Estimated Total Annual Burden: 9 burden hours.

General Description of Collection: An insured nonmember that functions as a transfer agent may withdraw from registration as a transfer agent by filing a written notice of withdrawal with the FDIC, as provided by the FDIC's regulations at 12 CFR 341.5.

Request for Comment

Comments submitted in response to this Notice will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology as well as other relevant aspects of the information collection request.

Dated at Washington, D.C., this 28th day of March, 1996.

Federal Deposit Insurance Corporation.

Jerry L. Langley,

Executive Secretary.

[FR Doc. 96–8110 Filed 4–2–96; 8:45 am]

BILLING CODE 6714–01–M

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

BACKGROUND: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number. A proposed renewal of the following currently approved collection of information is hereby published for comment. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimate of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before June 3, 1996.

ADDRESSES: Interested parties are invited to submit written comments to Steven F. Hanft, FDIC Clearance Officer, (202) 898–3907, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street N.W., Washington, D.C. 20429. All comments should refer to the OMB control number 3064–0029. Comments may be hand-delivered to Room F–400, 1776 F Street, N.W., Washington, D.C. 20429, on business days between 8:30 a.m. and 5:00 p.m. [FAX number (202) 898–3838; Internet address: comments@fdic.gov].

A copy of the comments may also be submitted to the OMB desk officer for the agencies: Milo Sunderhauf, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Steven F. Hanft, at the address identified above

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently Approved Collection of Information

Title: Notification of Performance of Bank Services.

Form Number: FDIC 6120/06.

OMB Number: 3064–0029.

Frequency of Response: On occasion.

Affected Public: Insured state nonmember banks.

Estimated Number of Respondents: 175.

Estimated Time per Response: 0.5 hours.

Estimated Total Annual Burden: 87.5 burden hours.

General Description of Collection: Insured state nonmember banks are required to notify the FDIC, under section 7 of the Bank Service Corporation Act (12 U.S.C. 1867), of any relationship with a bank service corporation. The form FDIC 6120/06, Notification of Performance of Bank Services, may be used by banks to satisfy the notification requirement. In lieu of the form, a bank may satisfy the notification requirement by submitting a letter stating the name of the servicer, the address at which the service is being performed, the service being performed, and the date the service commenced. According to the Bank Service Corporation Act, the service becomes subject to examination and regulation by federal bank regulatory agencies to the same extent as if the service were performed by the bank on its own premises.

Request for Comment

Comments submitted in response to this Notice will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All

comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology as well as other relevant aspects of the information collection request.

Dated at Washington, D.C., this 28th day of March, 1996.

Federal Deposit Insurance Corporation.

Jerry L. Langley,

Executive Secretary.

[FR Doc. 96–8111 Filed 4–2–96; 8:45 am]

BILLING CODE 6714–01–M

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

BACKGROUND: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number. A proposed renewal of the following currently approved collection of information is hereby published for comment. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimate of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before June 3, 1996.

ADDRESSES: Interested parties are invited to submit written comments to Steven F. Hanft, FDIC Clearance Officer, (202) 898–3907, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street N.W., Washington, D.C. 20429. All comments should refer to the OMB control number 3064–0104. Comments may be hand-delivered to Room F–400, 1776 F Street, N.W., Washington, D.C. 20429, on business days between 8:30 a.m. and 5:00 p.m. [FAX number (202) 898–3838; Internet address: comments@fdic.gov].

A copy of the comments may also be submitted to the OMB desk officer for the agencies: Milo Sunderhauf, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Steven F. Hanft, at the address identified above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently Approved Collection of Information

Title: Activities and Investments of Savings Associations.

Form Number: N/A.

OMB Number: 3064–0104.

Frequency of Response: On occasion.

Affected Public: Savings associations.

Estimated Number of Respondents: 45.

Estimated Time per Response: 8.89 hours.

Estimated Total Annual Burden: 400 burden hours.

General Description of Collection: Section 28 of the FDIC Act (12 U.S.C. 1831e) imposes restrictions on the powers of savings associations which reduce the risk of loss to the insurance funds and eliminate some differences between the powers of state associations and those of federal associations. Some of the restrictions apply to all savings associations, some to state chartered associations only, and some to federally chartered associations only. The statute exempts some federal savings banks and associations from the restrictions, and provides for the FDIC to grant exemptions to other associations under certain circumstances. The applications for exemption constitute this collection of information.

Request for Comment

Comments submitted in response to this Notice will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology as well as other relevant aspects of the information collection request.

Dated at Washington, D.C., this 28th day of March, 1996.

Federal Deposit Insurance Corporation.

Jerry L. Langley,

Executive Secretary.

[FR Doc. 96–8112 Filed 4–2–96; 8:45 am]

BILLING CODE 6714–01–M

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

BACKGROUND: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number. A proposed revision of the following currently approved collection of information is hereby published for comment. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practically utility; (b) the accuracy of the estimate of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: comments must be submitted on or before June 3, 1996.

ADDRESSES: Interested parties are invited to submit written comments to Steven F. Hanft, FDIC Clearance Officer, (202) 898–3907, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. All comments should refer to the OMB control number

3064–0061. Comments may be hand-delivered to Room F–400, 1776 F Street NW., Washington, DC 20429, on business days between 8:30 a.m. and 5:00 p.m. [FAX number (202) 898–3838; Internet address: comments@fdic.gov].

A copy of the comments may also be submitted to the OMB desk officer for the agencies: Milo Sunderhauf, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Steven F. Hanft, at the address identified above.

SUPPLEMENTARY INFORMATION:

Proposal To Revise the Following Currently Approved Collection of Information

Title: Summary of Deposits.
Form Number: 8020/05.
OMB Number: 3064–0061.
Frequency of Response: Annually.
Affected Public: All offices of all banks with branches in the United States.
Estimated Number of Respondents: 6,900.
Estimated Time per Response: 3 hours.
Estimated Total Annual Burden: 27,600 burden hours.

General Description of Collection: The Summary of Deposits (SOD) information collection system is an annual survey to obtain the amount of deposits held at each office of all banks with branches in the United States. The survey includes both commercial and savings banks. The survey date provide a basis for measuring the competitive impact of bank mergers and has additional use in banking research. The data are collected as of close of business, June 30.

The proposed revisions to the SOD are described as follows. Financial institutions previously were required to report three (3) separate categories for deposits at each branch: (1) ''Individual, partnership and corporation,'' (2) ''other,'' and (3) ''total.'' Now only one figure (total deposits) is required. This will lessen the reporting burden significantly. Reporters were always required to provide information on changes in address, relocations, new and purchased branches, and branches closed or sold. They were instructed to write the information on the form including type of facility and effective date of transaction. Reporting of changes has now been formalized by adding columns to report the effective date, type of transaction and type of facility. In addition to formalizing the reporting of changes, the new format will facilitate the automated interface of these changes to the Corporation's Structure database rather than doing them manually. The new SOD survey form will also facilitate electronic reporting of the Summary of Deposits survey in the future (1997) as well as be similar to the Thrift SOD survey provided the Office of Thrift Supervision.

Request for Comment

Comments submitted in response to this Notice will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology as well as other relevant aspects of the information collection request.

Dated at Washington, DC, this 28th day of March, 1996.

Federal Deposit Insurance Corporation.

Jerry L. Langley,

Executive Secretary.

[FR Doc. 96–8113 Filed 4–2–96; 8:45 am]

BILLING CODE 6714–01–M

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

BACKGROUND: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number. A proposed renewal of the following currently approved collection of information is hereby published for comment. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimate of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before June 3, 1996.

ADDRESSES: Interested parties are invited to submit written comments to Steven F. Hanft, FDIC Clearance Officer, (202) 898–3907, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street N.W., Washington, D.C. 20429. All comments should refer to the OMB control number 3064–0022. Comments may be hand-delivered to Room F–400, 1776 F Street, N.W., Washington, D.C. 20429, on business days between 8:30 a.m. and 5:00 p.m. [FAX number (202) 898–3838; Internet address: comments@fdic,gov].

A copy of the comments may also be submitted to the OMB desk officer for the agencies: Milo Sunderhauf. Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Steven F. Hanft, at the address identified above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently Approved Collection of Information

Title: Uniform Application/Uniform Termination Notice for Municipal Securities Principal or Representative.
Form Number: MSD–4/MSD–5.
OMB Number: 3064–0022.
Frequency of Response: On occasion.
Affected Public: Insured state nonmember banks which are municipal securities dealers.
Estimated Number of Respondents: 114.
Estimated Time per Response: 1 hour.
Estimated Total Annual Burden: 114 burden hours.

General Description of Collection: An insured state nonmember bank which serves as a municipal securities dealer must file Form MSD–4 or MSD–5, as applicable, to permit an employee to become associated or to terminate the association with the municipal securities dealer. The filing requirements are based on rules promulgated by the Municipal Securities Rulemaking Board under the authority of the 1975 Amendments to

the Securities Exchange Act of 1934 (15 U.S.C. 78–o–4).

Request for Comment

Comments submitted in response to this Notice will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology as well as other relevant aspects of the information collection request.

Dated at Washington, D.C., this 28th day of March, 1996.

Federal Deposit Insurance Corporation.

Jerry L. Langley,

Executive Secretary.

[FR Doc. 96–8114 Filed 4–2–96; 8:45 am]

BILLING CODE 6714–01–M

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

BACKGROUND: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number. A proposed renewal of the following currently approved collection of information is hereby published for comment. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimate of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before June 3, 1996.

ADDRESSES: Interested parties are invited to submit written comments to Steven F. Hanft, FDIC Clearance Officer, (202) 898–3907, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. All comments should refer to the OMB control number 3064–0115. Comments may be hand-delivered to Room F-400, 1776 F Street, NW., Washington, DC 20429, on business days between 8:30 a.m. and 5:00 p.m. [FAX number (202) 898–3838; Internet address: comments@fdic.gov].

A copy of the comments may also be submitted to the OMB desk officer for the agencies: Milo Sunderhauf, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Steven F. Hanft, at the address identified above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently Approved Collection of Information

Title: Prompt Corrective Action.
Form Number: N/A.
OMB Number: 3064–0115.
Frequency of Response: On occasion.
Affected Public: FDIC-insured institutions.
Estimated Number of Respondents: 50.
Estimated Time per Response: 4 hours.
Estimated Total Annual Burden: 200 burden hours.

General Description of Collection: The Prompt Corrective Actions provisions of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA, section 131) require or permit the FDIC and other federal banking agencies to take certain supervisory actions when the FDIC-insured institutions fall within one of five capital categories. They also restrict or prohibit certain activities and require the submission of a capital restoration plan when an insured institution becomes undercapitalized. Various provisions of the statute and the FDIC's implementing regulations require the prior approval of the FDIC before an FDIC-supervised institution can engage in certain activities, or allow the FDIC to make exceptions to restrictions that would otherwise be imposed. This collection consists of the applications that are required to obtain the FDIC's prior approval.

Request for Comment

Comments submitted in response to this Notice will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology as well as other relevant aspects of the information collection request.

Dated at Washington, DC., this 28th day of March, 1996.

Federal Deposit Insurance Corporation.

Jerry L. Langley,

Executive Secretary.

[FR Doc. 96–8115 Filed 4–2–96; 8:45 am]

BILLING CODE 6714–01–M

Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:00 a.m., on Tuesday, March 26, 1996, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and supervisory activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Andrew C. Hove, Jr., seconded by Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), concurred in by Director Joseph H. Neely (Appointive), Ms. Julie Williams, acting in the place and stead of Director Eugene A. Ludwig (Comptroller of the Currency), and Chairman Ricki Helfer, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(i), and (c)(9)(A)(ii) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)((4), (c)(6), (c)(8), (c)(9)(A)(i), and (c)(9)(A)(ii).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, N.W., Washington, D.C.

Dated: March 28, 1996.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 96–8234 Filed 4–1–96; 10:06 am]

BILLING CODE 6714–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Federal Maritime Commission hereby give notice that the following agreement(s) has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 State. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and may request a copy of each agreement and the supporting statement at the Washington, DC. Office of the Federal Maritime Commission, 800 North Capitol Street, NW., Room 1046.

Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC. 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments and protests are found in section 560.7 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of that document to the person filing the Agreement at the address shown below.

Agreement No.: 224–200976

Title: Port of Anchorage/Totem Ocean Trailer Express, Inc. Preferential Usage Agreement

Parties:

Port of Anchorage (Port)

Totem Ocean Trailer Express, Inc. (Totem)

Filing Agent: Shirley Maciejski, Office Supervisor, Port of Anchorage, 2000 Anchorage Port Road, Anchorage, Alaska 99501

Synopsis: The proposed Agreement authorities the Port to permit Totem preferential use of its facilities as specified in the Agreement for 156 vessels calls per calendar year.

Dated: March 28, 1996.

By Order of the Federal Maritime Commission

Ronald D. Murphy,

Assistant Secretary.

[FR Doc. 96–8058 Filed 4–2–96; 8:45 am]

BILLING CODE 6730–01–M

Notice of Agreement(s) Filed

The Federal Maritime Commission hereby gives notice that the following agreement(s) has been filed with the Commission pursuant to section 15 of the Shipping Act, 1916, and section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, D.C. Office of the Federal Maritime Commission, 800 North Capitol Street, N.W., 9th Floor. Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments and protests are found in section 560.602 and/or 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of that document to the person filing the agreement at the address shown below.

Agreement No.: 224–200506–003

Title: Burns International Harbor General Cargo Terminal Operating Agreement

Parties:

Indiana Port Commission (''Port'')

Lakes and Rivers Transfer, A division of Jack Gray Transport, Inc.

Filing Agent:

Hopewell H. Darneille III, Esquire, Verner, Liipfert, Bernhard, McPherson and Hand, 901 15th Street, N.W., Washington, DC 20005–2301

Synopsis: The proposed amendment (1) adds Transit Shed No. 1; (2) adjusts the compensation to the Port for the additional reights being granted to operate this additional facility; and (3) modifies the Agreement's terms. It also restates the Agreement.

Dated: March 29, 1996.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 96–8105 Filed 4–2–96; 8:45 am]

BILLING CODE 6730–01–M

Notice of Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, D.C. Office of the Federal Maritime Commission, 800 North Capitol Street, N.W., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in section 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202–009648A–073

Title: Inter-American Freight Conference

Parties:

A.P. Moller-Maersk Line

Empresa de Navegacao Alianca S.A.

Frota Amazonica S.A.

Columbus Line

Transroll/Sea-Land Joint Service

Crowley American Transport, Inc.

A/S Ivarans Rederi d/b/a Ivaran Lines

Companhia Maritima Nacional

Companhia de Navegacao Lloyd Brasileiro

Empresa Lineas Maritimas Argentinas

Compania Sud Americana de Vapores

Synopsis: The proposed amendment revises Article 8.02—Actions Without a Meeting, regarding actions that may be taken without a meeting, and 8.03(b) to provide that seven calendar days' written notice of a Principals' meeting shall be given to each member line.

Agreement No.: 203–011447–007

Title: U.S./Mediterranean Policing Agreement

Parties:

A.P. Moller-Maersk Line

Cho Yang Shipping Co., Ltd.

Compagnie Maritime D'Affretement

Contship Containerlines Limited

Croatia Line

d'Amico Societa di Navigazione per Azioni

DSR-Senator Lines GmbH

Evergreen Marine Corporation (Taiwan) Ltd.

Farrell Lines, Inc.

Hanjin Shipping Co., Ltd.

Italia di Navigazione, S.p.A.

Lykes Bros. Steamship Co., Inc.

Med-Pacific Express (a joint service between d'Amico Societa di Navagazione per Azioni and Italia di Navigazione S.p.A.)

Mediterranean Shipping Co.

Nedlloyd Lijnen B.V.

Nordana Line As

P&O Containers Limited

Sea-Land Service, Inc.

Tecomar, S.A. de C.V.
Transportation Maritima Mexicana, S.A.
United Arab Shipping Company (S.A.G.)
Zim Israel Navagation Company, Ltd.
Synopsis: The proposed amendment revises the withdrawal and duration provisions of the Agreement.

Agreement No.: 232–011537
Title: Frontier Liner Services/Flota Mercante Grancolombiana Space Charter and Sailing Agreement
Parties:
Frontier Liner Services
Flota Mercante Grancolombiana S.A.
Synopsis: The proposed Agreement permits the parties to consult and agree on the deployment and utilization of vessels, charter space to and from one another and to rationalize sailings in the trade between U.S. Atlantic Coast ports and points and ports and points on the Atlantic Coast of Columbia. The parties have requested a shortened review period.

Agreement No.: 217–011538
Title: Tricon/Italia-Slot Charter Agreement
Parties:
Cho Yang Shipping Co. Ltd.
DSR-Senator Lines Gmbh
Italia di Navigazione Spa (''Italia'')
Synopsis: The proposed Agreement permits the parties to charter space to Italia in the trade from and to U.S. Atlantic Coast ports (Bangor, ME/Key Wet, FL range) and to and from Mediterranean ports of Italy, France and Spain (Cadiz included).

Agreement No.: 232–011539
Title: CMN/Ivaran/TMM Space Charter and Sailing Agreement
Parties:
Companhia Maritima Nacional
A/S Ivarans Rederi
Transportacion Maritima Mexicana, S.A. DE C.V.
Synopsis: The proposed Agreement permits the parties to consult and agree upon the deployment and utilization of vessels, charter space from each other and to rationalize sailings in the trade between U.S. Gulf Coast ports and points, on the one hand, and ports on the East Coast of South America (including but not limited to Brazil, Argentina, Paraguay, Uruguay) and inland and coastal points in South America served via those ports on the other hand; and between U.S. Gulf Coast ports and points and ports and points in Mexico.

Agreement No.: 224–200006–004
Title: Port of Oakland/DSR-Senator Lines GmbH/Cho Yang Shipping Company, Ltd. Terminal Agreement
Parties:
Port of Oakland (''Port'')
DSR-Senator Lines GmbH (''DSR'')
Cho Yang Shipping Company, Ltd. (''Cho Yang'')
Synopsis: The proposed amendment adds certain provisions to the Agreement for wharfage of DSR or Cho Yang's cargo discharged from or loaded on Hanjin's vessels at the Port's Seventh Street Marine Container Terminal.

Agreement No.: 224–200974–001
Title: Tampa Port Authority/Tampa Bay International Terminals, Inc. Wharfage Incentive Agreement
Parties:
Tampa Port Authority
Tampa Bay International Terminals, Inc.
Synopsis: The proposed amendment provides a wharfage incentive rate of $1.05 per net ton on importing of reinforcing rods and iron or steel wire in coils based on a minimum annual volume of 10,000 net tons.

Agreement No.: 224–200977
Title: Port of Galveston/Suderman Contracting Stevedores, Inc. Terminal Agreement
Parties:
Port of Galveston (''Port'')
Suderman Contracting Stevedores, Inc. (''Suderman'')
Synopsis: The proposed Agreement permits Suderman to perform stevedoring services at the Port's East and General Marine Terminal.

Dated: March 29, 1996.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 96–8106 Filed 4–2–96; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 23, 1996.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Oliver B. Triplett, III, and Oliver B. Triplett Trust, Oliver B. Triplett, III, Trustee, Forest, Mississippi; to retain 20.41 percent of the voting shares of First Forest Corporation, Forest, Mississippi, and thereby retain shares of Bank of Forest, Forest, Mississippi.

B. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. First Grayson Bancshares, Inc. Employee Stock Ownership Plan, Celeste, Texas; to retain 15.82 percent of the voting shares of First Grayson Banchsares, Inc., Whitesboro, Texas, and thereby indirectly acquire Security Bank, Whitesboro, Texas.

2. Metroplex North Bancshares, Inc. Employee Stock Ownership Plan, Celeste, Texas; to retain 17.87 percent of the voting shares of Metroplex North Bancshares, Inc., Whitesboro, Texas, and thereby indirectly acquire First Bank, Celeste, Texas.

Board of Governors of the Federal Reserve System, March 28, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–8109 Filed 4–2–96; 8:45 am]

BILLING CODE 6210–01–F

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in

writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 26, 1996.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. KeyCorp, Cleveland, Ohio; to acquire 100 percent of the voting shares of Key Trust Company of Florida, National Association, Winchester, Ohio.

B. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Wildcat, Inc., Cedar Rapids, Iowa; to become a bank holding company by acquiring 100 percent of the voting shares of VCR Bancorporation, Ltd., Carlisle, Iowa, and thereby indirectly acquire Hartford-Carlisle Savings Bank, Carlisle, Iowa.

C. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Duncanville Bancshares, Inc., Duncanville, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of Duncanville National Bank, Duncanville, Texas.

2. Unicorp Bancshares - Texas, Inc., Orange, Texas; to acquire 100 percent of the voting shares of Unicorp Bancshares - Delaware, Inc., Wilmington, Delaware, and thereby indirectly acquire First Texas Bank, Vidor, Texas.

In connection with this application Unicorp Bancshares - Delaware, Inc., Wilmington, Delaware, also has applied to acquire 100 percent of the voting shares of First Texas Bank, Vidor, Texas, and 100 percent of the voting shares of OrangeBank, Orange, Texas.

Board of Governors of the Federal Reserve System, March 28, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–8107 Filed 4–2–96; 8:45 am]

BILLING CODE 6210–01–F

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The company listed in this notice has given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The notice is available for inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act, including whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 17, 1996.

A. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Texas Bancshares, Inc., San Antonio, Texas; to engage *de novo* in the activity of making loans to certain executive officers, directors, affiliates and principal shareholders of Texas Bancshares, Inc., San Antonio, Texas, and the certain executive officers and directors and their related interests of its wholly owned subsidiary banks, First National Bank of South Texas, San Antonio, Texas and The Bank of South Texas, Floresville, Texas, pursuant to § 225.25(b)(1).

Board of Governors of the Federal Reserve System, March 28, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–8108 Filed 4–2–96; 8:45 am]

BILLING CODE 6210–01–F

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, April 8, 1996.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any 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: March 29, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–8242 Filed 4–1–96; 10:07 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research, 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: Advisory Committee for Energy-Related Epidemiologic Research.

Times and Dates: 9 a.m.–5 p.m., April 18, 1996; 8:30 a.m.–12 noon, April 19, 1996.

Place: Inn of the Governors, 234 Don Gaspar, Santa Fe, New Mexico 87501.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice and recommendations to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, CDC; and the Administrator, Agency for Toxic Substances and disease Registry (ATSDR), on the establishment of a research agenda and the conduct of a research program pertaining to energy-related analytic epidemiologic studies. The Committee will take into consideration information and proposals provided by the Department of Energy (DOE), the Advisory Committee for Environment Safety and Health which was established by DOE under the guidelines of a Memorandum of Understanding between HHS and DOE, and other agencies and organizations, regarding the direction HHS should take in establishing the research agenda and in the development of a research plan.

Matters To Be discussed: Agenda items will include: presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health, and ATSDR updates on the progress of current studies; discuss working group recommendations, and public involvement activities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Nadine Dickerson, Program Analyst, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: March 27, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Center for Disease Control and Prevention (CDC).

[FR Doc. 96–8118 Filed 4–2–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96C–0097]

Ethicon, Inc.; Withdrawal of a Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 1C0100) proposing that the color additive regulations be amended to provide for the safe use of D&C Red No. 30 (Talc Lake) in cotton sutures.

FOR FURTHER INFORMATION CONTACT: Elke Jensen, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3109.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 26, 1971 (36 FR 12180), FDA announced that a color additive petition (CAP 1C0100) had been filed by Ethicon, Inc., P.O. Box 151, Somerville, NJ 08876–0151. The petition proposed that 21 CFR part 8, now 21 CFR part 74, of the color additive regulations be amended to provide for the certification and safe use of D&C Red No. 30 (Talc Lake) as a dyeing agent for non-absorbable cotton sutures (USP). Ethicon, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: March 26, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–8147 Filed 4–2–96; 8:45 am]

BILLING CODE 4160–01–F

Grassroots Regulatory Partnership Meeting; Southwest Region, Kansas City District Office; Medicated Feed Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Office of the Southwest Region, and Center for Veterinary Medicine) is announcing a free public meeting as a followup to a meeting held in April 1995. FDA's Kansas City District Office (Southwest Region) and the Center for Veterinary Medicine will meet with interested persons in the Southwest Region to address specific issues related to the medicated feed industry. The agency is holding this meeting to promote the President's initiative for a partnership approach between front-line regulators and the people affected by the work of the agency.

DATES: The public meeting will be held on Tuesday, April 30, 1996, from 8:45 a.m. to 4:10 p.m.

ADDRESSES: The public meeting will be held at the Holiday Inn, 6111 Fleur Dr., Des Moines, IA 50321.

FOR FURTHER INFORMATION CONTACT: James E. McDonald, FDA Kansas City District Office, P.O. Box 15905, Lenexa, KS 66285–5905, 913–752–2101, FAX 913–752–2111.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnership meetings would be held. Those persons interested in attending this public meeting should FAX their registration including name(s), affiliation, address, telephone and FAX numbers, and any specific questions about the workshop to James E. McDonald (address above), 913–752–2111. There is no registration fee for this meeting. However, due to space limitations, early registration is required. The goal of this meeting is to listen to concerns and ideas, and to identify possible next steps for the agency.

Dated: March 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8167 Filed 4–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0086]

Medical Device Industry Initiatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: FDA is initiating a pilot program in 1996 involving the medical device industry. This pilot program is intended to optimize resource utilization, enhance FDA/industry communication, and provide firms prompt closure to corrected inspectional observations and nonviolative inspections. This pilot program includes eligibility criteria and procedures for preannounced inspections, the annotation of items on form FDA–483–List of Inspectional Observations (FDA 483) with promised or completed corrections, and postinspectional notification to establishments regarding their compliance status.

EFFECTIVE DATE: April 1, 1996.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James L. Dunnie, Office of Regulatory Affairs (HFC–132), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3340, fax 301–827–0929.

SUPPLEMENTARY INFORMATION:

Background

During the recent FDA/medical device industry grassroots forums, several issues were discussed concerning FDA's interaction with the medical device industry. A decision was made to take action on three of the issues discussed. These included instituting: (1) Preannounced inspections, (2) listing promised or completed corrective actions on FDA–483 items, and (3) postinspectional notification to establishments regarding their compliance status.

After considering these issues, the agency decided to initiate a pilot program in fiscal year 1996 involving the medical device industry. This pilot program will occur during the 1996 calendar year and then be formally evaluated. The pilot program will include criteria and procedures for preannounced inspections, the annotation of FDA–483 items with promised or completed corrections, and postinspectional correspondence.

This initiative is currently restricted to inspections of medical device manufacturers that manufacture only medical device products, and not to those products that may cross different program areas like devices/drugs. This initiative may be expanded in the future to other areas after evaluation of the pilot program.

FDA currently maintains contracts with the States of California, Colorado, and Texas to conduct medical device inspections on behalf of FDA. This pilot program will not include those inspections done under State contract for FDA. Noncontract medical device inspections, however, done by FDA personnel in these States, will be eligible for this pilot program.

The purpose of the pilot program is to optimize resource utilization, enhance FDA/industry communication, and provide firms prompt closure to corrected inspectional observations and nonviolative inspections, and inspections in which voluntary action only is indicated.

Implementation of the pilot program will not impact on violative situations because there will not be a decreased level of enforcement, if enforcement is necessary. Previous FDA experience indicates that the overall out-of-compliance rate for preannounced foreign inspections is comparable or even greater than the overall out-of-compliance rate for domestic inspections where preannouncements generally are not made.

This pilot program for preannounced inspections will not affect any of the other current FDA programs that may involve prior inspectional notification.

Preannounced inspections will be offered to those medical device firms that meet the criteria for inclusion in the pilot program. FDA–483 annotations and the postinspectional notification will be done for all medical device inspections during the period of this pilot. The annotations and the notifications are independent of whether the inspection has been preannounced.

The elements of the pilot program are as follows:

I. Preannounced Inspections

A. Basic Premises

1. This pilot program is intended to be applied only to those medical device manufacturers that meet the criteria for consideration.

2. The eligibility of an individual firm for participation in this pilot is at the discretion of the district office using clearly described criteria. (See section I.B. of this document).

3. The implementation of this preannounced inspection program is intended to be flexible, based on appropriate considerations of the agency and firm.

4. The preannouncement should generally be no less than 5 calendar days in advance of the inspection. Should a postponement be necessary, the decision as to the time of rescheduling rests with the investigator/team, but the new inspection date should not exceed 5 calendar days from the originally set date. Inspections may be conducted sooner than 5 calendar days if requested by the firm and if this date is acceptable to the investigator/team.

5. To participate in this program, firms are expected to meet the commitment to have appropriate records and personnel available during the inspection.

6. Preannounced inspections will not limit an investigator's authority to conduct the inspection. Inspections will be as in depth as necessary.

B. Criteria for Consideration

The criteria to be used by the district office to determine whether it is appropriate to preannounce a planned inspection will include:

1. Type of Inspection:

a. Premarket inspections (PMA and 510(k)),

b. Foreign inspections,

c. Medical device bioresearch monitoring inspections,

d. Good manufacturing practice (GMP) inspections of medical device establishments:

- Biennial routine inspections,
- Initial inspections of newly registered establishments,
- Initial inspections of new facilities,
- Initial inspections under new management and/or ownership.

e. NonGMP inspections other than:

- Immediate and urgent responses to complaints,
- Immediate and urgent followup to informant information, and
- Immediate hazard to health recall followup inspections.

f. Recall followup inspections at medical device manufacturers/initial importers (under new regulations, the U.S. designated agent).

2. Eligibility Criteria:

a. GMP inspections of firms with nonviolative histories (inspections classified as no action indicated (NAI) or voluntary action indicated (VAI)). For VAI, adequate corrections of conditions observed and listed on FDA–483 during the previous inspection were verified and did not lead to any further agency action.

b. To remain eligible for preannounced inspections, firms must have a history of having individuals and/or documents identified in previous preannounced inspections reasonably available at the time of the inspection.

C. Procedures

1. The investigator designated to conduct the inspection will contact or, if unavailable at the time of the call, leave word for the most responsible individual at the facility.

2. Changes in dates should be kept to a minimum. If a change is made, a new date should be provided as soon as possible that will facilitate the inspection and accommodate the investigator's schedule.

3. Preannouncements are normally limited to the investigator (or lead investigator for a team inspection) informing the firm of an upcoming inspection. Usually it will be appropriate to inform the firm as to the purpose, estimated duration, and the

number of agency personnel expected to take part in the inspection. The products or processes to be covered should also be described if this will facilitate and be consistent with the objectives of the inspection.

4. When known, specific records/personnel will be requested at the time the inspection is scheduled.

D. Criteria for Assessing the Success of the Preannounced Inspections

1. Office of Regional Operations (ORO) will provide a questionnaire to be completed by district personnel for each of the inspections made under this pilot program. The districts will be responsible for tracking the responses to each of the questionnaires. An end of the calendar year survey of the districts will be conducted by the Division of Emergency and Investigational Operations (DEIO)/Investigations Branch.

2. Industry groups and involved firms will have an opportunity to provide their opinions and recommendations for improvement after FDA has had some experience with the pilot program, through such possible mechanisms as a customer satisfaction survey.

3. CDRH will be asked to provide comments.

4. Comments received in response to this notice will be considered.

II. FDA–483 Annotations

A. Basic Premise

1. In this pilot program for all medical device establishments, the investigator will annotate FDA–483 at the time of issuance to acknowledge an establishment's promised or completed corrective action. Industry should review the annotations on this issued FDA–483 to ensure that there are no misunderstandings on promised corrective actions.

2. A reportable item will not be deleted from FDA–483 because the establishment has promised or completed a corrective action.

The investigator will continue to have the latitude to delete the observation if the establishment's response to the observation clearly shows that the observation is in error or to clarify the observation based on additional information provided.

3. FDA investigators will continue to report only significant observations on FDA–483 and to discuss these and other less significant observations with the establishment's management.

B. Procedures

1. Investigators and analysts will discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when FDA–483 is issued. This discussion will include those observations that are potentially written FDA–483 items or oral observations. Industry should use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made as soon as possible during the inspection process. Investigators are encouraged to verify the establishment's completed corrective action as long as the verification does not unreasonably extend the duration of the inspection.

2. Where practical, FDA–483 observations should include the number of records of a given type examined, for example, ''Two out of 50 records examined were * * *.''

3. If the establishment has promised and/or completed a corrective action to an FDA–483 observation prior to the completion of the inspection, all copies of FDA–483 should be annotated (either following each observation or at the end of FDA–483) with one or more of the following comments, as appropriate:

Item # _____ reported corrected but not verified.

Item # _____ corrected and verified.

Correction of items _____, _____ and _____ promised by 00/00/96.

4. If an observation made during a prior inspection is noted as not being corrected or is a reoccurring observation, it is appropriate to note this on FDA–483.

5. All corrective action taken by the establishment and verified by FDA should be discussed in detail in the establishment inspection report and reported using the Corrective Action Reporting Systems (CARS).

C. Criteria for Assessing the Success of FDA–483 Annotations

1. ORO will provide a questionnaire to be completed by district personnel for each of the inspections made under this pilot program. The districts will be responsible for tracking the responses to each of the questionnaires. An end of the calendar year survey of the districts will be conducted by the DEIO/Investigations Branch.

2. Industry groups and involved firms will have an opportunity to provide their opinions and recommendations for improvement after FDA has had some experience with the pilot program, through such possible mechanisms as a customer satisfaction survey.

3. CDRH will be asked to provide comments.

4. Comments received in response to this notice will be considered.

III. Postinspectional Notification

A. Basic Premise

1. During this pilot program FDA will issue additional postinspectional notification to establishments regarding their compliance status.

2. The two new categories under which firms will receive postinspection notification are:

a. NAI situations where no FDA–483 was issued or only limited, less significant violations were reported.

b. VAI situations where an FDA–483 was issued but all profile classes were found acceptable. In this circumstance, no regulatory action is contemplated based on the inspection.

3. The postinspectional notification letters that are issued under this pilot program will be mailed under the signature of the district director, in that district in which the establishment is located.

4. For those inspectional followups where regulatory action is being considered, FDA's existing modes of notification will continue to be used.

B. Criteria for Assessing the Success of Postinspectional Notification

1. ORO will provide a questionnaire to be completed by district personnel for each of the inspections made under this pilot program. The districts will be responsible for tracking the responses to each of the questionnaires. An end of the calendar year survey of the districts will be conducted by the DEIO/Investigations Branch.

2. Industry groups and involved firms will have an opportunity to provide their opinions and recommendations for improvement after FDA has had some experience with the pilot program, through such possible mechanisms as a customer satisfaction survey.

3. CDRH will be asked to provide comments.

4. Comments received in response to this notice will be considered.

[The following is an example of a letter intended to be issued in situations classified as NAI where no FDA–483 was issued, or only limited less significant violations were reported:]

Date:
Name:
Address:
Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's (description) facility at (address) on (date). The inspection covered the products described below.

(list of products and their profile classes)

The areas inspected appear to be in substantial compliance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations.

Based on these findings, the agency is prepared to endorse applicable pending premarket (PMA) submissions or export certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address good manufacturing practices (GMP's) in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits, to ensure you are continuing to maintain conformance with GMP's.

For further information, please contact the following individual at this office:

(name and telephone number)

Sincerely,

[The following is an example of a letter intended to be used in situations classified as VAI where an FDA–483 was issued, but all profile classes were found to be acceptable. This type of letter should be issued only when no regulatory action is contemplated, including issuing a warning letter:]

Date:

Name:

Address:

Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's (description) facility at (address) on (date). The inspection covered the products described below.

(list of products and their profile classes)

While some adverse practices/conditions were observed during the inspection, they do not appear to warrant consideration of regulatory followup at this time. These problems were reported to you on an FDA–483 (copy enclosed) issued at the conclusion of the inspection. The problems should be corrected and we encourage you to advise us as to your followup actions.

Based on these findings, the agency is prepared to endorse applicable pending premarket (PMA) submissions or Export Certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address good manufacturing practices (GMP's) in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits, to ensure you are continuing to maintain conformance with GMP's.

For further information, please contact the following individual at this office:

(name and telephone number)

Sincerely,

Enclosures: FDA–483

Interested persons may, on or before June 3, 1996, submit comments to the Dockets Management Branch (address above). Two copies are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8185 Filed 3–29–96; 4:05 pm]

BILLING CODE 4160–01–F

[Docket No. 96N–0025]

Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a voluntary pilot program to test the feasibility of using third-party reviews to improve the efficiency of the agency's review of premarket notifications for medical devices. To implement the pilot program, FDA is announcing simplified agency procedures and practices to process premarket notifications (510(k)'s) submitted by, and with a review prepared by, third-party review organizations (third parties). In its discretion, FDA will select third parties pursuant to the general statements of policy with respect to competence and freedom from conflicts of interest announced in this document. FDA recognizes that it has long been common practice for some firms to engage third parties to make a preliminary review and assist in the quality control of documents prior to their submission in 510(k)'s. FDA believes a similar third-party effort may be useful to improve the efficiency of the agency's review process. The pilot program will allow FDA to evaluate the feasibility of using the results of a third party's review in lieu of the agency's initial review effort. This action is part of efforts in pursuit of the reinventing Government goals of the National Performance Review.

DATES: The pilot program will begin August 1, 1996, and will run for a 2-year period. FDA will apply the pilot program procedures to 510(k)'s received during this period from recognized third parties. FDA is now accepting applications for recognition of prospective third parties and will continue to do so through June 3, 1996. To help prospective third parties prepare these applications, FDA will hold an information session for prospective third parties on April 15, 1996, to review the third-party recognition process and criteria described in this notice, and to answer related questions.

Submit written comments on the pilot program by June 3, 1996.

Submit written comments on the information collection requirements by June 3, 1996. At FDA's request, the Office of Management and Budget (OMB) authorized emergency processing of this information collection. OMB approved the information collection for 90 days, under OMB control no. 0910–0318.

ADDRESSES: Prospective third parties should submit an application for recognition, in duplicate, to the Division of Small Manufacturers Assistance (HFZ–220), ATTN: Third-Party Recognition, Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 1–800–638–2041 or 301–443–7491, both at ext. 105, or FAX 301–443–8818. 510(k)'s reviewed by third parties should be submitted to the Document Mail Center (HFZ–401), ATTN: Third-Party Review, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

Written comments regarding the pilot program and the information collection requirements may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

Persons interested in attending the information session for prospective third parties should obtain registration information as soon as possible. Copies of a facsimile containing this

information are available from the Center for Devices and Radiological Health's (CDRH's) Facts on Demand system by dialing 1–800–899–0381 or 1–301–827–0111 and requesting document number 258. Internet users can obtain registration information by using the World Wide Web; FDA's home page address may be accessed at http://www.fda.gov and then select the Medical Devices and Radiological Health option. Then select the Topic Index option and then scroll down to the Third Party Review option. Registration information is also available from the electronic docket administered by the Division of Small Manufacturers Assistance and is available to anyone with a video terminal or personal computer with a modem (1–800–252–1366 or 1–301–594–2741) by making the following menu choices: 2–Medical Devices Regulations; 8–Third Party Review FR Notice. FDA encourages interested third parties to consider attending this session. FDA will make an initial list of recognized third parties publicly available before commencement of the pilot program, and will update the list as changes occur.

A package of information explaining the Third Party Review Program will be distributed at the information sesssion on April 15, 1996. If you are unable to attend the information session and would like the Third Party Review Program information package, please call 1–800–638–2041 or 301–443–7491, both at ext. 105, or FAX 301–443–8818 with your name and mailing address, and the package will be mailed after April 15, 1996.

FOR FURTHER INFORMATION CONTACT: Eric J. Rechen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

A. Purpose of Section 510(k)

The current regulatory framework for medical devices was created by the Medical Device Amendments of 1976 (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act), as modified by the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. The amendments established in section 513(a) of the act (21 U.S.C. 360c(a)) three device classes and directed FDA to publish regulations classifying each device on the market as of the amendments' enactment. Classification is based on the level of control necessary to provide reasonable assurance of the safety and effectiveness of a device. Class I devices are subject only to general controls, including manufacturer registration, device listing, 510(k), records and reports, and current good manufacturing practice requirements. FDA may, by regulation, exempt a class I device from certain of these requirements, including 510(k) requirements. Class II devices are subject to special controls in addition to general controls, such as promulgation of performance standards, postmarket surveillance, patient registries, and dissemination of guidelines and recommendations. Class III devices are subject to premarket approval and general controls. A preamendments class III device is not required to undergo premarket approval until the effective date of a regulation calling for premarket approval under section 515 of the act (21 U.S.C. 360e).

Section 513(f) of the act contains special classification provisions for postamendments devices. A device introduced on or after the amendments' enactment date (May 28, 1976) is automatically in class III and must receive premarket approval or be reclassified before marketing unless it is *substantially equivalent* to a predicate device (a device marketed before the amendments' enactment, or a device introduced after the amendments' enactment that FDA has reclassified from class III into class I or II).

Section 510(k) of the act provides a means to ensure that manufacturers do not intentionally or unintentionally circumvent the automatic classification provisions of § 513(f). Under § 510(k), a person who intends to begin introduction of a device into commercial distribution is required to report to FDA by submitting a 510(k) at least 90 days in advance. FDA reviews 510(k)'s to determine if a new device is substantially equivalent to a predicate device. For purposes of determining substantial equivalence, a new device may also be compared to a device that FDA has found to be substantially equivalent through the 510(k) process. A device determined by FDA to be substantially equivalent is in the same class and may be introduced to the market subject to the same regulatory controls as the device to which it is substantially equivalent. Before marketing the device, the manufacturer must receive an order, in the form of a letter, by which FDA finds the device to be substantially equivalent. A device determined to be not substantially equivalent is automatically in class III and must receive premarket approval or be reclassified before it is marketed.

The meaning of the term ''substantially equivalent'' is discussed in section 513(i) of the act. Substantial equivalence means, in essence, that a device: (1) Has the same intended use and the same technological characteristics as a predicate device; or (2) has the same intended use and different technological characteristics, but there is information in the 510(k) demonstrating that the device is as safe and effective as a legally marketed device and the device does not raise different questions of safety and effectiveness than the predicate device. Substantial equivalence determinations are currently made by scientific review staff within CDRH based primarily upon information provided by a manufacturer's 510(k). FDA has published regulations (part 807 (21 CFR part 807, subpart E)) specifying 510(k) content and procedures. FDA has also developed numerous guidance documents and policy memoranda for the 510(k) program that are available from CDRH's DSMA, as discussed later in this notice.

Since the inception of the 510(k) program in 1976, FDA has received more than 90,000 510(k)'s, approximately 6,000 of which were received in fiscal year (FY) 1995. Approximately 80 percent of 510(k)'s have resulted in substantially equivalent determinations, 2 percent in not substantially equivalent determinations, and the remainder in administrative actions such as withdrawal by the submitter or deletion by FDA due to lack of response by a submitter. During the second half of FY 1995, approximately 20 percent of substantially equivalent determinations were for class I devices, 76 percent were for class II devices, and 4 percent were for class III devices.

B. Initial Announcement of the Pilot Program

On April 6, 1995, FDA announced its intent to conduct a limited pilot program of third-party review of selected 510(k)'s (hereinafter referred to as the April announcement). This initiative is one aspect of FDA's efforts in pursuit of the reinventing Government goals of the National Performance Review. The purpose of the pilot program is to test the feasibility of third-party review of selected 510(k)'s, as an alternative to FDA's primary review.

In the Federal Register of June 1, 1995 (60 FR 28618), FDA published a notice providing an outline of the proposed pilot program (hereinafter referred to as the June 1 notice) and announcing a June 19, 1995, public workshop to

discuss the proposal. The June 1 notice and the April announcement described key elements of the proposed pilot program:

- FDA will designate the types of devices eligible for third-party review. The devices will be in class I or II, involve low- to moderate-risk, and have a clear basis for review. The pilot program will exclude 510(k)'s requiring clinical data for a decision.
- Third parties will be individually accepted by FDA. FDA will outline criteria covering personnel qualifications and controls over potential conflicts of interest.
- Industry participation will be voluntary. A manufacturer that chooses to participate will submit its 510(k) directly to a recognized third party; the third party may assess a fee for its services. Manufacturers that do not wish to participate may continue to submit 510(k)'s to FDA.
- The selected third party will conduct a complete review of the 510(k), document the review, and make a recommendation to FDA. FDA will check the review, make a substantial equivalence decision, and issue a decision letter.
- The pilot program will begin in FY 1996 and will operate for 2 years. FDA will evaluate it during the second year to determine whether it should be continued as is, modified, or terminated.

The June 19 public workshop provided a forum to discuss FDA's proposed approach to implementing third-party review of selected 510(k)'s and a means of obtaining public comments and suggestions that would help FDA refine its plans for the pilot program. Topics discussed at the workshop included: The role of third parties; types of devices eligible for third-party review; safeguards necessary to ensure the quality and integrity of the pilot program; and funding of third-party reviews. More than 200 persons attended the workshop, including representatives of the device industry, potential third parties, consumers, and health professionals. In addition to presentations and comments at the workshop, FDA accepted written comments through July 7, 1995.

In general, these presentations and comments showed broad support for a pilot program. Some industry representatives expressed concern, however, about limitations on the pilot program that may restrict manufacturers' incentive to participate. In particular, they commented that including only low- to moderate-risk devices in the pilot program and limiting third parties' role to making recommendations rather than final decisions might result in marketing clearance decisions that are no faster, and perhaps slower, than those made by FDA alone. In addition, some industry representatives advocated: Standards-based third-party reviews rather than reviews focused on substantial equivalence; increased harmonization with international standards; and reliance on existing accreditation systems and criteria for potential third parties. Only a few manufacturers expressed opposition to the pilot program, arguing that it would divert FDA's resources away from other reviews or result in inconsistent marketing clearance decisions.

Potential third parties expressed strong interest in the pilot program and indicated that they have the capability, independence, and controls to conduct sound and unbiased reviews. Most advocated that FDA rely on existing accreditation systems and criteria for potential third parties, and that the setting of fees should be left to market forces.

Consumer and professional representatives recommended that FDA proceed cautiously with the pilot program. They expressed concern that third-party review could result in some loss of public accountability and that effective controls are needed to ensure technically-competent reviews free of any conflict of interest that could undermine the objectivity of the review process.

In the months following the June 19 workshop, FDA has considered all comments provided at the workshop and in response to the June 1 notice. FDA has attempted to incorporate suggestions to the extent that they are consistent with existing statutory requirements and the pilot program's purpose and timeframe. For example, while FDA continues to believe that the pilot program should be limited to low- to moderate-risk devices, FDA is significantly expanding the number of devices (particularly in vitro diagnostics) eligible for third-party review and is accepting the suggestion that there be a 30-day performance goal for FDA's decisionmaking based on third-party reviews. Given that FDA's cumulative review time is currently averaging approximately 90 days for 510(k) decisions involving class I devices (and is higher for other 510(k) decisions), a 30-day performance goal for FDA decisions under the pilot program in conjunction with a timely third-party review should provide a tangible incentive for manufacturers to participate in the pilot program.

Similarly, while FDA is unaware of any existing accreditation program for potential third parties that is directly suited to 510(k) review—and is therefore unable to incorporate reliance on such an accreditation for purposes of this pilot program—FDA is establishing a streamlined process for third parties to seek participation in the pilot program. This process should not present an undue burden to qualified third parties that are ready to conduct reviews. However, FDA will only recognize third parties that establish stringent criteria regarding potential conflicts of interest. Having third parties who establish such criteria—in conjunction with FDA's oversight of all third-party reviews and potential for more indepth auditing—should ensure the quality and integrity of 510(k) decisions made under the pilot program.

FDA is not adopting the suggestion that it establish a specific performance goal for the timeliness of reviews by third parties. FDA believes such a goal is unnecessary because timeliness of third-party reviews is likely to be a contractual matter between manufacturers and third parties. In addition, market forces will provide an incentive for third parties to perform timely reviews, i.e., timeliness will be an important consideration when a manufacturer decides whether to submit a 510(k) to a particular third party or to FDA.

FDA has received suggestions that third parties be given final decisionmaking authority under the pilot program and that third parties conduct 510(k) reviews that are focused on criteria other than substantial equivalence. FDA is not adopting these suggestions in the pilot program. It is beyond the scope of the pilot program to test an approach that is completely harmonized with other regulatory systems, such as the third-party system of the European Union. The pilot program does contain key elements of the European model, however, and will provide information useful in assessing its potential applicability in this country. FDA remains committed to the goal of global harmonization and will continue to work with its regulatory counterparts toward that end.

FDA welcomes further comments concerning the pilot program. FDA will use comments to make necessary adjustments during implementation of the pilot program and to conduct an evaluation.

II. Outline of the Third-Party Review Pilot Program

A. Purpose

The overall purpose of the pilot program is to determine whether it is feasible for third parties in the private sector to conduct selected 510(k) reviews that, until now, have been conducted by FDA. This includes determining:

- The willingness of qualified third parties to participate;
- The willingness of manufacturers to submit 510(k)'s to a third party;
- The quality, timeliness, and independence of third-party reviews; and
- Any discernable impacts on FDA resource needs, review times, and decisions, and on the total time needed for manufacturers to obtain 510(k) decisions.

If the pilot approach proves successful, it will: (1) Enable FDA to target its scientific review resources at higher-risk devices while maintaining a high degree of confidence in the review by third parties of low- to moderate-risk devices; and (2) provide manufacturers of eligible devices an alternative review process that can yield more rapid 510(k) decisions. FDA intends the pilot program to test the feasibility of attaining these outcomes.

The pilot program includes safeguards to maintain a high level of quality in the review of 510(k)'s submitted to third parties.

Participation in the pilot is entirely voluntary. Manufacturers may continue to submit 510(k)'s directly to FDA. Manufacturers may also employ the assistance of third parties other than those recognized by FDA, but only 510(k)'s reviewed by recognized third parties will be eligible for the pilot program's simplified processing procedures.

Although the guidance set forth in this notice does not create or confer any rights on any person, and does not operate to bind FDA in any way, it does represent the agency's current thinking on third-party review of 510(k)'s.

B. Devices Eligible for Third-Party Review

During the pilot program, 510(k)'s for the following two categories of devices will be eligible for review by third parties, except when a determination of substantial equivalence necessitates review of clinical data:

- All class I devices that are not exempt from 510(k); and
- Class II devices designated by FDA for inclusion in the pilot program, for which FDA has made device-specific review guidance available.

There are more than 200 types of devices classified by FDA in class I that have not been exempted from 510(k), many of which are in vitro diagnostic devices. FDA is making available a list of these devices (see section III of this document for information on obtaining a copy). FDA currently receives approximately 1,100 510(k)'s per year for these devices.

FDA is also making available a preliminary list of class II devices that it intends to include in the pilot program (see section III of this document for information on obtaining a copy of the list or any associated review guidance). Prior to commencement of the pilot program, and on a quarterly basis during the program's first year, FDA will make review guidance available for a portion of the devices on the list and will update the list to designate those devices as being eligible for third-party review. FDA intends all of the class II devices on the preliminary list to be eligible for third-party review by the end of the first year of the pilot program, but this may be affected by factors such as workload or resource changes in CDRH's Office of Device Evaluation and the extent or nature of public comments received in the development of guidance documents.

Any 510(k) for which clinical data are needed to make a determination of substantial equivalence will continue to be subject to primary review by FDA and will not be processed by FDA under the special procedures for this pilot program. 510(k)'s for the above two categories of devices normally do not contain clinical data and will typically be candidates for inclusion in the pilot program. The need for clinical data is, however, a matter of expert judgment and is often dependent on the nature of any differences (e.g., new indications for use) between the new device and the device to which it is being compared. Manufacturers and third parties seeking guidance on the need for clinical data in a 510(k) should consult FDA's guidance documents and may also contact the appropriate review division in CDRH's Office of Device Evaluation.

C. Recognition of Third Parties

FDA will recognize those third parties whose reviews of 510(k)'s it will consider during the pilot program. While the number of third parties to be recognized by FDA will necessarily be dependent on the number of qualified applicants and the extent of their review capabilities, FDA believes that participation by 3 to 10 recognized third parties would be sufficient for purposes of the pilot program and would keep the pilot program within manageable limits. When selecting third parties for recognition, FDA will give foremost consideration to those third parties with the most qualified personnel and the most stringent conflict of interest standards that are capable of reviewing a broad range of device types or that are uniquely capable of reviewing specific types of devices. FDA will consider recognition requests from both domestic and foreign third parties.

CDRH will maintain a list of third parties eligible to submit 510(k) reviews to FDA. This list will provide the name, contact person, address, telephone number, and specialty (if any) of organizations that FDA has recognized for participation as third parties in the pilot program.

FDA is announcing that it intends to hold an information session for prospective third parties on April 15, 1996, in Rockville, MD, to review the third-party recognition process and criteria described in this notice, and to answer related questions. FDA encourages interested third parties to consider attending this session before submitting a request for recognition. Persons interested in attending should obtain registration information as soon as possible. Copies of a facsimile containing this information are available from CDRH's Facts on Demand system by dialing 1–800–899–0381 or 1–301–827–0111 and requesting document number 258. Internet users can obtain registration information by using the World Wide Web; FDA's home page address may be accessed at http://www.fda.gov and then select the Medical Devices and Radiological Health option. Then select the Topic Index option and then scroll down to the Third Party Review option. Registration information is also available from the electronic docket administered by the Division of Small Manufacturers Assistance and is available to anyone with a video terminal or personal computer with a modem (1–800–252–1366 or 1–301–594–2741) by making the following menu choices: 2–Medical Device Regulations; 8–Third Party Review FR Notice.

Qualified organizations that wish to become a recognized third party for the pilot program should submit the following materials, in duplicate, no later than June 3, 1996:

1. Information identifying the third party, including its name, contact person, address, telephone number, and fax number. A third party located outside the United States should also

identify the name, address, telephone number, and fax number of an authorized representative located within the United States who will serve as the third party's official correspondent with FDA.

2. Identification of the devices the third party seeks to review. If a third party seeks to review only a subset of the devices eligible for third-party review under this pilot program, the devices should be clearly identified, such as by classification panel (i.e., all eligible devices within the panel) or by specific classification name and Code of Federal Regulations citation.

3. Documentation that the third party meets its established criteria, as described in section II.D.1. and II.D.2. of this document, with respect to personnel qualifications and facilities.

4. A copy of the written policies and procedures established by the third party to ensure that it and its employees involved in the third-party review of 510(k)'s are free from conflicts of interest, as outlined in section II.D.3. of this document, and certification that the third party and its employees meet its established criteria.

5. A statement that the third party consents to FDA inspection and copying of all records, correspondence, and other materials relating to any review conducted by the third party under this pilot program, including records on personnel education, training, skills, and experience, all documentation on prevention of conflicts of interest, and the third party's fee schedule and invoices for conducting 510(k) reviews.

6. A statement that the third party will strictly preserve and protect the confidentiality of all information provided by any manufacturer and by FDA.

When these materials are received by DSMA, a date-stamped acknowledgment letter will be faxed to the third party's official correspondent. DSMA will coordinate CDRH's review of these materials and respond to the third party within 30 days of the completion of the time period for submitting such materials with one of the following: A letter of recognition, a denial of recognition, or a request for additional information. CDRH may deny a request for recognition for any reason, including if it determines that the third party's personnel qualifications or criteria for ensuring conflicts of interest are inadequate, or if the third-party's submission does not place it among the most highly qualified candidates. CDRH may deem incomplete and delete a request for recognition if a third party fails to respond to a request for additional information within 10 days. Third parties may make a written request to the Director, Office of Health and Industry Programs, CDRH for reconsideration of a decision to deny or delete a request for recognition.

A list of recognized third parties will be made available to the public through CDRH's Facts-on-Demand facsimile system (1–800–899–0381, document number 967), or the electronic docket (1–800–252–1366) (see section III. of this document for information on obtaining a copy) before commencement of the pilot program. The list will be updated as necessary and will be made available for the duration of the pilot program.

Unless the third party requests that it be removed from FDA's recognition list, or FDA finds for any reason in its sole discretion—including that the third party has not followed recognized rules of ethics or conduct, is not in fact independent, or has knowingly made any material misstatement of fact or circumstances or material misrepresentations of any kind—that the third party is no longer qualified, recognition will continue for the duration of the pilot program. If changes occur that significantly affect any information or certification provided to FDA, it is the responsibility of the third party to provide FDA with updated information and, if necessary, an updated certification, at the earliest possible opportunity.

If FDA has reason to believe that a recognized third party no longer meets the criteria for participation in the pilot program, an opportunity for a meeting with the Director, Office of Health and Industry Programs, CDRH, will be provided prior to any decision concerning removal of the third party from FDA's list of recognized third parties.

Consistent with current practice, FDA will accept 510(k)'s from third parties that have not been recognized, but FDA will give no weight to any review or recommendation provided by the nonrecognized third party and will treat the submission in the same manner as a 510(k) submitted by a consultant.

D. Criteria for Third Parties

To be recognized by FDA, a third party should demonstrate that it has the appropriate qualifications and facilities to conduct competent 510(k) reviews, and has instituted effective controls to prevent any conflict of interest or appearance of conflict of interest that might affect the review process.

1. Personnel Qualifications

FDA expects to recognize third parties that have sufficient personnel, with the necessary education, training, skills, and experience, to evaluate a substantial number of 510(k)'s in those categories of devices it accepts for review. FDA will consider several factors with respect to personnel qualifications when it considers who to recognize as third parties. These include:

(a) Whether the third party has established, documented, and executed policies and procedures to ensure that 510(k)'s are reviewed by qualified personnel, and whether it will maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the technical review of a 510(k);

(b) Whether the third party has made available to its personnel clear, written instructions for their duties and responsibilities with respect to 510(k) reviews;

(c) Whether the third party employs personnel who, as a whole, are qualified in all of the scientific disciplines addressed by the 510(k)'s that the third party accepts for review;

(d) Whether the third party has identified at least one individual who is responsible for providing supervision over 510(k) reviews and who has sufficient authority and competence to assess the quality and acceptability of these reviews; and

(e) Whether the third party is prepared to conduct technically competent reviews at the time of requesting recognition by FDA.

FDA is making available information on the general education and experience FDA requires of its scientific review personnel (see section III. of this document for information on obtaining a copy). Within CDRH's Office of Device Evaluation, the GS–12 level (as described in the information being made available) is usually considered to be the typical level at which reviewers assume full responsibility for conducting 510(k) reviews. A third party may adopt these criteria as one means of ensuring that its personnel having primary responsibility for review of a 510(k) for a class I device have appropriate education and experience. A third party may develop and apply alternative criteria that result in personnel having education and experience necessary and appropriate to review 510(k)'s for class I devices.

For appropriate review of a particular class II device, FDA will expect specialized education or experience consistent with assuring a technically competent review.

2. Facilities

FDA expects to recognize third parties that have the capability to interface with

FDA electronic data systems. At a minimum, this would include a computer system with a modem and an independent facsimile machine.

3. Prevention of Conflicts of Interest

FDA expects to recognize third parties that will be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of conflict of interest. To that end, when deciding whether to recognize a third party, FDA will consider whether the third party has established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest. Although it is not feasible to identify or state categorically or inflexibly all of the criteria for judging that a third party is free of conflicts of interest, the most common conditions that would indicate a potential conflict of interest are:

(a) The third party is owned, operated, or controlled by a device manufacturer or distributor;

(b) The third party or any of its personnel involved in 510(k) reviews has any ownership or other financial interest in any medical device, device manufacturer, or distributor;

(c) The third party or any of its personnel involved in 510(k) reviews participates in the design, manufacture, or distribution of any medical device;

(d) The third party or any of its personnel involved in 510(k) reviews provides consultative services to any device manufacturer or distributor regarding any specific devices;

(e) The third party or any of its personnel involved in 510(k) reviews participates in the preparation of any 510(k); or

(f) The fee charged or accepted by the third party is contingent or based upon the type of recommendation made by the third party.

Nevertheless, a third party may: Assess a fee for its services; conduct other activities, such as objective testing or inspection of devices, if they do not affect the impartiality of 510(k) reviews; and provide information on 510(k) requirements to improve the organization or content of a 510(k) that it is reviewing.

Where a third party uses the services of a contractor for 510(k) reviews, the third party is responsible for the contracted work of its contractor. The third party is to assure that the contractor meets the third party's established criteria for freedom from conflicts of interest.

FDA is making available information on the conflict of interest standards it applies to its own review personnel (see section III. of this document for information on obtaining a copy). A third party may adopt these standards as one means of safeguarding its operations against conflicts of interest.

FDA has considered additional mechanisms to ensure the independence of recognized third parties and to prevent even the appearance of forum shopping by manufacturers. One mechanism considered would be for manufacturers to submit their 510(k)'s first to FDA and then have the agency assign submissions to recognized third parties that are qualified to review them, much like FDA now assigns submissions to internal staff reviewers. Under this mechanism, manufacturers would then negotiate a fee with the third party and pay the fee directly. Although this mechanism would likely be effective in guarding against forum shopping, it has the major disadvantage, for purposes of the pilot program, of necessitating that FDA establish a special processing and assignment system for what could be a relatively large number of 510(k)'s submitted in the short period of the pilot program. It also would restrict manufacturers' ability to negotiate fees, and limit other potentially beneficial competitive influences on the pilot program.

Accordingly, for purposes of this pilot program, manufacturers are to contact recognized third parties directly to request review of their 510(k)'s. FDA may refuse, however, to provide expedited processing of a manufacturer's 510(k)'s and consideration of the accompanying third-party reviews if it appears to FDA, in its sole discretion, that the manufacturer has engaged in forum shopping. Although it is not feasible to identify or state categorically all of the criteria for evaluating whether a manufacturer has forum shopped, three factors that would indicate forum shopping are:

- A manufacturer has obtained reviews of the same 510(k) from more than one third party, or from a third party and directly from FDA;
- A manufacturer has contracted for a substantial number of third-party reviews (ordinarily more than 10 in 1 year) from the same third party when other recognized third parties have the necessary expertise and capacity to perform additional 510(k) reviews; or
- A manufacturer has contracted for reviews from the same third party the sum of fees for which is substantial (ordinarily exceeding $50,000 in 1 year) when other recognized third parties have the necessary expertise and capacity to perform additional 510(k) reviews.

If one (or more) of these factors is present, there will be a presumption of forum shopping and FDA may refuse to provide expedited processing of a manufacturer's 510(k)'s unless the manufacturer can explain why the circumstances do not indicate forum shopping. Manufacturers' avoidance of the last two factors will have the added benefit of enhancing manufacturers' ability to contribute to the evaluation of the pilot program, i.e., manufacturers that contract with more than one third party during the course of the pilot program will have a better basis for assessing how each performs.

E. Purpose and Nature of a Third-Party Review

The purpose of a third-party review is to evaluate a manufacturer's 510(k), document the review, and make a recommendation to FDA concerning the substantial equivalence of the device. FDA will provide information on procedures and criteria that it uses for 510(k) reviews in general guidance and in a training program to be made available by FDA before commencement of the pilot program (see section III. of this document for information on obtaining a copy of FDA's general review guidance). Until then, interested persons may consult existing guidance such as HHS Publication FDA 95–4158 ''Premarket Notification 510(k)—Regulatory Requirements for Medical Devices'' (August 1995). This publication provides an overview of device regulations, information on 510(k), FDA requirements concerning 510(k) content and format, a description of the 510(k) review process, copies of particularly important policy memoranda, and additional information useful to manufacturers and third parties. A copy of this publication may be obtained by contacting CDRH's DSMA (see section III. of this document for additional information on obtaining a copy).

FDA encourages third parties to be familiar with the requirements outlined in this publication and in subsequent guidance. The general guidance, as well as any device-specific review guidance made available by FDA, will assist the third party in producing reviews that are acceptable to FDA and that FDA can process in a timely manner.

F. Training for Recognized Third Parties

FDA is currently planning to hold one or more training sessions for recognized third parties. (This training is in addition to the prerecognition information session discussed earlier in

this notice.) Recognized third parties are to complete this training before conducting 510(k) reviews under the pilot program. The primary emphasis of this training will be on how to conduct an appropriate review of a 510(k). Depending on demand, one or more sessions may focus on specific types of devices, such as in vitro diagnostic devices. FDA will provide additional information on this training when it sends letters of recognition to third parties participating in the pilot program.

G. Review Materials to be Submitted to FDA by a Third Party

Upon completion of its review of a 510(k), a third party should submit the following documentation to FDA, in duplicate:

1. A cover letter signed by the third party's official correspondent clearly identifying: the purpose of the submission; the name and address of the third party; the name and address of the manufacturer; the name of the device (trade name, common or usual name, and FDA classification name); the third party's recommendation with respect to the substantial equivalence of the device; and the date the third party first received the 510(k) from the manufacturer.

2. A letter signed by the manufacturer authorizing the third party to submit the 510(k) to FDA on its behalf and to discuss its contents with FDA.

3. The manufacturer's complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.

4. A complete review of the 510(k), signed by all personnel who conducted the third-party review and by an individual within the third party responsible for supervising third-party reviews, with a recommendation concerning the substantial equivalence of the device.

5. A certification that the third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA; that statements made in the third party's review are true and accurate to the best knowledge of the third party; that the third party's review is based on the 510(k) that it is submitting with the review; and that the third party understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

6. Any other information requested in FDA's guidance for third parties.

FDA may not process a 510(k) submitted with a third-party review if this documentation is not included with the submission. Third-party reviews, along with the associated 510(k)'s, should be submitted to CDRH's Document Mail Center (address above). If a part of the material submitted is in a foreign language, it should be accompanied by an English translation verified to be complete and accurate.

H. Basic Document Processing

To ensure the integrity of the review process, all third-party review materials and the associated 510(k) are to be submitted directly to FDA by the third party. CDRH's Document Mail Center will receive all submissions, and will then route them to the appropriate review division in CDRH's Office of Device Evaluation. 510(k)'s reviewed and submitted by recognized third parties will bypass the first phases of FDA's normal review process, that is, the acceptance screening and initial scientific review, and will instead be routed directly to the appropriate supervisory official, typically a branch chief. The supervisory official will rely in part on the record of review prepared by the third party and will conduct a brief administrative assessment to determine whether the third party's review is acceptable to FDA. This assessment will apply the same criteria as for 510(k)'s reviewed entirely within FDA. If FDA has questions concerning the submission, the third party will be contacted. The supervisory official will prepare FDA's decision concerning the substantial equivalence of the device. Decision letters and other significant correspondence will be sent to the third party's official correspondent, which will be responsible for communicating with the manufacturer. FDA is establishing a 30-day performance goal for its decisions on 510(k)'s received under the pilot program.

As noted earlier, 510(k)'s submitted by third parties that have not been recognized by the agency will be accepted, but those submissions will not be eligible for processing under the pilot program's simplified procedures. Any such 510(k) will be processed in the same manner as a normal 510(k) submitted by a consultant.

I. Confidentiality of Information

A recognized third party is to conscientiously preserve and protect the confidentiality of all information provided to it by a manufacturer or by FDA. Except for authorized FDA employees or as otherwise provided by Federal or State law, no information pertaining to any review, including its existence, is to be made available to any person without the express written permission of the manufacturer employing the third party and written permission by FDA.

The releasability of third-party review information submitted to FDA will be determined by FDA in accordance with the agency's regulations (part 20 (21 CFR part 20) and § 807.95) implementing the Freedom of Information Act and related acts. In general, 510(k) reviews submitted by third parties (just like reviews conducted by FDA staff) will be available for disclosure by FDA after FDA has issued a substantial equivalence decision for a device, unless the information is exempt from public disclosure under part 20. If necessary, a review will be provided to the manufacturer for predisclosure notification pursuant to § 20.61. In addition, information submitted by a third party to obtain FDA's recognition for participation in the pilot program will be available for disclosure by FDA, unless exempt under part 20.

J. Records

A recognized third party should maintain complete records of its 510(k) reviews and other information necessary for participation in the pilot program. These records include documentation of the third party's policies and procedures under section II.D. of this document with respect to personnel qualifications and prevention of conflicts of interest; copies of all correspondence and other information to become recognized by FDA; copies of all 510(k) reviews, the associated 510(k)'s, and related correspondence with manufacturers and FDA; information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k); and the third party's fee schedule and invoices for conducting 510(k) reviews. Records should be in English or be accompanied by a complete and accurate English translation. Records should be retained for a reasonable period of time, but no less than 3 years following submission of a review to FDA. All records are subject to FDA inspection and copying.

K. Fees Assessed by Third Parties

Recognized third parties may assess a reasonable fee for their services. The fee for a third-party review is a matter to be determined by contract between the third party and the manufacturer, but will be considered by FDA to present a conflict of interest if it is contingent or based upon the type of recommendation made by the third party. As indicated above, the third party's fee schedule and invoices for conducting 510(k) reviews are subject to FDA inspection and copying.

L. Dates and Duration of the Pilot Program

The pilot program will begin August 1, 1996, and will run for a 2-year period. FDA will apply the pilot program procedures to 510(k)'s received during this period from recognized third parties. FDA is now accepting applications for recognition of prospective third parties and will continue to do so through June 3, 1996. FDA will closely monitor the operation of the pilot program and may modify its scope or conditions if necessary to protect the public health or to better achieve program objectives. During the second year of the pilot program, FDA will evaluate the pilot program and FDA will then determine whether it should be continued as is, modified, or terminated. FDA intends to complete this evaluation prior to the scheduled ending date for the pilot program.

M. Safeguards

The pilot program includes a number of safeguards to maintain a high level of quality in 510(k)'s reviewed by recognized third parties and to minimize risks to the public. Most of these safeguards have been discussed above, and are briefly listed here:

- Limitation of the pilot program to low- to moderate-risk class I or class II devices for which FDA has made review guidance available;
- Exclusion of any 510(k) that requires clinical data for a determination of substantial equivalence;
- FDA assessment and recognition of third parties before their participation in the pilot program;
- Personnel qualifications for third parties equivalent to the level within CDRH's Office of Device Evaluation;
- Criteria to prevent potential conflicts of interest that might affect the review process;
- FDA training for recognized third parties;
- FDA review of third-party reviews/recommendations and FDA's continued responsibility for the issuance of 510(k) decisions;
- Provision for FDA inspection of records, correspondence, and other materials relating to any third-party review;
- FDA monitoring and evaluation of the pilot program; and
- Continued applicability of any other regulatory controls (e.g., medical device reporting of post-marketing adverse events) normally applicable to devices included in the pilot program.

III. Obtaining Additional Information

Additional information on the pilot program can be obtained by contacting CDRH's DSMA at 1–800–638–2041 or 301–443–7491, both at ext. 105, or FAX 301–443–8818. Some information will only be available on the DSMA Facts-on-Demand facsimile system, which is accessed by touch-tone telephone or on the DSMA Electronic Docket, which is accessed via a computer with a modem. Information that DSMA will make available includes:

- This notice;
- Registration information for the information session to be held on April 15, 1996, in Rockville, MD, to review the third-party recognition process and criteria for prospective third parties;
- A checklist for third parties seeking FDA recognition;
- Information on the general education and experience requirements for FDA personnel involved in the technical review of 510(k)'s;
- Information on the conflict of interest standards FDA applies to its employees;
- A list of recognized third parties, updated as necessary (this information will only be available from the DSMA Facts-on-Demand system (1–800–899–0381, document number 967) or Electronic Docket (1–800–252-1366);
- A list of the devices eligible for third-party review, updated at least quarterly;
- Device-specific guidance for class II devices designated as eligible for third-party review;
- General guidance on 510(k) requirements and the content and format of third-party reviews; and
- Any additional information and guidance that FDA finds necessary or appropriate as the pilot program proceeds.

IV. Paperwork Reduction Act of 1995

This voluntary pilot program contains information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). At the agency's request, OMB conducted an emergency review of this information collection, as provided for under 5 CFR 1320.13. OMB approved the information collection within 10 days, as requested by FDA, for the maximum 90 days permitted under 5 CFR 1320.13, under OMB control no. 0910–0318. Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number.

Because the OMB emergency approval of this information collection is valid for only 90 days, FDA is also taking the appropriate steps to obtain a regular approval. Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c).

To comply with this requirement, FDA is publishing a notice of the information collection. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching data sources, gathering and maintaining the date needed, and completing and reviewing the collection of information.

With respect to the following collection of information, FDA invites comments on: (1) 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) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program

Description: This Federal Register notice announces a 2-year, voluntary pilot program to test the feasibility of using third-party reviews to improve the efficiency of FDA's review of premarket notifications under section 510(k) of the act. Participation is entirely voluntary. A third party wishing to participate will submit a request for recognition within 60 days of publication of the Federal Register notice. After reviewing a manufacturer's 510(k), a third party is to forward the 510(k) along with the third party's documented review and recommendation to FDA. Third parties should maintain records of their 510(k) reviews for a reasonable period of time, but no less than 3 years. This information collection will enable FDA to conduct a voluntary pilot program to determine the feasibility of third-party review of 510(k)'s to improve the efficiency of FDA's review of 510(k)'s for low- to moderate-risk devices.

Description of Respondents: Businesses or other for-profit, not-for-profit institutions.

Table 1.—Estimated Annual Reporting Burden for Third Parties

Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
II.C.1–5 (Recognition Requests):							
First Submission	15	0.5[1]	7.5	24	180		
Additional information	8	0.5[1]	4.0	4	16		
Updates	10	1.0	10.0	1	10		
510(k) Reviews							
II.G.1–6	10	50	500	40	20,000	57,250	28,625
Total					20,206	57,250	28,625

[1]These submissions are made in the first year only, the reporting frequency has been averaged over the pilot program's 2-year period to provide an annual frequency.

Table 2.—Estimated Annual Recordkeeping Burden

Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Recordkeeper	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
II.J.	10	252	2,520	63	630		

Capital costs and operating and maintenance costs are attributable to reporting and are included in the table above.

Organizations and individuals may submit comments regarding this information collection, including suggestions for reducing this burden, by June 3, 1996, and should direct them to the Dockets Management Branch (address above).

Dated: March 25, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–8149 Filed 4–1–96; 8:45 am]

BILLING CODE 4160–01–F

Investigational New Drugs; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical holds that the Center for Drug Evaluation and Research (CDER) has placed on certain investigational new drug trials. The committee was established as a 1-year experiment in August 1991. The committee met quarterly through 1992 and currently meets semiannually as a regular program. The committee last met in November 1995. FDA is inviting any interested drug company to use the confidential mechanism to submit to the committee for its review the name and number of any investigational new drug trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting is currently scheduled for June 1996. Drug companies may submit review requests for the June meeting before May 3, 1996.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Janet M. Jones, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane (WOC II rm. 6020), Rockville, MD 20857, 301–594–5445.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational drug. The IND must contain the study protocol, a summary of human and animal experience with the drug, and information about the drug's chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of subjects and, in phases 2, 3, and 4 of drug development, to help ensure that the quality of any scientific evaluation of drugs is adequate to permit an evaluation of the drug's efficacy and safety. An investigational new drug for which an IND is in effect is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may impose a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug as part of that study. When an ongoing study is placed on clinical hold, no new subjects may

be recruited to the study and placed on the investigational drug, and patients already in the study should stop receiving therapy involving the investigational drug unless FDA specifically permits it.

FDA regulations at § 312.42 describe the grounds for the imposition of a clinical hold. When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for the imposition of a hold order, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, the agency may order a clinical hold. In CDER, a clinical hold is ordered by the director of the new drug division that is responsible for review of the IND. The order identifies the studies under the IND to which the hold applies and explains the basis for the action. The hold order may be made by telephone or other means of rapid communication, or in writing. Within 5 working days of the imposition of the clinical hold, the division director provides the sponsor with a written explanation of the basis for the hold. Any sponsor who has not received a written explanation within 5 working days should notify the division and request that it be issued. In addition to providing a statement of reasons, this ensures that the hold is recorded in CDER's management information system.

The clinical hold order specifies whether the sponsor may resume the affected investigation without prior notification by FDA once the deficiency has been corrected. If the order does not permit the resumption, an investigation may resume only after the division director or his or her designee has notified the sponsor that the investigation may proceed. Resumption may be authorized by telephone or other means of rapid communication. If all investigations covered by an IND remain on clinical hold for 1 year or longer, FDA may place the IND on inactive status.

FDA regulations at § 312.48 and CDER's Manual of Policies and Procedures (MAPP 6030.1) provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, a sponsor may request a meeting with the review staff and management to discuss the hold.

Over the years, drug sponsors have expressed a number of concerns about the clinical hold process, including concerns about the scientific and procedural adequacy of some agency actions. FDA undertook several initiatives to evaluate the consistency and fairness of the Center's practices in imposing clinical holds.

One initiative undertaken by FDA was the establishment of a committee in CDER to review selected clinical holds for scientific and procedural quality. The committee held pilot meetings in 1991 and 1992. The trial phase of the committee review process confirmed the agency's view that the divisions in CDER impose clinical holds in a manner that is generally consistent with FDA's procedural requirements and that holds are imposed on scientifically supportable grounds.

The clinical hold committee review process is now a regular, ongoing program. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending hold to have that hold considered ''anonymously.'' The committee consists of senior managers in CDER, a senior official from the Center for Biologics Evaluation and Research, and the FDA Chief Mediator and Ombudsman. The committee now meets semiannually. The committee last met in November 1995.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review holds proposed for review by drug sponsors. In general, a drug sponsor should consider requesting review when it disagrees with the agency's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CDER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with agency regulations and CDER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, will be available through the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites drug companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational new drug trial that was placed on clinical hold during the past 12 months that they want the committee to review at its June meeting. Submissions should be made by May 3, 1996, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: March 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8165 Filed 4–2–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; 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 proposals for the collection of information. Interested persons are invited to send comments regarding this 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.

1. *Type of Request:* Revision of a currently approved collection; *Title of Information Collection:* Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services; *Form No.:* HCFA–2082; *Use:* The data reported in the HCFA–2082 are the basis of actuarial forecasts for Medicaid service utilization and costs; of analyses and cost savings estimates required for legislative initiatives relating to Medicaid and for responding to requests for information from HCFA components, the Department, Congress and other customers; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 54; *Total Annual*

Responses: 54; *Total Annual Hours:* 17,214.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, management Planning and Analysis Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 27, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–8053 Filed 4–2–96; 8:45 am]

BILLING CODE 4120–03–P

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

1. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* State Survey Agency List of Positions and Schedule of Equipment Purchases; *Form No.:* HCFA–1465, HCFA–1466; *Use:* The information collected is used by HCFA to determine the types of equipment being purchased and the need for such equipment, the information also provides HCFA with the types and skill levels of surveyor positions that are being requested by the State; *Frequency:* Annually; *Affected Public:* State, local, and tribal government; *Number of Respondents:* 53; *Total Annual Hours:* 239.

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to National Accreditation Organizations; *Form No.:* HCFA–R–191; *Use:* The information collected is used by HCFA to determine whether a private accreditation organization's criteria for granting accreditation is equal to or more stringent than the criteria used by Medicare to determine Ambulatory Surgical Center eligibility for participation in the Medicare Program; *Frequency:* Other (initial application, as needed); *Affected Public:* Not for profit institutions; *Number of Respondents:* 2; *Total Annual Hours:* 192.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.ssa.gov/hcfa/hcfahp2.html , 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: John Burke, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 27, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–8055 Filed 4–2–96; 8:45 am]

BILLING CODE 4120–03–P

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals 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 subject: (1) The necessity and utility of 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.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Maximizing the Effectiveness of Home Health Care: The Influence of Service Volume and Integration With Other Care Settings on Patient Outcomes; *Form No.:* HCFA–R–189; *Use:* This study will examine (1) the relationship of home health care service volume and patient outcomes, and (2) the relationship of the physician role and integration of other services and patient outcomes; *Frequency:* Other (periodically); *Affected Public:* Not-for-profit institutions, business or other for profit, and individuals or households; *Number of Respondents:* 6,300; *Total Annual Hours:* 3,573.

2. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services, Outpatient Physical Therapy Speech Pathology Survey Report; *Form Nos.:* HCFA–1856, HCFA–1893; *Use:* The Medicare Program requires outpatient physical therapy providers to meet certain health and safety requirements. The request for certification form is used by State agency surveyors to determine if minimum Medicare eligibility requirements are met. The survey report form records the result of the onsite survey; *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 1,700; *Total Annual Hours:* 446.25.

3. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Request for Certification as Supplier of Portable X-ray Services Under the Medicare/

Medicaid Programs, Portable X-ray Survey Report; *Form Nos.:* HCFA–1880, HCFA–1882; *Use:* The Medicare program requires portable x-ray suppliers to be surveyed for health and safety standards. The HCFA–1882 is the survey form that records survey results. The HCFA–1880 is used by the surveyors to determine if a portable x-ray applicant meets the eligibility requirements; *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 520; *Total Annual Hours:* 137.

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Physical Therapist in Independent Practice Request for Certification in the Medicare Program; *Form No.:* HCFA–262; *Use:* The HCFA–262 is used by the surveyors to determine if a physical therapist in independent practice requesting Medicare approval meets the eligibility requirements; *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 7,322; *Total Annual Hours:* 1,098.

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Request for Approval as a Hospital Provider of Extended Care Services (Swing-Bed) in the Medicare and Medicaid Programs; *Form No.:* HCFA–605; *Use:* The HCFA–605 is used for facility identification and screening. It will be completed by a hospital that is requesting approval and will initiate the process of determining the hospital's eligibility and for which bed count category the hospital wishes to request approval; *Frequency:* Other (one-time usage for initial application); *Affected Public:* Business or other for profit, not-for-profit institutions, Federal Government; *Number of Respondents:* 1,500; *Total Annual Hours:* 375.

6. Galley Revision of a currently approved collection; *Title of Information Collection:* Organ Procurement Organization's Request for Designation; *Form No.:* HCFA–576; *Use:* The information provided on this form serves as a basis for certifying organ procurement organizations (OPO) for participation in the Medicare and Medicaid programs and will indicate whether the OPO is meeting the specified performance standards for reimbursement of service; *Frequency:* Biennially; *Affected Public:* Business or other for profit, not-for-profit institutions; *Number of Respondents:* 80; *Total Annual Hours:* 160.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent 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: March 27, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–8054 Filed 4–2–96; 8:45 am]

BILLING CODE 4120–03–P–M

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory bodies scheduled to meet during the months of April and May 1996:

Name: National Advisory Council on Nurse Education and Practice

Date and Time: April 18–19, 1996 8:30 a.m. to 5:00 p.m.

Place: Chesapeake Conference Room, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. The meeting is open to the public with the exception of the period from approximately 9:30 a.m.—10:30 a.m. on April 19, when grant applications will be reviewed.

Agenda: Report on and discussion of the legislative and budget status of Title VIII nursing programs, discussion of follow-up actions from the Council on Graduate Medical Education/National Advisory Council on Nurse Education and Practice Joint Meeting, discussion of issues related to the basic nursing workforce, and review of applications for the Nursing Education Opportunities Program for Individuals from Disadvantaged Backgrounds.

The meeting will be closed to the public on April 19, 9:30 a.m. to 10:30 a.m. for review of grant applications. The closing is in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., and the Determination by the Associate Administrator for Policy Coordination, Health Resources and Services Administration, pursuant to Public Law 92–463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should write or contact Ms. Melanie Timberlake, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9–35, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–5688.

Name: National Advisory Council on the National Health Service Corps

Date and Time: April 26–28, 1996.

Place: Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, Maryland. The meeting is open to the public.

Agenda: The agenda will include orientation of new members, National Health Service Corps (NHSC) budget and policy updates, discussion of proposed strategies for fulfilling needs for oral health professionals, and workgroup meetings on NHSC policy issues.

The meetings will begin on Friday at 5:00 p.m. and adjourn at 9:00 p.m. On Saturday, the meeting will begin at 8:00 a.m. and adjourn at 5:30 p.m. Sunday's meeting will begin at 8:00 a.m. and adjourn at 12:00 noon.

Anyone requiring information regarding the subject Council should contact Ms. Jewel Davis, National Advisory Council on the National Health Service Corps, 8th floor, 4350 East West Highway, Rockville, Maryland 20857, Telephone (301) 594–4144.

Name: National Advisory Council on Migrant Health

Date and Time: May 2–3, 1996–8:00 a.m.

Place: Nashville Convention Center, 601 Commerce Street, Nashville, TN 37203–3724, 615/742–2000. The meeting is open to the public.

Agenda: The agenda includes a overview of Council general business activities and priorities. In addition, the Council will review and discuss the 1996 National Advisory Council on Migrant Health Recommendations.

The Council meeting is being held in conjunction with the National Association of Community Health Centers, Annual Farmworker Health Conference, May 4–6, 1996. The Conference will take place at the Stouffer Renaissance Nashville Hotel located at 611 Commerce Street, Nashville, TN 37203 (615/255–8400)

Anyone requiring information regarding the subject Council should contact Susan Hagler, Migrant Health Program, Staff Support to the National Advisory Council on Migrant Health, Bureau of Primary Care, Health Resources and Services Administration, 4350 East West Highway, Room 7–A51, Bethesda, Maryland 20814, Telephone (301) 594–4302.

Name: HRSA AIDS Advisory Committee

Time: May 22–23, 1996 8:30 a.m.

Place: Embassy Row Hotel, Ambassador Room, 2015 Massachusetts Avenue, N.W. Washington, D.C. 20036. The meeting is open to the public.

Agenda: The Committee will address the impact of Medicaid/Managed Care on service

delivery to individuals living with HIV/AIDS, as well as the impact of substance abuse on the HIV/AIDS epidemic, the Ryan White CARE Act and other HRSA AIDS activities.

Anyone requiring information regarding the subject Committee should contact Judy Hagopian, AIDS Program Office, Health Resources and Services Administration, Room 14A–21, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0866.

Agenda Items are subject to change as priorities dictate.

Dated: March 29, 1996.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 96–8091 Filed 4–2–96; 8:45 am]

BILLING CODE 4160–15–M

''Models That Work'' Campaign

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of cosponsorship opportunity.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the opportunity for private and public organizations to join us in cosponsoring the ''Models That Work'' Campaign. The Campaign is a nationwide, multi-year initiative designed to identify and promote programs that serve as models of innovative approaches to the delivery of primary and preventive health care to underserved and vulnerable populations. HRSA's Bureau of Primary Health Care launched the Campaign in the fall of 1994. The next cycle of the Campaign will begin May 1, 1996, with a national competition to identify model programs.

DATES AND ADDRESSES: Nominations are due on May 3, 1996, and should be sent to Dr. Regan Crump in HRSA's Bureau of Primary Health Care, 4350 East West Highway, Bethesda, Maryland, 20814.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on the ''Models That Work'' Campaign and cosponsorship should be directed to: Dr. Regan Crump, Health Resources and Services Administration, Bureau of Primary Health Care, 4350 East-West Highway, Bethesda, Maryland, 20814 Fax: (301) 594–4997; phone: (301) 594–4340. Email: RCRUMP@SSW.DHHS.GOV

SUPPLEMENTARY INFORMATION: The ''Model That Work'' Campaign has four main objectives: 1) to identify programs that serve as models of innovative approaches to the delivery of primary and preventive health care to underserved and vulnerable populations, 2) to share information about the Model programs and strategies with interested parties, 3) to maintain a dialogue with health care leaders and decisionmakers on the benefits of investing in new approaches for providing primary and preventive care, and 4) to stimulate public-private partnerships that support innovative community-based primary care infrastructures.

The next cycle of the Campaign will begin with a national competition to identify model programs. The winners of the competition will be featured at a national symposium to be held this fall in Washington, D.C. Lessons learned from the winning models will be shared through a variety of means, including process releases, articles, a video, a compendium, and exhibits at conferences. The winners are expected to be available to provide technical assistance to entities interested in replicating or adapting their model.

Expectation of Cosponsors

Cosponsoring organizations must have a substantive interest in the goals of the Campaign and are expected to be active participants in the Campaign. Cosponsorship involves joint development, support, implementation, and evaluation of the Campaign with the Health Resources and Services Administration's Bureau of Primary Health Care and other cosponsors. A copy of the Department of Health and Human Services guidelines on cosponsorship is available upon request.

Cosponsor Nomination Process

Representatives of interested organizations can nominate their organization by sending a 1–3 page letter that includes: (1) A description of the organization and its mission, (2) evidence of a substantive interest in the Campaign, and (3) a statement on how the organization's participation will enhance the ability of the Campaign to fulfill its purpose.

Dated: March 28, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–8092 Filed 4–2–96; 8:45 am]

BILLING CODE 4160–15–M

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Center Research Special Emphasis Panel (SEP) meeting:

Name of SEP: Clinical Research Infrastructure Initiative.

Date: April 29, 1996.

Time: 8:00 a.m.

Place: Residence Inn by Marriott, Kent Room, 7335 Wisconsin Avenue, Bethesda, MD 20814, (301) 718–0200.

Contact Person: Dr. John Lymangrover, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6106, Bethesda, MD 20892–7965, (301) 435–0820.

Purpose/Agenda: To evaluate and review grant applications.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.389 Research Centers in Minority Institutions, National Institutes of Health, HHS)

Dated: March 28, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–8153 Filed 4–2–96; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Notice of as Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, a amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Folow-up Analysis of Biologic Samples from the Ibuprofen Trial (Telephone Conference Call).

Date: April 25, 1996.

Time: 1:00 p.m.

Place: 6701 Rockledge Drive, Room 7220, Bethesda, Maryland 20892.

Contact Person: C. James Scheirer, Ph.D,, 6701 Rockledge Drive, Room 7220, Bethesda, Maryland 20892–7220, (301) 435–0266.

Purpose/Agenda: To review and evaluate a contract proposal.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the

disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: March 28, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–8154 Filed 4–2–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Committee Name: National Institute of General Medical Sciences Special Emphasis Panel—Pharmacology.

Date: April 19, 1996.

Time: 2 p.m.—adjournment

Place: Holiday Inn—Vanderbilt, 2613 West End Avenue, Nashville, TN 37203.

Contact Person: Dr. Bruce Wetzel, Scientific Review Administrator, NIGMS, 45 Center Drive, Room 1AS–19K, Bethesda, MD 20892–6200.

Purpose: To review and evaluate a grant application.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The discussion of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.821, Biophysics and Physiological Sciences; 93.859, Pharmacological Sciences; 93.862, Genetics Research; 93.863 Cellular and Molecular Basis of Disease Research; 93.880, Minority Access Research Careers [MARC]; and 93.375, Minority Biomedical Research Support [MBRS].

Dated: March 28, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–8152 Filed 4–2–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Child Health and Human Development; Closed Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Maternal and Child Health Research Subcommittee, National Institute of Child Health and Human Development Initial Review Group.

Purpose/Agenda: To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5, United States Code and section 10(d) of Pub. L. 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Scientific Review Administrator: Dr. Gopal Bhatnager, 6100 Executive Boulevard—Rm. 5E03, Telephone: 301–496–1696.

Date of Meeting: April 18, 1996.

Place of Meeting: Ramada Inn Bethesda, 8400 Wisconsin Avenue, Bethesda, Maryland 20814.

Time: 8:00 am—adjournment.

(Catalog of Federal Domestic Assistance Program No. 93.864, Population Research and No. 93.865, Research for Mothers and Children, National Institute of Health.)

Dated: March 28, 1996.

Susan K. Feldman,

Committee Management Officer, National Institutes of Health.

[FR Doc. 96–8155 Filed 4–2–96; 8:45 am]

BILLING CODE 4140–01–M

Meetings of the Deafness and Other Communication Disorders Programs Advisory Committee

Pursuant to Pub. L. 92–463, notice is hereby given of meeting of the Deafness and other Communications Disorders Programs Advisory Committee.

Place: Room 400C, 6120 Executive Blvd., Rockville, MD 20852, (telephone conference calls).

Date: May 21, 1996.

Time: 1:30 to 3:30 pm.

Agenda: Discussion of future scientific initiatives regarding smell and taste.

Date: May 22, 1996.

Time: 10:30 to 12:30 pm.

Agenda: : Discussion of future scientific initiatives regarding Voice, speech and language.

Date: May 22, 1996.

Time: 1:30 to 3:30 pm.

Agenda: Discussion of future scientific initiatives regarding hearing and balance and vestibular.

Contact Person: Ralph F. Naunton, M.D., Director, Division of Human Communication, NIH/NIDCD, Room 400C, 6120 Executive Boulevard, MSC 7180, Bethesda, MD 20892–7180, 301–496–1804.

The meetings will be open to the public, with attendance limited to space available. A summary of the meeting and a roster of the members may be obtained from Dr. Naunton's office. For individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations, pleace contact Dr. Naunton prior to the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communications Disorders)

Dated: March 28, 1996.

Susan K. Feldman,

Committee Management Officer, National Institutes of Health.

[FR Doc. 96–8160 Filed 4–2–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Mental Health Council of the National Institute of Mental Health for May 1996.

The meeting will be open to the public, as indicated, for discussion of NIMH policy issues and will include current administrative, legislative, and program developments. Attendance by the public will be limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the contact person named below in advance of the meeting.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, a portion of the Council will be closed to the public as indicated below for the review, discussion and evaluation of individual grant applications. These applications, evaluations, and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms Joanna L. Kieffer, Committee Management Officer, National Institute of Mental Health, Parklawn Building, Room 9–105, 5600 Fishers Lane, Rockville, MD 20857, Area Code 301, 443-4333, will provide a summary of the meeting and a roster of committee members.

Other information pertaining to the meeting may be obtained from the contact person indicated.

Name of Committee: National Advisory Mental Health Council.

Date: May 20–21, 1996.

Place:

May 20—Conference Room 10, Building 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

May 21—Conference Room D, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Open: May 20, 9 a.m. to 5 p.m.

Closed: May 21, 9:30 a.m. to adjournment.

Contact Person: Carolyn Strete, Ph.D., Executive Secretary, Parklawn Building, Room 9–105, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–3367.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: March 28, 1996.

Susan K. Feldman,

Committee Management Officer, National Institutes of Health.

[FR Doc. 96–8162 Filed 4–2–96; 8:45 am]

BILLING CODE 4140–01–M

Meetings: National Advisory Allergy and Infectious Diseases Council; Acquired Immunodeficiency Syndrome Subcommittee; Allergy and Immunology Subcommittee; Microbiology and Infectious Diseases Subcommittee

Pursuant to Public Law 92–463, notice is hereby given to the meeting of the National Advisory Allergy and Infectious Diseases Council, National Institute of Allergy and Infectious Diseases, and its subcommittees on May 20–21, 1996. Meetings of the Council, NAAIDC Allergy and Immunology Subcommittee and the NAAIDC Microbiology and Infectious Diseases Subcommittee will be held at the National Institutes of Health, Building 31C. The meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee will be held at the National Institutes of Health, Natcher Building, Bethesda, Maryland.

The meeting of the full Council will be open to the public on May 20 in Conference Room 6 from approximately 1 p.m. until 4 p.m. for opening remarks of the Institute Director, discussion of procedural matters, Council business, and a report from the Institute Director which will include a discussion of budgetary matters. The primary program will include an update on various Institute focus group activities and an NIAID vaccine update addressing the areas of AIDS and non-AIDS research.

On May 21 the meetings of the NAAIDC Allergy and Immunology Subcommittee and NAAIDC Microbiology and Infectious Diseases Subcommittee will be open to the public from 8:30 a.m. until adjournment. The subcommittees will meet in Building 31C, conference rooms 8 and 6 respectively. The meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee will be open to the public from 8:30 a.m. until adjournment, on May 21. The subcommittee will meet in Conference Room E1 at the Natcher Building.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Public Law 92–463, the meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee, NAAIDC Allergy and Immunology Subcommittee and the NAAIDC Microbiology and Infectious Diseases Subcommittee will be closed to the public for approximately four hours for review, evaluation, and discussion of individual grant applications It is anticipated that this will occur from 8 a.m. until approximately 1 p.m. on May 20, in conference rooms 7, 8 and 6 respectively. The meeting of the full Council will be closed from 4 p.m. until recess on May 20 for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Claudia Goad, Committee Management Officer, National Institute of Allergy and Infectious Diseases, Solar Building, Room 3C26, National Institutes of Health, Bethesda, Maryland 20892, 301–496–7601, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Goad in advance of the meeting.

Dr. John J. McGowan, Director, Division of Extramural Activities, NIAID, NIH, Solar Building, Room 3C20, 6003 Executive Boulevard, Rockville, Maryland 20892, telephone 301–496–7291, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 93.855 Immunology, Allergic and Immunologic Diseases Research, 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: March 29, 1996.

Susan K. Feldman,

Committee Management Officer, National Institutes of Health.

[FR Doc. 96–8163 Filed 4–2–96; 8:45 am]

BILLING CODE 4140–01–M

Division of Research Grants; Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Microbiological and Immunological Sciences.

Date: April 8, 1996.

Time: 8:30 a.m.

Place: Governor's House Hotel, Washington, DC.

Contact Person: Dr. Martin Slater, Scientific Review Administrator, 6701 Rockledge Drive, Room 4184, Bethesda, Maryland 20892, (301) 435–1149.

Name of SEP: Microbiological and Immunological Sciences.

Date: April 9, 1996.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 4210, Telephone Conference.

Contact Person: Dr. Bruce A. Maurer, Scientific Review Administrator, 6701 Rockledge Drive, Room 4210, Bethesda, Maryland 20892, (301) 435–1225.

Name of SEP: Biological and Physiological Sciences.

Date: April 9, 1996.

Time: 11:00 a.m.

Place: NIH, Rockledge 2, Room 5122, Telephone Conference.

Contact Person: Dr. Michael Lang, Scientific Review Administrator, 6701 Rockledge Drive, Room 5122, Bethesda, Maryland 20892, (301) 435–1265.

Name of SEP: Microbiological and Immunological Sciences.

Date: April 10, 1996.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 4210, Telephone Conference.

Contact Person: Dr. Bruce A. Maurer, Scientific Review Administrator, 6701 Rockledge Drive, Room 4210, Bethesda, Maryland 20892, (301) 435–1225.

Name of SEP: Biological and Immunological Sciences.

Date: April 11, 1996.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 5198, Telephone Conference.

Contact Person: Dr. Peggy McCardle, Scientific Review Administrator, 6701 Rockledge Drive, Room 5198, Bethesda, Maryland 20892, (301) 435–1258.

This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing

limitations imposed by the grant review and funding cycle.

Name of SEP: Microbiological and Immunological Sciences.
Date: April 16, 1996.
Time: 10:00 a.m.
Place: NIH, Rockledge 2, Room 4190, Telephone Conference.
Contact Person: Dr. Garrett Keefer, Scientific Review Administrator, 6701 Rockledge Drive, Room 4190, Bethesda, Maryland 20892, (301) 435–1152.

Name of SEP: Biological and Physiological Sciences.
Date: April 22, 1996.
Time: 9:00 a.m.
Place: NIH, Rockledge 2, Room 5122, Telephone Conference.
Contact Person: Dr. Michael Lang, Scientific Review Administrator, 6701 Rockledge Drive, Room 5122, Bethesda, Maryland 20892, (301) 435–1265.

Name of SEP: Biological and Physiological Sciences.
Date: April 24, 1996.
Time: 9:00 a.m.
Place: NIH, Rockledge 2, Room 5122, Telephone Conference.
Contact Person: Dr. Michael Lang, Scientific Review Administrator, 6701 Rockledge Drive, Room 5122, Bethesda, Maryland 20892, (301) 435–1265.

Name of SEP: Biological and Physiological Sciences.
Date: April 25, 1996.
Time: 2:00 p.m.
Place: NIH, Rockledge 2, Room 5138, Telephone Conference.
Contact Person: Dr. Gerhard Ehrenspeck, Scientific Review Administrator, 6701 Rockledge Drive, Room 5138, Bethesda, Maryland 20892, (301) 435–1022.

Name of SEP: Chemistry and Related Sciences.
Date: April 30, 1996.
Time: 1:00 p.m.
Place: NIH, Rockledge 2, Room 5154, Telephone Conference.
Contact Person: Dr. Alec Liacouras, Scientific Review Administrator, 6701 Rockledge Drive, Room 5154, Bethesda, Maryland 20892, (301) 435–1740.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 28, 1996.
Susan K. Feldman,
Committee Management Officer, National Institutes of Health.

[FR Doc. 96–8161 Filed 4–2–96; 8:45 am]
BILLING CODE 4140–01–M

Public Health Service

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) (NIH) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 61 FR 3722, February 1, 1996), is amended to reflect the reorganization of the National Center for Research Resources (NCRR) (HNR). This reorganization streamlines the structure of NCRR by consolidating seven extramural programs into four extramural areas and five extramural support functions into three. Specifically, the reorganization consists of the following: (1) Retitle the General Clinical Research Centers Program (HNRB) to Clinical Research and revise its functional statement; (2) retitle the Comparative Medicine Program (HNR8) to Comparative Medicine (CM), transfer the functions of the Biological Models and Materials Research Program (BMMRP) (HNRH) to CM, abolish BMMRP, and revise CM's functional statement; (3) retitle Biomedical Research Technology Program (HNRC) to Biomedical Technology (BT), transfer the Shared Instrumentation Grant Program within the Biomedical Research Program (BRSP) (HNRE) to BT, and revise BT's functional statement; (4) establish Research Infrastructure (RI) (HNRL); (5) transfer the functions of the Research Centers in Minority Institutions Program (RCMIP) (HNRG) and Research Facilities Improvement Program (RFIP) (HNR9) to RI, transfer the functions of the remaining two BRSP programs (Institutional Development Award Program [IDeA] and Science Education Program Award (SEPA) to RI; and (6) abolish the RCMIP, RFIP, BRSP. In the Office of the Director, NCRR (HNR1) (1) establish the Office of Extramural Activities (OEA) (HNR17); (2) transfer the functions of the Office of Grants and Contracts Management (OGCM) (HNR13) and the Office of Review (OR) (HNR16) to the OEA and abolish OGCM and OR; (3) transfer the Committee Management Office function from the immediate Office of the Director to the OEA; (4) transfer the functions of the Office of Science and Health Reports (OSHR) (HNR12) to the Office of Science Policy (OSP) (HNR15), revise OSP's functional statement, and abolish OSHR; and (5) retitle the Office of Administrative Management (HNR14) to Office of Administration (OA) and revise its functional statement.

Section HN–B Organization and Functions is amended as follows: (1) Under the heading *National Center for Research Resources (HNR),* insert the following:

Research Infrastructure (HNRL). (1) Supports programs to improve the representation of minority investigators who are underrepresented in biomedical research; (2) enhances the research environment and faculty development at minority colleges and universities that award doctoral degrees in the health sciences; (3) provides matching grants to improve biomedical and behavioral research facilities through construction and renovation; (4) supports science education opportunities for minority high school students and their teachers interested in science careers; (5) supports K–12 science teacher education and skills development; and (6) supports innovation and improvement in pre-college science education and in the public's understanding of health-related science.

(2) Under the heading *General Clinical Research Centers Program (HNRB), and Biomedical Research Technology Program (HNRC),* delete the titles and functional statements in their entirety and substitute the following:

Comparative Medicine (HNR8). (1) Provides high quality, disease-free animal models and specialized and research facilities for biomedical investigators; (2) supports the development of a wide-range of research models, particularly marine invertebrates and lower vertebrates; (3) provides access for biomedical researchers to an array of important biological materials, such as viruses, bacteria and fungi as well as cell lines, genetic material, and human cells and organs; (4) supports research activities at seven Regional Primate Centers; (5) supports the identification and development of new and improved animal models for the study of human diseases; (6) supports improvement of the health and well-being of laboratory animals; (7) supports training and career development for veterinarians; (8) provides repositories for the storage and distribution of genetically altered animal models; and (9) supports the breeding accessibility of scarce research animals.

Clinical Research (HNRB). (1) Supports a national network of clinical research centers in academic medical hospitals for interdisciplinary clinical research into the prevention, diagnosis and treatment of disease, providing cost-effective, centralized access to research facilities, specially trained research nurses and dietitians, core laboratories, biostatisticians, and computerized database management and analysis systems; (2) supports professional development of junior career physicians and dentists involved in clinical research; and (3) supports other shared resources for clinical research.

Biomedical Technology (HNRC). (1) Supports research, development and access to sophisticated technologies at biomedical technology resource centers; (2) provides grants for acquisition of new state-of-the-art shared instrumentation; (3) supports special emphasis technology development in high performance computing, molecular and cellular structural biology technologies, biomedical engineering, noninvasive imaging and spectroscopy, mathematical modeling and computer simulations through grants, contacts and cooperative agreements.

(3) Under the headings *Biomedical Research Support Program (HNRE), Research Centers in Minority Institutions Program (HNRG), Biological Models and Materials Research Program (HNRH),* and *Research Facilities Improvement Program (HNR9),* delete the titles and functional statements in their entirety.

(4) Under the heading *National Center for Research Resources (HNR), Office of the Director (HNRI),* insert the following:

Office of Extramural Activities (HNR17). (1) Provides oversight and direction for the review of grant applications and contract proposals; (2) manages the National Advisory Research Resources Council and other advisory and review committees; (3) provides oversight and direction for the grant management functions of the NCRR.

(5) Under the heading *Office of Administrative Management (HNR14),* delete the title and functional statement in its entirety and substitute the following:

Office of Administration (HNR14). (1) Plans, implements, and evaluates administrative and management services and provides support to the programs and activities of the Center; (2) provides budgetary support for budget formulation and execution; (3) provides personnel management services, management analysis and advice; (4) plans and operates the NCRR Data Systems; (5) maintains liaison with the Office of Administration, NIH; and (6) interprets and implements new/revised administrative policies/regulations affecting the overall mission of the Center.

(6) Under the heading *Office of Science Policy (HNR15)* delete the functional statement in its entirety and substitute the following:

Office of Science Policy (HNR15). (1) Advises the Director of the National Center for Research Resources on policy matters, scientific developments and other relevant issues that may affect NCRR programs and initiatives; (2) assists in the establishment of NCRR objectives and in the development or modification of programs to meet these objectives; (3) evaluates the performance and impact of NCRR programs and related PHS programs and activities; (4) acquires data and performs analyses for use in NCRR planning and development; (5) coordinates the presentation of the Center's plans and reports; (6) conducts the Center's legislative liaison activities; (7) serves as a clearinghouse and focal point for the Center's efforts to interpret the goals and results of NCRR-supported research programs and projects and to disseminate information to the biomedical research community, to Congress and the Executive Branch, to other specialized groups, and to the general public; and (8) conducts the Center's Freedom of Information and Privacy Act activities.

(7) Under the headings *Office of Science and Health Reports (HNR 12), Office of Grants and Contracts Management (HNR13), and Office of Review (HNR16),* delete the titles and functional statements in their entirety.

Dated: March 21, 1996.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 96–8164 Filed 4–2–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4012–N–02]

Office of the Assistant Secretary for Community Planning and Development; Notice of Funding Availability for Housing Opportunities for Persons with AIDS; Technical Correction

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of Funding Availability (NOFA); technical correction.

SUMMARY: On February 28, 1996, HUD published a Notice of Funding Availability for the Housing Opportunities for Persons with AIDS program, 61 FR 7664. This document corrects several minor and inadvertent omissions from that notice.

EFFECTIVE DATE: The effective date of this correction is February 28, 1996.

FOR FURTHER INFORMATION CONTACT: The Community Connections information center at 1–800–998–9999 (voice) or 1–800–483–2209 (TTY) or by internet at gopher://amcom.aspensys.com:75/11/funding.

SUPPLEMENTARY INFORMATION: On February 28, 1996, HUD published a Notice of Funding Availability to announce the potential availability of up to $17,100,000 in funds to be allocated by competition for housing assistance and supportive services under the Housing Opportunities for Persons with AIDS (HOPWA) program. This document corrects several minor and inadvertent omissions from that notice regarding how to obtain information that is available in connection with the application package, provides a 1–800 TTY phone number, corrects the room number for the Processing Control Unit for the receipt of applications, notes the use of the Headquarters lobby for receipt of applications after standard work hours on the due date, removes a duplicative phone number and corrects the authorization citation.

Accordingly, FR Doc. 96–4012, a NOFA published in the Federal Register on February 28, 1996 (61 FR 7664) is corrected as follows:

1. On page 7664, in column three, the paragraph titled **FOR A COPY OF APPLICATION PACKAGES CONTACT:** is removed and replaced with a paragraph to read as follows:

FOR A COPY OF APPLICATION PACKAGES CONTACT: The Community Connections information center at 1–800–998–9999 (voice) or 1–800–483–2209 (TTY) or by internet at gopher://amcom.aspensys.com:75/11/funding for the application package and supplemental information. You can also purchase, for a nominal fee, a video that walks you through the application package and provides general background that can be useful in preparing your application. The fee for the video may be waived in cases of financial hardship.

2. On page 7664, in column three, the paragraph titled **ADDRESSES:** is removed

and replaced with paragraphs to read as follows:

ADDRESSES: Before 7:00 p.m. Eastern Time on the deadline date, completed applications will be accepted at the following address: Office of Community Planning and Development, Processing Control Branch, Room 7251, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410. On the deadline date from 7:00 pm until midnight Eastern Time, hand-carried applications will be received at the South Lobby of the Department of Housing and Urban Development at the above address.

HUD will treat as ineligible for consideration applications that are received after the deadline. A copy also must be sent to the HUD Field Office serving the area in which the applicant's project is located. A list of field offices appears at the end of this NOFA. The Department will not accept any application that is submitted to HUD via facsimile (FAX) transmission.

* * * * *

3. On page 7664, in column three, the paragraph titled **FOR FURTHER INFORMATION CONTACT:** is removed and replaced with a paragraph to read as follows:

FOR FURTHER INFORMATION CONTACT: The Community Connections information center at 1–800–998–9999 (voice) or 1–800–483–2209 (TTY) or by internet at gopher://amcom.aspensys.com:75/11/funding.

* * * * *

4. On page 7664, at the bottom of the page, the chart entitled ''ELIGIBLE APPLICANTS AND SCHEDULE OF COMPETITIONS IN 1996:'' is amended by removing the row entitled ''Where to obtain application packages'' and the row entitled ''Applications to be sent to'' and replacing them, respectively, with rows to read as follows:

ELIGIBLE APPLICANTS AND SCHEDULE OF COMPETITIONS IN 1996:

* * * * *

Where to obtain application packages.	Contact the Community Connections information center at 1–800–998–9999 (voice) or 1–800–483–2209 (TTY) or by internet at gopher://amcom.aspensys.com:75/11/funding for the application package and supplemental information. You can also purchase, for a nominal fee, a video that walks you through the application package and provides general background that can be useful in preparing your application. The fee for the video may be waived in cases of financial hardship.
* * * * * * * * *	
Applications to be sent to.	Original to HUD Headquarters (Room 7251) and one copy to the area HUD Office (CPD office); on the deadline date from 7:00 pm until midnight Eastern Time, hand-carried applications will be received at the South Lobby of HUD Headquarters.

5. On page 7665, in the first column, the paragraph entitled ''(b) Authority.'' is removed and replaced with a paragraph to read as follows:

(b) Authority. The assistance that may be made available under this NOFA is authorized by the AIDS Housing Opportunity Act (42 U.S.C. 12901). The Congress has not yet enacted a FY 1996 appropriation for HUD. However, HUD is publishing this notice in order to give potential applicants adequate time to prepare applications. The amount of funds announced in this NOFA is an estimate of the amount that may be enacted for fiscal year 1996. HUD is not bound by the estimate set forth in this notice. The regulations for HOPWA are found at 24 CFR part 574.

6. On page 7666, in the third column, the paragraph titled ''(b) Competition.'' is amended by adding in the second sentence after the word ''panel'' the phrase ''or panels'' and by adding after the word ''obtain'' the phrase ''certain expertise and''.

7. On page 7666, in the first column, the first full paragraph is revised by removing the third sentence and replacing it with a sentence that reads: **SUPPLEMENTAL INFORMATION** to the application package will contain information that further describes examples of model efforts.

8. On page 7669, in the second column, the last words ''or (202) 708–9300'' of the introductory paragraph of Appendix A are removed and the term ''(TDD)'' is replaced where ever it appears in the notice with the term ''(TTY)''.

Dated: March 27, 1996.

Andrew Cuomo,

Assistant Secretary for Community Planning and Development.

[FR Doc. 96–8130 Filed 4–2–96; 8:45 am]

BILLING CODE 4210–29–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*):

PRT–812789

Applicant: Peregrine Fund, Inc., Boise, ID.

The applicant requests a permit to import blood from Madagascar fish eagles (*Haliaeetus vociferoides*) from The Peregrine Fund Project, Madagascar for the purpose of scientific research to benefit the species in the wild.

PRT–812795

Applicant: The Institute of Wildlife & Environmental Toxicology, Clemson University, Pendleton, SC.

The applicant requests a permit to import 30 non-viable Morelet's crocodile (*Crocodylus moreletii*) eggs from Belize for the purpose of enhancement of the survival of the species through scientific research.

PRT–810167

Applicant: World Bird Sanctuary, St. Louis, MO.

The applicant requests a permit to authorize interstate commerce for two captive-bred white-naped cranes (*Grus vipio*) from the Cincinnati Zoo for the purpose of enhancement of the survival of the species through conservation education.

PRT–813008

Applicant: Florida Audubon Society, Casselberry, FL.

The applicant requests a permit to import one Kemp's ridley turtle (*Lepidochelys kempii*) from Center National de la Mer, Boulogne-sur-Mer, France for the purpose of releasing this rehabilitated turtle into waters off Florida for enhancement of the survival of the species.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 430, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and*

Freedom of Information Act, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 430, Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

Dated: March 29, 1996.

Mary Ellen Amtower,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 96–8182 Filed 4–2–96; 8:45 am]

BILLING CODE 4310–55–P

Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of Application for Incidental Take Permit for Construction of One Single Family Residence on 1109 Patterson Rd., Lot 4, Angelwylde, Section 1, Travis County, TX

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Paul A. Locus (Applicant) has applied to the Fish and Wildlife Service for an Incidental Take Permit pursuant to Section 10(a) of the Endangered Species Act (Act). The Applicant has been assigned permit number 809215. The requested permit, which is for a period of 1 year, would authorize the incidental take of the endangered golden-cheeked warbler (Dendroica chrysoparia). The proposed incidental take would occur as a result of the construction of one single family residence at 1109 Patterson Rd., Lot 4, Anglewylde, Section 1, Austin, Travis County, Texas.

The Fish and Wildlife Service has prepared an Environmental Assessment/ Habitat Conservation Plan (EA/HCP) for the incidental take application. A determination of whether jeopardy to the species will result from this action, or a Finding of No Significant Impact (FONSI), will not be made before 30 days from the date of publication of this notice. The notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on these documents should be submitted on or before May 3, 1996.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Joseph E. Johnston or Mary Orms, Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, Texas 78758, (512/490–0063). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8:00 to 4:30) at the U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application and EA/HCPs should be submitted to the Field Supervisor, Ecological Services Field Office, Austin, Texas (see address above). Please refer to permit number 809215 when submitting comments.

FOR FURTHER INFORMATION CONTACT:

Joseph E. Johnston or Mary Orms at the above Austin Ecological Services Field Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act prohibits the ''taking'' of endangered species such as the gold-cheeked warbler. However, the Fish and Wildlife Service, under limited circumstances, may issue permits to take endangered wildlife species when such take is incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

Applicant

Paul A. Locus plans to construct a single family residence on 1109 Patterson Rd., Lot 4, Angelwylde, Section 1, Austin, Travis County, Texas. This action will eliminate less than 1 acre of warbler habitat and indirectly impact less than one-half additional acre of golden-cheeked warbler habitat. The applicant proposes to compensate for this incidental take of golden-cheeked warbler habitat by placing $1,500.00 into the City of Austin Balcones Canyonlands Conservation Fund to acquire/manage lands for the conservation of the golden-cheeked warbler. Alternatives to this action were rejected because selling or not developing the subject property with federally listed species present was not economically feasible.

Nancy Kaufman,

Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–8172 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–55–M

Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of Application for Incidental Take Permit for Construction of Three Single Family Residences in Austin, Travis County, TX

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Jalil and Judy Mirzadegan (Applicant) have applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a) of the Endangered Species Act (Act). The applicant has been assigned permit number PRT–809220. The requested permit, which is for a period of 5 years, would authorize the incidental take of the endangered golden-checked warbler (*Dendroica chrysoparia*). The proposed take would occur as a result of the construction of three single family residences, one each on Lots 54, 55 and 83, and a driveway on Lot 82, located on Arkansas Bend Peninsula, north of Fawn Ridge Circle. Austin, Travis County, Texas.

The Service has prepared the Environmental Assessment/Habitat Conservation Plan (EA/HCP) for the incidental take applications. A determination of whether jeopardy to the species will occur or a Finding of No Significant Impact (FONSI), will not be made before 30 days from the date of publication of this notice. This notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application should be received on or before May 3, 1996.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Joseph E. Johnston or Mary Orms, Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490–0063). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8:00 to 4:30) at the above U.S. Fish and Wildlife Service address in Austin, Texas.

Written data or comments concerning the application and EA/HCP should be submitted to the Field Supervisor, Ecological Services Field Office, Austin, Texas (see **ADDRESSES** above). Please refer to permit number PRT–809220 when submitting comments.

FOR FURTHER INFORMATION CONTACT: Joseph E. Johnston or Mary Orms at the above Austin Ecological Services Field Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act prohibits the ''taking'' of endangered species such as the golden-cheeked warbler. However, the Service, under limited circumstances, may issue permits to take endangered wildlife species when such taking is incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

Applicant

Jalil and Judy Mirzadegan plan to construct three single family residences, one each on Lots 54, 55 and 83, and a driveway on Lot 82, located on Arkansas Bend Peninsula, north of Fawn Ridge Circle, Austin, Travis Country, Texas. This action will eliminate less than 1.5 acres of golden-cheeked warbler habitat and indirectly impact less than 1.5 additional acres of golden-cheeked warbler habitat per residence on Lots 54, 55, 82 and 83. The applicant proposes to compensate for this habitat loss by placing $1,500 for each residence to be constructed into the City of Austin Balcones Canyonlands Conservation Fund to acquire/manage lands for conservation of the golden-cheeked warbler.

Alternatives to this action were rejected because selling the subject property with federally listed species present, or not developing the property is not economically feasible.

Nancy Kaufman,

Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–8173 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–55–M

Ramesh Perera, Austin, TX; Incidental Take Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Application for Incidental Take Permit for Ramesh Perera in Cat Mountain, Austin, TX.

SUMMARY: Ramesh Perera has applied to the Fish and Wildlife Service for an incidental take permit pursuant to Section 10(A)1(a) of the Endangered Species Act, for the purpose of scientific research and enhancement of propogation and survival of the species as prescribed by Service recovery documents. The applicant has been assigned permit number PRT—811461. The requested permit, which is for a period of 2 years, would authorize the incidental take of the Golden-cheeked warber (Dendroica chrysoparia) and Black-capped vireo (Viero atricapillus).

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Assistant Regional Director, Ecological Services, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103, and must be received by the Assistant Regional Director within 30 days of the date of this publication. Please refer to permit number PRT–811461 when submitting comments.

Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the above office within 30 days of the date of publication of this notice.

Nancy Kaufman,

Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 96–8174 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–55–M

Bureau of Land Management

[NM–010–1430–01;NMNM 95845]

A Direct Sale of Public Land to the Dixon Plaza Preservation Association of Dixon, NM

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice of Realty Action.

SUMMARY: The following public land has been found suitable for direct sale under section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713). The land will not be offered for sale until at least 60 days after the date of this notice.

New Mexico Principal Meridian

T. 23 N., R. 10 E.,
Sec. 28: lot 127.

The subject public land containing 2.52 acres, more or less, will be sold to the Dixon Plaza Preservation Association of Dixon, New Mexico, which was created and incorporated under the New Mexico Nonprofit Corporation Act. The sale will help to preserve the integrity of the existing roads and plazas within the Dixon Plaza area. The disposal is consistent with State and local government programs, plans, and applicable regulations.

EFFECTIVE DATE: Interested parties may submit comments on the direct sale by May 20, 1996.

ADDRESSES: Comments should be sent to the District Manager, BLM, Albuquerque District Office, 435 Montano NE, Albuquerque, New Mexico 87107.

FOR FURTHER INFORMATION CONTACT: Lora Yonemoto, BLM, Taos Resource Area Office, 226 Cruz Alta Road, Taos, New Mexico 87571, or at (505)758–8851.

SUPPLEMENTARY INFORMATION: The direct sale will be subject to:

1. A reservation to the United States of a right-of-way for ditches or canals constructed by the authority of the United States in accordance with the Act of August 30, 1890 (43 U.S.C. 945).

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove the minerals. A more detailed description of this reservation, which will be incorporated in the patent document or other document of conveyance is available for review at this BLM office.

Publication of this notice in the Federal Register will segregate the public land from appropriation under the public land laws including the mining laws but not the mineral leasing laws. This segregation will terminate upon the issuance of a patent or other document of conveyance, 270 days from date of publication of this notice in the Federal Register or upon publication of a Notice of Termination, whichever occurs first.

Any adverse comments will be evaluated by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

Michael R. Ford,

District Manager.

[FR Doc. 96–8064 Filed 4–2–96; 8:45 am]

BILLING CODE 4310–FB–U

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–372]

Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing Same; Notice of Issuance of General Exclusion Order and Cease and Desist Order and Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has issued a general exclusion order and a cease and desist order to domestic respondent Hennaco Excell, Inc. in the above-captioned

investigation and terminated the investigation.

FOR FURTHER INFORMATION CONTACT: Lyle B. Vander Schaaf, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202–205–3107.

SUPPLEMENTARY INFORMATION: This investigation was initiated by the Commission on March 3, 1995, based on a complaint filed by Crucible Materials Corp. On December 11, 1995, the presiding administrative law judge (ALJ) issued his final initial determination (ID) on the merits in the investigation. The ALJ found a violation of section 337 of the Tariff Act of 1930, as amended, based on his findings that (1) claims 1–3 of the patent in controversy, U.S. Letters Patent 4,588,439 (the '439 patent), are valid and enforceable; (2) there is a domestic industry manufacturing and selling products covered by the patent claims in issue; (3) respondents Novel Hightech, Ltd., Hennaco Industrial Enterprises, Inc., Hennaco Excell, Inc., Sino American Products, Ltd., and Injohnson Precision Industrial Co. infringe claims 1–3 of the '439 patent. The ALJ specifically found that the Novel, Injohnson, Sino American, and Hennaco respondents literally infringe each of the claims in issue and found that the Hennaco respondents and respondent Injohnson infringe the claims in issue under the doctrine of equivalents.

On February 14, 1996, the Commission issued notice of its determination not to review the final ID, and requested written submissions on the issues of remedy, the public interest, and bonding. 61 FR 6863 (Feb. 22, 1996). Submissions were received from complainant Crucible, the Commission investigative attorney, and respondents San Huan New Materials, Ningbo Konit, and Tridus International. Complainant and the Commission investigative attorney also filed reply submissions on those issues.

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission made its determinations on the issues of remedy, the public interest, and bonding. The Commission determined that the appropriate form of relief is a general exclusion order prohibiting the unlicensed importation of infringing neodymium-iron-boron magnets and magnet alloys. In addition, the Commission issued a cease and desist order directed to domestic respondent Hennaco Excell, Inc. requiring that firm to cease and desist from the following activities in the United States: importing, selling, marketing, distributing, offering for sale, or otherwise transferring (except for exportation) in the United States infringing imported neodymium-iron-boron magnets or magnet alloys.

The Commission also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) and (f) do not preclude the issuance of the general exclusion order and cease and desist order, and that the bond during the Presidential review period shall be in the amount of 100 percent of the entered value of the articles in question.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and section 210.50 of the Commission's Rules of Practice and Procedure (19 CFR § 210.50).

Copies of the Commission's remedial orders, the Commission opinion in support thereof, and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202–205–2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

Issued: March 29, 1996.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 96–8151 Filed 4–2–96; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Office of Redress Administration, Civil Rights Division; Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of Information Collection Under Review; Redress Payments for Japanese Americans: Guidelines for Individuals Who Involuntarily Relocated to Japan During the War, and Guidelines Under *Ishida* v. *United States.*

The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for 60 days from the date listed at the top of this page in the Federal Register.

Request written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your 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 agencies 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.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact the Office of Redress Administration Clearance Officer, 202–219–6900, or Telephone Device for the Deaf (TDD) 202–219–4710, Civil Rights Division, U.S. Department of Justice, Room N1519, 200 Constitution Avenue, NW, Washington, D.C. 20001 or P.O. Box 66260, Washington D.C. 20035–6260.

Overview of this information collection:

(1) *Type of Information Collection:* Existing Collection in Use without an OMB Number.,

(2) *Title of the Form/Collection:* Redress Payments for Japanese Americans: Guidelines for Individuals Who Involuntarily Relocated to Japan During the War and Guidelines Under *Ishida* v. *United States.*

(3)*Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form: None. Office of Redress Administration, Civil Rights Division, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals. Other: None. The information collected is used to process requests for redress payments to recipients of funds pursuant to the Civil Liberties Act of 1988. Upon receipt, review, and approval of the Declaration and supporting documents, if any, the agency will notify the individual of his or her eligibility under

the Civil Liberties Act of 1988 and mail a Treasury check for the $20,000 redress payment to the individual with a copy of the President's apology letter.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 140 responses of Declaration at 10 minutes per response; and 2,000 responses at 10 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 356 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: March 28, 1996.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 96–8096 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–13–M

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act; Farmland Industries, Inc., et al.

In accordance with Departmental policy, 28 CFR 50.7, and 42 U.S.C. 9622(d)(2), notice is hereby given that a proposed consent decree in *United States v. Farmland Industries, Inc. and Cooperative Producers, Inc.,* Civil Action No. 4: 96CV3076, was lodged on March 18, 1996 with the United States District Court for the District of Nebraska. The Consent Decree addresses the responsibility of Farmland Industries, Inc. and Cooperative Producers, Inc. for the clean-up of contamination at the FAR–MAR–CO Subsite of the Hastings Ground Water Contamination Superfund Site in Hastings, Nebraska. The Consent Decree provides for payment by the Defendants of $954,019.00 for past EPA response costs; the performance of certain components of the remedial action for the Subsite at an estimated cost of $1.2 to $1.5 million; and payment of certain future response costs incurred by the United States in connection with the FAR–MAR–CO Subsite.

The Department of Justice will receive written comments relating to the proposed Consent Decree for thirty (30) days from the date of publication of this notice. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, U.S. Department of Justice, Washington, DC 20530, and should refer to *United States v. Farmland Industries, Inc. and Cooperative Producers, Inc.,* D.J. Ref. No. 90–11–3–1393. Commenters may request an opportunity for a public meeting in the affected area, in accordance with section 7003(d) of the Resource Conversation and Recovery Act, 42 U.S.C. 6973 (RCRA).

The proposed consent decree may be examined at the office of the United States Attorney, 215 North 17th St., Zorinsky Federal Building, Room 7401, Omaha, Nebraska; the Region VII Office of the Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, Kansas 66101; and at the Consent Decree Library, 1120 G Street NW., 4th Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street NW., 4th Floor, Washington, DC 20005. In requesting a copy please refer to the referenced case and enclose a check in the amount of $44.55 (25 cents per page reproduction costs), payable to the Consent Decree Library.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–8050 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Notice of Lodging of Consent Decree; H.S. Fishing Products Corp.

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on March 18, 1996, a proposed Consent Decree in *United States v. H.S. Finishing Products Corporation,* CV–94–5603 (JS), was lodged with the United States District Court for the Eastern District of New York. The proposed Consent Decree settles the United States' claims that the defendant had violated provisions of the Clean Air Act. The defendant operates a surface coating facility in Brooklyn, New York.

Under the terms of the Consent Decree, the defendant will pay a $50,000 civil penalty. The defendant will also be required to use only coating materials which, by formulation, are capable of complying with the requirements of the federally-enforceable State Implementation Plan (''SIP'') for the State of New York. Specifically, the defendant will comply with the New York SIP requirements limiting volatile organic compound emissions into the atmosphere from surface coating processes and which were alleged in the complaint to have been violated.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, U.S. Department of Justice, Washington, DC 20530, and should refer to *United States v. H.S. Finishing Products Corporation,* D.O.J. Ref. 90–5–2–1–1912.

The proposed Consent Decree may be examined at any of the following locations: the office of the United States Attorney for the Eastern District of New York, 1 Pierrepont Plaza, Brooklyn, New York 11201; the Region II Office of the United States Environmental Protection Agency, 290 Broadway, New York, New York 10007; and at the Environmental Enforcement Section Document Center, 1120 G Street, NW., 4th Floor, Washington, DC 20005 (202/624–0892). A copy of the proposed Consent Decree may be obtained in person or by mail from the Environmental Enforcement Section Document Center, 1120 G Street, NW., 4th Floor, Washington, DC 20005. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $6.25 (25 cents per page reproduction cost) made payable to Consent Decree Library.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–8049 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act; IT Corp. et al.

In accordance with the policy of the Department of Justice, 28 CFR 50.7, and 42 U.S.C. 9622(d)(2)(B), notice is hereby given that a proposed Fifth Partial Consent Decree in *United States* v. *IT Corporation et al.*, Civil Action No. 96–1969 ABC, was lodged on March 19, 1996, with the United States District Court for the Central District of California. That action was brought pursuant to the Comprehensive Environmental Response, Compensation and Liability Act for cleanup and cost recovery at the Operating Industries, Inc. Superfund site in Monterey Park, California.

Pursuant to the Consent Decree, thirty settling parties will pay approximately $18.7 million to resolve their liability for the performance of certain specific remedial actions at the Operating

Industries site, and for reimbursement of costs incurred by the United States at the site through December 31, 1990. Work is ongoing at the site to perform the remedial actions by other parties who have settled in previous consent decrees for the same matters as this consent decree.

As provided in 28 CFR 50.7 and 42 U.S.C. 9622(b)(2)(B), the Department of Justice will receive comments from persons who are not named as parties to this action relating to the proposed Consent Decree for a period of thirty days from the date of this publication. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530. All comments should refer to *United States* v. *IT Corporation*, D.J. Ref. 90–11–2–156H.

The proposed Consent Decree may be examined at the office of the United States Attorney, 300 North Los Angeles Street, Los Angeles, California 90012, and at the Region IX office of the U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, California 94105. A copy of the proposed Consent Decree may also be examined at the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005 (202) 624–0892. A copy of the proposed Consent Decree may be obtained in person or by mail from the consent Decree Library. In requesting a copy, please enclose a check in the amount of $10.75 for a copy of the consent decree without any signature pages, attachments or exhibits to the Decree, or $101.50 with all signature pages, attachments and exhibits (25 cents per page reproduction costs) payable to ''Consent Decree Library.''

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–8051 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Notice of Lodging of Consent Decree Pursuant to the Clean Air Act

In accordance with Departmental policy, 28 C.F.R. § 50.7, 38 Fed. Reg. 19029, notice is hereby given that on March 14, 1996, a proposed Consent Decree in *United States* v. *Northeast Food, Inc.*, Civil Action No. 96–1136 (AMW), was lodged with the United States District Court for the District of New Jersey resolving the matters alleged in the United States' complaint filed on that date. The proposed Consent Decree represents a settlement of the United States' claims against Northeast Foods, Inc. under the Clean Air Act and the New Jersey State Implementation Plan for emissions of volatile organic compounds (''VOCs'') in excess of the emission limit provided in Title 7, Chapter 27, Subchapter 16.6(a) and Table 4 of the New Jersey Administrative Code, N.J.A.C. 7:27–16.16(a) (codified as amended at N.J.A.C. 7:27–1616 (1994)), from Northeast's Automatic Division located at One Gourmet Lane, Edison, New Jersey (the ''Automatic Facility'').

Under the proposed Consent Decree the Defendant shall pay to the United States a civil penalty in the amount of eighty-one thousand, three hundred and eighty one dollars ($81,381), plus interest, within fifteen (15) days of lodging of the Consent Decree. The proposed Consent Decree also requires that Northeast shall: (1) comply with the Volatile Organic Compound (''VOC'') emissions limitations contained in the federally approved New Jersey State Implementation Plan (''SIP''), including any amendments thereto: (2) provide written certification to EPA throughout the period the Decree remains in effect that documents the emissions capture, enclosure, and/or incinerator devices are performing adequately; and (3) perform any emissions and performance testing, pursuant to a submitted protocol for testing, within thirty days of receipt of notification from EPA of a testing requirement.

The Department of Justice will receive, for thirty (30) days from the date of publication of this notice, written comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice, Washington, D.C. 20530 and should refer to *United States* v. *Northeast Foods, Inc.*, D.O.J. Ref. No. 90–5–2–1–1685.

The proposed Consent Decree may be examined at the Office of the United States Attorney for the District of New Jersey located at 970 Broad Street, 5th Floor, Newark, New Jersey 07102; at the Region II Office of the Environmental Protection Agency located at 290 Broadway, New York, New York 10007; and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C., 20005, (202)–624–0892. A copy of the proposed Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C., 20005. In requesting a copy, please enclose a check in the amount of $6.75 (25 cents per page reproduction charge) payable to the Consent Decree Library.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources, Division.

[FR Doc. 96–8040 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Antitrust Division

United States and State of Texas v. Kimberly-Clark Corp. and Scott Paper Co.; Public Comments and Response on Proposed Final Judgment

Pursuant to the Antitrust Penalties and Procedures Act, 15 U.S.C. §§ 16(c)–(h), the United States publishes below the comments received on the proposed Final Judgment in *United States and State of Texas* v. *Kimberly-Clark Corp. and Scott Paper Co.*, No. 3:95 CV 3055–P, filed in the United States District Court for the Northern District of Texas, together with the United States' response to those comments.

Copies of the comments and the response to comments are available for inspection and copying in Room 207 of the U.S. Department of Justice, Antitrust Division, 325 7th Street, NW., Washington, DC 20530 [telephone: (202) 514–2481], and at the office of the Clerk of the United States District Court for the Northern District of Texas, Dallas Division, 1100 Commerce Street, Room 14A20, Dallas, TX 75242. Copies of these materials may be obtained upon request and payment of a copying fee.

Rebecca P. Dick,

Deputy Director of Operations.

Cynthia Adams,
2712 Taylor St., Marinette, WI 54143.
December 18, 1995.

Mr. Anthony V. Nanni, Chief, Litigation I Section, Antitrust Division,
U.S. Department of Justice, Suite 4000, 1401 H Street NW., Washington, DC 20530.

Dear Mr. Nanni: I wish to comment on the consent decree concerning the merger of Scott Paper Co. with Kimberly-Clark. The Justice Department has included in the terms of the consent decree that two (2) of four (4) tissue mills be divested. Included in that list is half of the former Scott Paper Co. mill in Marinette, WI.

This facility employs 525 union employees affiliated with the United Paperworkers International Union. If this mill is divested from Kimberly-Clark approximately 300 union employees will go with one company and 225 will remain with Kimberly-Clark. Kimberly-Clark is honoring the union contract negotiated with Scott Paper Co., while there is no guarantee that the company buying the tissue part of the mill will honor that same contract. This could result in the union employees in the Kimberly-Clark half of the mill working for better wages and

benefits. It would be better to sell the Scottie name and allow Kimberly-Clark employees to run the product for the owner at a predetermined price.

The Marinette facility makes a variety of products, including facial tissue (Scotties), approximately 27 people are involved in producing this product on a full time basis. I can not understand the logic behind selling a portion of this facility that makes toilet tissue, napkins, and facial tissue because one (1) converting unit and a part of a papermachine produces facial. The vast majority of the employees produce Cottonelle toilet paper, Scottissue toilet paper, and various brands of napkins.

I believe that the Justice Department should reconsider their consent decree and remove the Marinette Tissue mill from this order.

Sincerely,

Cynthia Adams

Same or substantially similar letter sent by:

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Mr. Gary Marineau, N3051 Green Gable Rd., Marinette, WI 54143
Ms. Irene Martin, N4608 Schacht Rd., Marinette, WI 54143
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Ms. Irene Mayou, 818 Terrace Ave., Marinette, WI 54143
Ms. Betty Messenger, 2911 Riverside Ave., Marinette, WI 54143
Ms. Marjorie Messenger, 1709 Carney Ave., Marinette, WI 54143
Mr. Steve Messenger, W1652 Steven Ln., Marinette, WI 54143
Mr. Roger Meyer, 826 Gladstone St., Marinette, WI 54143
Ms. Margaret Meyers, 2201 13th Ave., Menominee, MI 49858
Mr. Myron Michalski, 1359 Main St., Marinette, WI 54143
Mr. David Miller, N1985 Kutz Rd., Marinette, WI 54143
Mr. Don H. Miller, W1512 Rader Rd., Marinette, WI 54143
Mr. Donald H. Miller, W1512 Rader Rd., Marinette, WI 54143
Mr. Donald L. Miller, 4120 13th St., Menominee, MI 49858
Mr. Jeffrey Miller, 1326 Oak St., Marinette, WI 54143
Mr. John Mollus, N2963 Roosevelt Rd., Marinette, WI 54143
Mr. Peter Morgenson, N4470 Sandberg Rd., Marinette, WI 54143
Mr. Roger Moyle, N1595 Shore Drv., Marinette, WI 54143
Mr. David Mudrak, N840 River Drv., Menominee, MI 49858
Mr. Jeffrey Mullins, W5396 Evergreen Rd., Menominee, MI 49858
Leslie Mulzer, W5316 Cty. Rd. 342, Wallace, MI 49893
Mr. Richard Mushynski, 1900 23rd Ave., Menominee, MI 49858
Mr. Richard Naffier, 1306 1st St., Menominee, MI 49858
Mr. Thomas Nast, 3042 Carney Ave., Marinette, WI 54143
610 McCagg St., Peshtigo, WI 54157
Mr. David Nelson, W6396 Little River Rd., Peshtigo, WI 54157
Mr. Paul Nelson, 1004 8th Ave., Menominee, MI 49858

Mr. Randolph Nerat, W5890 Sobieski Rd., Menominee, MI 49858
Mr. Laurence Nichols, W3409 Grasser Rd., Marinette, WI 54143
Mr. Michael Nicklaus, 1201 Main St., Apt. 1, Marinette, WI 54143
Mr. Rick Nicklaus, W6540 No. 10 Rd., Wallace, MI 49893
Mr. Robert Nicklaus, 1620 Parnell St., Marinette, WI 54143
Mr. Jack Noha, W7004 3.5 Rd., Menominee, MI 49858
Mr. Jeffrey Nutt, Rt. 1 Box, 233A, Wausaukee, WI 54177
Mr. Gary Nyman, P.O. Box 293, Menominee, MI 49858
Mr. Rodney Nystrom, 711 Dawes St., Marinette, WI 54143
Ms. Peggy O'Brien, 2306 14th Ave., Monominee, MI 49858
Mr. Leonard Odea, Jr., 3721 13th St., Menominee, MI 49858
Mr. Jeffrey Olive, W5006 Hilldale Drv., Porterfield, WI 54159
Mr. James Olsen, 3912 13th St., Menominee, MI 49858
Mr. John Olson, P.O. Box 111, Menominee, MI 49858
Mr. Larry Olson, 2118 Ella Court, Marinette, WI 54143
Mr. Leroy Olson, Jr., W5946 Fawn Ln., Peshtigo, WI 54157
Mr. Steven Olson, 632 Elizabeth Ave., Marinette, WI 54143
Mr. Anthony Paidl, W6517 Cty. Rd. G–12, Stephenson, MI 49887
Ms. Sharon Paitl, 7370 Goatsville Rd., Lena, WI 54139
Mr. Daniel Parmelee, W4702 8.5 Rd., Menominee, MI 49858
Dale Patenaude, N2092 Halel Rd., Peshtigo, WI 54157
Mr. Daniel Paul, 1713 20th Ave., Menominee, MI 49858
Mr. Bradley Paulsen, N1738 M–35, Menominee, MI 49858
Ms. Sandra Paulsen, N1738 M–35, Menominee, MI 49858
Mr. Lowell Pelnar, 1300 Logan Ave., Marinette, WI 54143
Mr. David Perkins, 900 Gladstone St., Marinette, WI 54143
Mr. Richard Pesmark, 829 Marinette, WI 54143, Marinette, WI 54143
Mr. Gregor Petersen, N3585 River Rd., Wallace, MI 49893
Mr. Kevin Peterson, N6656 Hwy. 180, Marinette, WI 54143
Ms. Linda Peterson, 3701 15th St., Menominee, MI 49858
Mr. Richard Peterson, N2087 Bonnie Ln., Marinette, WI 54143
Mr. Tim Peterson, 1116 Elizabeth Ave., Marinette, WI 54143
Ms. Julie Petrosky, W2402 Old Peshtigo Rd., Marinette, WI 54143
Mr. Patrick Phillipps, Rt. 2, Box 20–A, Wallace, MI 49893
Mr. Daniel Pichette, 339 State St., Marinette, WI 54143
Mr. Frank Pichette, 1005 Edgewood Circle, Marinette, WI 54143
Mr. Jeffrey Plautz, N1512 S–1 Ln., Menominee, MI 49858
Mr. Kenneth Pleshek, 3415 Pierce Ave., Lot 60, Marinette, WI 54143
Mr. Larry Polzin, N3362 Rehms Rd., Pehtigo, WI 54157
Mr. Martin Porter, 744 Owena St., Marinette, WI 54143
Ms. Kathy Przewrocki, W6499 Birch Crk. Rd. #5, Menominee, MI 49858
Jean Pusich, 4063 US Hwy. 141, Pound, WI 54161
Mr. Vernon Quever, 2000 Carney Ave., Marinette, WI 54143
Mr. Steven Quintana, N4508 North Shore Drive, Menominee, MI 49858
Mr. Larry Race, 1523 Elizabeth Ave., Marinette, WI 54143
Mr. David Radtke, 421 West Front St., Pehtigo, WI 54157
Mr. Richard Rebbie, 921 41st Ave., Menominee, MI 49858
H. John Redelings, 1412 23rd Ave., Menominee, MI 49858
Mr. Robert Reines, W1898 Rader Rd., Marinette, WI 54143
Mr. Philip Risner, 149 Prairie Court, Coleman, WI 54112
Ms. Kathleen Roach, 1720 10th St., Menominee, MI 49858
Mr. Anthony Rodriquez, 330 Van Clev Ave., Marinette, WI 54143
Mr. Timothy Roeder, W1252 Cty. B., Marinette, WI 54143
Ms. Viola Rondeau, 2711 Merchant St., Marinette, WI 54143
Laurie Rose, 901 Aubin, Lot 96, Peshtigo, WI 54157
Mr. August Ruus, 1605 13th Ave., Menominee, MI 49858
Mr. Timothy Rysewyk, N2696 Hwy. 141 South, Coleman, WI 54112
Ms. Sylvia Rzeminski, N3504 M–35, Menominee, MI 49858
Mr. Gary Sadowski, 1801 34th Ave., Menominee, MI 49858
Mr. Michael Schact, 800 Kentucky Court, Peshtigo, WI 54157
Mr. David Schewe, W6969 3.5 Rd., Menominee, MI 49858
Mr. Michael Schewe, 2107 Thomas St., Marinette, WI 54143
Mr. Robert Schleihs, 1103 Sunnyfield Court, Marinette, WI 54143
Mr. Norman Schoenborn, 337 N. Oakland Ave., Oconto Falls, WI 54154
Mr. Gary Scholtz, Sr., N10380 Cty. TR JJ, Wausaukee, WI 54177
Mr. Richard Schomer, 2317 18th Ave., Menominee, MI 49858
Mr. Michael Schultz, 300 State St., Marinette, WI 54143
Shawn Schultz, 1334 Oakes St., Marinette, WI 54143
Ms. Diane Sedlar, W4038 Cty. Rd. G, Porterfield, WI 54159
Mr. Richard Seymour, 1112 Morningside Crt., Marinette, WI 54143
Mr. John Shaver, 2800 Minnesota St., Marinette, WI 54143
Mr. John Shaver, Jr., W6544 1.25 Rd., Menominee, MI 49858
Mr. David Shehow, 1144 Garfield Ave., Marinette, WI 54143
Ms. Joan Shepherd, 1034 Hockridge St., Marinette, WI 54143
Mr. Jeffrey Sieminski, W6224 #6 Rd., Menominee, MI 49858
Mr. Joseph Slawik, 311 Carney Blvd., Marinette, WI 54143
Ms. Sheila Soletske, N4221 Schacht Rd., Marinette, WI 54143
Mr. Christopher Spies, 214 1st St., Menominee, MI 49858
Mr. William Sporrer, W2722 Plantation Road, Porterfield, WI 54159
Layne Stank, N1344 River Drv., Menominee, MI 49858
Mr. Scott Stansfield, N5084 Hwy. 180, Marinette, WI 54143
Ms. Debbie Stello, N4508 Bridge Rd., Peshtigo, WI 54157
Mr. Paul Stello, N4508 Bridge Rd., Peshtigo, WI 54157
Mr. Allen Stepniak, 508 Park St., Marinette, WI 54143
Mr. Patrick Stepniak, 3128 Carney Ave., Marinette, WI 54143
Mr. Thomas Strojny, N4852 Bagley Rd., Marinette, WI 54143
Mr. Duane Stuart, W2629 Cty. B, Marinette, WI 54143
Mr. Leroy Suennen, W2368 Cty. JJ, Wausaukee, WI 54177
Ms. Crystal Svoboda, N1834 South N–3 Drv., Menominee, MI 49858
Ms. Mary Swanson, W6536 38th Rd., Menominee, MI 49858
Mr. Jerome Szymik, N2509 Shore Drv., Marinette, WI 54143
Mr. Roger Tachick, 480 Aubin St., Peshtigo, WI 54157
Ms. Joyce Tackmier, 345 Russell St., Marinette, WI 54143
Mr. Donald Tanguay, 1311 22nd Ave., Menominee, MI 49858
Mr. David Tessmer, 330 Point St., Marinette, WI 54143
Mr. Larvell Thomas, N1387 US 41, Menominee, MI 49858
Mr. Todd Topel, W706 Leaf Rd., Marinette, WI 54143
Ms. Carma Tress, W3221 Aspen Ln., Marinette, WI 54143
Mr. Walter Trinkl, N5460 Hwy 180, Marinette, WI 54143
Mr. Douglas Trippler, W2107 Krause Rd., Marinette, WI 54143
Mr. Henry Truitt, Jr., N8995 Camp O Ln., Cedar River, MI 49813
Ms. Karen Turpin, 1313 Armstrong St., Marinette, WI 54143
Mr. Donald Twork, Jr., 1908 16th Ave., Menominee, MI 49858
Mr. Tom Uecke, N520 River Rd., Menominee, MI 49858
Mr. Stephen Uecke, W2170 Raygo Ln., Marinette, WI 54143

Ms. Mary Urbaniak, W3763 Peters Rd., Marinette, WI 54143
Mr. Scott Urbaniak, N7261 Shady Ln., Porterfield, WI 54159
Mr. William Urbaniak, 817 Madison, Marinette, WI 54143
Ms. Rose Vaness, 508 4th Ave., Menominee, MI 49858
Mr. Daniel Vanidestine, 828 Miller St., Marinette, WI 54143
Mr. Richard Varney, 2807 Hall Ave., Marinette, WI 54143
Mr. Edward Vieth, 931 Miller St., Marinette, WI 54143
Mr. Kenneth Vieth, 1729 Daggett St., Marinette, WI 54143
Mr. Michael Vieth, 2508 17th Ave., Menominee, MI 49858
Mr. Stephen Vitkovic, 2207 Thomas, Marinette, WI 54143
Mr. Douglas Wagner, N6194 Biehl Rd., Porterfield, WI 54159
Mr. Russell Wagner, N5941 Hwy. 180, Marinette, WI 54143
Ms. Donna Wahlen, 1035 Currie St., Marinette, WI 54143
Mr. Ted Wagner, N6812 Hwy. 180, Marinette, WI 54143
Mr. Michael Walker, N2165 Shore Drv., Marinette, WI 54143
Mr. Gerald Walters, N5514 Ferndale Rd., Porterfield, WI 54159
Ms. Rita Walters, 3325 Pierce Ave., Lot 517, Marinette, WI 54143
Mr. Ronald Walters, N3910 Right-of-Way Rd., Peshtigo, WI 54157
Mr. Russell Walters, 222 Van Clev Ave., Marinette, WI 54143
Mr. William Warren, 451 Pine St., Peshtigo, WI 54157
Mr. Kenneth Watz, W6507 38th Ave., Menominee, MI 49858
Mr. Luke Weinschrott, 2017 16th Ave., Menominee, MI 49858
Mr. Daniel Wesoloski, 1816 14th Ave., Menominee, MI 49858
Ms. Mary Westberg, W5553 Powers Rd., Peshtigo, WI 54157
Ms. Bonnie Wicklund, 2138 Shore Drv., Marinette, WI 54143
Mr. William Wicklund, 2138 Shore Drv., Marinette, WI 54143
Mr. Willis Wickman, Box 105, Abrams, WI 54101
Mr. Ernest Wiedemeier, N4733 West Townline Rd., Marinette, WI 54143
Ms. Darlene Williams, 209 Lake St., Marinette, WI 54143
Mr. Brian Wiltzius, W2294 Hwy. 64, Marinette, WI 54143
Mr. Stephen Woods, N6621 Hwy. 180, Marinette, WI 54143
Mr. Michael Yashinsky, 8255 Yashinsky Rd., Lena, WI 54139
Mr. James Zellner, W3425 Hudak Rd., Porterfield, WI 54159
Mr. Daniel Zoeller, 529 6th St. Oconto, WI 54153
Mr. Steven Zylkowski, 611 Point St., Marinette, WI 54143

The Antitrust Division sent the following response to Ms. Cynthia Adams and to each of the individuals listed above who submitted comments identical or substantially similar to those provided by Ms. Adams:

City Center Building,
1401 H Street, NW., Washington, DC 20530.
March 22, 1996.

Ms. Cynthia Adams,
2712 Taylor Street, Marinette, WI 54143.

Re: Public Comment on Consent Decree in United States and State of Texas v. Kimberly-Clark Corp. and Scott Paper Co., No. 3:95–CV–3055–P (N.D. Tex., filed Dec. 12, 1995)

Dear Ms. Adams: This letter responds to your written comment on the proposed final judgment in *United States v. Kimberly-Clark Corp.*, now pending in federal district court in Dallas, Texas. The complaint in that case charged that Kimberly-Clark's acquisition of Scott Paper would substantially lessen competition in the sale of consumer facial tissue and baby wipes. The proposed judgment would settle the case by requiring the defendants (a) to divest Scott's Scotties-brand facial tissue and any two of four tissue mills (viz., Marinette, WI; Ft. Edward, NY; and the Lakeview and Badger-Globe mills in Neenah, WI); and (b) to divest Scott's baby wipes brands and its Dover, DE wet wipes plant.

Your letter raises several issues related to the proposed divestiture of Scott's facial tissue business, and specifically to the labor union agreement at the Marinette, WI mill. You point out that because the judgment would not require the purchaser of a divested mill to honor existing labor agreements, the new owner, after the divestiture, may reduce the wages or benefits of mill employees. You question whether divestiture of the Marinette mill is necessary to alleviate our competitive concerns, or whether those concerns could be met by permitting Kimberly-Clark to retain ownership of that mill, but make Scotties facial tissue under contract to the brand's new owner.

We believe that in this case, the decision whether to continue an existing labor agreement should be left to the purchaser, rather than mandated by consent decree. If the agreement is competitive, the new owner will bargain to continue it. It is possible, however, that an existing, outdated labor agreement may unnecessarily increase a purchaser's costs and hamper its ability to compete in the market. And requiring the new owner of a divested tissue mill to operate under such an agreement would undermine our goal of ensuring that the divestiture ordered by this judgment will create a strong, viable competitor in the sale of consumer facial tissue.

However, your specific concerns about continuation of the labor agreement at the Marinette mill are premature. Though the defendants have solicited bids on Scott's consumer facial tissue business, they have not selected a purchaser. The Marinette mill is now only one of four candidate mills available for sale under is now only one of four candidate mills available for sale under the judgment, and ultimately, it may or may not be sold. Even if the Marinette mill were sold to an approved purchaser, its new owner may choose to extend the current labor agreement. In short, it is too early to say whether selling the Marinette mill will adversely affect any union employee.

Finally, as to your suggestion that it may be inappropriate to sell the Marinette mill to alleviate our competitive concerns, two points must be made. First, Marinette is a modern, relatively low cost, centrally-located mill that, before the merger, produced and distributed the bulk of the Scotties facial tissue sold in the Midwest. Thus, this mill should be an attractive asset to any purchaser that wishes to become a viable competitor in the sale of consumer facial tissue, and for that reason, we bargained with the defendants to include it among the tissue mills available for sale under the judgment.

Second, the competitive problem created by Kimberly-Clark's acquisition of Scott Paper cannot be cured by requiring Kimberly-Clark to divest the Scotties brand name and commit to make that facial tissue under contract to its new owner. We doubt that a purchaser who acquires the business under these terms would be a viable competitor since all of its production capacity and costs would remain under the ownership and control of its principal competitor, Kimberly-Clark.

Thank you for bringing your concerns to our attention; we hope that this information will help alleviate them. Pursuant to the Antitrust Procedures and Penalties Act, a copy of your letter and this response will be published in the Federal Register and filed with the Court.

Sincerely yours,

Anthony E. Harris,

Attorney, Litigation II Section .

Same or substantially similar response was sent to all individuals commenting on the proposed Final Judgment.

[FR Doc. 96–8039 Filed 4–2–96; 8:45 am]
BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Northeast Energy Alliance Joint Research Venture

Notice is hereby given that, on February 27, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301, *et seq.* (''the Act''), Boston Edison Company, on behalf of the members of a cooperative venture entitled the Northeast Energy Alliance (the ''Alliance''), has filed written notifications simultaneously with the Attorney General and with the Federal Trade Commission disclosing (1) the identities of the parties to the Alliance and (2) the nature and objectives of the research program to be performed in accordance with the joint venture. The

notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the current parties participating in the Northeast Energy Alliance are: Boston Edison Company, Boston, MA; Consolidated Edison Company of New York, Inc., New York, NY; GPU Nuclear Corporation, Parsippany, NJ; Maine Yankee Atomic Power Co., Brunswick, ME; Power Authority of the State of New York, New York, NY; Niagara Mohawk Power Corporation, Syracuse, NY; Northeast Utilities System, Berlin, CT; Rochester Gas and Electric Corp., Rochester, NY; Vermont Yankee Nuclear Power Corporation, Brattleboro, VT; and Yankee Atomic Electric Company, Bolton, MA.

The nature and objective of the Northeast Energy Alliance joint research venture is to identify and facilitate efficiencies in the operation and management of nuclear generating stations in the northeastern United States in order to improve the quality and efficiency and reduce the cost of service to consumers of electricity in that region. The general areas of activity of the Alliance will include identifying common issues in the management or operation of nuclear generation plants, including engineering and support services issues, and jointly investigating, developing and implementing common solutions to such issues.

Additional information about the Northeast Energy Alliance may be obtained by contacting Mr. John Fulton, Boston Edison Company, Boston, MA.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–8044 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The Consortium for Non-Contact Gauging

Notice is hereby given that, on February 21, 1996, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301, *et seq.* (''the Act''), the participants in the Consortium for Non-Contact Gauging (''CNCG'') have filed written notifications simultaneously with the Attorney General and with the Federal Trade Commission disclosing a change in project membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the following party has joined CNCG as its new systems integrator: Brown & Sharpe Manufacturing Company, North Kingston, RI. The original systems integrator for the Consortium, Giddings & Lewis, has terminated its membership.

No other changes have been made in either the membership or the planned activities of the Consortium.

On March 7, 1995, CNCG filed its original and only notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to section 6(b) of the Act of May 24, 1995 (60 FR 27559).

Participation in this group research project remains open, and CNCG intends to file additional written notification disclosing all changes in membership. Information regarding participation in the project may be obtained from Eileen Picket, Ohio Aerospace Institute, Cleveland, OH.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–8046 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Petrotechnical Open Software Corporation

Notice is hereby given that, on January 24, 1996, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Petrotechnical Open Software Corporation (''POSC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the following additional parties have become new nonvoting members of POSC: Australian Geodynamics Research Corporation, Glen Waverly, Victoria, AUSTRALIA; and Pride AS, Forus, NORWAY.

No other changes have been made in either the membership or planned activity of POSC.

On January 14, 1991, POSC filled its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to section 6(b) of the Act on February 7, 1991, (56 FR 5021).

The last notification was filed with the Department on November 2, 1995. A notice was published in the Federal Register pursuant to section 6(b) of the Act on December 20, 1995, (60 FR 65670).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–8048 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Rotorcraft Industry Technology Association, Inc.

Notice is hereby given that, on September 28, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Rotorcraft Industry Technology Association, Inc. (''RITA'') has filed written notices simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the project. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties are: Bell Helicopter Textron, Inc., Fort Worth, TX; The Boeing Company, on behalf of Boeing Helicopters, Philadelphia, PA; McDonnell Douglas Helicopter Company, Mesa, AZ; and Sikorsky Aircraft Corporations, Stratford, CT.

The nature and objectives of the research programs are to support and stimulate cooperative research and development of advanced rotorcraft technology in conjunction with the National Aeronautics and Space Administration (''NASA''), the United States Department of Defense (''DOD''), and the Federal Aviation Administration (''FAA''). The purpose of RITA is to develop technology processes and standards to improve the international competitiveness capabilities of the U.S. Rotorcraft Industry and to ensure the superiority of the U.S. Military Rotorcraft. The joint venture seeks to further these goals in cooperation with NASA, DOD, and the FAA, as well as other interested parties. RITA's primary functions will include selection of research and development projects, conduct of research and development projects, evaluation of

research and development projects, and related activities.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–8041 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Springback Predictability Venture

Notice is hereby given that, on February 26, 1996, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), parties to the Springback Predictability Venture filed notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties are Aluminum Company of America, Alcoa Technical Center, Alcoa Center, PA; The Budd Company, Troy, MI; Chrysler Corporation, Auburn Hills, MI; Environmental Research Institute of Michigan, Ann Arbor, MI; Ford Motor Company, Dearborn, MI; General Motors Corporation, Warren, MI; and US Steel Group, USX Corporation, Troy, MI. The purpose of the joint venture is to conduct certain specified research to develop and validate a three-dimensional computer code to accurately predict stress, strain, fracture and geometrical imperfection, such as highs, lows, wrinkles and sidewall curling, in sheet metal draw, restrike and flanging dies, with an emphasis on springback after removal from the die and after trimming, using an incremental theory of elastro-plasticity. The activities of this project will be partially funded by an award from the Advanced Technology Program, National Institute of Standards and Technology, Department of Commerce.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–8047 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–01–M

Drug Enforcement Administration

[Docket No. 94–81]

Shahid Musud Siddiqui, M.D.; Revocation of Registration

On September 8, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Shahid Musud Siddiqui, M.D. (Respondent), of Brooklyn, New York, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AS5232979, under 21 U.S.C. 824(a)(4) and (5), and deny any pending applications for renewal of this registration under 21 U.S.C. 823(f), because his continued registration under 21 U.S.C. 823(f), because his continued registration would be inconsistent with the public interest, and because he had been mandatorily excluded from participation in a program pursuant to 42 U.S.C. 1310a–7(a).

In a letter dated September 21, 1994, the Respondent, through counsel, requested a hearing, and the matter was docketed before Administrative Law Judge Paul A. Tenney. The Respondent requested numerous delays. On March 16, 1995, he filed his Prehearing Statement, writing that at that time he was proceeding *pro se* in this matter.

On September 1, 1995, counsel for the Government field a Motion for Summary Disposition, asserting that the Respondent was not duly authorized to possess, prescribe, dispense, or otherwise handle controlled substances under State law in the State of New York, the jurisdiction in which he is registered with the DEA. Attached to the motion was a copy of the State of New York Department of Health, State Board for Professional Medical Conduct's (Medical Board) Determination and Order dated October 26, 1994, revoking the Respondent's license to practice medicine in the State of New York. Also attached was a copy of the Administrative Review Board's Decision and Order issued on March 13, 1995, which sustained the Medical Board's revocation of the Respondent's medical license.

On September 20, 1995, the Respondent filed a response to the Government's motion, asserting that factual and legal errors were made in the proceedings resulting in the revocation of his medical license in the State of New York. However, the Respondent did not dispute the authenticity of the Medical Board's revocation order or of the Administrative Review Board's order sustaining the actions of the Medical Board.

On September 27, 1995, Judge Tenney issued his Opinion and Recommended Ruling, finding that the Respondent (1) lacked authorization to practice medicine in the State of New York, (2) lacked authorization to handle controlled substances in that State, and (3) that there was no genuine issue of material fact in that regard. Accordingly, Judge Tenney granted the Government's Motion for Summary Disposition and recommended that the Respondent's DEA Certificate of Registration be revoked. Neither party filed exceptions to his decision, and on October 27, 1995, Judge Tenney transmitted the record of these proceedings and his opinion to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 C.F.R. 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The deputy Administrator adopts, in full, the decision of the Administrative Law Judge.

The DEA does not have the statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts his business. 21 U.S.C. 802(21), 823(f), and 824(a)(3). This prerequisite has been consistently upheld. See Dominick A. Ricci, M.D., 58 FR 51,104 (1993); James H. Nickens, M.D., 57 FR 59,847 (1992); Roy E. Hardman, M.D., 57 FR 49,195 (1992); Myong S. Yi, M.D., 54 FR 30,618 (1989); Bobby Watts, M.D., 53 FR 11,919 (1988). As Judge Tenney correctly noted, ''[i]n the instant case, it is clear [that] the Respondent is not authorized to practice medicine in the State of New York, nor is he authorized to handle controlled substances in that State.'' Although the Respondent asserted that he was licensed to practice medicine in New Jersey, as Judge Tenney noted, such an assertion is irrelevant. The DEA Certificate of Registration at issue in these proceedings was granted to allow the Respondent to handle controlled substances for his medical practice in New York.

Judge Tenney also properly granted the Government's Motion for Summary Disposition. Here, the parties did not dispute the fact that the Respondent was unauthorized to handle controlled substances in New York. The Respondent did assert that the Medical Board wrongfully had revoked his medical license. However, as Judge Tenney correctly noted, the DEA

administrative proceeding ''is not an appropriate forum for wholesale review of state criminal and administrative actions taken by the State of New York arising out of the laws of the State of New York. To allow it to be so would be to permit a wide collateral attack upon such convictions. See Lowell O. Kir, M.D., 58 FR 15,378 (1993). The convictions in state court are considered res judicata and [the] Respondent may not relitigate these matters. See Robert A. Leslie, M.D., 60 FR 14,004 (1995).''

Therefore, it is well-settled that when no question of material fact is involved, a plenary, adversary administrative proceeding involving evidence and cross-examination of witnesses is not obligatory. See Dominick A. Ricci, M.D., *supra*. See also Phillip E. Kirk, M.D., 48 FR 32,887 (1983), *aff'd sub nom* Kirk V. Mullen, 749 F.2d 297 (6th Cir. 1984); Alfred Tennyson Smurthwaite, M.D., 43 FR 11,873 (1978); *NLRB* v. *International Association of Bridge, Structural and Ornamental Ironworkers, AFL–CIO*, 549 F.2d 634 (9th Cir. 1977).

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AS5232979, issued to Shahid Musud Siddiqui, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for the renewal of such registration be, and they hereby are, denied. This order is effective May 3, 1996.

Dated: March 28, 1996.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 96–8043 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 95–52]

Stan White; Denial of Application

On July 20, 1995, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Stan White (Respondent), of Hardwick, Massachusetts, notifying him of an opportunity to show cause as to why DEA should not deny his application for a DEA Certificate of Registration as a practitioner under 21 U.S.C. 823(f), because he lacked authorization to handle controlled substances within the Commonwealth of Massachusetts.

In a letter dated August 17, 1995, the Respondent, acting pro se and responding to the Order to Show Cause, requested a hearing, and the matter was docketed before Administrative Law Judge Mary Ellen Bittner. On August 30, 1995, counsel for the Government filed a Motion for Summary Disposition, asserting that the Respondent was not duly authorized to possess, prescribe, dispense, or otherwise handle controlled substances under State law in the Commonwealth of Massachusetts, the jurisdiction in which he proposed to conduct his business. Attached to the motion was a copy of the Respondent's application for registration and a copy of a letter dated August 28, 1995, from the Massachusetts Executive Office of Health and Human Services, denying the Respondent's application to obtain Schedule II controlled substances as a researcher.

The Respondent did not file a response to the Government's motion. Further, the Respondent has not filed anything denying his lack of a state registration to handle controlled substances.

On October 3, 1995, Judge Bittner issued her Opinion and Recommended Decision, finding that the Respondent lacked authorization to handle controlled substances in the Commonwealth of Massachusetts, and that there was no genuine issue of material fact in that regard. Accordingly, Judge Bittner granted the Government's Motion for Summary Disposition and recommended that the Respondent's application for a DEA Certificate of Registration be denied. Neither party filed exceptions to her decision, and on November 6, 1995, Judge Bittner transmitted the record of these proceedings and her opinion to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 C.F.R. 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the decision of the Administrative Law Judge.

The DEA does not have statutory authority under the Controlled Substances Act to issue a registration if the applicant is without state authority to handle controlled substances in the state in which he conducts his business. 21 U.S.C. 802(21), 823(f), and 824(a)(3). This prerequisite has been consistently upheld. See Dominick A. Ricci, M.D., 58 FR 51,104 (1993); James H. Nickens, M.D., 57 FR 59,847 (1992); Roy E. Hardman, M.D., 57 FR 49,195 (1992); Myong S. Yi, M.D., 54 FR 30,618 (1989); Bobby Watts, M.D., 53 FR 11,919 (1988). As Judge Bittner correctly noted, ''[i]n the instant case it is clear that [the] Respondent is not currently authorized to handle controlled substances in Massachusetts. It is equally clear that because [the] Respondent lacks this state authority, he is not currently entitled to a DEA registration.''

Judge Bittner also properly granted the Government's Motion for Summary Disposition. Here, the parties did not dispute the fact that the Respondent was unauthorized to handle controlled substances in Massachusetts. Therefore, it is well-settled that when no question of material fact is involved, a plenary, adversary administrative proceeding involving evidence and cross-examination of witnesses is not obligatory. See Dominick A. Ricci, M.D., *supra*, (finding it well settled that where there is no question of material fact involved, a plenary, adversarial administrative hearing was not required); see also Phillip E. Kirk, M.D., 48 FR 32,887 (1983), *aff'd sub nom* Kirk V. Mullen, 749 F.2d 297 (6th Cir. 1984); Alfred Tennyson Smurthwaite, M.D., 43 FR 11,873 (1978); *NLRB* v. *International Association of Bridge, Structural and Ornamental Ironworkers, AFL–CIO*, 549 F.2d 634 (9th Cir. 1977).

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 28 CFR 0.100(b) and 0.104, hereby orders that the application submitted by Stan White for a DEA Certificate of Registration be, and it hereby is, denied. This order is effective May 3, 1996.

Dated: March 28, 1996.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 96–8042 Filed 4–2–96; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

March 28, 1996.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) 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 this individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor Acting Departmental Clearance Officer, Theresa M. O'Malley ([202]

219–5095). 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 through Friday.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment and Training Administration, Office of Management and Budget, Room 10235, Washington, DC 20503 ([202] 395–7316), by May 3, 1996.

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: Employment and Training Administration

Title: Application for Alien Employment Certification

OMB Number: 1205–0015

Agency Number: ETA 750 A and B

Frequency: On occasion

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government

Number of Respondents: 54,000

Estimated Time per Respondent: 3 hours

Total Burden Hours: 151,200

Total Annualized capital/startup costs:: 0

Total annual costs (operating/maintaining systems or purchasing services): 0

Description: The ETA 750 provides the necessary information required to implement the labor certification process. This record is used to compile internal reports to management as well as answering public inquiries about the status.

Theresa M. O'Malley,

Acting Departmental Clearance Officer.

[FR Doc. 96–8076 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of March, 1996.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) that sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–31,793; Pershield, Inc., Campaign, TN

TA–W–31,891; Medical Textiles, Inc., South Boston, VA

TA–W–31,979; Quality Aluminum Castings Co., Waukesha, WI

TA–W–31,759; Carr Leather Co., Inc., Lynn, MA

TA–W–31,718; Controlled Power Corp., Canton, OH

TA–W–32,036; Imperial Metal & Chemical Co., Philadelphia, PA

TA–W–32,059; Triangle Wire & Cable, Inc., Glen Dale, WV

TA–W–31,935; Parsons Textile, Arizona City, AZ

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

TA–W–31,758; Campbell Industries, San Diego, CA

TA–W–31,967; GE Corporated Computer Services (CCS), Schenectady, NY

TA–W–31,890; Christian Brothers Logging, Inc., Cascade, ID

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–31,888; Porter house Ltd (AKA Regina Porter), New York, NY

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name & location for each determination references the impact date for all workers for such determination.

TA–W–31,834; Windsurfing Hawaii, Stevenson, WA: January 5, 1995.

TA–W–31,818; Cytec Industries, Inc., Marietta, OH: December 29, 1994.

TA–W–31,927; Selmet, Inc., Golf Products Div., Albany, OR: January 19, 1995.

TA–W–31,952; St. Mary's Sewing Ind., Edcouch, TX: January 29, 1995.

TA–W–31,903; West Point Stevens, Inc., AKA West Point Pepperell, Biddeford, ME.

TA–W–31,874; Seacraft Instrument, Batavia, NY: January 23, 1995.

TA–W–31,779; Dayton Racquet Co., Inc., Arcanum, OH: December 1, 1994.

TA–W–31,948; Molycorp, Inc., Washington, PA: January 2, 1995.

TA–W–31,842; DDJ Mfg., Madera, PA: January 9, 1995.

TA–W–32,055; Simpson Street Cutting, Luzerne, PA: March 1, 1995.

TA–W–31,996; Dutchess Lingerie dba Sylvester Textile, Sylvester, GA: February 22, 1995.

TA–W–32,008; Fun-Tees, Inc., Dadeville, AL: April 27, 1996.

TA–W–31,845; G-Tee, Cullman, AL: January 9, 1995.

TA–W–31,875; Rivera Mfg., Pontotoc, MS: April 27, 1995.

TA–W–32,028; General Electric Co., GE Lighting Bucyrus Lamp Plant, Bucyrus, OH: February 14, 1995.

TA–W–31,809; Eaton Corp.—Cutler Hammer Products, Bowling Green, KY: December 13, 1994.

TA–W–31,911; Bausch & Lomb, Eyewear Div., Oakland, MD: January 26, 1995.

TA–W–31,980; Santana, Inc., West Blocton, AL: February 15, 1995.

TA–W–31,960 & A; Bausch & Lomb, 465 Paul Rd., Rochester, NY & 1 Bausch & Lomb Rd., Rochester, NY: February 23, 1995.

TA–W–31,958; TRW, Inc., Automotive Electronics Group, Union Springs, NY: February 1, 1995.
TA–W–32,002; Mission Packaging, Inc., Tigard, OR: February 12, 1995.
TA–W–31,940; Alphabet, A Div. of Stoneridge, Inc., Nappanee, IN: February 7, 1995.
TA–W–31,863; WDC Holdings, Inc., Attleboro Falls, MA: January 16, 1995.

All workers engaged in employment related to the production of metal mesh handbags and accessories on or after January 16, 1995. All workers engaged in employment related to the production of metal safety gloves are denied.

TA–W–31,937; Capital-Mercury Shirt Corp: White River Shirt Co., Melbource, AR: February 2, 1995.
TA–W–31,938; Capital-Mercury Shirt Corp: Des Arc Shirt Co., Des Arc, AR: February 2, 1995.
TA–W–31,939 & A,B,C,D,E; Capital-Mercury Shirt Corp: Lawrence United Shirt Co., Walnut Ridge, AR, Mar-Bax Shirt Co., Gassville, AR, Flint Rock Shirt Co., Marshall, AR, Blanchard Shirt Co., Mountain View, AR, Tri-County Shirt Co., Salem AR, & Marion County Shirt Co., Yellville, AR: February 2, 1995.

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with Section 250(a) Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of March, 1996.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of Section 250 of the Trade Act must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases in imports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers' separations. There was no shift in production from the subject firm to Canada or Mexico during the relevant period.

NAFTA–TAA–00818; Medical Textiles, Inc., South Boston, VA
NAFTA–TAA–00812; Quality Aluminum Casting Co., Waukesha, WI
NAFTA–TAA–00816; Horseshoe Bar Ranch, Ola, ID
NAFTA–TAA–00827 & A; Parsons Textile, Arizona City, AZ & A&M Textile, Casa Grande, AZ
NAFTA–TAA–00782; Aeroquip Corp. (A.K.A. Trinova Corp), Automotive Products Group, Henderson, KY
NAFTA–TAA–00841; Cascade Timber Co., Inc., Klamath Falls, OR
NAFTA–TAA–00861; Cleo, Inc., McAllen, TX
NAFTA–TAA–00810; Pope & Talbot, Inc., Eau Claire, WI

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

None

Affirmative Determinations NAFTA–TAA

The following certifications have been issued; the date following the company name & location for each determination references the impact date for all workers for such determination.

NAFTA–TAA–00803; C.R. Bard, Inc., Midical Div., Nogales, AZ: February 13, 1995.
NAFTA–TAA–00820 & A, B, C, D, E, F, G, H; Capital-Mercury Shirt Corp: White River Shirt Co., Melbource, AR, Des Arc Shirt Co., Des Arc, AR, Lawrence United Shirt Co., Walnut Ridge, AR, Mar-Bax Shirt Co., Gassville, AR, Flint Rock Shirt Co., Marshall, AR, Blanchard Shirt Co., Mountain View, AR, Tri-County Shirt Co., Salem, AR, Marion Country Shirt Co., Yellville, AR: February 2, 1995.
NAFTA–TAA–00825; TRW, Inc., Automotive Electronics Group, Union Springs, NY: February 1, 1995.
NAFTA–TAA–00853; Dutchess Lingerie, dba Sylvester Textile, Sylvester, GA: February 22, 1995.
NAFTA–TAA–00832; Elf Atochem North America, Inc., Industrial Chemicals Group, Calvert City, KY: February 12, 1995.
NAFTA–TAA–00835; Converse, Inc., Lumberton, NC: February 13, 1995.
NAFTA–TAA–00859; Eaton Corp., Forge Div., Marion, OH: January 31, 1995.
NAFTA–TAA–00846; General Electric Co., GE Lighting—Bucyrus Lamp Plant, Bucyrus, OH: February 14, 1995.
NAFTA–TAA–00844 & A; Bike Athletic Co., Cherryville, NC & Knoxville, TN: February 22, 1995.
NAFTA–TAA–00809; Textile Networks, Inc., Knoxville, TN: November 4, 1995.
NAFTA–TAA–00811; St. Mary's Sewing Ind., Edcouch, TX: January 22, 1995.
NAFTA–TAA–00867; Neles-Jamesbury, Inc., Glens Falls, NY: February 21, 1995.
NAFTA–TAA–00860; Branson Ultrasonics Corp., Branson Precision Cleaning Co., Paramount, CA: January 23, 1995.

I hereby certify that the aforementioned determinations were issued during the month of March 1996. Copies of these determinations are available for inspection in Room C–4318, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: March 25, 1996.

Russell Kile,

Acting Program Manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8083 Filed 4–2–96; 8:45 am]
BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Program Manager of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may

request a public hearing, provided such request is filed in writing with the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than April 15, 1996.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than April 15, 1996.

The petitions filed in this case are available for inspection at the Office of the Program Manager, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 18th day of March, 1996.

Russell Kile,

Acting Program Manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

Appendix

PETITIONS INSTITUTED ON MARCH 18, 1996

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
32,030	Allied Signal Corp. (IAM&AW)	So. Montrose, PA	02/28/96	Cockpit Instrumentation.
32,031	Brown Group, Inc. (Wkrs)	Clayton, MO	2/12/96	Ladies' Shoes.
32,032	Oregon Cedar Products Co. (Wkrs)	Springfield, OR	2/15/96	Lumber.
32,033	3M (Wkrs)	Wahpeton, ND	03/04/96	Beta Recording Tapes.
32,034	Elco Corporation (IBEW)	Huntingdon, PA	03/04/96	Electrical Components.
32,035	Price Pfister (Wkrs)	Pacoima, CA	02/19/96	Faucets and Parts.
32,036	Imperial Metal and Chemic (Wkrs)	Philadelphia, PA	02/20/96	Aluminum Lithographic Printing Plates.
32,037	Century Place Inc. (Wkrs)	Salisbury, NC	02/22/96	Shirt Collars.
32,038	Allied Signal, Inc. (Wkrs)	Rumford, RI	01/29/96	Air, Oil & Gas Filters.
32,039	Turbine Engine Components (UAW)	Danville, PA	03/08/96	Turbine Engine Components.
32,040	Hughes Training, Inc. (Wkrs)	Binghamton, NY	03/06/96	Flight Simulators.
32,041	Manhattan Fashions (Wkrs)	Union City, NJ	02/27/96	Ladies' Coats.
32,042	Dye-Tex Limited L.L.C. (Wkrs)	Roanoke, VA	03/05/96	Tee Shirts and Sweat Shirts.
32,043	ALPS Manufacturing (Wkrs)	Garden Grove, CA	02/15/96	Computer Peripheral Devices.
32,044	Forest Oil Corporation (Wkrs)	Denver, CO	02/09/96	Crude Oil, Natural Gas.
32,045	NorAm Gas Transmission (Wkrs)	Shreveport, LA	02/14/96	Natural Gas Transmission.
32,046	Skyline Sportswear (Wkrs)	Floyd, VA	02/11/96	Ladies' Blazers & Blouses.
32,047	Ladyfare Mills Corp (Wkrs)	Ratcliff, AR	02/23/96	Ladies' Lingerie, Leggings.
32,048	Chicago Miniature Lamp (Wkrs)	Pauls Valley, OK	02/21/96	Incandescent Lamps.
32,049	Lifeline Manufacturing (Wkr)	Swainsboro, GA	02/27/96	Commercial Furniture.
32,050	Geomartec, Inc. (Co.)	Houston, TX	02/26/96	Cable Products: Cables & Connectors.
32,051	United Technologies Auto (Co.)	Dearborn, MI	02/20/96	Electrical Wire Harnesses.
32,052	Vulcan Corporation (USWA)	Clarksville, TN	03/04/96	Shoe Heels, Boot Heels.
32,053	General Mirror Corp. (Wkrs)	Clifton, NJ	02/28/96	Automobile Side View Mirrors.
32,054	Norminjil Sportswear Corp (UNITE)	Luzerne, PA	03/01/96	Girl's Sportswear.
32,055	Simpson Street Cutting (UNITE)	Luzerne, PA	03/01/96	Girl's Sportswear.
32,056	Herald Handbag (UFCW)	New York, NY	02/29/96	Ladies' Leather Handbags.
32,057	Henry Vogt Machine Co. (USWA)	Louisville, KY	03/06/96	Ice Machines, Valves, Forges, Boilers.
32,058	Pittsburgh Brewing, Co. (TWU)	Pittsburgh, PA	02/27/96	Glass Bottles.
32,059	Triangle Wire and Cable (IBEW)	Glendale, WV	02/20/96	Electrical Tubing.
32,060	Rhubarb Fashions (Co.)	Jersey City, NJ	02/28/96	Ladies' Sportswear.

[FR Doc. 96–8082 Filed 4–2–96; 8:45 am]
BILLING CODE 4510–30–M

[TA–W–31,615, 615A]

Dalen Resources Oil and Gas Company a/k/a Enserch Exploration, Inc., Dallas, Texas and Various Locations in Texas; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 30, 1996, applicable to all workers of Dalen Resources Oil and Gas Company, Dallas, Texas and various locations within the State of Texas. The notice was published in the Federal Register on February 21, 1996 (61 FR 6659).

At the request of the company, the Department reviewed the certification for workers of the subject firm. The workers are engaged in employment related to the exploration and production of crude oil and natural gas. New information provided by the company shows that it was their intent to include employees of Enserch Exploration, Inc., an affiliate of Dalen Resources. New findings show that workers of Enserch Exploration, Inc. were inadvertently excluded from the certification.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by imports. Accordingly, the Department is amending the certification to include workers of Enserch Exploration, Inc.

The amended notice applicable to TA–W–31,615 and TA–W–31,615A is hereby issued as follows:

''All workers of Dalen Resources Oil and Gas Company, Dallas, Texas (TA–W–31,615) and various locations within the State of Texas (TA–W–31,615A) who became totally or partially separated from employment on or after October 24, 1994 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, D.C. this 20th day of March 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8080 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,622 and TA–W–31,623]

Hill Company, Incorporation, Fort Smith, AR, and Charleston, AR; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of February 15, 1996, the petitioners requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance for workers of the subject firm. The denial notice was signed on January 18, 1996 and published in the Federal Register on February 6, 1996 (61 FR 4486).

The petitioner presents evidence that the Department's survey of the subject firm's customers was incomplete.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, D.C., this 22nd day of March 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8085 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,865]

Monticello Mfg., Inc./Oxford Slacks, Monticello, Georgia; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) as amended by the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418), the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is determined in this case that all of the requirements have been met.

The investigation was initiated in response to a petition received on February 5, 1996, and filed on behalf of workers at Monticello Mfg., Inc./Oxford Slacks, Monticello, Georgia. The workers produce men's and ladies' slacks and shorts.

Sales and production declined in 1995 compared with 1994.

The firm is closing the Monticello plant and transferring production of slacks abroad. Company imports of slacks from the foreign facilities have increased in 1995 and will replace production at the subject plant.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increase of imports of articles like or directly competitive with men's and ladies' slacks produced at Monticello Mfg., Inc./Oxford Slacks, Monticello, Georgia, contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

''All workers of Monticello Mfg., Inc./ Oxford Slacks, Monticello, Georgia, who became totally or partially separated from employment on or after January 8, 1995, through two years from the date of certification are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed in Washington, D.C. this 16th day of February, 1996

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8081 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31, 368 and TA–W–31, 369]

Roxanne of New Jersey, Neptune, New Jersey and Art San Corporation, Neptune, New Jersey; Notice of Revised Determination on Reopening

On March 21, 1996, the Department, on its own motion, reopened its investigation for the former workers of the subject firm.

The initial investigation resulted in a negative determination on October 26, 1995, because the ''contributed importantly'' test of the Group Eligibility Requirements of the Trade Act was not met for workers at the subject firm. The denial notice was published in the Federal Register on November 9, 1995 (60 FR 56619).

Late responses to a customer survey conducted by the Department show customers of the subject firm increased import purchases of swimsuits during the time period relevant to the investigation. Other new findings show increased aggregate U.S. imports of women's and girls' swimwear from 1993 to 1994 and in the twelve months through September 1994 and 1995.

Conclusion

After careful consideration of the new facts obtained on reopening, it is concluded that increased imports of articles like or directly competitive with women's swimsuits produced by the subject firm contributed importantly to the declines in sales and to the total or partial separation of workers of the subject firm. In accordance with the provisions of the Trade Act of 1974, I make the following revised determination:

''All workers of Roxanne of New Jersey, Neptune, New Jersey (TA–W–31, 368), and Art San Corporation, Neptune, New Jersey (TA–W–369) who became totally or partially separated from employment on or after August 17, 1994, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed in Washington, D.C. this 26th day of March 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8084 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,832]

Spring Town Knitwear, Incorporated, a/k/a Spring City Knitting, Carterville, Georgia; Notice of Termination of Certification

This notice terminates the Certification Regarding Eligibility to Apply for Worker Adjustment Assistance issued by the Department on March 11, 1996, for the workers of Spring Town Knitwear, Incorporated, a/k/a Spring City Knitting, Carterville, Georgia. The notice will soon be published in the Federal Register.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. New findings show that on October 27, 1995, under petition TA–W–31,410, the Department certified all workers of Springtown Knitwear, Incorporated. The certification was amended to include the former workers of Spring City Knitting.

Therefore, since the adversely affected workers are currently certified,

continuing the certification for TA–W–31,832 would serve no purpose and the certification is terminated.

Signed at Washington, D.C., this 20th day of March 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8079 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,410]

Springtown Knitwear Incorporated, Formerly Spring City Knitting, Cartersville, Georgia; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on October 27, 1995, applicable to all workers at Springtown Knitwear, Incorporated, located in Cartersville, Georgia. The notice was published in the Federal Register on November 9, 1995 (60 FR 56619).

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. New information received from the State Agency shows that after the closure of Spring City Knitting in August 1994, Springtown Knitwear began operations in the same building, with many of the former workers of Spring City Knitting. The workers were engaged in the production of knitwear. Springtown Knitwear closed in August 1995.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports. The Department is amending the certification to cover the former Spring City Knitting workers.

The amended notice applicable to TA–W–31,410 is hereby issued as follows:

''All workers of the Springtown Knitwear Incorporated, formerly Spring City Knitting, Cartersville, Georgia who became totally or partially separated from employment on or after August 31, 1994 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, D.C. this 20th day of March 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8078 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

Job Training Partnership Act; Lower Living Standard Income Level

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of determination of lower living standard income level.

SUMMARY: The Job Training Partnership Act (JTPA) provides that the term ''economically disadvantaged'' may be defined as 70 percent of the ''lower living standard income level'' (LLSIL). To provide the most accurate data possible, the Department of Labor is issuing revised figures for the LLSIL.

EFFECTIVE DATE: This notice is effective on April 3, 1996.

ADDRESSES: Send written comments to: Ms. Diane Mayronne, Office of Employment and Training Programs, Employment and Training Administration, Department of Labor, Room N–4463, 200 Constitution Avenue NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Ms. Diane Mayronne, Telephone: 202–219–5305 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: It is a purpose of the Job Training Partnership Act (JTPA) ''to afford job training to those economically disadvantaged individuals . . . who are in special need of such training to obtain productive employment.'' JTPA Section 2; see 20 CFR 626.1 and 626.3(b). JTPA Section 4(8) defines, for the purposes of JTPA eligibility, the term ''economically disadvantaged'' in part by reference to the ''lower living standard income level'' (LLSIL). See 20 CFR 626.5.

The LLSIL figures published in this notice shall be used to determine whether an individual is economically disadvantaged for applicable JTPA purposes. JTPA Section 4(16) defines the LLSIL as follows:

The term ''lower living standard income level'' means that income level (adjusted for regional, metropolitan, urban, and rural differences and family size) determined annually by the Secretary [of Labor] based on the most recent ''lower living family budget'' issued by the Secretary.

The most recent lower living family budget was issued by the Secretary in the fall of 1981. Using those data, the 1981 LLSIL was determined for programs under the now-repealed Comprehensive Employment and Training Act. The four-person urban family budget estimates previously published by the Bureau of Labor Statistics (BLS) provided the basis for the Secretary to determine the LLSIL for training and employment program operators. BLS terminated the four-person family budget series in 1982, after publication of the Fall 1981 estimates.

Under JTPA, the Employment and Training Administration (ETA) published the 1995 updates to the LLSIL in the Federal Register of April 25, 1995. 60 FR 20283. ETA has again updated the LLSIL to reflect cost of living increases for 1995 by applying the percentage change in the December 1995 Consumer Price Index for All Urban Consumers (CIP–U), compared with the December 1994 CPI–U, to each of the April 25, 1995, LLSIL figures. Those updated figures for a family of four are listed in Table 1 below by region for both metropolitan and nonmetropolital areas. Since eligibility is determined by family income at 70 percent of the LLSIL, pursuant to Section 4(8) of JTPA, those figures are listed below as well.

Jurisdictions included in the various regions, based generally on Census Divisions of the U.S. Department of Commerce, are as follows:

Northeast

Connecticut	New York
Maine	Pennsylvania
Massachusetts	Rhode Island
New Hampshire	Vermont
New Jersey	Virginia Islands

Midwest

Illinois	Missouri
Indiana	Nebraska
Iowa	North Dakota
Kansas	Ohio
Michigan	South Dakota
Minnesota	Wisonsin

South

Alabama	Kentucky
American Samoa	Lousiana
Arkansas	Marshall Islands
Delaware	Maryland
District of Columbia	Mississippi
Florida	Micronesia
Georgia	North Carolina
Northern Marianas	Tennessee
Oklahoma	Texas
Palau	Virginia
Puerto Rico	West Virginia
South Carolina	

West

Arizona	New Mexico
California	Oregon
Colorado	Utah
Idaho	Washington
Montana	Wyoming
Nevada	

Additionally, separate figures have been provided for Alaska, Hawaii,and Guam as indicated in Table 2 below.

For Alaska, Hawaii, and Guam, the 1996 figures were updated by creating a ''State Index'' based on the ratio of the urban change in the State (using Anchorage for Alaska and Honolulu for Hawaii and Guam) compared to the

West regional metropolitan change, and then applying that index to the West regional nonmetropolitan change.

Data on 25 selected Metropolitan Statistical Areas (MSAs) are also available. These are based on monthly, bimonthly or semiannual CPI–U changes for a 12-month period ending in December 1995. The updated LLSIL figures for these MSAs, and 70 percent of the LLSIL, rounded to the next highest ten, are set forth in Table 3 below.

Table 4 below is a listing of each of the various figures at 70 percent of the updated 1996 LLSIL for family sizes of one to six persons. For families larger than six persons, an amount equal to the difference between the six-person and the five-person family income levels should be added to the six-person family income level for each additional person in the family. Where the poverty level for a particular family size is greater than the corresponding LLSIL figures, the figure is indicated in parentheses.

Section 4(8) of JTPA defines ''economically disadvantaged'' as, among other things, an individual whose family income was not in excess of the higher of the poverty level or 70 percent of the LLSIL. The Department of Health and Human Services published the annual update of the poverty-level guidelines at 61 FR 8286 (March 4, 1996).

Use of These Data

Based on these data, Governors should provide the appropriate figures to service delivery areas (SDAs), State Employment Security Agencies, and employers in their States to use in determining eligibility for JTPA. The Governor should designate the appropriate LLSILs for use within the State from Tables 1 through 3. Table 4 may be used with any of the levels designated.

Information may be provided by disseminating information on MSAs and metropolitan and nonmetropolitan areas within the State, or it may involve further calculations. For example, the State of New Jersey May have four or more figures: Metropolitan, nonmetropolitan, for portions of the State in the New York City MSA, and for those in the Philadelphia MSA. If an SDA includes areas that would be covered by more than one figure, the Governor may determine which is to be used. Pursuant to the JTPA regulations at 20 CFR 627.200, guidelines, interpretations, and definitions adopted by the Governor shall be accepted by the Secretary for the extent that they are consistent with the JTPA and the JTPA regulations.

Disclaimer on Statistical Uses

It should be noted that the publication of these figures is only for the purpose of determining eligibility for applicable JTPA programs. BLS has not revised the lower living family budget since 1981, and has no plans to do so. The four-person urban family budget estimates series has been terminated. The CPI–U adjustments used to update the LLSIL for this publication are not precisely comparable, most notably because certain tax items were included in the 1981 LLSIL, but are not in the CPI–U.

Thus, these figures should not be used for any statistical purposes, and are valid only for eligibility determination purposes under the JTPA program.

Signed at Washington, DC, this 25th day of March, 1996.

Josephine Nieves,

Associate Assistant Secretary.

Appendix

TABLE 1.—LOWER LIVING STANDARD INCOME LEVEL BY REGION [1]

Region	1996 adjusted LLSIL	70 percent LLSIL
Northeast:		
Metro	26,840	18,790
Non-Metro	26,920	18,840
Midwest:		
Metro	24,840	17,390
Non-Metro	23,640	16,550
South:		
Metro	23,700	16,590
Non-Metro	22,340	15,640
West:		
Metro	26,290	18,400
Non-Metro	26,110	18,270

[1] For ease of calculation, these figures have been rounded to the next highest ten dollars.

TABLE 2.—LOWER LIVING STANDARD INCOME LEVEL—ALASKA, HAWAII AND GUAM [1]

Region	1996 adjusted LLSIL	70 percent LLSIL
Alaska:		
Metro	33,980	23,790
Non-Metro	33,070	23,150
Hawaii-Guam:		
Metro	36,940	25,860
Non-Metro	35,950	25,160

[1] Rounded to the next highest ten dollars.

TABLE 3.—LOWER LIVING STANDARD INCOME LEVEL—25 MSAS [1]

Region MSA	1996 adjusted LLSIL	70 percent LLSIL
Anchorage, AK	33,980	23,790
Atlanta, GA	23,620	16,530
Baltimore, MD	25,060	17,542
Boston-Lawrence-Salem, MA/NH	28,120	19,680
Buffalo-Niagara Falls, NY	24,360	17,050
Chicago-Gary-Lake County, IL/IN/WI	25,990	18,200
Cinicinnati-Hamilton, OH/KY/IN	25,140	17,600
Cleveland-Akron-Lorain, OH	25,600	17,920
Dallas-Ft Worth, TX	22,570	15,800
Denver-Boulder, CO	25,460	17,820
Detroit-Ann Arbor, MI	24,010	16,800
Honolulu, HI	36,940	25,860
Houston-Galveston-Brazoria, TX	22,280	15,600
Kansas City, MO/KS	23,870	16,700
Los Angeles-Anaheim-Riverside, CA	27,150	19,010
Milwaukee, WI	25,290	17,700
Minneapolis-St Paul, MN/WI	24,250	16,980
New York-Northern N.J.-Long Island, NY/NJ/CT	28,010	19,610
Philadelphia-Wilmington-Trenton, PA/NJ/DE/MD	26,310	18,420
Pittsburgh-Beaver Valley, PA	25,140	17,600
St Louis-East St Louis, MO/IL	24,050	16,800
San Diego, CA	27,390	19,170
San Francisco-Oakland-San Jose, CA	27,050	18,940
Seattle-Tacoma, WA	28,130	19,690
Washington, DC/MD/VA	28,540	19,980

[1] Rounded to the next highest ten dollars.

TABLE 4.—SEVENTY PERCENT OF UPDATED 1996 LLSIL, BY FAMILY SIZE [1]

Family of one	Two	Three	Four	Five	Six
(5,620)	(9,200)	(12,640)	15,600	18,410	21,530
(5,630)	(9,230)	(12,670)	15,640	18,460	21,580
(5,690)	(9,320)	(12,800)	15,800	18,640	21,800
(5,950)	(9,750)	13,390	16,530	19,510	22,810
(5,960)	(9,770)	13,410	16,550	19,530	22,840
(5,970)	(9,790)	13,440	16,590	19,580	22,890
(6,010)	(9,850)	13,530	16,700	19,710	23,050
(6,050)	(9,910)	13,610	16,800	19,820	23,180
(6,110)	(10,020)	13,750	16,980	20,040	23,430
(6,140)	(10,060)	13,810	17,050	20,120	23,530
(6,260)	(10,260)	14,090	17,390	20,520	24,000
(6,320)	(10,350)	14,210	17,540	20,700	24,210
(6,340)	10,380	14,260	17,600	20,770	24,290
(6,370)	10,440	14,340	17,700	20,890	24,430
(6,420)	10,510	14,430	17,820	21,030	24,590
(6,450)	10,570	14,520	17,920	21,150	24,730
(6,550)	10,740	14,740	18,200	21,480	25,120
(6,580)	10,780	14,800	18,270	21,560	25,210
(6,620)	10,860	14,900	18,400	21,710	25,390
(6,630)	10,870	14,920	18,420	21,740	25,420
6,760	11,090	15,220	18,790	22,170	25,930
6,780	11,120	15,260	18,840	22,230	26,000
6,820	11,180	15,340	18,940	22,350	26,140
6,840	11,220	15,400	19,010	22,430	26,230
6,900	11,310	15,530	19,170	22,620	26,460
7,060	11,570	15,880	19,610	23,140	27,060
7,090	11,610	15,940	19,680	23,220	27,160
7,090	11,620	15,590	19,690	23,230	27,170
7,190	11,790	16,180	19,980	23,580	27,570
8,330	13,660	18,750	23,150	27,320	31,950
8,560	14,040	19,270	23,790	28,070	32,830
9,060	14,840	20,380	25,160	29,690	34,720
9,310	15,260	20,950	25,860	30,520	35,690

[1] Figures provided in Tables 1–3 of this notice are for a family of four persons. To use Table 4, the appropriate figure should be found in the Family of Four column. Then one may read across the row for family sizes other than four in the appropriate column.

[FR Doc. 96–7944 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

[NAFTA–00690]

Carpenter Manufacturing, Incorporated Mitchell, IN; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Program Manager of the Office of Trade Adjustment Assistance for workers at Carpenter Manufacturing, Inc., Mitchell, Indiana. The review indicated that the application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

NAFTA–00690; Carpenter Manufacturing, Inc., Mitchell, Indiana (March 22, 1996)

Signed at Washington, D.C. this 25th day of March, 1996.

Russell T. Kile,

Acting Program Manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8086 Field 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

[NAFTA—00907]

Pam-Cor, Portland, Oregon; Notice of Termination of Investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance, hereinafter called (NAFTA–TAA), and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2273), an investigation was initiated on March 14, 1996 in response to a petition filed on behalf of workers at Pam-Cor located in Portland, Oregon.

It was discovered that the sole petitioner has never worked for Pam-Cor and furthermore the company has not been in existence for a number of years. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, D.C., this 26th day of March 1996.

Russell T. Kile,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 96–8077 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–30–M

Pension and Welfare Benefits Administration

[Prohibited Transaction Exemption 96–20; Exemption Application No. D–09848, et al.]

Grant of Individual Exemptions; Associated Hospital Service of Maine (d/b/a Blue Cross and Blue Shield of Maine)

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of Individual Exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Notices were published in the Federal Register of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, D.C. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of proposed exemption were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

Associated Hospital Service of Maine (d/b/a Blue Cross and Blue Shield of Maine) and Blue Alliance Mutual Insurance Company

Located in Portland, Maine

[Prohibited Transaction Exemption 96–20 Exemption Application No. D–09848]

Exemption

The restrictions of sections 406(a), 406(b)(1), and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply, effective August 18, 1993, to the past sales of certain securities (the Securities) by the Associated Hospital Service of Maine Retirement Plan (the Plan) to the Associated Hospital Service of Maine (d/b/a Blue Cross and Blue Shield of Maine) (BCBSME) and Blue Alliance Mutual Insurance Company (Blue Alliance), parties in interest with respect to the Plan; provided that the following conditions were met: (a) The sales of the Securities were one-time transactions for cash; (b) the purchase price paid by BCBSME and Blue Alliance was no less than the fair market value of the Securities on the date of the sales; (c) the fair market value of the Securities were determined by reference to an objective third party pricing service, as of the date of the sales; (d) the terms of the transactions were no less favorable to the Plan than those obtainable in similar transactions negotiated at arm's length with unrelated third parties; and (e) the Plan paid no costs, fees, or commissions associated with the transactions, nor other expenses associated with the application for exemption.

EFFECTIVE DATE: This exemption is granted and is effective as of August 18, 1993, the date of the sales of the Securities to BCBSME and Blue Alliance.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the Notice of Proposed Exemption published on January 31, 1996 at 61 FR 3467.

FOR FURTHER INFORMATION CONTACT: Angelena C. Le Blanc of the Department, telephone (202) 219–8883 (This is not a toll-free number.)

W.W. Taylor, Jr., M.D., P.C. Money Purchase Pension Plan (the Plan)

Located in Memphis, Tennessee

[Prohibited Transaction Exemption 96–21;

Exemption Application No. D–10118]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the past contribution by W.W. Taylor, M.D., P.C. to the Plan of certain publicly traded securities (the Securities), provided: a) the contribution was a one-time transaction; b) the Securities were valued at their fair market value as of the date of the contribution as determined by an independent broker; c) no commissions were paid in connection with the transaction; and d) the Securities represented less than 25% of the assets of the Plan at the time of the contribution.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on January 31, 1996 at 61 FR 3487.

EFFECTIVE DATE: This exemption is effective October 7, 1994.

FOR FURTHER INFORMATION CONTACT: Gary H. Lefkowitz of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

First Union Corporation (First Union)

Located in Charlotte, North Carolina

[Prohibited Transaction Exemption 96–22; Exemption Application No. D–10165]

Exemption

I. Transactions

A. The restrictions of sections 406(a) and 407(a) of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c)(1)(A) through (D) of the Code shall not apply to the following transactions involving trusts and certificates evidencing interests therein:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and an employee benefit plan when the sponsor, servicer, trustee or insurer of a trust, the underwriter of the certificates representing an interest in the trust, or an obligor is a party in interest with respect to such plan;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates; and

(3) The continued holding of certificates acquired by a plan pursuant to subsection I.A.(1) or (2).

Notwithstanding the foregoing, section I.A. does not provide an exemption from the restrictions of sections 406(a)(1)(E), 406(a)(2) and 407 for the acquisition or holding of a certificate on behalf of an Excluded Plan by any person who has discretionary authority or renders investment advice with respect to the assets of that Excluded Plan.[1]

B. The restrictions of sections 406(b)(1) and 406(b)(2) of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c)(1)(E) of the Code shall not apply to:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and a plan when the person who has discretionary authority or renders investment advice with respect to the investment of plan assets in the certificates is (a) an obligor with respect to 5 percent or less of the fair market value of obligations or receivables contained in the trust, or (b) an affiliate of a person described in (a); if:

(i) The plan is not an Excluded Plan;

(ii) Solely in the case of an acquisition of certificates in connection with the initial issuance of the certificates, at least 50 percent of each class of certificates in which plans have invested is acquired by persons independent of the members of the Restricted Group and at least 50 percent of the aggregate interest in the trust is acquired by persons independent of the Restricted Group;

(iii) A plan's investment in each class of certificates does not exceed 25 percent of all of the certificates of that class outstanding at the time of the acquisition; and

(iv) Immediately after the acquisition of the certificates, no more than 25 percent of the assets of a plan with respect to which the person has discretionary authority or renders investment advice are invested in certificates representing an interest in a trust containing assets sold or serviced by the same entity.[2] For purposes of this paragraph B.(1)(iv) only, an entity will not be considered to service assets contained in a trust if it is merely a subservicer of that trust;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates, provided that the conditions set forth in paragraphs B.(1) (i), (iii) and (iv) are met; and

(3) The continued holding of certificates acquired by a plan pursuant to subsection I.B. (1) or (2).

C. The restrictions of sections 406(a), 406(b) and 407(a) of the Act, and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c) of the Code, shall not apply to transactions in connection with the servicing, management and operation of a trust, provided:

(1) Such transactions are carried out in accordance with the terms of a binding pooling and servicing arrangement; and

(2) The pooling and servicing agreement is provided to, or described in all material respects in the prospectus or private placement memorandum provided to, investing plans before they purchase certificates issued by the trust.[3]

Notwithstanding the foregoing, section I.C. does not provide an exemption from the restrictions of section 406(b) of the Act or from the taxes imposed by reason of section 4975(c) of the Code for the receipt of a fee by a servicer of the trust from a person other than the trustee or sponsor, unless such fee constitutes a ''qualified administrative fee'' as defined in section III.S.

D. The restrictions of sections 406(a) and 407(a) of the Act, and the taxes imposed by sections 4975 (a) and (b) of the Code by reason of sections 4975(c)(1) (A) through (D) of the Code, shall not apply to any transactions to which those restrictions or taxes would otherwise apply merely because a person is deemed to be a party in interest or disqualified person (including a fiduciary) with respect to a plan by virtue of providing services to the plan (or by virtue of having a relationship to such service provider described in section 3(14) (F), (G), (H) or (I) of the Act or section 4975(e)(2) (F), (G), (H) or (I) of the Code), solely because of the plan's ownership of certificates.

[1] Section I.A. provides no relief from sections 406(a)(1)(E), 406(a)(2) and 407 for any person rendering investment advice to an Excluded Plan within the meaning of section 3(21)(A)(ii) and regulation 29 CFR 2510.3–21(c).

[2] For purposes of this exemption, each plan participating in a commingled fund (such as a bank collective trust fund or insurance company pooled separate account) shall be considered to own the same proportionate undivided interest in each asset of the commingled fund as its proportionate interest in the total assets of the commingled fund as calculated on the most recent preceding valuation date of the fund.

[3] In the case of a private placement memorandum, such memorandum must contain substantially the same information that would be disclosed in a prospectus if the offering of the certificates were made in a registered public offering under the Securities Act of 1933. In the Department's view, the private placement memorandum must contain sufficient information to permit plan fiduciaries to make informed investment decisions.

II. General Conditions

A. The relief provided under Part I is available only if the following conditions are met:

(1) The acquisition of certificates by a plan is on terms (including the certificate price) that are at least as favorable to the plan as they would be in an arm's-length transaction with an unrelated party;

(2) The rights and interests evidenced by the certificates are not subordinated to the rights and interests evidenced by other certificates of the same trust;

(3) The certificates acquired by the plan have received a rating at the time of such acquisition that is in one of the three highest generic rating categories from either Standard & Poor's Corporation (S&P's), Moody's Investors Service, Inc. (Moody's), Duff & Phelps Inc. (D & P) or Fitch Investors Service, Inc. (Fitch);

(4) The trustee is not an affiliate of any member of the Restricted Group. However, the trustee shall not be considered to be an affiliate of a servicer solely because the trustee has succeeded to the rights and responsibilities of the servicer pursuant to the terms of a pooling and servicing agreement providing for such succession upon the occurrence of one or more events of default by the servicer;

(5) The sum of all payments made to and retained by the underwriters in connection with the distribution or placement of certificates represents not more than reasonable compensation for underwriting or placing the certificates; the sum of all payments made to and retained by the sponsor pursuant to the assignment of obligations (or interests therein) to the trust represents not more than the fair market value of such obligations (or interests); and the sum of all payments made to and retained by the servicer represents not more than reasonable compensation for the servicer's services under the pooling and servicing agreement and reimbursement of the servicer's reasonable expenses in connection therewith; and

(6) The plan investing in such certificates is an ''accredited investor'' as defined in Rule 501(a)(1) of Regulation D of the Securities and Exchange Commission under the Securities Act of 1933.

B. Neither any underwriter, sponsor, trustee, servicer, insurer, nor any obligor, unless it or any of its affiliates has discretionary authority or renders investment advice with respect to the plan assets used by a plan to acquire certificates, shall be denied the relief provided under Part I, if the provision of subsection II.A.(6) above is not satisfied with respect to acquisition or holding by a plan of such certificates, provided that (1) Such condition is disclosed in the prospectus or private placement memorandum; and (2) in the case of a private placement of certificates, the trustee obtains a representation from each initial purchaser which is a plan that it is in compliance with such condition, and obtains a covenant from each initial purchaser to the effect that, so long as such initial purchaser (or any transferee of such initial purchaser's certificates) is required to obtain from its transferee a representation regarding compliance with the Securities Act of 1933, any such transferees will be required to make a written representation regarding compliance with the condition set forth in subsection II.A.(6) above.

III. Definitions

For purposes of this exemption:

A. ''Certificate'' means:

(1) A certificate—

(a) That represents a beneficial ownership interest in the assets of a trust; and

(b) That entitles the holder to pass-through payments of principal, interest, and/or other payments made with respect to the assets of such trust; or

(2) A certificate denominated as a debt instrument—

(a) That represents an interest in a Real Estate Mortgage Investment Conduit (REMIC) within the meaning of section 860D(a) of the Internal Revenue Code of 1986; and

(b) That is issued by and is an obligation of a trust;

with respect to certificates defined in (1) and (2) above for which First Union is either (i) the sole underwriter or the manager or co-manager of the underwriting syndicate, or (ii) a selling or placement agent.

For purposes of this exemption, references to ''certificates representing an interest in a trust'' include certificates denominated as debt which are issued by a trust.

B. ''Trust'' means an investment pool, the corpus of which is held in trust and consists solely of:

(1) Either

(a) Secured consumer receivables that bear interest or are purchased at a discount (including, but not limited to, home equity loans and obligations secured by shares issued by a cooperative housing association);

(b) Secured credit instruments that bear interest or are purchased at a discount in transactions by or between business entities (including, but not limited to, qualified equipment notes secured by leases, as defined in section III.T);

(c) Obligations that bear interest or are purchased at a discount and which are secured by single-family residential, multi-family residential and commercial real property (including obligations secured by leasehold interests on commercial real property);

(d) Obligations that bear interest or are purchased at a discount and which are secured by motor vehicles or equipment, or qualified motor vehicle leases (as defined in section III.U);

(e) ''Guaranteed governmental mortgage pool certificates,'' as defined in 29 CFR 2510.3–101(i)(2);

(f) Fractional undivided interests in any of the obligations described in clauses (a)–(e) of this section B.(1);

(2) Property which had secured any of the obligations described in subsection B.(1);

(3) Undistributed cash or temporary investments made therewith maturing no later than the next date on which distributions are to made to certificateholders; and

(4) Rights of the trustee under the pooling and servicing agreement, and rights under any insurance policies, third-party guarantees, contracts of suretyship and other credit support arrangements with respect to any obligations described in subsection B.(1).

Notwithstanding the foregoing, the term ''trust'' does not include any investment pool unless: (i) The investment pool consists only of assets of the type which have been included in other investment pools, (ii) certificates evidencing interests in such other investment pools have been rated in one of the three highest generic rating categories by S&P's, Moody's, D & P, or Fitch for at least one year prior to the plan's acquisition of certificates pursuant to this exemption, and (iii) certificates evidencing interests in such other investment pools have been purchased by investors other than plans for at least one year prior to the plan's acquisition of certificates pursuant to this exemption.

C. ''Underwriter'' means:

(1) First Union;

(2) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with First Union; or

(3) Any member of an underwriting syndicate or selling group of which First Union or a person described in (2) is a manager or co-manager with respect to the certificates.

D. ''Sponsor'' means the entity that organizes a trust by depositing

obligations therein in exchange for certificates.

E. ''Master Servicer'' means the entity that is a party to the pooling and servicing agreement relating to trust assets and is fully responsible for servicing, directly or through subservicers, the assets of the trust.

F. ''Subservicer'' means an entity which, under the supervision of and on behalf of the master servicer, services loans contained in the trust, but is not a party to the pooling and servicing agreement.

G. ''Servicer'' means any entity which services loans contained in the trust, including the master servicer and any subservicer.

H. ''Trustee'' means the trustee of the trust, and in the case of certificates which are denominated as debt instruments, also means the trustee of the indenture trust.

I. ''Insurer'' means the insurer or guarantor of, or provider of other credit support for, a trust. Notwithstanding the foregoing, a person is not an insurer solely because it holds securities representing an interest in a trust which are of a class subordinated to certificates representing an interest in the same trust.

J. ''Obligor'' means any person, other than the insurer, that is obligated to make payments with respect to any obligation or receivable included in the trust. Where a trust contains qualified motor vehicle leases or qualified equipment notes secured by leases, ''obligor'' shall also include any owner of property subject to any lease included in the trust, or subject to any lease securing an obligation included in the trust.

K. ''Excluded Plan'' means any plan with respect to which any member of the Restricted Group is a ''plan sponsor'' within the meaning of section 3(16)(B) of the Act.

L. ''Restricted Group'' with respect to a class of certificates means:

(1) Each underwriter;

(2) Each insurer;

(3) The sponsor;

(4) The trustee;

(5) Each servicer;

(6) Any obligor with respect to obligations or receivables included in the trust constituting more than 5 percent of the aggregate unamortized principal balance of the assets in the trust, determined on the date of the initial issuance of certificates by the trust; or

(7) Any affiliate of a person described in (1)–(6) above.

M. ''Affiliate'' of another person includes:

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(2) Any officer, director, partner, employee, relative (as defined in section 3(15) of the Act), a brother, a sister, or a spouse of a brother or sister of such other person; and

(3) Any corporation or partnership of which such other person is an officer, director or partner.

N. ''Control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

O. A person will be ''independent'' of another person only if:

(1) Such person is not an affiliate of that other person; and

(2) The other person, or an affiliate thereof, is not a fiduciary who has investment management authority or renders investment advice with respect to any assets of such person.

P. ''Sale'' includes the entrance into a forward delivery commitment (as defined in section Q below), provided:

(1) The terms of the forward delivery commitment (including any fee paid to the investing plan) are no less favorable to the plan than they would be in an arm's length transaction with an unrelated party;

(2) The prospectus or private placement memorandum is provided to an investing plan prior to the time the plan enters into the forward delivery commitment; and

(3) At the time of the delivery, all conditions of this exemption applicable to sales are met.

Q. ''Forward delivery commitment'' means a contract for the purchase or sale of one or more certificates to be delivered at an agreed future settlement date. The term includes both mandatory contracts (which contemplate obligatory delivery and acceptance of the certificates) and optional contracts (which give one party the right but not the obligation to deliver certificates to, or demand delivery of certificates from, the other party).

R. ''Reasonable compensation'' has the same meaning as that term is defined in 29 CFR 2550.408c–2.

S. ''Qualified Administrative Fee'' means a fee which meets the following criteria:

(1) The fee is triggered by an act or failure to act by the obligor other than the normal timely payment of amounts owing in respect of the obligations;

(2) The servicer may not charge the fee absent the act or failure to act referred to in (1);

(3) The ability to charge the fee, the circumstances in which the fee may be charged, and an explanation of how the fee is calculated are set forth in the pooling and servicing agreement; and

(4) The amount paid to investors in the trust will not be reduced by the amount of any such fee waived by the servicer.

T. ''Qualified Equipment Note Secured By A Lease'' means an equipment note:

(1) Which is secured by equipment which is leased;

(2) Which is secured by the obligation of the lessee to pay rent under the equipment lease; and

(3) With respect to which the trust's security interest in the equipment is at least as protective of the rights of the trust as would be the case if the equipment note were secured only by the equipment and not the lease.

U. ''Qualified Motor Vehicle Lease'' means a lease of a motor vehicle where:

(1) The trust holds a security interest in the lease;

(2) The trust holds a security interest in the leased motor vehicle; and

(3) The trust's security interest in the leased motor vehicle is at least as protective of the trust's rights as would be the case if the trust consisted of motor vehicle installment loan contracts.

V. ''Pooling and Servicing Agreement'' means the agreement or agreements among a sponsor, a servicer and the trustee establishing a trust. In the case of certificates which are denominated as debt instruments, ''Pooling and Servicing Agreement'' also includes the indenture entered into by the trustee of the trust issuing such certificates and the indenture trustee.

For a more complete statement of the facts and representations supporting the Department's decision to grant the exemption, refer to the notice of proposed exemption published on February 13, 1996 at 61 FR 5577.

FOR FURTHER INFORMATION CONTACT: Gary Lefkowitz of the Department, telephone (202)219–8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemptions do not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and

beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, D.C., this 29th day of March, 1996.

Ivan Strasfeld,

Director of Exemption Determinations Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 96–8137 Filed 4–2–96; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL SCIENCE FOUNDATION

Collection of Information Submission for OMB Review; Comments Requested by April 16, 1996, Title of Proposed Collection, ''Science Resources Studies Customer Satisfaction Survey''

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, on Tuesday, April 11, 1995, Federal Register, Vol. 60, No. 69 18427, the National Science Foundation (NSF) published, for public comment, a proposed generic clearance for collection of information, ''generic Clearance—NSF Surveys to Measure Customer Satisfaction.'' *No Public comments were received.* A proposed collection to be considered under that generic clearance is being forwarded to the Office of Management and Budget for consideration. Comments on the proposed data collection plans and instruments may be directed to OMB at the following address: Office of Management and Budget, IRA, ATTN.: Jonathan Winer, New Executive Office Building, Room 3208, Washington, DC 20503.

Written comments should be received by April 16, 1996.

Abstract: This survey is to be directed at actual and potential users of NSF's science and engineering data and analyses. It is not intended to develop a national sampling frame representing this entire community. Instead, it shall focus on a smaller group of actual and potential users with some well defined pertinent characteristics. The primary objective of this survey is to determine the kind and quality of science and engineering policy information desired by these users and their level of satisfaction with existing information.

Respondents and burden hours: 200 respondents at approximately 30 minutes per response.

Dated: March 28, 1996.

Herman G. Fleming,

NSF Clearance Officer.

[FR Doc. 96–8073 Filed 4–2–96; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. Type of submission, new, revision, or extension: Revision/Extension.

2. The title of the information collection: 10 CFR Part 100, Appendix A, ''Seismic and Geologic Siting Criteria for Nuclear Power Plants.''

3. The form number if applicable: Not applicable.

4. How often the collection is required: As necessary in order for NRC to assess the adequacy of proposed seismic design bases and the design bases for other geological hazards for nuclear power plants constructed and licensed in accordance with 10 CFR Part 50 and the Atomic Energy Act of 1954, as amended.

5. Who will be required or asked to report: Applicants and licensees for nuclear power plants.

6. An estimate of the number of responses: 1.

7. The estimated number of annual respondents: 2.

8. An estimate of the total number of hours needed annually to complete the requirement or request: 10,000.

9. An indication of whether Section 3507(d), Pub. L. 104–13 applies: Not applicable.

10. Abstract: Utilities that propose to build and operate nuclear power plants are required to design, construct, and maintain those plants to withstand geologic hazards, such as faulting, seismic hazards, and the maximum credible earthquake, to protect the health and safety of the public and the environment. NRC uses the information required by 10 CFR Part 100, Appendix A, to assess the adequacy of proposed seismic design bases and the design bases for other geological hazards for nuclear power plants.

A copy of the submittal may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC. Members of the public who are in the Washington, DC, area can access the submittal via modem on the Public Document Room Bulletin Board (NRC's Advanced Copy Document Library) NRC subsystem at FedWorld, 703–321–3339. Members of the public who are located outside of the Washington, DC, area can dial FedWorld, 1–800–303–9672, or use the FedWorld Internet address: fedworld.gov (Telnet). The document will be available on the bulletin board for 30 days after the signature date of this notice. If assistance is needed in accessing the document, please contact the FedWorld help desk at 703–487–4608. Additional assistance in locating the document is available from the NRC Public Document Room, nationally at 1–800–397–4209, or within the Washington, DC, area at 202–634–3273.

Comments and questions should be directed to the OMB reviewer by May 3, 1996: Peter Francis, Office of Information and Regulatory Affairs (3150–0093), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo Shelton, (301) 415–7233.

Dated at Rockville, Maryland, this 27th day of March 1996.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 96–8102 Filed 4–2–96; 8:45 am]

BILLING CODE 7590–01–P

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. Type of submission, new, revision, or extension: Revision/Extension.

2. The title of the information collection: Exercise of Discretion for an Operating Facility, NRC Enforcement Policy (NUREG–1600).

3. The form number if applicable: Not applicable.

4. How often the collection is required: On occasion.

5. Who will be required or asked to report: Nuclear power reactor licensees.

6. An estimate of the number of responses: 1.

7. The estimated number of annual respondents: 36.

8. An estimate of the total number of hours needed annually to complete the requirement or request: 2,160.

9. An indication of whether Section 3507(d), Pub. L. 104–13 applies: Not applicable.

10. Abstract: The NRC's revised Enforcement Policy includes the circumstances in which the NRC may exercise enforcement discretion. This enforcement discretion is designated as a Notice of Enforcement Discretion (NOED) and relates to circumstances which may arise where a licensee's compliance with a Technical Specification Limiting Condition for Operation or with other license conditions would involve an unnecessary plant transient or performance of testing, inspection, or system realignment that is inappropriate for the specific plant conditions, or unnecessary delays in plant startup without a corresponding health and safety benefit. A licensee seeking the issuance of a NOED must provide a written justification, which documents the safety basis for the request and provides whatever other information the NRC staff deems necessary to decide whether or not to exercise discretion.

A copy of the submittal may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC. Members of the public who are in the Washington, DC, area can access the submittal via modem on the Public Document Room Bulletin Board (NRC's Advanced Copy Document Library) NRC subsystem at FedWorld, 703–321–3339. Members of the public who are located outside of the Washington, DC, area can dial FedWorld, 1–800–303–9672, or use the FedWorld Internet address: fedworld.gov (Telnet). The document will be available on the bulletin board for 30 days after the signature date of this notice. If assistance is needed in accessing the document, please contact the FedWorld help desk at 703–487–4608. Additional assistance in locating the document is available from the NRC Public Document Room, nationally at 1–800–397–4209, or within the Washington, DC, area at 202–634–3273.

Comments and questions should be directed to the OMB reviewer by May 3, 1996: Peter Francis, Office of Information and Regulatory Affairs (3150–0136), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 415–7233.

Dated at Rockville, Maryland, this 27th day of March 1996.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 96–8103 Filed 4–2–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 50–498 and 50–499]

Houston Lighting and Power Company, City Public Service Board of San Antonio Central Power and Light Company, City of Austin, Texas; Notice of Consideration of Issuance of Amendments to Facility Operating Licenses; Proposed Involves No Significant Hazards; Consideration, Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License Nos. NPF–76 and NPF–80, issued to Houston Lighting & Power Company, et. al., (the licensee) for operation of the South Texas Project, Units 1 & 2, located in Matagorda County, Texas. The original application dated May 30, 1995, was previously published in the Federal Register on July 19, 1995 (60 FR 37092). That application was supplemented by letter dated February 8, 1996.

The proposed amendment would increase the spent fuel pool heat load licensing basis to provide greater flexibility for normal refueling practices.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 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:

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated because:

(a) The Spent Fuel Pool conditions are not indicative of accident initiators.

(b) Design and operability requirements of equipment important to safety are not affected.

(c) Spent Fuel Pool boiling will not occur and the Spent Fuel Pool components will remain within their design bases.

(d) The complete loss of Spent Fuel Pool cooling event has previously been analyzed and described in Supplement 6 to the Safety Evaluation Report, Appendix BB. The dose consequences for this event have been evaluated and the safety evaluation is described in Updated Final Safety Analysis Report Section 9.1.3.3.4. The results of the evaluation show that the Spent Fuel Pool components would remain within their design bases. Also, the dose consequences of iodine release as a result of Spent Fuel Pool boiling are significantly below the allowable dose limits of 10 CFR 100.

2. The proposed changes do not create the possibility of a new or different kind of accident from any accident previously because:

(a) The operability of safety-related equipment is not impacted.

(b) The probability of safety-related equipment malfunctioning is not increased.

(c) The scope of the change does not establish a potential new accident precursor.

(d) The Spent Fuel Pool design considers design basis heat loads for the modified refueling procedure which includes a full-core offload.

(e) For the design basis case, the integrity of the Spent Fuel Pool Boraflex is not adversely impacted.

3. The proposed changes do not involve a significant reduction in a margin of safety because:

(a) No fuel damage would occur as a result of the proposed change.

(b) Technical Specification operability and surveillance requirements are not reduced.

(c) The Spent Fuel Pool boiling doses would be significantly below the allowable dose limits of 10 CFR 100.

(d) The modified refueling procedure (full-core offload) continues to have acceptable margins of safety.

(e) The integrity of the Spent Fuel Pool Boraflex is not adversely impacted.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-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 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By May 3, 1996, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to William D. Beckner, Director, Project Directorate IV–1: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Jack R. Newman, Esq., Newman & Holtzinger, P.C., 1615 L Street, N.W., Washington, D.C. 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 amendment dated May 30, 1995, as supplemented by letter dated February 8, 1996, 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 Wharton County Junior College, J.M. Hodges Learning Center, 911 Boling Highway, Wharton, TX 77488.

Dated at Rockville, Maryland, this 27th day of March 1996.

For the Nuclear Regulatory Commission
Thomas W. Alexion,
Project Manager, Project Directorate IV–1, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 96–8100 Filed 4–2–96; 8:45 am]
BILLING CODE 7590–01–P

[IA 96–018]

Donald J. McDonald, Jr.; Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)

I

Mr. Donald J. McDonald, Jr., was employed as an Authorized Nuclear In-service Inspector for Factory Mutual Engineering, which is owned by Arkwright Mutual Insurance Company, Inc., a contractor of the Illinois Power Company (Licensee). Licensee is the holder of License No. NPF–62 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 50 on April 17, 1987. The license authorizes the operation of Clinton Power Station (facility) in accordance with the conditions specified therein. The facility is located on the Licensee's site in Clinton, Illinois.

II

Mr. McDonald first applied for unescorted access to the Clinton Power Station by completing a background screening questionnaire on March 22, 1994. In response to a question on the questionnaire as to whether he had ever been convicted of a felony or misdemeanor, he listed one driving while under the influence conviction (DWI). However, unescorted access was not pursued further at the time. Mr. McDonald completed a second background screening questionnaire on November 3, 1994, in which he listed no criminal history in response to the same question. Subsequently, the Licensee submitted fingerprint cards to the Federal Bureau of Investigations (FBI) and was informed that Mr. McDonald had a record of three convictions. Illinois Power Company denied Mr. McDonald unescorted access to the Clinton Power Station. The investigation also determined that Mr. McDonald had falsified his educational record.

The NRC Office of Investigations conducted a transcribed interview of Mr. McDonald on November 30, 1995. When asked by the NRC Investigator about the failure to list the convictions on the background screening questionnaires, Mr. McDonald admitted that he knowingly provided inaccurate and incomplete information.

III

Based on the above, Mr. McDonald engaged in deliberate misconduct on March 22, 1994, and November 3, 1994, in that he deliberately provided incomplete and inaccurate information on two different access authorization applications. The Commission's regulations in 10 CFR 50.5, in part, prohibit any employee of a contractor of a licensee from deliberately submitting to the licensee information that the employee knows to be incomplete or inaccurate in some respect material to the NRC. Information concerning criminal history and educational history is material to the determination the licensee must make in granting or denying unescorted access to its facility pursuant to 10 CFR 73.56(b)(2). Mr. McDonald's actions constituted a violation of 10 CFR 50.5(a).

The NRC must be able to rely on the Licensee, its contractors, and contractor employees to comply with NRC requirements, including the requirement to provide information that is complete and accurate in all material respects. Mr. McDonald's actions in deliberately providing incomplete and inaccurate information to the Licensee constituted deliberate violations of Commission regulations and raised serious doubt as to whether he can be relied upon to comply with NRC requirements and to provide complete and accurate information to the NRC in the future.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Mr. McDonald were permitted at this time to be involved in NRC-licensed activities or were permitted unescorted access to protected or vital areas of NRC-licensed facilities. Therefore, the public health, safety and interest require that Mr. McDonald be prohibited from any involvement in NRC-licensed activities and be prohibited from obtaining unescorted access for a period of three years from the date of this Order and, if Mr. McDonald is currently involved with an employer in NRC-licensed activities, he must immediately cease such activities, inform the NRC of the name, address and telephone number of the employer, and provide a copy of this Order to the employer. Additionally, for his first acceptance of an employment offer involving NRC-licensed activities or the assumption of duties in an existing job involving NRC-licensed activities following the three

year period of prohibition, Mr. McDonald shall provide notice to the NRC within 20 days of the acceptance of the name, address, and telephone number of the employer or the entity where he is, or will be, involved in the NRC-licensed activities, and certify that he will comply with NRC regulatory requirements in such employment. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of Mr. McDonald's conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 103, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, and 10 CFR 50.5, *it is hereby ordered*, effective immediately, that:

1. (a) Mr. Donald J. McDonald, Jr., is prohibited from engaging in NRC-licensed activities and from obtaining unescorted access to protected and vital areas of facilities licensed by the NRC for a period of three years from the date of this Order. For the purposes of this Order, licensed activities include the activities licensed or regulated by: (1) NRC; (2) an Agreement State, limited to the licensee's conduct of activities within NRC jurisdiction pursuant to 10 CFR 150.20; and (3) an Agreement State where the licensee is involved in the distribution of products that are subject to NRC jurisdiction.

(b) If Mr. McDonald is currently involved in NRC-licensed activities with an employer, he shall immediately cease such activities, inform the NRC of the name, address and telephone number of the employer, and provide a copy of this Order to the employer.

2. Following the three year period of prohibition, at the time of his first acceptance of an employment offer involving NRC licensed activities as defined in Paragraph IV.1 above, or the first assumption of duties in an existing job that involve licensed activities, Mr. McDonald shall provide notice to the NRC within 20 days of the acceptance or assumption of duties of the name, address, and telephone number of the employer or the entity where he is, or will be, involved in the NRC-licensed activities. This notice (a) shall be provided to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555, and (b) shall certify Mr. McDonald's commitment to compliance with regulatory requirements and provide the basis as to why the Commission should have confidence that Mr. McDonald will now comply with applicable NRC requirements.

The Director, OE, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. McDonald of good cause.

V

In accordance with 10 CFR 2.202, Mr. McDonald must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, and include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Mr. McDonald or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, IL 60532–4351, and to Mr. McDonald if the answer or hearing request is by a person other than Mr. McDonald. If a person other than Mr. McDonald requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Mr. McDonald or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Mr. McDonald, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

Dated at Rockville, Maryland this 27th day of March 1996.

For the Nuclear Regulatory Commission.

James L. Milhoan,

Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research.

[FR Doc. 96–8101 Filed 4–3–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–286]

Power Authority of the State of New York, Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–64 issued to New York Power Authority for operation of the Indian Point Nuclear Generating Unit No. 3 (IP3) located in Westchester County, New York.

The proposed amendment would allow a one-time extension of the test intervals for the pressurizer safety valve (PSV) setpoint and snubber functional testing that is due in may 1996.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 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:

A. Pressurizer Safety Valves

(1) Does the proposed license amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response

The proposed license amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated. As discussed in Section II, ''Evaluation of Changes,'' based on the analysis of the test results for the past four outages, there is a high level of confidence that PSV setpoint drift at IP3 is not time dependent. Past test results also indicate that out of 69 set pressure ''pops'', 46 were within plus or minus 1% of the 2485 psig setpoint and only two test results exceeded plus or minus 3% allowance. These test results indicate a high degree of reliability for the PSVs. Therefore, a one-time extension of the test interval for the PSVs till the next refueling outage but no later than May 31, 1997 is not expected to adversely affect the functioning of the PSVs and will not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Does the proposed license amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response

The proposed license amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change does not involve the addition of any new or different type of equipment, nor does it involve operating equipment required for safe operation of the facility in a manner different than addressed in the Final Safety Analysis Report. Also, as stated, the increased surveillance interval (one-time only) is not expected to adversely affect the functioning of the PSVs and will not result in any new failure modes. Therefore, the proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Does the proposed amendment involve a significant reduction in a margin of safety?

Response

The proposed license amendment does not involve a significant reduction in a margin of safety. The proposed change, for one-time extension of the test interval, for the PSVs does not adversely affect the performance of any safety related system, component or instrument or safety system setpoints and does not result in increased severity of any of the accidents considered in the safety analysis. Based on past test results, the one-time extension for the PSV testing should not adversely affect the lift settings or the relieving capacities of the valves, and the safety limit of 2735 psig (110% of design pressure) as described in Section 2.2 of the Technical Specifications will be protected. Therefore, this change does not create a significant reduction in a margin of safety.

B. Snubbers

(1) Does the proposed license amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response

The proposed license amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated. An inoperable snubber could cause an increase in probability of structural damage to piping in the event of thermal or dynamic loads. As discussed in Section II, ''Evaluation of Changes,'' based on the last six snubber functional tests, 136 snubbers were functionally tested and only 1 snubber failure was noted. Thus, past snubber functional test results indicate a high degree of reliability for the snubbers. Furthermore, past test results also indicate a high level of confidence that snubber failure at IP3 is not time dependent. Therefore, a one-time extension of the functional test interval for the snubbers till the next refueling outage but no later than May 31, 1997, will not significantly increase the probability of snubber inoperability and will not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Does the proposed license amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response

The proposed license amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change does not involve the addition of any new or different type of equipment, nor does it involve the operation of equipment required for safe operation of the facility in a manner different from those addressed in the Final Safety Analysis Report. Also, as stated, the proposed one-time interval extension is not expected to adversely affect the functioning of the snubbers and will not result in any new failure modes. Therefore, the proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Does the proposed amendment involve a significant reduction in a margin of safety?

Response

The proposed license amendment does not involve a significant reduction in a margin of safety. The proposed change, for one-time extension of the test interval, for the snubber functional testing does not adversely affect the performance of any safety related system, component or instrument or safety system setpoints and does not result in increased severity of any of the accidents considered in the safety analysis. Also, snubber visual inspection frequency is based on maintaining a constant level of snubber protection to systems, and the visual inspection frequency will remain the same. Therefore, this one-time functional testing extension has no adverse effect on any margin of safety and, therefore, does not create a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-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 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By May 3, 1996, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the White Plains Public Library, 100 Martine Avenue, White Plains, New York 10601. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1- (800) 248–5100 (in Missouri, 1- (800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Susan F. Shankman: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Mr. Charles M. Pratt, 10 Columbus Circle, New York, New York 10019, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated March 14, 1996, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the White Plains Public Library, 100 Martine Avenue, White Plains, New York 10601.

Dated at Rockville, Maryland, this 28th day of March 1996.

For the Nuclear Regulatory Commission.

George F. Wunder,

Project Manager, Project Directorate I–1, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 96–8098 Filed 4–2–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 50–373 and 50–374]

Commonwealth Edison Company; Lasalle County Station, Units 1 and 2 Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from the requirements of Appendix J to 10 CFR Part 50 for Facility Operating License Nos. NPF–11 and NPF–18, issued to Commonwealth Edison Company (ComEd, the licensee), for

operation of the LaSalle County Station, Units 1 and 2, located in LaSalle County, Illinois.

Environmental Assessment

Identification of Proposed Action

Section III.A.5(b) of Appendix J to 10 CFR Part 50 contains acceptance criteria for the maximum allowable measured leakage rates from a plant's primary reactor containment structure for Type A leakage tests at both a reduced pressure and at a peak pressure.

Section III.C.3 of 10 CFR Part 50, Appendix J, contains acceptance criteria for the combined leakage rate for: (1) all primary reactor containment penetrations as defined in Section II.G which are subject to Type B tests; and (2) all containment isolation valves as defined in Section II.H which are subject to Type C tests.

The exemption request will replace a portion of a prior exemption granted in NUREG–0519, ''Safety Evaluation Report Related to the Operation of LaSalle County Station Units 1 and 2,'' (SER) dated March 1981, as modified by Supplement No. 6 to that SER, dated November 1983. The exemption request will raise the maximum allowable TS value of the main steamline isolation valve (MSIV) leakage rate through all four of the main steamlines to 400 standard cubic feet per hour (scfh) from the present value of 100 scfh. This exemption request was submitted by ComEd in its letter dated August 28, 1995, in conjunction with its request for license amendments for Units 1 and 2. These amendment requests propose to delete the present MSIV leakage control system (LCS) and replace this system with an alternate leakage treatment (ALT) path for leakage past the MSIVs in the event of a design basis accident loss-of-coolant (DBA–LOCA).

The Need for the Proposed Action

The proposed exemption would allow the licensee to continue to perform the Type A, B and C tests in the same manner required by 10 CFR Part 50, Appendix J, without penalizing the performance of these primary reactor containment leakage tests by including the proposed increase in the TS allowable leakage past the MSIVs. Specifically, the exemption granted in NUREG–0519 and its supplement cited above, excluded the MSIV leakage from the Type A, B and C tests and the present exemption will also continue to do so but at a higher allowable MSIV leakage rate.

Environmental Impacts of the Proposed Action

The radiological consequences of a potential release of fission products through the ALT path would be still subject to the radiation exposure guidelines at the site boundary as contained in 10 CFR Part 100 and also subject to the control room dose guidelines in General Design Criteria (GDC) 19 of Appendix A to 10 CFR Part 50. In addition, the licensee has demonstrated that the ALT path would remain structurally sound in the event of the design basis earthquake. Accordingly, granting of the requested exemption will still satisfy the requirement of limiting radiation exposures to acceptable limits in the event of a DBA–LOCA.

Specifically, both the MSIV leakage and the primary containment leakage, is used to calculate the maximum radiological consequences of a postulated DBA–LOCA as shown in Table 15.2 of NUREG–0519. (Table 15.1 of Supplement No. 6 to NUREG–0519 replaced this earlier table.) Conservative assumptions were used in the staff's reevaluation of the offsite and control room doses, including the doses due to the increased TS allowable MSIV leakage, which could result from a postulated DBA–LOCA. The staff's analyses demonstrate that the proposed leakage rate of 400 scfh past all the MSIVs results in potential dose exposures to the public which remain within the guideline exposure limits in 10 CFR Part 100. These analyses also demonstrate that the potential doses to the control room personnel meet the requirements in GDC 19 of Appendix A to 10 CFR Part 50.

With respect to the proposed deletion of the MSIV–LCS, this action will reduce the overall occupational radiation dose exposures and reduce the generation of low level radioactive waste due to the elimination of maintenance and surveillance activities associated with the present LCS. The dose exposure associated with deleting the LCS will satisfy the as low as reasonably achievable (ALARA) requirements in 10 CFR Part 20 and will be less than the radiation doses which would result from maintenance and surveillance activities associated with the present leakage control system if it were continued to be used for the remainder of the station's life. Accordingly, the potential releases will not differ significantly from those determined previously, and the proposed amendments do not otherwise affect facility radiological effluent or occupational exposures.

Therefore, there will not be a significant increase in the types and amounts of any effluent that may be released offsite and, as such, the proposed amendments do not alter any initial conditions assumed for the DBAs previously evaluated. Finally, the proposed ALT path is capable of mitigating the radiological consequences of these postulated DBAs.

Furthermore, the proposed exemption will not result in a significant increase to the LOCA doses previously evaluated against the offsite dose guideline values contained in 10 CFR Part 100 and in the limits in GDC 19 of Appendix A to 10 CFR Part 50.

With regard to potential nonradiological impacts, the proposed actions involve features located entirely within the restricted area as defined in 10 CFR Part 20. They do not affect nonradiological plant effluents and have no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological impacts associated with the proposed actions.

The Commission concludes that: (1) the proposed actions will not increase the probability or consequences of accidents; (2) no changes are being made in the types of effluents which may be released offsite; and (3) there is no significant increase in the allowable individual cumulative occupational radiation exposure nor in radiation exposure of the public.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed actions, any alternatives with equal or greater environmental impact need not be evaluated. As an alternative to the proposed actions, the Commission considered denial of the proposed actions. Denial of the application would result in no change in current environmental impacts.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for the LaSalle County Station dated November 1978.

Accordingly, the impacts of the proposed action and the alterative action are similar.

Agencies and Persons Consulted

In accordance with its stated policy, on February 21, 1996, the NRC staff consulted with the Illinois State Official, Mr. Frank Niziolek, Head, Reactor Safety Section, Division of Engineering, Illinois Department of

Nuclear Safety; 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 exemption.

For further details with respect to the proposed action, see the request for exemption dated August 28, 1995, 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 Jacobs Memorial Library, Illinois Valley Community College, Oglesby, Illinois 61348.

Dated at Rockville, Maryland, this 26th day of March 1996.

For the Nuclear Regulatory Commission

Robert A. Capra,

Project Director, Project Directorate III–2, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 96–8298 Filed 4–2–96;8:45am]

BILLING CODE 7590–01–P

[Docket Number 40–6622]

Pathfinder Mines Corporation

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final Finding of No Significant Impact of Mill Decommissioning; Notice of Opportunity for Hearing.

SUMMARY: Notice is hereby given that the U.S. Nuclear Regulatory Commission has amended Pathfinder Mines Corporation's (PMC's) Source Material License SUA–442 for the Shirley Basin facility on finding of no significant impact due to mill decommissioning. The Mill Decommissioning Plan, its Supplemental Environmental Report, and a license amendment request were submitted by PMC's letters dated July 1, 1992, February 3, 1993, and November 30, 1994, respectively. An Environmental Assessment was performed by the NRC staff 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.

SUPPLEMENTARY INFORMATION:

Background

PMC's Shirley Basin Mill is wholly owned by Cogema, Inc. The mill is located at Shirley Basin in Carbon County, Wyoming. The mill started operation in early 1971, and the last ore feed to the plant occurred in May 1992.

An environmental statement for the uranium milling facility was prepared in December 1974, by the United States Atomic Energy Commission. Subsequent to this statement, the mill was operated and the environment was monitored. In consideration of PMC's application dated August 19, 1982, for renewal of Source Material License SUA–442, the NRC staff issued a detailed Environmental Assessment (EA) on September 14, 1984.

The decommissioning plan discusses the processes involved in dismantling and disposing of the mill and associated buildings at the Shirley Basin mill. Details of the final disposal of the dismantled mill are included as part of the site reclamation plan. The decommissioning plan also includes PMC's plan to survey areas around the mill site for contamination by areal gamma scan and soil sampling.

Included in the plan's description of dismantling the site facilities is a discussion of the radiation safety program to be used during the decommissioning. In general, the in-place radiation program was to be relied on with minor changes focusing on the problems associated with decommissioning and dismantling. The plan maintains emphasis on occupational health physics, even though the problems related to daughter products of uranium during operation will be reduced. The plan indicates that the decommissioning will be completed such that personnel exposures are as low as reasonably achievable (ALARA) by including pre-decommissioning cleaning of the facility, use of standard operating procedures and radiation work permits, and establishment of administrative dose limits.

Review Scope

The environmental review of PMC's request for approval of its decommissioning at the Shirley Basin Mill site included evaluation of the Mill Decommissioning Plan dated June 1992, and the accompanying Mill Decommissioning Environmental Report Supplement dated February 1993. In addition, PMC submitted a letter dated May 19, 1994, clarifying that materials and spare equipment parts in the salvage yard, which were radioactively contaminated and could not be cleaned to meet releasable limits, would be buried at the mill site or in the tailings ponds. This clarification is in agreement with the 1992 Decommissioning Plan which states on page 3–1 ''Equipment and materials that can not be decontaminated for release for unrestricted use will be disposed of by burial at the mill site or within the tailings impoundment* * *''

Environmental Assessment

The staff evaluated the decommissioning plan submitted by PMC. The plan satisfies the needs of 10 CFR Part 20 and 10 CFR Part 40 and is similar to other decommissioning plans for mill facilities. The plan appropriately focuses on the implementation of the ALARA program during decommissioning and demolition of the mill buildings. Environmental monitoring plans for contamination on the property satisfy the requirements to identify areas that require clean-up. PMC intends to dispose of the concrete floor of the mill building in place, after survey for unrestricted release, and will fracture the floor before final cover placement. The fracturing of the concrete floor is intended to eliminate ponding in the two-foot cover. The contaminated equipment and buildings are to be disposed of in an interim burial pit; final disposal will occur during future reclamation activities.

The environmental impacts associated with this licensing action are within the scope of the detailed EA issued by the NRC staff, dated September 14, 1984. No further assessment of this decommissioning action is necessary.

Conclusion

The staff has no technical objections related to radiological safety for the submitted decommissioning plan for the Shirley Basin Mill. The plan provides for mill and site decommissioning that will be completed in accordance with the regulations of 10 CFR Part 20 and 10 CFR Part 40. Inspection staff should be cognizant that the submitted plan referenced old Part 20, while the actual decommissioning of the mill was to be done under the current 10 CFR Part 20.

Alternatives to the Proposed Action

Since the NRC staff has concluded that there are no significant environmental impacts associated with the proposed action, any alternatives with equal or greater environmental impacts need not be evaluated. The principal alternative to the proposed action would be to deny the requested action. Since the environmental impacts of the proposed cleanup action are

obviously less than this no-action alternative, there is no need to further evaluate alternatives to the proposed action.

Finding of No Significant Impact

The conclusion of the Environmental Assessment is a Finding of No Significant Impact (FONSI) for this licensing action. Therefore, preparation of an Environmental Impact Statement is not warranted.

PMC's amended License, and the Environmental Assessment prepared by NRC staff are being made available for public inspection at the Commission's Public Document Room at 2120 L Street, NW (Lower Level), Washington, DC 20555.

Notice of Opportunity for Hearing

The NRC hereby provides notice of an opportunity for a hearing on the license amendment under the provisions of 10 CFR Part 2, Subpart L, ''Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings.'' Pursuant to § 2.1205(a), any person whose interest may be affected by this proceeding may file a request for a hearing. In accordance with § 2.1205(c), a request for hearing must be filed within 30 days of the publication of this notice in the Federal Register. 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.

In accordance with 10 CFR 2.1205(e), each request for a hearing must also be served, by delivering it personally or by mail, to:

(1) The applicant, Pathfinder Mines Corporation, 935 Pendell Boulevard, P.O. Box 730, Mills, Wyoming 82644, Attention: Tom Hardgrove; and

(2) The NRC staff, by delivery to the Executive Director for Operations, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852 or 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 NRC'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).

The request must also set forth the specific aspect or aspects of the subject matter of the proceeding as to which petitioner wishes a hearing.

FOR FURTHER INFORMATION CONTACT: Mohammad W. Haque, Uranium Recovery Branch, Division of Waste Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone (301) 415–6640.

Dated at Rockville, Maryland, this 26th day of March 1996.

Joseph J. Holonich,

Chief, Uranium Recovery Branch Division of Waste Management Office of Nuclear Material Safety and Safeguards.

[FR Doc. 96–8099 Filed 4–2–96; 8:45 am]

BILLING CODE 7590–01–P

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on May 3, 1996. The ACMUI will discuss the Advance Notice for Proposed Rulemaking for 10 CFR Part 33 and prepare for an afternoon Commission briefing (to be noticed separately). All sessions of the meeting will be open to the public.

DATES: The meeting will begin at 8 a.m., on May 3, 1996. The Commission briefing will begin at 2 p.m. on May 3, 1996.

ADDRESS: The morning session will be held at the U.S. Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Room T2B3, Rockville, MD 20852–2738. The Commission briefing will be held at the U.S. Nuclear Regulatory Commission, in the Commissioners' hearing room, located on the lobby level of One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738.

FOR FURTHER INFORMATION, CONTACT: Patricia K. Holahan, Ph.D., U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, MS T8F5, Washington, DC 20555, Telephone (301) 415–7847. For administrative information, contact Torre Taylor, (301) 415–7900.

Conduct of the Meeting:

Barry Siegel, M.D., will chair the meeting. Dr. Siegel will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit a reproducible copy to Patricia K. Holahan (address listed previously), by April 26, 1996. Statements must pertain to the topics on the agenda for the meeting.

2. At the meeting, questions from members of the public will be permitted at the discretion of the Chairman.

3. The transcript and written comments will be available for inspection, and copying, for a fee, at the NRC Public Document Room, 2120 L Street, N.W., Lower Level, Washington, DC 20555, telephone (202) 634–3273, on or about May 14, 1996. Minutes of the meeting will be available on or about June 7, 1996.

4. Seating for the public will be on a first-come, first-served basis.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, *U.S. Code of Federal Regulations,* Part 7.

Dated: March 28, 1996

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 96–8104 Filed 4–2–96; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–21862/International Series Release No. 960; 812–9916]

Compañía de Minas Buenaventura S.A.; Notice of Application

March 28, 1996.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the ''Act'').

APPLICANT: Compañía de Minas Buenaventura S.A.

RELEVANT ACT SECTIONS: Applicant requests an order under section 3(b)(2) or, in the alternative, section 6(c).

Applicant also requests an order under section 45(a).

SUMMARY OF APPLICATION: Applicant requests an order declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities, and therefore is not an ''investment company'' as defined in the Act. In the alternative, Applicant seeks an order exempting it from all provisions of the Act. Applicant also seeks an order granting confidential treatment with respect to certain asset valuation information.

FILING DATES: The application was filed on December 21, 1995 and an amended and restated application was filed on March 19, 1996.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on April 18, 1996, and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reasons for the request, and the issues contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant: Carlos Villarán 790, Santa Catalina, Apartado 2055, Lima 13, Peru with a copy to Douglas W. Jones, Esq., or Arnold B. Peinado III, Esq., Milbank, Tweed, Hadley & McCloy, 1 Chase Manhattan Plaza, New York, New York 10005–1413.

FOR FURTHER INFORMATION CONTACT: H.R. Hallock, Jr., Special Counsel at (202) 942–0564 or Robert A. Robertson, Branch Chief, (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is a Peruvian ''sociedad anónima,'' an entity similar to a corporation established under state law in the United States. Applicant's common shares (a class of voting equity securities) and ''labor'' shares (a class of non-voting equity securities) have been listed in Peru on the *Bolsa de Valores de Lima* (the ''Lima Stock Exchange'') since the 1970s. As of December 31, 1995, Applicant had a total market capitalization of S/.1,577,091,515 (US$682,723,600),[1] making it one of the largest companies on the Lima Stock Exchange.

2. Applicant was founded in 1953 by Mr. Alberto Benavides de la Quintana, the Chairman and Chief Executive Officer of Applicant, to engage in the mining business in Peru. Other members of Mr. Benavides' family (collectively, the ''Benavides Family'') serve as officers or directors of Applicant and its subsidiaries, and one of them directs Applicant's exploration projects. The Benavides Family currently owns approximately 42% of Applicant's outstanding common shares. No other shareholder or group of shareholders owns a greater share percentage, and, as a result, the Benavides Family effectively controls Applicant.

3. Since 1953, Applicant has been principally engaged in the exploration and development of mining properties in Peru, the mining and processing of gold, silver, zinc and other metals, and the sale worldwide of its mining products. Until the 1980s, Applicant's revenue was principally derived from silver mining. Applicant began to diversify in the 1980s, and now gold mining accounts for a significant part of its revenues. Applicant is Peru's largest private producer of silver, and Minera Yanacocha S.A. (''Yanacocha''), which is 43.65% owned by Applicant through its 99.99% owned subsidiary, Compañía Minera S.A. (''Condesa''), is South America's largest producer of gold.

4. Applicant currently conducts its mining operations directly and through various majority-owned subsidiaries, Yanacocha (a controlled company) and other affiliated companies. Although Applicant has tended to place significant new mining prospects into separate subsidiaries, Applicant continues to hold directly two significant mining properties, Julcani and Uchucchacua. Applicant and such majority-owned subsidiaries, Yanacocha and other affiliated companies are engaged solely in mining or ancillary businesses.

5. Applicant currently has ten majority-owned subsidiaries, seven of which are principally engaged in the mining business in Peru.[2] The most significant majority-owned subsidiaries, in terms of assets, currently are Orcopampa, Shila and Iminsur. Orcopampa, which has its labor shares listed on the Lima Stock Exchange, is currently Peru's fifth largest gold producer. Shila and Iminsur are currently Peru's ninth and twelfth largest producers of gold, respectively. In contrast, the aggregate value of the three majority-owned subsidiaries that provide ancillary services to mining, BISA (engineering), Contacto (insurance) and CONENHUA (electric power), was S/.21.945,000 (US$9,500,000), or only about 2.68% of Applicant's total assets at December 31, 1995.

6. Yanacocha was formed in 1992 by the Applicant (acting through Condesa), in association with Newmont Second Capital Corporation (''Newmont Second''), a wholly-owned subsidiary of Newmont Gold Company (''Newmont'') and Societé d'Etudes, de Recherches et d'Exploitations Minières (''SEREM''), then a wholly-owned subsidiary of Bureau de Recherches Geólogiques et Minières (''BRGM''), to explore for and exploit large-scale gold deposits in northern Peru. Newmont and BRGM are both international mining companies. Condesa acquired only a minority position in Yanacocha principally because of the large expected capital investment in the project and Applicant's desire to diversify its risk and benefit from a strategic alliance with Newmont and BRGM.

7. Currently, Applicant (through Condesa) owns 43.65% of Yanacocha, with the balance owned by Newmont Second (51.35%) and the International Finance Corporation (''IFC'') (5%).[3] Applicant is involved in legal proceedings in the Peruvian courts regarding its ownership of shares representing an 11.35% interest in Yanacocha. One of the issues in dispute in these proceedings is the valuation of

[1] References to ''S/.'' are to Peruvian Nuevos Soles. United States dollar amounts have been translated at the exchange rate of S/.2.31 per US $1.00, the average rate for dollars on December 31, 1995, as published by the Peruvian ''Superintendencia de Banca y Seguros'' (the Superintendency of Banks and Insurance).

[2] Buenaventura Ingenieros S.A. (''BISA'') (99.99%), Contacto Corredores de Seguros S.A. (''Contacto'') (99.98%), Compañía de Minas Orcopampa S.A. (''Orcopampa'') (83.43%), Minera Shila S.A. (''Shila'') (67.45%), Compañía Minera Colquirrumi S.A. (55.94%)/. Compañía de Minas Recuperada S.A. (86.40%), Metalúrgica Los Volcanoes S.A. (83.42%), Condesa (99.99%), Inversions Mineras del Sur S.A. (''Iminsur'') (51%) and Consorcio Energético Huancavelica S.A. (''CONENHUA'') (85.78%).

[3] At the time of Yanacocha's organization, Condesa, Newmont Second and SEREM owned 34%, 40% and 26%, respectively, of Yanacocha's shares. In 1993, the IFC provided financing to Yanacocha in return for a 5% equity interest. In 1994, as a result of a restructuring of SEREM, BRGM transferred control of its interest in Yanacocha to an Australian mining company.

Yanacocha as of certain specified dates.[4] As a result of its greater than 25% ownership interest in Yanacocha, Applicant is presumed under section 2(a)(9) of the Act to control Yanacocha.

8. Applicant also believes that it controls Yanacocha in fact, for purposes of section 2(a)(9), through its power to exercise a controlling influence over the management and policies of Yanacocha, even though it shares control with Newmont Second. Yanacocha was created and is governed by a Peruvian legal document known as its estatutos (the ''Estatutos''), which combines the attributes of a U.S. corporation's articles of incorporation and by-laws. Pursuant to the Peruvian *Ley General de Sociedades* (''Peruvian Corporations Law'') and the Estatutos, the prior consent of Condesa and Newmont Second must be obtained before certain major corporate events may occur. Thus, for example, Applicant and Newmont Second must jointly approve an increase or decrease in Yanacocha's capital; the issuance of any debt; and the merger' dissolution or liquidation of Yanacocha.

9. Pursuant to Yanacocha's Estatutos, its Board of Directors consists of six directors: three elected by Condesa and three by Newmont Second. A director elected by Newmont Second has been appointed Chairman, and Mr. Alberto Benavides has been appointed Vice Chairman, of Yanacocha's Board of Directors. The shareholders of Yanacocha also participate in an informal ''Technical Committee'' that reviews various matters, including the management of Yanacocha and its budgeted financial statements. Condesa and Newmont Second have each designated two persons on the four-member Technical Committee. Therefore, through Condesa's representatives on Yanacocha's Board of Directors and the Technical Committee, Applicant exerts significant influence over the management and direction of Yanacocha.

10. Applicant also owns interests in ten other affiliated companies.[5] The activities of these companies principally consist of exploiting mining interests in Peru (or holding interests in Peruvian mining companies). Except for the affiliated, companies, the majority-owned subsidiaries previously identified and Yanacocha, Applicant does not own any securities of any corporation or other entity. Furthermore, Applicant has continued to actively seek and evaluate potential new mining concessions throughout Peru. As a result of this exploration campaign, Applicant is one of the largest holders of mining rights in Peru.

11. Mr. Alberto Benavides holds a B.S. degree in engineering and an M.S. in geology. Most of Applicant's other directors and officers have degrees in the same fields. Applicant's directors and senior executive officers also have extensive experience in the mining industry. All of Applicant's senior executive officers, except its general counsel, devote their full time to management of the mining operations of Applicant and its majority-owned subsidiaries. None of them has experience as an investment manager or adviser, and none of them devotes any business time to investment management, apart from management of Applicant's cash. Applicant does not employ securities analysts and does not engage in the trading of securities for short-term speculative purposes, investment purposes or otherwise.

12. Applicant has not previously offered its securities in the United States. Applicant now desires, however, to offer its securities (or depositary receipts representing such securities) in the United States in registered public offerings or in private placements or to qualified institutional buyers pursuant to rule 144A under the Securities Act of 1933.

Applicant's Legal Analysis

A. Sections 3(b)(2) and 6(c)

1. Section 3(a)(3) of the Act defines an ''investment company,'' in relevant part, as any issuer that engages in the business of investing, reinvesting, owning, holding, or trading in securities, and that owns ''investment securities'' (as that term is defined in section 3(a)(3)) having a value in excess of 40% of the value of such issuer's total assets (excluding Government securities and cash items) on an unconsolidated basis.

2. Applicant may be deemed to be an investment company under section 3(a)(3) because it owns ''investment securities,'' within the meaning of section 3(a)(3), that significantly exceed 40% of its assets, principally due to the value (calculated in accordance with section 2(a)(4)) of its ownership interest in Yanacocha. Applicant does not appear to qualify for the exemption provided by rule 3a–1 under the Act because it does not meet the 45% asset and income requirements set forth in the rule, principally due to its ownership interest in Yanacocha. Even though Applicant holds a greater than 25% interest in Yanachocha, and thus is presumed to control Yanacocha, Applicant lacks the ''primary control'' required by rule 3a–1 because Newmont Second holds a larger control position.

3. As an investment company under section 3(a)(3), section 7(d) of the Act would prohibit Applicant from making a public offering of its securities in the United States. Applicant might also be prohibited from making a private placement of its securities, if, upon completion of the offering, more than 100 United States residents were beneficial owners of its securities. Accordingly, Applicant requests an order under section 3(b)(2) declaring that it is not an investment company or, in the alternative, under section 6(c) granting an exemption from all the provisions of the Act. As discussed below, Applicant also seeks an order under section 45(a) granting confidential treatment with respect to the valuation of certain of its assets.

4. Section 3(b)(2) authorizes the SEC to issue an order excepting an issuer from the section 3(a)(3) definition of an investment company if it finds the entity to be primarily engaged in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities either directly or (a) through majority-owned subsidiaries or (b) through controlled companies conducted similar types of businesses. Section 6(c) authorizes the SEC to issue an order of exemption from any or all provisions of the Act and the rules thereunder if the exemption is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

5. In determining the primary business in which a company is engaged for purposes of section 3(b)(2), the SEC traditionally has considered the following factors: (a) The company's historical development, (b) the company's public representations of policy, (c) the activities of the

[4] After BRGM's transfer of control of its Yanacocha shares in 1994, Applicant and Condesa, together with Newmont and Newmont Second, filed suit to, among other things, exercise their rights of first refusal with respect to those shares. In 1995, the Peruvian courts preliminarily ruled in favor of Applicant and the other plaintiffs, fixing a provisional aggregate sale price for the disputed Yanacocha shares at US$90 million. Condesa and Newmont Second together deposited the required funds and Yanacocha shares in escrow pending final resolution of the case, including the final purchase price of the shares. Not including the disputed shares, Applicant (through Condesa) currently has a 32.30% interest in Yanacocha.

[5] Compañía Minera Coimolanche S.A. (36.25%), Compañía de Exploraciones, Desarollo e Inversiones Mineras S.A. (35%), Sociedad Minera de Responsabilidad Limitada Chaupiloma Dos De Cajamarca (34%), Inversions Colquijirca S.A. (22%), Sociedad Minera El Brocal S.A. (11.22%), Compañía Minera Caudalosa S.A. (35.85%), Minas Conga S.R. Ltda (34%), Minera Paula 49 S.R. Ltda (17.50%), Sociedad Minera Coshuro S.A. (35%), and Sociedad Minera Cerro Verde S.A. (9.17%).

company's and directors, (d) the nature of the company's assets, and (e) the sources of the company's income.[6] Applicant submits that a review of these factors supports the conclusion that Applicant is primarily engaged, directly and through majority-owned subsidiaries and a controlled company, in the mining business.

a. *Historical Development.* Since its organization in 1953, Applicant has been engaged primarily in the mining business, and has engaged in no other business, except for businesses ancillary to its mining business. In addition to exploiting existing mining rights, Applicant is activity seeking and evaluating potential new mining concessions throughout Peru. This exploration campaign demonstrates that Applicant is and will be fully committed to the exploration and development of mining priorities and the operation and management of its operations in the foreseeable future.

b. *Public Representations of Policy.* Applicant has always held itself out to its shareholders and the public as a mining company and has never held itself out as an investment company within, the meaning of the Act. This is supported by, among other things, statements in its annual reports. In addition, Applicant has been characterized as a mining company in numerous newspaper articles and in the reports of securities analysts and other publications. Its common shares, for example, are listed in the Peruvian newspapers under the heading ''Mining Companies.''.

c. *Activities of Officers and Directors.* Applicant's senior executive officers and directors, most of whom hold engineering or geology degrees, are actively involved in Applicant's mining business. All of Applicant's senior executive officers except its general counsel devote their full time to management of the mining operations of Applicant and its majority-owned subsidiaries. None of Applicant's directors or senior executive officers provides investment advice or devotes any business time to investment management, apart from cash management. Applicant does not maintain any staff for securities investment activities.

d. *Nature of Assets.* As of December 31, 1995, the value of Applicant's total assets (exclusive of U.S. government securities and cash items and calculated in accordance with section 2(a)(41)) was S/.819,853,000 (US$354,915,000). At the same date, the value (calculated in accordance with section 2(a)(41)) of all securities owned by Applicant, other than securities of Applicant's majority-owned subsidiaries and its controlled company Yanacocha, was S/.75,640,000 (US$32,745,000) or approximately 9.23% of Applicant's total assets.

e. *Sources of Income.* Applicant has never derived any material income from selling appreciated securities and its primary source of income was and is derived directly and indirectly from its mining and mining-related operations. For the 12 months ended December 31, 1995, Applicant's net income was S/.41,231,000 (US$17,849,000). For the sasme period, Applicant's investments in investment securities represented by its affiliated companies (other than its majority-owned subsidiaries and Yanacocha) accounted for S/.9,513,000 (US$4,118,000) or a little more than 23% of Applicant's net income (about 6.6% of net income not including the gain on the sale of shares of another mining company).[7]

6. In the alternative to exemptive relief under section 3(b)(2), Applicant submits that an exemption under section 6(c) of the Act is warranted under the circumstances here. Applicant was structured for valid economic and legal reasons and not with the Act in mind. Consequently, Applicant believes that it would be inappropriate and detrimental to Applicant and its shareholders to be treated as an investment company and made subject to the Act. Furthermore, Applicant believes that it is not the type of company and does not engage in the activities the Act was designed to regulate. Accordingly, Applicant submits that requiring its compliance with the provisions of the Act would be inconsistent with the purposes fairly intended by the policy and provisions of Act and would neither be necessary or appropriate in the public interest nor consistent with the protection of investors.

B. Section 45(a)

1. Section 45(a) provides that the information contained in any application filed with the SEC under the Act shall be made available to the public, unless the SEC finds that public disclosure is neither necessary nor appropriate in the public interest or for the protection of investors. Applicant requests an order granting confidential treatment under section 45(a) for information submitted in an exhibit to the application pertaining to the value of Applicant's investments in Yanacocha and its majority-owned subsidiaries. Applicant also seeks confidential treatment of information pertaining to the percentage of total assets represented by each of these investments, since that information can be used to calculate Applicant's estimate of the value of Yanacocha.

2. Public disclosure of the value of Applicant's investments in Yanacocha and its majority-owned subsidiaries is not necessary to calculate the value of the total assets represented by Applicant's investments in all securities owned by Applicant, excluding, consistent with section 3(b)(2), the value of securities representing Applicant's investments in majority-owned subsidiaries and Yanacocha. Therefore, Applicant believes that public disclosure of this information is not necessary in the public interest or for the protection of investors.

3. Applicant also believes that public disclosure of the value of Applicant's investment in Yanacocha could result in harm to the shareholders of Applicant because it could influence the procedure set up by the Peruvian courts to calculate the value of Yanacocha or otherwise be used to the Applicant's detriment. As Applicant's estimate in the application under section 2(a)(41) of the Act may not match the methodology required for the Peruvian court's evaluation, such introduction could be confusing and may make public confidential and important competitive information that could materially prejudice Applicant's interests. For these reasons, Applicant believes that public disclosure of the information is not appropriate in the public interest or for the protection of investors.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–8168 Filed 4–2–96; 8:45 am]

BILLING CODE 8010–01–M

[6] *See* Tonopah Mining Company of Nevada, 26 S.E.C. 426 (1946).

[7] Applicant sold all of its shares of Empresa Minera Iscaycruz S.A. because it determined that it could not exert significant influence over its mining operations and did not wish to hold the shares solely for investment purposes.

[Release No. 34–37038; International Release No. 959; File No. SR–OPRA–96–2]

Options Price Reporting Authority; Notice of Filing and Immediate Effectiveness of Amendment to OPRA Fee Schedule Amending Certain Fees With Respect to OPRA's Basic/Index Service and Foreign Currency Options Service

March 28, 1996.

Pursuant to Rule 11Aa3–2 under the Securities Exchange Act of 1934 (''Exchange Act''), notice is hereby given that on March 18, 1996, the Options Price Reporting Authority (''OPRA'')[1] submitted to the Securities and Exchange Commission (''SEC'' or ''Commission'') an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (''Plan''), amending certain fees with respect to OPRA's basic/index service and foreign currency options (''FCO'') service. OPRA has designated this proposal as establishing or changing a fee or other charge collected on behalf of all of the OPRA participants in connection with access to or use of OPRA facilities, permitting the proposal to become effective upon filing pursuant to Rule 11Aa3–2 (c)(3)(i) under the Exchange Act. The Commission is publishing this notice to solicit comments from interested persons on the amendment.

I. Description and Purpose of the Amendment

The purpose of the amendment is to amend OPRA's direct access and redistribution fees in order to make the allocation of revenue derived from OPRA's basic/index and FCO services conform to the allocation of certain expenses between the accounting centers that are associated with these services. This allocation will be revised to reflect the addition of a sixth high speed output line at the OPRA Processor.

In accordance with the OPRA Plan, costs and expenses of OPRA's Processor attributable to more than one accounting center are allocated between accounting centers in the same proportion as the Processor's line output capacity is available to the service associated with each accounting center. At present, the Processor provides five 19.2 kbps lines to OPRA, four of which are for the basic/index service and one of which is for the FCO service. Accordingly, in conformity with the OPRA Plan, the Processor's costs are currently allocated 80% (4/5) to the basic and index accounting centers and 20% (1/5) to the FCO accounting center. Reflecting this allocation of expenses, and in order to continue to permit the recovery of Processor costs from these two fees, at the time OPRA unbundled these fees for its basic/index and FCO services, it divided the $900 direct access fee and the $1,800 redistribution fee between the two services in the same 80/20 proportion.[2]

Commencing April 1, 1996, a sixth 19.2 kbps output line will be added at the Processor, which will be devoted entirely to OPRA's basic/index service. Under the OPRA Plan, this will result in 5/6 of the Processor's costs being allocated to the basic and index accounting centers and 1/6 to FCO accounting center. This amendment proposes to make a corresponding change to the way in which the direct access and redistribution fees are divided between the basic/index and FCO service.[3] The effect of the amendment is to cause a $30 and $60 increase, respectively, in the direct access and redistribution fees paid for the basic/index service, and a $30 and $60 decrease, respectively, in the direct access and redistribution fees for the FCO service. Those vendors subject to all four fees will see no change in the total amount of OPRA fees they pay as a result of this amendment. In the amendment, OPRA calls for the fees to go into effect on April 1, 1996, the same date for the addition of the sixth high speed line.[4]

II. Solicitation of Comments

Pursuant to Rule 11Aa3–2(c)(3), the amendment is effective upon filing with the Commission. The Commission may summarily abrogate the amendment within 60 days of its filing and require refiling and approval of the amendment by Commission order pursuant to Rule 11Aa3–2(c)(2), if it appears to the Commission that such action is necessary or appropriate in the public interest; for the protection of investors and the maintenance of fair and orderly markets; to remove impediments to, and perfect the mechanisms of, a National Market System; or otherwise in furtherance of the purposes of the Exchange Act.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, and all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available at the principal offices of OPRA. All submissions should refer to file number SR–OPRA–96–2 and should be submitted by April 24, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–8169 Filed 4–2–96; 8:45 am]

BILLING CODE 8010–01–M

[File No. 500–1]

The Enstar Group, Inc.; Order of Suspension of Trading

March 29, 1996.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the cancelled common stock of The Enstar Group, Inc. (''Enstar''), which is currently a debtor-in-possession pending liquidation pursuant to Chapter 11 of the U.S. Bankruptcy Code. On May 31, 1991, Enstar filed for bankruptcy protection in U.S. Bankruptcy Court for the Middle District of Alabama. On February 24,

[1] OPRA is a National Market System Plan approved by the Commission pursuant to Section 11A of the Exchange Act and Rule 11Aa3–2 thereunder. Securities Exchange Act Release No. 17638 (Mar. 18, 1981).

The Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the five member exchanges. The five exchanges which agreed to the OPRA Plan are the American Stock Exchange (''AMEX''); the Chicago Board Options Exchange (''CBOE''); the New York Stock Exchange (''NYSE''); the Pacific Stock Exchange (''PSE''); and the Philadelphia Stock Exchange (''PHLX'').

[2] *See* Securities Exchange Act Release No. 36450 (November 1, 1995), 60 FR 56380 (November 8, 1995) (a direct access fee of $720 for the basic/index service and $180 for the FCO service, and a redistribution fee of $1,440 for the basic/index service and $360 for the FCO service).

[3] The result of the amendment will be a direct access fee of $750 for the basic/index service and $150 for the FCO service, and a redistribution fee of $1,500 for the basic/index service and $300 for the FCO service.

[4] In the event that the sixth speed line does not become operational on April 1, 1996, the fees associated with this line may not go into effect until such time as the line is actually operating.

[5] 17 CFR 200.30–3(a)(29).

1992, the bankruptcy court approved a plan to liquidate and dissolve Enstar. This plan provided: ''Effective upon [June 1, 1992], all Common Stock shall be cancelled and the holders of Shareholder Interests shall receive nothing on account of such Shareholder Interests, which shall be discharged.'' On June 9, 1992, Enstar filed with the Commission a certificate of termination of registration of its common stock. Because of a change in the value of Enstar's assets, on August 25, 1993, without reinstating the cancelled common stock, the court approved a modification to the plan whereby Enstar's shareholders of record as of June 1, 1992, could potentially receive distributions and proceeds from any property in the bankruptcy estate after ''such time as the holders of [specified priority claims] that are entitled to receive Property pursuant to [the plan] have been paid in full [plus accrued interest].'' The modification specifically prohibited the trading or transfer of any claims, including Shareholder Interests, absent authorization from either Enstar or the court. Therefore, according to the bankruptcy plan, unless a claim transfer has been authorized by Enstar or the bankruptcy court, current holders of Enstar's cancelled common stock who were not also shareholders of record on June 1, 1992, may not be entitled to receive distributions or any proceeds from the liquidation of Enstar's property.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the cancelled common stock of the above company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange of 1934, that trading in the above company is suspended for the period from 3:00 p.m. EST, March 29, 1996, through 2:59 p.m. EST, on April 11, 1996.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 96–8196 Filed 3–29–96; 4:15 pm]

BILLING CODE 8010–01–M

[Release No. 34–37026; File No. SR–CBOE–96–16]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to the Listing of Options on the CBOE Computer Networking Index

March 26, 1996.

Pursuant to Section 19(b)(1) of the Securities and Exchange of 1934 (''Act''), 15 U.S.C. 78s(b)(1), notice is hereby given that on March 13, 1996, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to list for trading cash-settled, European-style [1] options on the CBOE Computer Networking Index (''Computer Networking Index'' or ''Index''), an index comprised of the stocks of 15 widely held companies involved in providing computer networking services, and in the design and manufacture of software and hardware that facilitates computer networking.

The text of the proposed rule changes is available at the Office of the Secretary, CBOE, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

[1] A European-style option can be exercised only during a specified period immediately prior to the expiration of the option.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to permit the Exchange to list and trade cash-settled, European-style options on the Index. According to the CBOE, the Index meets all of the generic criteria for listing options on narrow-based indexes as set forth in CBOE Rule 24.2, ''Designation of the Index,'' and in the Commission's order approving CBOE Rule 24.2.[2] In accordance with CBOE Rule 24.2, the CBOE proposes to list and trade options on the Index beginning 30 days from the filing date of the proposed rule change.

The Index consists of the stocks of 15 widely held companies involved in providing computer networking services, and in the design and manufacture of software and hardware that facilitates computer networking.[3] According to the CBOE, no proxy for the performance of this industry group is currently available in the U.S. derivative markets, and options on the Index will provide investors with a low-cost means to participate in the performance of this sector or to hedge against the risk of investing in this sector.

Index Design. All of the stocks currently comprising the Index are U.S. securities that trade on the New York Stock Exchange, Inc. (''NYSE'') or through the facilities of the National Association of Securities Dealers Automated Quotation System (''NASDAQ''). Additionally, all of the Index's component stocks are ''reported securities'' as defined in Rule 11Aa3–1 under the Act.

According to the CBOE, each of the stocks in the Index has a market capitalization in excess of $200 million. Specifically, as of February 21, 1996, the stocks comprising the Index ranged in capitalization from $204 million to $25.82 billion, and the Index's total capitalization was $68.1 billion. In addition, as of February 21, 1996, the mean capitalization of the Index's component stocks was $4.54 billion and the median capitalization was $2.98 billion.

The CBOE represents that all of the Index's component stocks have had

[2] See Securities Exchange Act Release No. 34157 (June 3, 1994), 59 FR 30062 (June 10, 1994) (''Generic Index Approval Order'').

[3] The components of the Index are: Ascend Communications, Inc., Bay Networks Inc.; 3Com Corporation; Cabletron Systems, Inc.; Cascade Communications Corporation; Cisco Systems, Inc.; Digi International, Inc.; Fore Systems, Inc.; FTP Software Inc.; Madge Networks, NV; Network General Corporation; Netmanage, Inc.; Newbridge Networks Corporation; Stratacom, Inc.; and Xircom, Inc.

monthly trading volume well in excess of 1 million shares over the six-month period through June 1996, and that the average monthly volumes for these stocks over the six-month period ranged from a low of 3.04 million shares to a high of 231.8 million shares. Thus, the 100% of the weight of the Index and 100% of the number of components will be eligible for options trading. According to the CBOE, each of the Index's component stocks is currently the subject of options trading.

The Index is an equal dollar-weighted index, with each stock comprising 6.67% of the total Index weight. The top five stocks in the Index account for 33.35% of the Index. Accordingly, the Index meets the Exchange's generic listing standards for narrow-based indexes with respect to market capitalization, weighting constraints, options eligibility, and trading volume.

Calculation: The Index will be calculated on a real-time basis using last-sale prices by the CBOE or its designee, and will be disseminated every 15 seconds by the CBOE. If a component stock is not being traded currently, the CBOE will use the most recent price at which the stock traded to calculate the Index. At the close on February 21, 1996, the value of the Index was 220.20.

The Index is equal dollar-weighted and reflects changes in the prices of the component stocks relative to the Index base date, December 16, 1994, when the Index was set at 100.00. Specifically, each of the component securities is initially represented in equal dollar amounts, with the level of the Index equal to the combined market value of the assigned number of shares for each of the Index components divided by the current Index divisor. The Index divisor is adjusted to maintain continuity in the Index at the time of certain types of changes, including, but not limited to, quarterly re-balancing, special dividends, spin-offs, certain rights issuances, and mergers and acquisitions.

Maintenance: The CBOE will maintain the index. The Index will be re-balanced after the close of business on expiration Fridays on the March quarterly cycle. In addition, the CBOE staff will review the Index on approximately a monthly basis. The CBOE may change the composition of the Index at any time to reflect changes affecting the components of the Index or the computer networking industry generally. If it becomes necessary to remove a stock from the Index (for example, because of a takeover or merger), the CBOE will add only a stock having characteristics that will permit the Index to remain within the maintenance criteria specified in the CBOE's rules and in the Generic Index Approval Order.[4] The CBOE will take into account the capitalization, liquidity, volatility, and name recognition of any proposed replacement stock.

Absent prior Commission approval, the CBOE will not increase to more than 20, or decrease to fewer than 10, the number of stocks in the Index. In addition, the CBOE will not make any change in the composition of the Index that would cause fewer than 90% of the stocks by weight, or fewer than 80% of the total number of stocks in the index, to qualify as stocks eligible for equity options trading under CBOE Rule 5.3, ''Criteria for Underlying Securities.'' [5]

If the Index fails at any time to satisfy the maintenance criteria, the Exchange will notify the Commission of that fact immediately and will not open for trading any additional series of options on the Index unless the CBOE determines that such failure is not significant and the Commission concurs in that determination, or unless the Commission approves the continued listing of options on the Index under Section 19(b)(2) of the Act.

Index Options Trading: The CBOE proposes to base trading in Index options on the full value of the Index. The CBOE may list full-value long-term index option series (''LEAPS''), as provided in CBOE Rule 24.9, ''Terms of Index Option Contracts.'' The Exchange also may provide for the listing of reduced-value LEAPS, for which the underlying value would be computed at one-tenth of the value of the Index. The current and closing index value of any such reduced-value LEAP will be rounded to the nearest one-hundredth after the initial calculation.

Exercise and Settlement: Index options will have European-style exercise and will be ''A.M.-settled Index Options'' within the meaning of the rules in Chapter XXIV, ''Index Options,'' of the CBOE's rules, including CBOE Rule 24.9, ''Terms of Index Option Contracts,'' which the CBOE is amending to refer specifically to Index options. The proposed options will expire on the Saturday following the third Friday of the expiration month. Thus, the last day for trading in an expiring series will be the second business day (ordinarily a Thursday) preceding the expiration date.

Exchange Rules Applicable: Except as modified herein, the rules in Chapter XXIV of the CBOE's rules will apply to the Index. Options based on the Index will be subject to the position limit requirements of CBOE Rule 24.4A, ''Position Limits for Industry Index Options.'' Currently, the position limit for Index options is 12,000 contracts. Ten reduced-value Index options will equal one full-value Index option for position and exercise limit purposes.

The CBOE represents that the Exchange has the necessary systems capacity to support new series that will result from the introduction of Index options. In addition, the Options Price Reporting Authority (''OPRA'') has the capacity to support the new series.[6]

The CBOE believes that the proposal is consistent with Section 6(b) of the Act, in general, and, in particular, with Section 6(b)(5), in that it will permit trading in options based on the Index pursuant to rules designed to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade, and thereby will provide investors with the ability to invest in options based on the additional index.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change complies with the standards set forth in the Generic Index Approval Order,[7] it has become effective pursuant to Section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b–4 thereunder. Pursuant to the Generic Index Approval Order, the Exchange may not list Index options for trading prior to 30 days after March13, 1996, the date of the proposed rule change was filed with the Commission. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for

[4] See note 2, *supra.*

[5] Under the CBOE's rules, the Index must continue to satisfy this requirement. *See* CBOE Rule 24.2(c)(1).

[6] *See* Memorandum from Joseph P. Corrigan, Executive Director, OPRA, to William Speth, CBOE, dated March 1, 1996.

[7] *See* note 2, *supra.*

the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by April 24, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–8170 Filed 4–2–96; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of Reporting Requirements Submitted for Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the Federal Register notifying the public that the agency has made such a submission.

DATES: Comments should be submitted on or before May 3, 1996. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416, Telephone: (202) 205–6629

OMB Reviewer: Donald Arbuckle, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503

Title: Survey of Minority and Woman Franchise Ownership.

Form No.: SBA Temporary Form 1969.

Frequency: One Time Survey.

Description of Respondents: Minority and Women-owned Franchises.

Annual Responses: 300.

Annual Burden: 160.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 96–8183 Filed 4–2–96; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Proposed Advisory Circular—Flight Test Guide for Certification of Transport Category Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed advisory circular and request for comments.

SUMMARY: This notice requests comments on a proposed revision to Advisory Circular (AC) 25–7, ''Flight Test Guide for Certification of Transport Category Airplanes.'' The proposed revision consists of several elements that will: (1) Update the existing Subpart B (Flight) material to reflect current FAA regulations and policy, (2) essentially harmonize, with the European Joint Aviation Authorities (JAA) and Transport Canada Aviation (TCA), the methods and procedures used to show compliance with the requirements of Subpart B, and (3) add considerable material related to flight test procedures necessary to show compliance with regulatory requirements outside of Subpart B (i.e., propulsion, systems, and equipment, etc.). This notice provides interested persons an opportunity to present their views on the proposed revision to the AC.

DATES: Comments must be received on or before September 30, 1996.

ADDRESSES: Send all comments on the proposed AC to: Federal Aviation Administration, Attn: Patricia Siegrist, Transport Airplane Directorate, Aircraft Certification Service, Regulations Branch, ANM–114, 1601 Lind Avenue SW., Renton, WA 98055–4056. Comments may be inspected at the above address between 7:30 a.m. and 4:00 p.m. weekdays, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Patricia Siegrist, Regulations Branch, ANM–114, at the above address, telephone (206) 227–2126 or facsimile (206) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

A copy of the proposed AC may be obtained by contacting the person named above under **FOR FURTHER INFORMATION CONTACT**. Interested persons are invited to comment on the proposed AC by submitting such written data, views, or arguments as they may desire. Commenters must identify the AC by title and submit comments in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Transport Airplane Directorate before issuing the final AC.

Discussion

The current version of AC25–7, as modified by Change 1 on June 6, 1996, provides guidance only for the flight testing necessary to show compliance with the airplane performance and handling characteristics requirements of Subpart B of part 25; flight test guidance for showing compliance with other part 25 regulatory requirements remains in FAA Order 8110.8, ''Engineering Flight Test Guide for Transport Category Airplanes.''

Considerable changes in technology have occurred since AC25–7 was issued and Order 8110.8 was last revised (1974). The FAA has established new and revised guidance and policy material during this time period to keep pace with these changes in technology, and also to improve certification practices based on service history information. The proposed revision to AC25–7 updates the existing Subpart B guidance by incorporating this new and revised material. Similarly, the guidance material currently contained in Order 8110.8 is updated to reflect certification standards and flight test methods for

[8] 17 CFR 200.30–3(a)(12) (1995).

showing compliance with regulatory requirements outside of Subpart B. This material has been incorporated in the proposed revision to AC25–7, and following its issuance, Order 8110.8 will be canceled.

Many of the proposed revisions to the Subpart B guidance have resulted from efforts to harmonize with the JAA and TCA to establish standardized regulatory requirements and means of compliance. To aid the readers in their review of the proposed revisions to the Subpart B guidance, deletions are denoted by ''strikeout'' text (i.e.,), while new and revised material is underlined (i.e., *new text*) and denoted by revision bars in the left margin.

Since harmonization efforts related to guidance and policy material not related to Subpart B have been fairly limited to date, the FAA is unable to make a determination on the feasibility of publishing a fully harmonized flight test guide during this revision. It is more probable that the comments received from the JAA and TCA will be transmitted to the appropriate technical specialists for resolution as part of the next revision to AC 25–7.

The proposed revision to AC 25–7 provides a means of compliance with part 25 as amended through Amendment 25–84, effective July 10, 1995. Some of the incorporated material, which reflects established FAA policy, has also been published in conjunction with proposed part 25 rule changes. An example of an overlap condition is the proposed 1g stall criteria of NPRM 95–17 (61 FR 1260, January 18, 1996); the 1g stall criteria has been applied to many transport airplane certifications over the last decade and consequently is published in an appendix to the proposed AC 25–7 revision.

The proposed revision to AC 25–7 is also intended to serve as a repository for historical information related to the certification of transport category airplanes. The FAA considers it important to retain those noncurrent regulations and guidance materials that are of significance, to provide a better understanding of the current standards. As such, Civil Aviation Regulations (CAR) 4b, Special Regulations (SR) 422, 422A, and 422B, which developed performance standards for turbojet-powered airplanes, are contained in Appendix 1. Similarly, Appendix 2 contains historical guidance material related to determining accelerate-stop distances, which can also be used for the certification of derivative and modified airplane types, where appropriate. Commenters are requested to provide their views on the merits of retaining such information in AC 25–7.

Order 8110.8 contained what could be termed ''practical aids'' in some appendices; one appendix provided a cross reference listing of CAR 4b and FAR part 25 regulations, while another presented an example of a certification flight test program. The FAA considers it worthwhile to continue publishing a sample flight test program, particularly for the smaller modification enterprises. To that end, the proposed revision to AC 25–7 presents a sample flight test program in Appendix 6; that program is reproduced from Order 8110.8 and is intended only to serve as an example in terms of format and general content. Commenters are requested to provide their views on the merits of publishing an updated version of this sample flight test program in the revised AC 25–7.

Due to the sheer volume of material in the proposed revision to AC 25–7, interested parties are encouraged to either make copies of the document or to divide it into appropriate segments to ensure adequate time for review by the pertinent specialists, particularly since some material will require review by specialists from more that one discipline.

For the ease of the reader, the FAA has modified the standard AC page numbering system for the proposed AC 25–7 revision. With the exception of Chapter 8, which has no specific regulatory reference, a three-element page numbering system has been used, the first number being the chapter, the second number the section, and the third number the page number within that section (e.g., pg. 2–3–6 is page 6 of Chapter 2, Section 3). Each ''chapter'' of AC 25–7 corresponds to a Subpart of part 25, and each ''section'' corresponds to the major subgroups of regulations within individual subparts. The standard AC page numbering system will be incorporated for the final release of the revised AC.

Issued in Renton, Washington, on March 20, 1996.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate Aircraft Certification Service.

[FR Doc. 96–8035 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–13–M

Proposed Establishment of the Sheppard AFB, Wichita Falls, TX, Class C Airspace Area; Public Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: This notice is announcing a fact-finding informal airspace meeting to solicit information from airspace users and others concerning a proposal to establish Class C airspace at Sheppard AFB, Wichita Falls, TX. The United States Air Force is holding this meeting to provide interested parties the opportunity to present input on the proposal. All comments received during the meeting will be considered prior to any establishment or issuance of a notice of proposed rulemaking.

TIME AND DATE: The informal airspace meeting will be held on Thursday, May 16, 1996, starting at 7:00 p.m. comments must be received on or before May 1, 1996.

PLACE: Multi-purpose Event Center's Exhibit Hall, The Lecture Room, 1000 5th Street, Wichita Falls, TX 76301.

COMMENTS: Send or deliver comments on the proposal in triplicate to: Manager, Air Traffic Division, ASW–500, Federal Aviation Administration, 2601 Meacham Blvd., Fort Worth, TX 76137–4298.

FOR FURTHER INFORMATION CONTACT: Alvin DeVane, FAA, Southwest Regional Office, ASW–530, (817) 222–5568.

SUPPLEMENTARY INFORMATION:

Meeting Procedures

(a) The meeting will be informal in nature and will be conducted by a representative of the FAA Southwest Region. Representatives from the FAA will present a formal briefing on the proposed establishment of the Class C airspace area. Each participant will be given an opportunity to deliver comments or make a presentation.

(b) The meeting will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate.

(c) Any person wishing to make a presentation to the FAA panel will be asked to sign in and estimate the amount of time needed for such presentation. This will permit the panel to allocate an appropriate amount of time for each presenter. The panel may allocate the time available for each presentation in order to accommodate all speakers. The meeting will not be adjourned until everyone on the list has had an opportunity to address the panel. The meeting may be adjourned at any time if all persons present have had the opportunity to speak.

(d) Position papers or other handout material relating to the substance of the meeting will be accepted. Participants wishing to submit handout material should present *three* copies to the presiding officer. There should be

additional copies of each handout available for other attendees.

(e) The meeting will not be formally recorded. However, a summary of the comments made at the meeting will be filed in the docket.

Agenda for the Meeting

Opening Remarks and Discussion of Meeting Procedures
Briefing on Background for Proposal
Public Presentations
Closing Comments

Issued in Washington, DC, on March 27, 1996.

Nancy B. Kalinowski,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 96–8034 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–13–M

National Highway Traffic Safety Administration

Announcing the General Estimates System Users Meeting

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Meeting Announcement.

SUMMARY: This notice announces a public meeting at which NHTSA will conduct a National Accident Sampling System General Estimates System (GES) Users Meeting. The users are those members of the highway safety community that analyze data from the General Estimates System.

DATE AND TIME: The meeting is scheduled from 9:30 a.m. to 11:30 a.m., on Monday, April 15, 1996.

ADDRESSES: The meeting will be held in Rooms 3200–04 of the U.S. Department of Transportation Building, which is located at 400 Seventh Street, S.W., Washington, D.C.

SUPPLEMENTARY INFORMATION: NHTSA is reviewing the GES data elements to identify which may be deleted, modified or added to better support their data users in the highway safety community. The attendees will be able to provide information and discuss their recommendations to NHTSA on data elements that could be collected in GES and would support their analytic efforts for the highway safety community. A complete list of the GES variables is available from the contact listed below. Comments are requested prior to the meeting.

The meeting is open to the public, but attendance may be limited due to space availability. Participation by the public will be determined by the meeting coordinator.

FOR FURTHER INFORMATION CONTACT: Ms.Terry Shelton, General Estimates System, National Center for Statistics and Analysis, NRD–31, 400 Seventh Street, S.W., Washington, D.C. 20590, telephone: (202) 366–5362; Internet: tshelton@nhtsa.dot.gov; fax: (202) 366–7078.

William A. Boehly,

Associate Administrator for Research and Development.

[FR Doc. 96–8175 Filed 4–2–96; 8:45 am]

BILLING CODE 4910–59–P

Surface Transportation Board

[Ex Parte No. 388]

State Intrastate Rail Rate Authority Public Law 96–448

AGENCY: Surface Transportation Board.

ACTION: Notice that regulatory jurisdiction formerly exercised by certain States over intrastate rail transportation ceased to be effective as of January 1, 1996.

SUMMARY: The Board is giving notice that the authority of certain States to regulate intrastate rail matters was terminated by the ICC Termination Act of 1995, effective January 1, 1996.

EFFECTIVE DATE: January 1, 1996.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 927–5610. [TDD for the hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: Prior to January 1, 1996, old 49 U.S.C. 11501(b)(1) provided that States could exercise jurisdiction over intrastate transportation by a rail carrier furnishing transportation subject to the jurisdiction of the Interstate Commerce Commission (ICC) under old 49 U.S.C. 10501, but only if the appropriate State authority exercised jurisdiction exclusively in accordance with the provisions of old 49 U.S.C. 10101–11917. To exercise jurisdiction over intrastate rates, a State had to be certified under old 49 U.S.C. 11501(b)(2)–(5). Under the certification regime, States that desired to regulate intrastate rail matters were required to adopt standards and procedures in accordance with those used by the ICC to regulate interstate rail matters. The ICC, if it determined that a State's standards and procedures were in accordance with federal law, was required to certify the State authority. Certification continued for a 5-year period commencing on the date of certification; and if, prior to the end of the 5-year period, the State resubmitted its standards and procedures, its regulatory authority could be recertified.

As of December 31, 1995, the following States were certified (technically, ''recertified'') to exercise jurisdiction over intrastate rail rates, classifications, rules, and practices: Alabama, Arkansas, Colorado, Georgia, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Montana, New Mexico, New York, North Dakota, Oklahoma, Oregon, South Carolina, Virginia, West Virginia, and Wisconsin. *See* 60 FR 42181 (8/15/95) (Alabama); 60 FR 16664 (3/31/95) (Arkansas); 56 FR 28924 (6/25/91) (Colorado); 60 FR 42181 (8/15/95) (Georgia); 55 FR 51511 (12/14/90) (Iowa); 60 FR 42181 (8/15/95) (Kansas); 56 FR 9738 (3/7/91) (Kentucky); 55 FR 50783 (12/10/90) (Maryland); 55 FR 51356 (12/13/90) (Michigan); 56 FR 9977 (3/8/91) (Minnesota); 60 FR 12784 (3/8/95) (Mississippi); 60 FR 49631 (9/26/95) (Montana); 58 FR 17626 (4/5/93) (New Mexico); 55 FR 48931 (11/23/90) (New York);[1] 56 FR 446 (1/4/91) (North Dakota); 60 FR 46134 (9/5/95) (Oklahoma);[2] 57 FR 11970 (4/8/92) (Oregon); 60 FR 56066 (11/6/95) (South Carolina); 59 FR 60164 (11/22/94) (Virginia); 60 FR 62476 (12/6/95) (West Virginia); and 60 FR 49286 (9/22/95) (Wisconsin).

The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803 (ICCTA), enacted on December 29, 1995, and effective January 1, 1996, abolished the ICC but transferred certain of its rail regulatory functions to a newly created Surface Transportation Board (Board). *See* ICCTA Section 101 (abolition of the ICC). *See* also new 49 U.S.C. 701(a) (establishment of the Board) and new 49 U.S.C. 10101–11908 (new regulatory provisions applicable to rail carriers).

The *new law* (the law in effect on and after January 1, 1996) differs in several important respects from the *old law* (the law in effect prior to January 1, 1996). For present purposes, it suffices to note that the certification regime of old 49 U.S.C. 11501(b)(2)–(5) no longer exists, because the underlying State regulatory role no longer exists. See new 49 U.S.C. 10501(a)(2)(A) (jurisdiction of the Board extends to transportation between a place in a State and a place in the same State as part of the interstate rail network), and new 49 U.S.C. 10501(b) (jurisdiction of the Board is exclusive). It follows that the certifications (technically, the ''recertifications'') that were effective as of December 31, 1995, ceased to be effective as of January 1,

[1] On 12/13/95, the State of New York filed a recertification application, which automatically resulted in a provisional recertification.

[2] On 10/26/95, the State of Oklahoma filed a recertification application, which automatically resulted in a provisional recertification.

1996. We are therefore discontinuing the proceedings heretofore instituted in Ex Parte No. 388 (Sub-Nos. 1, 2, 3, 5, 9, 10, 11, 13, 14, 15, 16, 18, 22, 23, 24, 26, 27, 29, 33, 35, and 36) (the certification sub-dockets for Alabama, Arkansas, Colorado, Georgia, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Montana, New Mexico, New York, North Dakota, Oklahoma, Oregon, South Carolina, Virginia, West Virginia, and Wisconsin, respectively).

A copy of this notice will be served on the Governor of each State, the Public Service Commission (or other appropriate regulatory agency) in each State, and all other parties of record in Ex Parte No. 388, Ex Parte No. 388 A, and Ex Parte No. 388 (Sub-Nos. 1 through 37).

This action (we are simply stating the effect that ICCTA had on the preexisting certification regime) will not significantly affect either the quality of the human environment or energy conservation.

Decided: March 21, 1996.

By the Board, Chairman Morgan, Vice Chairman Simmons and Commissioner Owen.

Vernon A. Williams,

Secretary.

[FR Doc. 96–8012 Filed 4–2–96; 8:45 am]

BILLING CODE 4915–00–P

Surface Transportation Board [1]

[STB Docket No. AB–467X]

J.P. Rail Inc., T/A Southern Railroad Company of New Jersey—Abandonment Exemption; in Linwood, Atlantic County, NJ

J.P. Rail Inc., T/A Southern Railroad Company of New Jersey (SRNJ) filed a notice of exemption under 49 CFR part 1152 Subpart F; *Exempt Abandonments* to abandon a 3.38 mile line of its rail line known as the Linwood Industrial Track, from that point on the line in Pleasantville, in the vicinity of Decatur Avenue (approximately milepost 0.31+) to the end of the line in the vicinity of Wilson Avenue and Poplar Avenue (approximately milepost 3.69+) in Linwood, Atlantic County, NJ.[2]

SRNJ has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to use of this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on May 3, 1996, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[3] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[4] and trail use/rail banking requests under 49 CFR 1152.29[5] must be filed by April 15, 1996. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by April 23, 1996, with: Office of the Secretary, Case Control Branch, Surface Transportation Board, 1201 Constitution Avenue, NW, Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicant's representative: John K. Fiorilla, Watson, Stevens, Fiorilla & Rutter, 390 George Street, P.O. Box 1185, New Brunswick, NJ 08903.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

SRNJ has filed an environmental report which addresses the abandonments effects, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by April 8, 1996. Interested persons may obtain a copy of the EA by writing to SEA (Room 3219, Surface Transportation Board, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEA, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: March 26, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–8013 Filed 4–2–96; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Departmental Offices, Debt Management Advisory Committee; Meeting

Notice is hereby given, pursuant to 5 U.S.C. App. 10(a)(2), that a meeting will be held at the U.S. Treasury Department, 15th and Pennsylvania Avenue, NW., Washington, DC, on April 30 and May 1, 1996, of the following debt management advisory committee:

Public Securities Association
Treasury Borrowing Advisory Committee

The agenda for the meeting provides for a technical background briefing by Treasury staff on April 30, followed by a charge by the Secretary of the Treasury or his designate that the committee discuss particular issues, and a working session. On May 1, the committee will present a written report of its recommendations.

The background briefing by Treasury staff will be held at 11:30 a.m. Eastern time on April 30 and will be open to the public. The remaining sessions on April

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[1] The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803 (the Act), which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission (ICC) and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 10903.

[2] The verified notice of exemption was filed on March 5, 1996. Board staff contacted SRNJ and requested clarification of its verified notice. SRNJ supplemented the record by letter filed March 14, 1996. Because the notice must be filed with the Board at least 50 days before the abandonment is to be consummated, consummation may not occur before May 3, 1996. *See* 49 CFR 1152.50(d)(2). SRNJ has confirmed that the correct consummation date of the abandonment will be May 3, 1996. As noted subsequently in this notice, the exemption will be effective on that date.

[3] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[4] *See Exempt. of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

[5] The Board will accept late-filed trail use requests so long as the abandonment has not been consummated and the abandoning railroad is willing to negotiate an agreement.

30 and the committee's reporting session on May 1 will be closed to the public, pursuant to 5 U.S.C. App. 10(d).

This notice shall constitute my determination, pursuant to the authority placed in heads of departments by 5 U.S.C. App. 10(d) and vested in me by Treasury Department Order No. 101–05, that the closed portions of the meeting are concerned with information that is exempt from disclosure under 5 U.S.C. 552b(c)(9)(A). The public interest requires that such meetings be closed to the public because the Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decision on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community. When so utilized, such a committee is recognized to be an advisory committee under 5 U.S.C. App. 3.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of the advisory committee, premature disclosure of the committee's deliberations and reports would be likely to lead to significant financial speculation in the securities market. Thus, these meetings fall within the exemption covered by 5 U.S.C. 552b(c)(9)(A).

The Office of the Assistant Secretary for Financial Markets is responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of committee activities and such other matters as may be informative to the public consistent with the policy of 5 U.S.C. 552b.

Dated: March 27, 1996.

Darcy Bradbury,

Assistant Secretary, Financial Markets.

[FR Doc. 96–8088 Filed 4–2–96; 8:45 am]

BILLING CODE 4810–25–M

Office of the Comptroller of the Currency

[Docket No. 96–07]

Covered Executive Branch Officials at the Office of the Comptroller of the Currency Under the Lobbying Disclosure Act of 1995

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice.

SUMMARY: The Office of the Comptroller of the Currency is publishing a list of the current ''covered executive branch officials'' at the agency for purposes of the Lobbying Disclosure Act of 1995 (the Act) and the name of an office at the agency that will identify ''covered executive branch officials'' for purposes of the Act.

EFFECTIVE DATE: January 1, 1996.

FOR FURTHER INFORMATION CONTACT: Barrett Aldemeyer, Senior Counsel, Administrative and Internal Law Division, 202–874–4460; Heidi Thomas, Legislative Counsel, or Nancy Michaleski, Assistant Director, Legislative and Regulatory Activities Division, 202–874–5090, Office of the Comptroller of the Currency, 250 E Street SW., Washington, DC 20219.

Covered Executive Branch Officials at the OCC

The Act (Pub. L. 104–65, 109 Stat. 691), codified at 2 U.S.C. 1601 *et seq.*, repeals the Federal Regulation of Lobbying Act, 2 U.S.C. 261 *et seq.*, and puts into place new Federal requirements for the disclosure and registration of individuals who make lobbying contacts with covered Federal legislative and executive branch officials. The Act generally became effective on January 1, 1996.

To assist individuals in complying with the requirements of the Act, the OCC is publishing the names of the officials at the OCC who currently are ''covered executive branch officials.'' The Act defines a ''covered executive branch official,'' among other things, to include any officer or employee serving in a position in Levels I through V of the Executive Schedule, or any officer and employee serving in a position of a confidential, policy-determining, policy-making, or policy-advocating character described in section 5 U.S.C. 7511(b)(2).[1]

The OCC has determined that the following individuals are currently covered by the Act and have been covered since the date of enactment because they serve in positions in the Executive Service or in Schedule C positions:

- Eugene A. Ludwig, Comptroller
- Mark P. Jacobsen, Senior Advisor to the Comptroller
- Konrad S. Alt, Senior Deputy Comptroller
- Douglas E. Harris, Senior Deputy Comptroller

The Act requires each ''covered executive branch official'' or, in the alternative, the official's employing office, to identify whether the official is covered by the Act upon the request of a person making a lobbying contact. To obtain updated information from the OCC about whether an OCC employee is a ''covered executive branch official,'' an individual may contact the following OCC office: Office of Communications, Office of the Comptroller of the Currency, 250 E St., SW., Washington, D.C. 20219, (202) 874–4700, *Attention*: Frank Vance, Disclosure Officer. In addition, as necessary, the OCC may publish a revised list of OCC ''covered executive branch officials.''

Dated: March 27, 1996.

Eugene A. Ludwig,

Comptroller of the Currency.

[FR Doc. 96–8131 Filed 4–2–96; 8:45 am]

BILLING CODE 4810–33–P

[1] Recent guidance issued by the Clerk of the House of Representatives and the Secretary of the Senate states that the Office of Personnel Management (OPM) has indicated that all Schedule C employees are within 5 U.S.C. 7511(b)(2) and, therefore, covered by the Act. The recent guidance also indicates that OPM may find that additional positions are covered by 5 U.S.C. 7511(b)(2). However, this information is provided only as guidance and it is not legally binding. The guidance states that the Act does not provide the Clerk or the Secretary with authority to issue substantive regulations or definitive interpretations of the law.

Customs Service

Application for Recordation of Trade Name: ''OMI Industries, Inc.''

ACTION: Notice of Application for Recordation of Trade Name.

SUMMARY: Application has been filed pursuant to section 133.12, Customs Regulations (19 CFR 133.12), for the recordation under section 42 of the Act of July 5, 1946, as amended (15 U.S.C. 1124), of the trade name ''OMI INDUSTRIES, INC.,'' used by OMI Industries, Inc., a corporation organized under the laws of the State of Ohio, located at 310 Outerbelt Street, Columbus, Ohio 43213.

The application states that the trade name is used in connection with aluminum and steel die cast products. The merchandise is manufactured in Russia.

Before final action is taken on the application, consideration will be given to any relevant data, views, or arguments submitted in writing by any person in opposition to the recordation of this trade name. Notice of the action taken on the application for recordation of this trade name will be published in the Federal Register.

DATES: Comments must be received on or before June 3, 1996.

ADDRESSES: Written comments should be addressed to U.S. Customs Service, Attention: Intellectual Property Rights Branch, 1301 Constitution Avenue,

NW., (Franklin Court), Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Delois P. Johnson, Intellectual Property Rights Branch, 1301 Constitution Avenue, NW., (Franklin Court), Washington D.C. 20229 (202–482–6960).

Dated: March 27, 1996.

John F. Atwood,

Chief, Intellectual Property Rights Branch.

[FR Doc. 96–8021 Filed 4–2–96; 8:45 am]

BILLING CODE 4820–02–P

Internal Revenue Service

[Delegation Order No. 247]

Delegation of Authority

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Delegation of authority.

SUMMARY: Provides resolution authority to Examination on coordinated issues in the Industry Specialization Program (ISP) and International Field Assistance Specialization Program (IFASP) for those issues on which Appeals has coordinated issue papers containing settlement guidelines or positions. Examination resolution may be reached only subject to the concurrence of both the Examination and Appeals ISP and/or IFASP Coordinators. The text of the delegation order appears below.

EFFECTIVE DATE: March 15, 1996.

FOR FURTHER INFORMATION CONTACT: Harry E. Lebedun, CP:EX:C:C, Room 2036, 1111 Constitution Ave., NW, Washington, DC. 20224, (202) 622–3654 (not a toll free number).

Order No. 247

Effective Date: March 15, 1996.

Authority of Examination Case Managers to Accept Settlement Offers and Execute Closing Agreements on Industry Specialization Program (ISP) and International Field Assistance Specialization Program (IFASP) Issues.

The authority vested in the Commissioner of the Internal Revenue by Treasury Order Nos. 150–07, 150–09, 150–10 and the authority contained in 26 U.S.C. Section 7121 is hereby delegated as follows:

1. All examination case managers are delegated discretionary authority in Coordinated Examination Program cases under their jurisdiction to accept settlement offers, regardless of the amount of the liability sought to be compromised, with respect to coordinated issues within the ISP and IFASP on which Appeals has coordinated issue papers containing settlement guidelines or positions. Prior to finalization, the proposed settlement, together with any related closing agreement and/or Form 870–AD, Offer of Waiver of Restrictions on Assessment and Collection of Deficiency in Tax and of (to be completed by case manager), and supporting documentation, shall be reviewed and approved by the appropriate specialists/coordinators for ISP and IFASP within Examination, International and the Appeals functions.

2. For purposes of this limited delegation of settlement authority, coordinated issues within the ISP and IFASP are those issues published in the Internal Revenue Manual.

3. All examination case managers are delegated authority to execute closing agreements and/or the Form 870–AD in order to effect any settlement reached in a Coordinated Examination case involving ISP and IFASP issues.

4. This authority delegated in this order may not be redelegated.

5. The authority contained in this Order supplements the authority contained in Delegation Order 97 (as revised).

Dated: March 15, 1996.

Michael P. Dolan

Deputy Commissioner.

[FR Doc. 96–8029 Filed 4–2–96; 8:45 am]

BILLING CODE 4830–01–P

[Delegation Order No. 236 (Rev. 2)]

Delegation of Authority

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Delegation of Authority.

SUMMARY: The delegation order has been revised to eliminate terms that are causing unnecessary confusion in applying the delegation order and to expand the scope to include certain directly-related parties to covered transactions. The text of the delegation order appears below.

EFFECTIVE DATE: March 15, 1996.

FOR FURTHER INFORMATION CONTACT: Harry E. Lebedun, CP:EX:C:C, Room 2036, 1111 Constitution Ave., NW, Washington, DC. 20224, (202) 622–3654 (not a toll free number).

Delegation Order No. 236 (Rev. 2)

Effective date: March 15, 1996.

Application of Appeals Settlement to Coordinated Examination Program Taxpayers

The authority vested in the Commissioner of the Internal Revenue by Treasury Order Nos. 150–07, 150–09 and 150–10 and the authority contained in 26 U.S.C. Section 7121 is hereby delegated as follows:

1. All examination case managers are delegated discretionary authority under section 7121 of the Internal Revenue Code to accept settlement offers on any issue in a Coordinated Examination Program case under their respective jurisdiction. This authority applies, regardless of the amount of liability sought to be compromised, where a settlement (including a hazards settlement) has been effected by Appeals in a previous, subsequent or the same tax period (the settled period) with respect to the same issue of the same taxpayer, or of another taxpayer who was directly involved in the transaction or taxable event. Prior to finalization, the proposed settlement, together with any related closing agreement or Form 870–AD, Offer of Waiver of Restrictions on Assessment and Collection of Deficiency in Tax and of (to be completed by case manager), shall be reviewed and approved by the appropriate branch chief within the Examination function.

2. For purposes of this delegation of limited settlement authority, no settlement shall be effected unless all of the following factors are present in the tax year currently under Examination jurisdiction:

(a) The facts surrounding a transaction or taxable event in the tax period under examination are substantially the same as the facts in the settled period.

(b) The legal authority relating to such issue must have remained unchanged.

(c) The underlying issue must have been settled by Appeals independently of other issues (e.g. no trading of issues) in the settled tax period.

(d) The issue must have been settled in Appeals with respect to the same taxpayer (including consolidated and unconsolidated subsidiaries) or another taxpayer who was directly involved in the transaction or taxable event in the settled tax period.

3. The criteria in section 2 apply to taxpayers ''directly involved'' in the transaction. Illustrations of a taxpayer ''directly involved'' in the transaction are as follows:

(a) Taxpayers A and B are directly involved in the same transaction or taxable event in tax period 19xx where A and B would logically receive similar tax treatment. Taxpayer A's treatment of the transaction is adjusted by Examination and settled in Appeals. The adjustment involves the same legal issue with respect to taxpayer B. Examination may resolve Taxpayer B's case in a manner consistent with the Appeals settlement of Taxpayer A.

(b) Taxpayers A and B are directly involved in the same transaction or taxable event in tax period 19xx where A and B would logically receive similar tax treatment. Taxpayer A's treatment of the transaction is adjusted by Examination and settled by Appeals. In addition, taxpayer A or B (or both) is directly involved in a separate, but similar transaction or taxable event in the same, prior, or subsequent tax period involving the same legal issue as above. Such issue for taxpayers A or B only may also be settled in a consistent manner provided it involves substantially the same facts.

4. All examination case managers are delegated authority to execute closing agreements and the Form 870–AD in order to effect any final settlement reached in a Coordinated Examination case.

5. For settlement authority of Industry Specialization and International Field Assistance Specialization Program coordinated issues, see Delegation Order No. 247.

6. The authority delegated in this Order may not be redelegated.

7. The authority contained in this Order supplements the authority contained in Delegation Order 97 (as revised).

8. Delegation Order No. 236 (Rev.1), effective June 3, 1994, is superseded.

Dated: March 15, 1996.

Michael P. Dolan,

Deputy Commissioner.

[FR Doc. 96–8030 Filed 4–2–96; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; Amendment of System of Records

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

Notice is hereby given that the Department of Veterans Affairs (VA) is adding a new routine use to the system of records entitled ''General Personnel Records (Title 38)—VA'' (76VA05) as set forth in the Federal Register 53 FR 27258 (7/19/88) and amended in 55 FR 42534 (10/19/90) and 58 FR 40852 (7/30/93). This system of records is a repository of existing and future records, reports of personnel actions, and the documents and papers required in connection with these actions that were or will be effected during a Title 38 employee's service with VA.

Public Law 103–94 (October 6, 1993) permits the garnishment of Federal employees' wages. The Office of Personnel Management (OPM) has issued regulations (5 CFR part 582) which implement the legislation. Section 582.306(c) of these regulations states that if an employee, whose wages have been garnished, transfers to another agency or is now employed by a private employer, then the original agency must provide the name and address of the new employer, when available, to the garnishing party (garnisher). However, VA's General Counsel has determined that the name and address of a new employer of a former VA employee cannot be released to a garnisher without the former employee's consent or through a published routine use, unless the new employer is another Federal department or agency.

VA would add a new routine use No. 40 to its system of records, 76VA05. This new routine use will specifically permit the disclosure of information to a garnisher concerning the name and address of any new employer of a former VA employee who is the subject of a court ordered garnishment.

VA has determined that the release of information for this purpose is a necessary and proper use of the information in this system of records and that the new specific routine use for transfer of this information is appropriate.

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposed routine use of the system of records to the Director, Office of Regulations Management (02D), 810 Vermont Avenue, NW., Washington, DC 20420. All relevant material received before May 3, 1996, will be considered. All written comments received will be available for public inspection in the Office of Regulations Management, Room 1176, 801 I Street, NW., Washington, DC 20001 only between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

If no public comment is received during the 30-day review period allowed for public comment, or unless otherwise published in the Federal Register by VA, the new routine use statement is effective May 3, 1996.

Approved: March 26, 1996.

Jesse Brown,

Secretary of Veterans Affairs.

Notice of Amendment to System of Records

In the system of records identified as 76VA05, ''General Personnel Records (Title 38)—VA,'' as set forth in the Federal Register 53 FR 27258 (7/19/88) and amended in 55 FR 42534 (10/19/90) and 58 FR 40852 (7/30/93), is revised as follows:

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

* * * * *

40. Relevant information from this system of records concerning the departure of a former VA employee, who is the subject of a garnishment pursuant to a legal process as defined in 5 U.S.C. 5520a, as well as the name and address of the designated agent for the new employing agency or the name and address of any new private employer, may be disclosed to the garnishing party (garnisher).

[FR Doc. 96–8057 Filed 4–2–96; 8:45 am]

BILLING CODE 8320–01–M

Federal Register

Wednesday
April 3, 1996

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 900

Mammography Quality Standards; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 95N–0192]

RIN 0910–AA24

Quality Mammography Standards; General Preamble and Proposed Alternative Approaches

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its interim regulations issued under the Mammography Quality Standards Act of 1992 (the MQSA). In addition, FDA is also setting forth ideas for the application of alternative performance and outcome-based standards to ensure quality mammography. FDA is soliciting comments on these alternatives as possible ways of meeting the objectives of Executive Order 12866, which requires Federal agencies to, where feasible, specify performance objectives, rather than specifying the behavior and manner of compliance and to avoid duplicative regulations. Elsewhere in this issue of the Federal Register, FDA is proposing amendments to the requirements for accreditation bodies, procedures for facility certification and quality standards for mammography personnel, equipment and practices, including quality assurance. These actions are being taken to ensure adequate and consistent evaluation of mammography facilities on a nationwide basis.

DATES: Written comments on the proposed rule by July 2, 1996. Written comments on the information collections should be submitted by May 3, 1996.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Regulatory Impact Study (RIS) is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

Submit written comments on the information collections to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th St. NW., rm. 10235, Washington DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. General Preamble

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, 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. The American Cancer Society projects that in 1995 there will be 180,000 new cases of breast cancer among women in the United States (Ref. 1). Of these new cases, it is estimated that approximately 46,000 of these women will die from the disease. The lifetime risk of developing breast cancer is increasing. In 1993, breast cancer was projected to affect 1 in 8 women in their lifetime, as compared to 1 in 11 in 1980, 1 in 14 in 1960, and 1 in 20 in 1940 (Ref. 2).

Early detection of breast cancer, typically involving breast physical examination and mammography, is the best means of preventing deaths that can result when the diagnosis is delayed until the onset of more advanced symptoms. The value of undergoing screening mammography is that it can detect cancers that are asymptomatic. 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. 3).

However, according to the General Accounting Office, 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 mastectomy. Further, 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 examinee, 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: (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 legislation 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, after October 1, 1994, only those facilities that comply with minimum Federal standards for safe, high-quality mammography services may lawfully continue to operate. Operation after that date is contingent on receipt of an FDA certificate attesting that the facility meets the minimum mammography quality standards issued under section 354(f) of the Public Health Service Act (the PHS Act)(42 U.S.C. 263b(f)). These standards are intended to apply equally to screening and diagnostic mammography.

Specifically, the MQSA required the following:

(1) Accreditation of mammography facilities by private, nonprofit organizations or State agencies that have met the standards established by FDA for accreditation bodies and have been approved by FDA. The MQSA requires a direct Federal audit of the accreditation bodies through facility inspections by Federal inspectors. It 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 programs.

(7) Establishment by the Secretary of a National Mammography Quality Assurance Advisory Committee (NMQAAC). Among other things, the NMQAAC is required to advise FDA on appropriate quality standards for mammography facilities and accreditation bodies.

(8) Standards governing recordkeeping for examinee files and requirements for mammography reporting and examinee notification by physicians.

The MQSA replaced a patchwork of Federal, State, and private standards in order to guarantee sufficient oversight of mammography facilities to ensure that all women nationwide will receive high quality mammography services.

B. Interim Regulations

On December 14, 1993, the President signed legislation (H. Rept. 2202) granting interim rule authority to the Secretary (and by delegation, to FDA) to issue interim quality standards under MQSA. This authorization was provided in recognition of the fact that FDA certification of the over 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 the 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.

Under the interim rule legislation, FDA was authorized to issue temporary interim regulations setting forth standards for approving accreditation bodies and quality standards for mammography facilities.

Under the abbreviated process, Congress expected FDA to adopt existing standards to the maximum extent feasible, such as those established by the Health Care Financing Administration (HCFA), private voluntary accreditation bodies such as the American College of Radiology (ACR), and some States. The Secretary was not required to consult with the NMQAAC in developing the interim regulations. However, following issuance of the interim standards, Congress intended that FDA proceed with the more extensive rulemaking procedures envisioned under the MQSA, including consultation with the NMQAAC.

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 legally providing 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).

There are several reasons why it is important to replace the existing interim regulations on quality mammography standards with more comprehensive final regulations, apart from strong congressional encouragement for such action when the agency was granted interim regulation authority. In a 1995 report by the Physician Insurers Association of America, misdiagnosis of breast cancer remains the most common charge against radiologists in malpractice situations. In addition, there was considerable variation in clinical performance of mammography facilities in 1992 and 1993 despite compliance with existing voluntary accreditation standards that were similar to the interim regulations published by FDA (Ref. 4). FDA believes that more comprehensive final regulations would optimize facility performance.

The interim regulations, for reasons stated above, were based primarily upon the voluntary standards of the American College of Radiology (ACR) Mammography Accreditation Program (MAP). Applying these standards to all facilities has had a significant impact on mammography nationwide but evaluations of the ACR program (Ref. 5) have shown that further improvement is possible through more comprehensive standards than those of MAP.

This is especially true in the equipment area where the MAP standards were minimal and where the FDA's authority under the Medical Device Amendments to the Food, Drug, and Cosmetic Act is limited because presently used mammography systems are pre-amendment devices. To provide greater assurances of quality equipment performance (and to meet a priority identified in ''The National Strategic Plan for the Early Detection of Breast and Cervical Cancers'' (Ref. 7), the ACR, with the Centers for Disease Control and Prevention had convened expert committees to develop specifications for mammography equipment. The reports of these expert committees were an important basis for the equipment provisions in the proposed regulations.

Other portions of the proposed regulations, such as those providing standards for imaging patients with breast implants, are required by the MQSA. In addition, some of the details contained in the proposed regulations, such as requirements to ensure that personnel have practical training on equipment they use, reflect areas of concern that were inadvertently neglected in the interim regulations.

For all of these reasons, therefore, it is necessary to replace the interim regulations with more comprehensive final regulations if the highest quality mammography that is reasonably achievable is to be obtained.

In issuing the interim regulations, FDA attempted to balance the pressing need to put national mammography standards into effect with the agency's concern that facilities be provided a reasonable amount of time to comply with these standards. The interim regulations were drafted and implemented to maximize lawful operation by facilities under existing quality standards, and to ensure adequate examinee access to quality mammography during the transition to more comprehensive national standards.

For example, the ACR, a private, nonprofit association of radiologists, began a voluntary Mammography Accreditation Program (MAP) in 1987 to provide assurance of quality to examinees seeking services at ACR-accredited facilities. Many of the requirements under the interim rules were derived from the ACR's MAP program, as well as from HCFA regulations and some State programs. The MAP included a number of procedural and image quality requirements for facilities applying for ACR accreditation, including an evaluation of actual clinical images produced by each facility. In the absence of a national regulatory requirement, only those facilities that voluntarily sought accreditation pursued the ACR accreditation process. Nevertheless, many mammography facilities applied for and obtained ACR accreditation. Historically, approximately 30 percent of the facilities that applied for ACR

accreditation failed to become accredited on their first attempt, although many of these were subsequently able to improve their services and gain accreditation on a second attempt.

C. Accreditation and Certification

Before the October 1, 1994, statutory deadline, FDA approved the ACR and the State of Iowa as accreditation bodies and issued certificates to the more than 6,000 facilities (out of an estimated total of 10,666 facilities in the United States) accredited by these bodies. The States of Arkansas and California were also approved by FDA as accreditation bodies and began accrediting mammography facilities within their States after the statutory deadline. These facilities were subsequently certified by FDA.

In addition, the MQSA permitted FDA to issue 6-month provisional certificates to facilities whose applications for accreditation had not been approved by the statutory deadline but were sufficiently complete to be accepted for review by an FDA-approved accreditation body. The statute also allowed FDA to extend a facility's provisional certificate once, for up to 90 days, if: (1) The owner, lessor, or agent of the facility could demonstrate that, without such an extension, access to mammography in the geographic area served by the facility would be significantly reduced; and (2) the owner, lessor, or agent described in a report the steps that would be taken to qualify for full certification (42 U.S.C. 263b(c)(2)).

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 increased demands placed on accreditation bodies during the initial implementation of the MQSA, FDA issued 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. These 6-month provisional certificates were extendable for an additional 90 days for those facilities that satisfied the extension criteria under the statute (42 U.S.C. 263b(c)(2)) and had diligently pursued accreditation, but had not yet completed all aspects of the accreditation process before expiration of their provisional certificate.

Of the more than 10,000 facilities that provide mammography services in the United States, the vast majority have received full accreditation and certification. By October 1, 1994, FDA had issued approximately 6,000 certificates and 4,800 provisional certificates. Moreover, over 50 percent of those facilities issued provisional certificates on October 1, 1994, subsequently became accredited and FDA-certified by March 31, 1994, which was the closing date for the 6-month provisional period. The remainder of the provisionally certified facilities satisfied the extension criteria and were granted a 90-day extension to obtain accreditation and certification.

The agency estimates that 427 mammography facilities closed between October 1993 and October 1994. These closings were due to a number of reasons, including failure to apply for certification, voluntary closure, and failure to successfully complete the accreditation process. By April 26, 1995, 4 weeks after the end of the 6-month provisional period, 153 additional facilities had to close either because they did not pursue accreditation (57 facilities) or they failed accreditation (96 facilities). Sometime during the 6-month provisional certification period, 187 facilities voluntarily withdrew from the accreditation process.

D. Onsite Inspection of Facilities

In accordance with the MQSA, FDA established an annual onsite inspection program to monitor facility compliance with MQSA standards. FDA has trained and certified inspectors from most States, and inspection of mammography facilities began in January 1995. As of February 21, 1996, 7,265 inspections had been conducted and the results have been reported to the agency.

E. Role of the States

The MQSA explicitly states that nothing in the statute is intended to limit the authority of any State to enact State laws relating to mammography that are at least as stringent as the MQSA or regulations under the MQSA (42 U.S.C. 263b(m)). In addition to ensuring that States retain their authority to pass laws that raise mammography standards even higher, Congress provided a significant role for States to play in implementing the regulatory scheme and nationwide standards required by the MQSA.

A State may apply to FDA to become an accreditation body to accredit mammography facilities operating within the State. As earlier described, three States—Iowa, California, and Arkansas—have been approved to accredit the facilities operating within their respective jurisdictions. A State also may apply to the agency to become the certifying authority for mammography facilities operating within its borders (42 U.S.C 263b(q)). The agency currently is conducting research into various alternatives that would allow States to fulfill this role.

The statute also permits States to perform annual onsite facility inspections to ensure that facilities operating within the State are performing quality mammography (42 U.S.C 263b(g)). To date, the District of Columbia, Puerto Rico, New York City, and all of the States, except New Mexico, have negotiated contracts with the agency to perform these annual inspections.

Facilities located in States that elect to serve as accreditation bodies may elect to be accredited either by the State or the ACR, a private national approved accreditation body. Both types of accreditation bodies are audited by FDA to ensure that MQSA standards are being satisfied.

As mentioned above, most States contract with FDA to perform the annual inspection required under MQSA. These inspections are subject to audit by FDA. In those cases where States do not do the inspection, Federal personnel conduct the required annual inspection.

States' participation and implementation of MQSA is funded in a variety of ways. Because the MQSA provides for but does not mandate a particular level of State involvement in the mammography program, a State can choose to participate at a level that does not require the appropriation or expenditure of State funds. States acting as accreditation bodies may charge and collect a reasonable fee from the facilities which seek the States' accreditation. States that currently participate in the annual onsite inspection of facilities are paid by FDA through contract. The agency charges the facilities a reasonable inspection fee for this service in accordance with 42 U.S.C 263b(r). Once the agency issues provisions to permit States to serve as certifiers of mammography facilities, MQSA requires States that elect voluntarily to serve in this capacity to devote adequate funds to the administration and enforcement of MQSA requirements.

F. Development of Proposed Regulations

Coincident with the implementation of the interim rules, work was proceeding on the development of proposed regulations to replace the interim rules. As discussed previously, the MQSA established an advisory committee (NMQAAC) to advise FDA in this effort. By statute, the NMQAAC is to consist of 13 to 19 members, including health professionals whose work focused significantly on

mammography, as well as representatives of consumer groups. The 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 proposed regulations as then drafted. Many of the requirements in the proposed regulations are based on advice obtained from the NMQAAC during these meetings.

G. Framework of Proposed Regulations

FDA is issuing five separate proposed rules to amend the interim regulations. All of these proposals are published in this issue of the Federal Register. The first proposed rule as set forth below, contains background information (given above), a summary of the preliminary analysis of the costs and benefits of the proposed amendments to 21 CFR part 900, a description of the information collection requirements, proposed revisions to §§ 900.1 *Scope* (21 CFR 900.1) and 900.2 *Definitions* (21 CFR 900.2), and proposed alternative approaches to mammography quality standards and a request for comments on the proposed alternatives. The other four proposals set forth requirements related to: (1) Accreditation bodies; (2) general facility requirements, including requirements for a medical reporting and recordkeeping program, a medical outcomes audit program, special methods for examining individuals with breast implants, a consumer complaint mechanism, and a variance procedure for requesting FDA approval of alternative standards; (3) personnel requirements for interpreting physicians, radiologic technologists, and medical physicists; and (4) definitions, mammography equipment standards, and quality assurance requirements for mammography equipment.

The agency believes that the proposed amendments, when implemented, will increase the quality of mammography nationwide and facilitate the early diagnosis and treatment of breast cancer or other diseases of the breast.

In drafting the proposed regulations, and in consultation with the NMQAAC, FDA has established specific requirements for those areas that the agency believes are essential to the practice of quality mammography. Conversely, in those areas where the agency is aware of multiple methods or procedures for effectively accomplishing the same task, the proposed requirements have been drafted in more general terms, to give facilities more flexibility to accomplish a particular quality practice. In some cases, FDA will provide guidance documents that explain methods and practices that the agency recommends, based on its current thinking, but does not require by regulation.

The rules that are developed and finalized as a result of this rulemaking will replace the interim rules issued on December 21, 1993. The interim rules will continue to apply until final rules become effective.

II. Alternative Approaches for Quality Mammography

Executive Order 12866 requires Federal agencies to identify and assess alternative forms of regulation and, where feasible, specify performance objectives, rather than specifying the behavior and manner of compliance that regulated entities must adopt (E.O. 12866, Section 1(b)(8)). In addition, Executive Order 12866 (Section 1(b)(10)) requires each agency to avoid regulations that duplicate other regulations. In proposing final standards, FDA is aware that there can be alternative means for ensuring quality mammography other than through those presented in these proposals. FDA notes that the MQSA itself establishes many overlapping requirements relating to quality mammography which are reflected in the proposed final regulations. FDA also recognizes that many of the proposed final regulations contain design specifications, training and educational requirements, and process requirements, rather than performance or outcomes standards. In order to meet objectives established by the Executive Order 12866, FDA is soliciting comments on the following alternative approaches to achieve quality mammography under the MQSA. FDA encourages comments on these alternative approaches to be as detailed as possible. Comments that address and describe the application of specific performance or outcomes standards will be most useful in the event the agency is persuaded that this alternative is the more desirable approach.

Overlapping functions for facilities, accreditation bodies, and FDA have advantages and disadvantages. As an example, under section 354(e)(1)(B)(v) of the Public Health Service Act (PHS Act) (42 U.S.C. 263b(e)(1)(B)(v)), as amended by the MQSA, the accreditation body is required to perform monitoring and evaluation of medical physicists' annual surveys. At the same time, under section 354(g)(1)(B)(v) of the PHS Act, the MQSA requires FDA to annually inspect facility compliance with quality standards, including compliance with the section of the MQSA that requires each facility to have a qualified medical physicist annually survey mammography equipment (42 U.S.C. 263b(f)(1)(F)). In this instance, therefore, annual physicist surveys are being reviewed by both the accreditation body and the inspector. FDA's experience under the interim final regulations is that of 7,431 MQSA inspections in 1995, only 5 accredited facilities were without annual physicist surveys. This suggests that duplicative review serves a compliance purpose. However, it may be possible under a different approach for the accreditation body to accept inspection reviews of surveys, or, for inspectors to accept an accreditation body's review of a facility's survey. While there are strengths in a program that has multiple checks and overlapping areas of responsibility to ensure compliance, there are also cost and resource considerations that may favor alternative approaches to satisfy statutory mandates. Such alternative approaches will need to adequately ensure integrity of the evaluation if oversight mechanisms are decreased. FDA is soliciting comments on approaches that would reduce the overlapping nature of many quality assurance provisions proposed, while maintaining assurances for integrity of the evaluation.

Advantages and disadvantages exist in adopting an approach that utilizes detailed design and qualification-based standards versus an approach based on performance standards and outcomes measures. For example, detailed design and behavior-based standards may be clear and precise; they can provide an objective evaluation of compliance during an inspection and make clear to facilities what is expected of them. However, these standards can limit flexibility and innovation and do not ensure that everyone who meets the established criteria is indeed competent. On the other hand, performance standards and outcome measures may allow greater variability in behavior and methods of compliance. However, while outcome measures may reflect the true nature of performance in a population and be an incentive to good performance, they may also be subject to adjustments to circumvent low performance. FDA is soliciting comments on the possibility of pursuing

quality mammography through more performance and outcome-based standards. FDA would also like comments on the anticipated economic consequences of this approach compared to the approach of the proposed regulations. FDA hopes the comments will provide more information regarding the short and long-term viability of this alternative approach for purposes of mammography regulation.

The following sections discuss ideas for the application of performance and outcome-based standards to mammography facility operations:

A. Mammography Equipment and Quality Control

Under current proposals, FDA has specified mammography equipment performance and design requirements. While design specifications are clear, they may inadvertently impede technical innovation. An alternative proposal would be to use phantom image testing as a complete equipment system test, thereby eliminating the need for other specific quality control tests, or, permitting those other tests to be conducted less frequently. The phantom image test is currently being proposed to be done weekly as a part of the facility's ongoing quality assurance program. The current phantom used, however, is not the optimal design if phantom image testing were to serve as a single system performance evaluation criterion. A recent article (Ref. 8) suggested that the current phantom has limitations in simulating the average breast. Research may be necessary to design a phantom whose image will be significantly affected by enough characteristics of the system so that other tests could be eliminated.

Another issue associated with the use of phantom image testing as a single system evaluation test is that there is inadequate information available on how phantom images correlate with actual clinical images. There is concern that no phantom image evaluation will adequately predict the clarity and characteristics of the entire biologic spectrum of breast tissue.

FDA believes it is theoretically possible to substitute phantom image testing for some equipment requirements and some quality control tests if some other standards were made more stringent and the phantom were suitable. For example, the frequency of phantom image testing might be increased to daily if the backing material could be changed to be more tissue equivalent, if different thicknesses could be developed to represent the range of actual breast thicknesses encountered in daily practice, and if research established appropriate performance parameters based on these changes. A step wedge might be included in the design of the phantom so that, after a trial period, daily sensitometry could be eliminated. It may be necessary to record the mAs value daily, so that when deviations occur, it would be possible to determine if it was an x-ray machine variation or film processor variation. Ideally, this image test would be combined with a dose measurement, at least periodically, so that an even more complete system test would be conducted.

Another possible performance measure for equipment and substitute for equipment specifications and quality control tests is an ongoing analysis of a facility's repeat rate. Under both the interim final regulations and the proposed final regulations set forth elsewhere in this issue of the Federal Register, the repeat rate is to be analyzed every 3 months, and up to 250 exams are used. Ongoing repeat analysis might substitute for some quality control tests, equipment requirements, and technologist requirements. Using the repeat rate as a performance outcome might be appropriate if repeat analysis were conducted continuously, rather than periodically, if personnel were trained to evaluate the films according to the criteria currently used by accreditation bodies for clinical image review, and if trends or problems were identified and corrected immediately. One potential problem with this approach is that the repeat rate is easily altered by a facility through the acceptance of all examinations of any quality performed. Thus, a facility could conceivably have a zero repeat rate, but many problems. Adopting use of repeat rates as a performance measure would require the development of mechanisms to minimize this type of manipulation.

B. Mammography Personnel: The Interpreting Physician and the Medical Audit

Under the current proposal for final standards, interpreting physicians would be required to meet initial qualifications through board certification or training, mammography-specific training and experience, and continuing education and experience requirements. While these requirements for training and experience guarantee familiarity with mammography and interpretation issues, it is possible that interpretation performance can be less than optimal despite meeting these requirements. An alternative means to ensuring the MQSA's mandate of ''* * * quality assurance * * * at each facility that is adequate and appropriate to ensure the reliability, clarity, and accuracy of interpretation of mammograms * * *'' (42 U.S.C. 263b(A)(1)(A)) may be to use performance-based standards.

The use of specific medical outcomes measures is discussed in the proposal entitled ''Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements'', published elsewhere in this issue of the Federal Register. FDA recognizes the significant cost and effort associated with tracking examinations interpreted as nonmalignant. While the absence of cancer registries in many locales limits the feasibility of collecting many outcomes measures, those locales with cancer registries may be able to collect data on sensitivity and specificity. These locales might be able to forego compliance with all or some of the proposed personnel qualifications so long as sensitivity and specificity for screening mammography, or other measures such as minimal cancer detection rates, were within an acceptable range, e.g., the Agency for Health Care and Policy Research guidelines. These ranges may have to be refined using other data from recently published practice patterns, clinical trials, and information from the National Cancer Institute's Breast Cancer Consortium studies. In order to be valid, facilities would have to track other variables of the screening clientele that could affect sensitivity and specificity such as age and other parameters that are currently being identified through research. This data collection, while time-consuming, would enhance the validity of calculated statistics.

In areas without cancer registries, positive predictive value may be calculated to assist in ensuring appropriateness and accuracy of physician recommendations. FDA notes that there is not yet a consensus on what ranges of the positive predictive value are acceptable, and that this value is subject to intentional adjustment by practices in the facility. However, use of the positive predictive value coupled with indices of early detection, such as sizes of cancers detected, could reduce concerns about intentional manipulation of data and provide a useful measure of an individual physician's comparative performance from year to year.

FDA recognizes concerns raised by the NMQAAC about public disclosure of statistics, including issues of legal liability and public confusion over the meaning and limitations of statistics.

The agency believes that data generated and reviewed for mammography audits should be used internally by each facility to improve individual and group performance. The agency further recognizes that State laws with respect to medical audit information vary and may not prevent disclosure in State courts through discovery or other procedures established by State law. However, concerns raised about public disclosure of statistics and consumers not understanding their limitations could be addressed through active consumer education to assist consumers in analyzing information and making health care decisions. A recent summary of the New York State experience with public reporting of cardiovascular surgery mortality outcomes showed improved risk-adjusted operative mortality beyond what was expected using nationwide trends for adjustment. The summary states that the collection data on mortality and reporting risk-adjusted mortality rates to hospitals and physicians contributed to improved outcomes (Ref. 9).

Finally, FDA is aware that substantial differences in statistics can arise from differences in definitions of screening mammography. Under an outcomes measurement approach, it might be necessary for the agency to define the precise situations that would constitute screening. For example, a woman with implants might have a diagnostic mammogram, meaning the procedure was under the direct supervision of an interpreting physician and consisted of more than standard mediolateral oblique/craniocaudal views. However, this woman's mammogram interpretation and her medical outcome might be classified by FDA as screening for statistical calculations if she was asymptomatic at the time of the examination. Thus, choosing to use outcomes measures could require the agency to establish certain definitions of medical practice.

Another alternative to proposed training and experience regulations is to have interpreting physicians undergo proficiency testing on mammogram interpretation. While the establishment of such tests and their periodic administration would be challenging, this testing, perhaps administered through the accreditation bodies, would allow for direct assessment of mammography interpretive skills. Remedial programs and reassessments would have to be established as well. FDA is aware of the ACR's Committee on Mammography Interpretive Skills Assessment (COMISA), created in 1992. COMISA is charged with development of an educational examination tool. Experiences gained through this project could be used for development of a proficiency test.

It is possible that regulations for interpreting physician qualifications could include all three options: Training and experience requirements, medical outcomes audit statistics and acceptable ranges, and an option for periodic proficiency testing, or some combination allowing for choice of compliance option. Again, FDA solicits comments on the utility and advisability of this approach.

C. Mammography Personnel: The Radiologic Technologist

Under the current proposal for final standards, radiologic technologists would be required to meet initial qualifications through board certification or training, mammography-specific training and experience, and continuing education and experience requirements. While these requirements for training and experience guarantee familiarity with the performance of mammograms and mammography issues, it is possible that the technologist's own performance can be less than optimal despite meeting these requirements. An alternative means to ensure proper mammography performance is to consider using clinical image review as a performance assessment tool. Clinical image review of a sufficient number of mammograms performed by the radiologic technologist would provide information on compression, positioning, selection of adequate technique factors, and production of clear and reliable mammograms. This assessment would have to control for equipment performance and processing in order for it to be a true measure of technologist performance. This could perhaps be accomplished through appropriate daily phantom imaging as discussed above. In addition, the method for selection of mammograms would have to be carefully defined to allow for representative sampling of technologist performance given differences in patients' habitus, breast morphology, and cooperativeness with the procedure. The assessment would also have to be correlated with repeat rate. It would be undesirable for the technologist to achieve a high level of clinical image quality at the cost of a high repeat rate.

As with interpreting physicians, the development of a technologist proficiency test that would include a practical examination could also be viewed as a performance-based measure. Currently, the ARRT's certification in mammography only includes a written examination. Expansion of this to include a practical examination along with periodic recertification examinations would increase the viability of ensuring competency in mammographic procedures.

D. Mammography Personnel: The Mammography Medical Physicist

Under the current proposal for final standards, medical physicists must be either board certified in an appropriate specialty or State approved, and, in addition, meet education and experience requirements. While these requirements are meant to ensure knowledge and experience in surveying and overseeing mammography machines and quality control, they do not necessarily ensure good performance. Alternative performance measures would include the development of a written examination along with a practical survey test. The survey test, while most reflective of actual practice, still could not test for all possible situations a medical physicist is called upon to deal with at facilities. It would be necessary to have this proficiency test repeated periodically, requiring the development of new logistic and administrative procedures. If this approach were adopted, the practicing medical physicist's actual performance outside of the testing environment still must be correlated to test performance. Development of an accurate and predictive tool would require adequate resources.

E. Request for Comments

FDA is interested in comments on the desirability of any of the approaches described above, and on any other possible approaches that would address the issue of performance-based standards. If performance-based standards are considered desirable, there may be need for additional research to provide information to make scientifically sound and cost effective performance based standards. There are several options as to how the agency could proceed while such research is being performed. The agency could leave the interim final standards in place, or, the agency could make minor amendments to the interim final standards to clarify points but not add any new requirements, or, the agency could proceed with final implementation of the set of standards contained in this proposal as modified after consideration of the comments. FDA invites comment on the pursuit of any of these or other options.

III. Scope and Definitions

A. Scope

Proposed § 900.1 summarizes the scope of part 900 (21 CFR part 900), which contains two subparts implementing different sections of 42 U.S.C. 263b. Subpart A of part 900 establishes application procedures and requirements for accreditation bodies. Subpart B of part 900 establishes procedures for mammography facility certification and quality standards for mammography facilities. The proposed requirements for subpart B of part 900 are published elsewhere in this issue of the Federal Register.

B. Definitions

FDA is proposing amendments and additions to the definitions established in § 900.2 of the interim regulations. These proposed definitions apply to the regulations in this proposal and in the other MQSA proposals published elsewhere in this issue of the Federal Register.

1. Amendments

a. *Mammography.* The amendments to the interim regulations published in the Federal Register of September 30, 1994 (59 FR 49808), added definitions of ''screening mammography'' and ''diagnostic mammography'' to clarify the applicability of the interim regulations to various types of facilities. However, differences of opinion within the professional community regarding the distinction between these two types of mammography became apparent in discussions between NMQAAC members and consultants at the January 1995 NMQAAC meeting. In addition, proposed changes to the interim regulations have made it unnecessary to define screening and diagnostic mammography for the purpose of these regulations. Therefore, FDA is proposing to delete these two definitions. The reference to screening and diagnostic mammography previously included in the interim definition of ''interpreting physician'' also would be deleted.

The definitions of screening and diagnostic mammography were intended to clarify which breast cancer screening or diagnostic mammography activities conducted by a facility were exempt from the MQSA regulations. Such exempted activities included any breast imaging conducted in a research setting as part of a scientific study to evaluate experimental mammography devices, in accordance with FDA's investigational device exemption regulations (21 CFR part 812). This exclusion did not apply to mammography conducted using any conventional mammography device as part of the scientific study to provide baseline data for evaluating the safety and efficacy of the experimental device. An exemption was also made for interventional mammography, which involves the use of breast radiography devices to produce radiographic images of the breast in association with localization or biopsy procedures.

These exemptions were based on FDA's belief that science had not advanced to the point where effective national quality standards could be developed for these devices. Because FDA still believes this to be the case, the agency is proposing to retain these exemptions, but to incorporate them into the proposed definition of ''mammography.'' Eventually, FDA does expect to develop standards for interventional mammography devices and for research devices that come into standard use.

b. *Interpreting physician.* Throughout the MQSA regulations, FDA is proposing to use only the term ''interpreting physician'' to refer to persons who interpret mammograms or perform clinical image reviews. Therefore, the agency is deleting the interim definition for ''qualified practicing physician.'' Also, as discussed previously, the term ''interpreting physician'' would be modified to refer to mammography, rather than screening and diagnostic mammography.

c. *Patient.* In the interim regulations, the term ''patient'' is used to mean any individual who undergoes clinical evaluation in a mammography facility, regardless of whether the person is referred by a physician or self-referred. However, most individuals who undergo mammography are not ill and do not have a condition requiring medical care. Therefore, FDA is proposing to substitute the term ''examinee'' for the term ''patient.''

2. New Definitions

a. *Personnel qualifications.* During implementation of the interim regulations, questions were raised concerning how physicians, technologists, or physicists in training, who had not satisfied the personnel requirements by October 1, 1994, or who failed to maintain them after October 1, 1994, might establish or reestablish their credentials. In response to these concerns, FDA is proposing amendments (published elsewhere in this issue of the Federal Register) to the personnel requirements in § 900.12(a) (21 CFR 900.12(a)). For the purpose of implementing these provisions, FDA is proposing to add definitions of ''contact hour,'' ''direct instruction,'' and ''direct supervision.'' The intent of these definitions is to clarify that: (1) The individuals providing training to mammography personnel must be in contact with the trainees, at least to the extent of evaluating their work; and (2) those who are supervising the trainees must be available to review, and, if necessary, correct the trainees' work.

The proposed revisions to § 900.12(a) also would ensure that individuals trained in the use, survey, or interpretation of images produced using one modality do not begin work using another modality without first receiving training related to that modality. The addition of this requirement made it necessary to define the term ''modality.'' FDA is proposing to define this as a form of technology, within the scope of the MQSA, for performing radiography of the breast. The technologies considered to be modalities under this proposed definition would include existing technologies, such as screen-film systems and xeromammography, and any future technologies within the scope of the MQSA. Technologies such as ultrasound that are used to image breast tissue but do not fall within the scope of the MQSA would not be considered modalities for the purpose of this proposed rule.

Under the interim regulations, interpreting physicians are allowed to use double reading to meet the initial and continuing experience requirements for physicians. The proposed requirements would permit this practice to continue. However, because there was some confusion over the meaning of the term, FDA is proposing to add a definition of ''double reading.''

A major concern of the NMQAAC was to make sure that the initial experience requirement for interpreting physicians did not cause problems for diagnostic residency programs that schedule the mammography rotations in the first 6 months of the final year. At the same time, it was considered important that interpreting physicians meet this requirement in a relatively short time before beginning to interpret mammograms independently. To meet both goals, FDA is proposing (elsewhere in this issue of the Federal Register) to require residents to become certified at the ''first allowable time'' if they want to use residency training to meet the initial experience requirement. Therefore, a definition of the term ''first allowable time'' has been added to the proposed regulations.

The interim requirements in § 900.12(a)(3) deal specifically with the qualifications of the medical physicist.

The interim regulation refers to requirements for degree programs in ''physical science.'' This term can cover a broad spectrum of scientific disciplines, some of which are unrelated to the knowledge and skills needed for mammography. For this reason, a narrower definition of physical science is needed (with respect to both bachelor's and advanced degrees). FDA is proposing that only physics, chemistry, radiation science (including medical physics and health physics), and engineering be considered as physical sciences for the purpose of this regulation.

b. *Equipment.* Standards for equipment used in mammography were established in § 900.12(b) of the interim regulations. Because of additional proposed equipment requirements, FDA is adding a definition for the term ''mean optical density,'' defined as the average of optical densities measured for specified phantom thicknesses at clinically appropriate peak kilovoltage (kVp) levels. A definition of the term ''mammography unit'' is being added to clarify that when this term is used, the reference is to the x-ray generator and associated components.

c. *Quality assurance.* Proposed § 900.12(d) would specify new requirements for the individuals responsible for various aspects of the facility quality assurance program. These proposed changes have made it necessary to define the terms ''lead interpreting physician'' and ''quality control technologist.'' The lead interpreting physician would be the interpreting physician with primary responsibility for ensuring that the facility quality assurance program meets the requirements of paragraphs (d) through (f) of § 900.12. It would be left to the discretion of the facility whether this individual would also have other supervisory duties. The quality control technologist(s) would be responsible for those aspects of the quality assurance program not carried out by the lead interpreting physician or medical physicist.

Several definitions are being added to proposed § 900.2 on quality assurance requirements for equipment. These include a definition for ''time cycle,'' which means the film development time, and for ''traceability,'' which relates to calibration of radiation measuring instruments.

d. *Mammography medical outcomes audit.* Discussions with the NMQAAC regarding the medical auditing requirements in proposed § 900.12(f) indicated a need to define medical audit. Therefore, FDA is proposing to define the ''mammography medical outcomes audit'' as a systematic collection of mammography results and the comparison of these results with outcome data (e.g., results of subsequent biopsy followup procedures).

For use with the mammography medical outcomes audit, FDA is also defining a ''positive mammogram'' as one with an overall assessment of findings that are either ''suspicious'' or ''highly suggestive of malignancy.'' This definition incorporates two of the assessment categories described in § 900.12(c)(1)(iii) (published elsewhere in this issue of the Federal Register) for use in mammography records and reports.

e. *Breast implant.* Proposed § 900.12(g), published elsewhere in this issue of the Federal Register, contains new standards for mammography of examinees with breast implants. Establishment of such standards is required by the MQSA. FDA is proposing to define a ''breast implant'' as a prosthetic device implanted in the breast.

f. *Consumer complaint mechanism.* FDA is proposing new requirements in §§ 900.4(g) and 900.12(h), published elsewhere in this issue of this Federal Register, for consumer complaint mechanisms to be established by facilities and accreditation bodies. The purpose of these new requirements is to ensure that serious complaints about the quality of the MQSA-related mammography services are adequately addressed without unduly burdening facilities and accreditation bodies with Federal regulations requiring extensive consideration of relatively minor complaints (e.g., complaints about facility air temperature). Therefore, FDA is proposing to add definitions of ''adverse event,'' ''serious adverse event,'' and ''serious complaint'' to clarify the kinds of situations that would require full investigation and correction under the statute. These definitions also would clarify that any substantive complaints that warrant attention, but are not within the scope of the MQSA (e.g., discrimination or harassment), must be handled through other mechanisms.

FDA is proposing to add a definition of ''consumer'' to clarify that the consumer complaint process also can be used by interested parties other than the examinee (e.g., family members or referring physicians).

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

This proposed rule sets forth preliminary ideas for the application of alternative performance and outcome-based standards to ensure quality mammography. FDA requests that comments submitted on this proposal also address the estimated costs and benefits of such alternatives.

FDA has examined together the impacts of the remaining four proposed rules to implement the MQSA requirements, published concurrently in this issue of the Federal Register, under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96–354), 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 proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). The agency has conducted preliminary analyses of the proposed rules, and has determined that the proposed rules are consistent with the principles set forth in the Executive Order and in these two statutes. The Regulatory Impact Study that details the agency's calculation of these economic impacts is available at the Dockets Management Branch for review. A brief summary of the cost and benefit determination follows.

Incremental annual costs were estimated for each section of the proposed regulations. Actions expected to be taken by mammography facilities to come into compliance with the proposal were identified and current compliance levels were estimated in conjunction with agency experts and industry consultants. Costs were determined for a 10-year analysis period. Yearly costs of compliance for mammography facilities were estimated to range from a high of $203.2 million during the first year of implementation

to $25.2 million during the 10th year (2005). These yearly costs differed due to the phased implementation dates for some of the proposed requirements. Overall, average annualized costs of this proposal (at a 7-percent discount rate) are preliminarily estimated to equal $61.4 million.

Over the full 10-year analysis period, expenditures for the largest cost element (replacement of mammography units and film processors with units meeting standards required in proposed § 900.12(b)) could total more than $270 million and contribute approximately $35 million in average annual costs (57 percent of total average annual costs). Other major cost components include proposed § 900.12(c)(2)(i) (written notification of patient) which accounts for average annual costs of $14 million (23 percent of total average annual costs), proposed § 900.12(c)(3)(ii) (telephone contact with referring physicians) which accounts for over $4 million in annual costs (7 percent of total average annual costs), and proposed § 900.12(e)(2) (requiring weekly image quality tests) which accounts for average annual costs of almost $2 million (3 percent of total average annual costs).

The benefits of the proposed rule were estimated as illustrations of the expected health outcomes for given levels of quality improvement. FDA believes that the proposed rules are complementary, and that quality improvements are limited by the ''weakest link'' in the process of conducting or interpreting a mammographic examination. Thus, benefits were estimated assuming compliance with all of the proposed requirements at the same level of overall quality.

Benefit scenarios were based on an outcome prediction model that forecast breast cancer survival based on stage-determination at the time of identification. In addition, FDA estimated the reduction in costs attributable to the avoidance of followup procedures for those patients correctly diagnosed as not having cancer due to a range of quality gains that may occur as a result of the proposed rule. The calculated benefits are illustrative of the magnitude of health gains that would be expected to follow heightened quality levels of sensitivity and specificity. For example, a 5-percent gain in a sensitivity measurement of 80 percent would indicate a revised sensitivity level of 81 percent (a reduction of the rate of false positives from 20 percent to 19 percent).

Overall, the agency could not predict precise quality improvement gains. FDA estimates, however, those 5-year survival rates of all patients identified with breast cancer would increase by 0.006 percent if quality improves by 1 percent, 0.028 percent if the proposed rules result in a 5-percent gain in quality, and 0.084 percent if the quality improvements induce a 20-percent gain in sensitivity. (These are equal to increased survival rates of 0.02, 0.1, and 0.3 percent for all screened patients at the estimated levels of improvement.) Based on current disease prevalence rates, these results project that a 1-percent quality improvement would avert 10 breast cancer fatalities annually (based on 5-year survival rates), whereas quality improvement levels of 5 and 20 percent, respectively, would prevent 50 and 150 cancer fatalities.

Several analyses have estimated that society has indicated a willingness to pay to avoid a statistical death of approximately $5 million. Therefore, a 1-percent improvement in sensitivity as a result of this proposal would have monetized benefits of $50 million. Likewise, 5 and 20 percent improvements would bring annual benefits of $250 million and $750 million, respectively.

In addition, the proposed rules are anticipated to result in corresponding percent improvements in specificity, which would reduce the number of followup procedures in nondiseased patients. An improvement of 1 percent would reduce current annual medical expenditures by approximately $14 million. If the improvement in specificity were as high as 5 percent, the annual reduction in medical costs would equal $72 million. A 20-percent improvement in quality would reduce current annual medical costs by $287 million.

FDA recognizes that the nature of these proposed regulations may have a disproportionate effect on 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. FDA is currently collecting additional information on the potential impact on this industry sector, and requests comments that will assist it in accounting for this impact.

The agency also notes that average annual compliance costs of $61.4 million could increase the cost per screening mammogram at certain clinics by from 2 to 6 percent. FDA has estimated that if these costs are passed on to consumers, the demand for mammograms could be reduced by approximately 200,000 per year (or 0.9 percent of current demand). However, the agency believes that quality improvement savings may more than balance these expected price effects.

FDA also examined the effect of alternative implementation schedules for this proposal. An alternative requiring even more elaborate equipment upgrade immediately upon issuance of the regulations was rejected as putting an unnecessary burden on the industry, with estimated average annual costs of more than $120 million. By eliminating some specifications that were considered marginal to ensuring mammography quality, and phasing in some requirements to allow for normal replacement of current equipment, the agency reduced the cost of compliance. FDA also found that delaying the implementation of the proposed equipment requirements by an additional year, while reducing the average annual compliance costs by $7.1 million, would mitigate the expected impact of the proposed rule on quality improvements. Therefore, the proposed implementation schedule was selected as a reasonable balance between compliance costs and quality improvements.

MQSA includes a separate reimbursement mechanism to repay State, local, or tribal governments for the costs of inspections required by these proposed regulations. Consequently, no unfunded mandate is placed on local governments as a result of these proposals.

In summary, FDA expects that the proposal would lead to mammography quality increases. Average annual costs of compliance with this proposal are estimated to be $61.4 million. The estimated benefits accrue as a result of fewer breast cancer mortalities as well as the avoidance of unnecessary surgery. While the magnitude of the expected quality increases are currently under investigation, an improvement of only 1 percent would result in monetized annual benefits of $64 million including 10 fewer cancer mortalities, which slightly exceed the estimated compliance costs. If the quality improvements range to 5 or 20 percent, the benefits would increase proportionately. A 5-percent improvement projects average annual monetized benefits of $322 million. At this level of quality improvement, the cost savings of avoiding surgery are, by themselves, greater than compliance costs. This would occur in addition to 50 fewer breast cancer mortalities per year. A 20-percent quality improvement would result in average annual monetized benefits of $1,037 million, with 150 fewer annual breast cancer deaths due to earlier detection.

Because of the preliminary nature of these estimates, FDA requests comments on all of the methodology and projections included in this analysis. Comments may be submitted to the Dockets Management Branch (address above).

IV. Paperwork Reduction Act of 1995

The information collections contained in the December 21, 1993, interim regulations implementing the MQSA were approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13) under control number 0910–0309, which includes OMB approval for Form FD–3422. The approval will expire July 31, 1998. Three of the five proposed rules to amend 21 CFR part 900, published together in this issue of the Federal Register, contain amendments to the approved information collections, and these revisions are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the revised information collections to 21 CFR part 900 are shown below with an estimate for any annual reporting and recordkeeping burdens which will be changed by these proposed rules. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Mammography Facilities.

Description: 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, 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.

Therefore, the agency solicits public comments on the revised information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

PROPOSED REQUIREMENTS FOR ACCREDITATION BODIES OF MAMMOGRAPHY FACILITIES

[Table 1a.—Estimated Annual Reporting Burden]

CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours	Total capital costs	Total operating and maintenance costs
900.3(b)(3) ..... 900.4(a)(7) [1]. 900.4(b)(2) [1]. 900.4(c) [1]. 900.4(d) [1]. 900.4(e)(1) [1]. 900.4(e)(2) [1]. 900.4(h)(1) [1]. 900.4(h)(3) [1]. 900.4(i)(1)[1]. 900.4(i)(2)[1].	10.0	1.0	10.0	60	600	$50	
Total	.....	.....	.....	.....	600	$50	0

[1] There is no additional burden.

PROPOSED REQUIREMENTS FOR ACCREDITATION BODIES OF MAMMOGRAPHY FACILITIES

[Table 1b.—Estimated Annual Recordkeeping Burden]

CFR section	Number of recordkeeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours	Total capital costs	Total operating and maintenance costs
900.3(f)(1) ..... 900.4(c) [1]. 900.4(c)(2)(viii) [1]. 900.4(c)(5)(iii) [1]. 900.4(d) [1]. 900.4(d)(5)(iii) [1]. 900.4(e)(1) [1]. 900.4(e)(2) [1]. 900.4(f)(2) [1]. 900.4(g) [1]. 900.4(h)(1) [1].	10	130	1,300	200	2,000		
Total	.....	.....	.....	.....	2,000	0	0

[1] There is no additional burden.

QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR MAMMOGRAPHY FACILITIES; GENERAL FACILITY REQUIREMENTS

[Table 2a.—Estimated Annual Reporting Burden]

CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours	Total capital costs	Total operating and maintenance costs
900.11(b)(1)[1]	.....	.....	.....	.....	.....	.....	.....
900.11(b)(2)[1]	.....	.....	.....	.....	.....	.....	.....
900.11(b)(3)[1]	.....	.....	.....	.....	.....	.....	.....
900.11(c)	10,000	0.005	50	20	1,000	.....	$1,000
900.12(c)(1)[1]	.....	.....	.....	.....	.....	.....	.....
900.12(c)(2)(i)[1]	.....	.....	.....	.....	.....	.....	.....
900.12(c)(3)(i)[1]	.....	.....	.....	.....	.....	.....	.....
900.15(d)(3)(ii)	10,000	0.002	20	2	40	.....	100
900.18(c)	10,000	0.0005	6	2	12	.....	60
900.18(e)[1]	10	0.1	1	1	1	.....	10
Total	.....	.....	.....	.....	1,053	0	$1,170

[1] There is no additional burden.

QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR MAMMOGRAPHY FACILITIES; GENERAL FACILITY REQUIREMENTS

[Table 2b.—Estimated Annual Recordkeeping Burden]

CFR section	Number of recordkeeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours	Total capital costs	Total operating and maintenance costs
900.12(c)(4)[1]	.....	.....	.....	.....	.....	.....	.....
900.12(d)(2)(i)[1]	.....	.....	.....	.....	.....	.....	.....
900.12(d)(2)(ii)	10,000	1	10,000	0.25	2,500		
900.12(d)(2)(iii)	10,000	1	10,000	1	10,000		
900.12(d)(2)(iv)[1]	.....	.....	.....	.....	.....	.....	.....
900.12(f)(2)[1]	.....	.....	.....	.....	.....	.....	.....
900.12(f)(4)[1]	.....	.....	.....	.....	.....	.....	.....
900.12(h)(2)	10,000	2	20,000	0.5	10,000	.....	$20,000
Total	.....	.....	.....	.....	22,500	0	$20,000

[1] There is no additional burden.

QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR MAMMOGRAPHY FACILITIES; PERSONNEL REQUIREMENTS

[Table 3.—Estimated Annual Recordkeeping Burden]

CFR Section	Number of recordkeeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours	Total capital costs	Total operating and maintenance costs
900.12(a)(4)[1]	.....	.....	.....	.....	.....	.....	.....

[1] There is no additional burden.

Under OMB information collection no. 0910–0309, 82,810 burden hours were approved for information collection currently contained in 21 CFR part 900. The additional requirements contained in these proposed rules will add 26,153 burden hours to this estimate, resulting in a total annual burden of 108,963.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted a copy of the five proposed rules amending 21 CFR part 900 to OMB for its review of the revised information collection requirements; these five proposed rules are published together in this issue of the Federal Register. Other organizations and individuals interested in submitting comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA. Written comments on the information collections should be submitted by May 3, 1996.

VII. Comments

The agency will consider any comments submitted in response to this proposed rule in its evaluation of the proposed alternative approaches for quality mammography and the four proposed amendments to the interim regulations published elsewhere in this issue of the Federal Register. FDA advises that, under 21 CFR 10.30(d), any comments submitted in response to this notice will be included under the docket number found in brackets in the heading of this document.

Interested persons may, on or before July 2, 1996, submit to the Dockets Management Branch (address above) written comments regarding this NPRM. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. 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. Wingo, P. A., T. Tong, and S. Bolden, ''Cancer Statistics 1995,'' *CA: A Cancer Journal for Clinicians*, 45:8–30, 1995.

2. Feuer, E. J., L. M. Wun, and C. C. Boring, et al., ''The Lifetime Risk of Developing Breast Cancer,'' *Journal of the National Cancer Institute*, 85:892–897, 1993.

3. 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.

4. Brown, M. L., F. Houn, E. A. Sickles, L.G. Kessler, ''Screening Mammography in Community Practice: Positive Predictive Value of Abnormal Findings and Yield of Follow-Up Diagnostic Procedures,'' *American Journal of Radiology*, 165:1373–1377; 1995.

5. Kuester, G. F., S. M. Wolfe, ''HRG Report on Screening Mammography, Public Citizen Health Research Group,'' July 1991.

6. Conway, B. J., O. H. Suleiman, F. G. Rueter, R. G. Antonsen, R. J. Slayton, J. L. McCrohan, ''Does Credentialing Make a Difference in Mammography?,'' U.S. Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD, Presented to the Radiological Society of North America, November 19, 1992.

7. ''The National Strategic Plan for the Early Detection and Control of Breast and Cervical Cancers,'' U.S. Department of Health and Human Services, Public Health Service.

8. Geise, R. A., A. Palchevsky. Composition of Mammographic Phantom Materials. *Radiology* 198:347–350, 1996.

9. Chassin, M. R., E. L. Hannan, B. A. DeBuono. Benefits and Hazards of Reporting Medical Outcomes Publicly. The New England Journal of Medicine, pp. 394–398 February 8, 1996.

List of Subjects in 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, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 900 be amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. Sections 900.1 and 900.2 are revised to read as follows:

§ 900.1 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (42 U.S.C. 263b). The intent of subpart A of this part is to establish procedures whereby an entity can apply to become an 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. The intent of subpart B of this part is to establish 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 42 U.S.C. 263b(e)(1)(A) 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 of the equipment 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 the self-referred examinee (as specified in § 900.12(c)(2) and (c)(3)(i)); and

(3) Use of personnel that do not meet the applicable requirements of § 900.12(a).

(d) *Breast implant* means a prosthetic device implanted in the breast.

(e) *Certificate* means the certificate described in 42 U.S.C. 263b(b)(1).

(f) *Certification* means the process of approval of a facility by FDA to provide mammography services.

(g) *Clinical image* means a mammogram.

(h) *Consumer* means an individual who chooses to comment or complain in reference to a mammography examination, including the examinee or representatives of the examinee (e.g., family members or referring physicians).

(i) *Contact hour* means an hour of training received through direct instruction.

(j) *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).

(k) *Direct supervision* means that:

(1) During joint interpretation of mammograms, the supervising physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the examinee's records; and

(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.

(l) *Double reading* means two or more interpreting physicians interpreting the same clinical image.

(m) *Examinee* 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.

(n) *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.

(o) *First allowable time* means the earliest time a resident is eligible to take the diagnostic radiology boards from an FDA-approved certifying body. The ''first allowable time'' may vary with the certifying body.

(p) *Interpreting physician* means a physician who interprets mammograms and who meets the requirements set forth in § 900.12(a)(1).

(q) *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 this individual, if any, are left to the discretion of the facility.

(r) *Mammogram* means a radiographic image produced through mammography.

(s) *Mammography* means radiography of the breast, but does not include:

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed as part of a scientific study to evaluate an investigational mammography device conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

(t) *Mammography equipment evaluation* means an onsite assessment of a mammography unit or image processor 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).

(u) *Mammography medical outcomes audit* means a systematic collection of mammography results and the comparison of those results with outcomes data.

(v) *Mammography unit* or *unit* 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 necessary supporting structures for these components.

(w) *Mean optical density* means the average of the optical densities measured for phantom thicknesses of 2 centimeters to 6 centimeters using values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

(x) *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).

(y) *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.

(z) *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.

(aa) *Phantom image* means a radiographic image of a phantom.

(bb) *Physical science* means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(cc) *Positive mammogram* means a mammogram that has an overall assessment of findings that are either ''suspicious'' or ''highly suggestive of malignancy.''

(dd) *Provisional certificate* means the provisional certificate described in 42 U.S.C. 263b(c)(2).

(ee) *Quality control technologist* means an individual meeting the requirements of § 900.12(a)(2)(i) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

(ff) *Radiographic equipment* means x-ray equipment used for the production of static x-ray images.

(gg) *Radiologic technologist* means an individual specifically trained in the use of radiographic equipment and the positioning of examinees for radiographic examinations and who meets the requirements set forth in § 900.12(a)(2).

(hh) *Serious adverse event* means 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.

(ii) *Serious complaint* means a report of a serious adverse event.

(jj) *Survey* means an onsite physics consultation and evaluation of a facility performed by a medical physicist.

(kk) *Time cycle* means the film development time.

(ll) *Traceability* means the ability to show that an instrument has been

calibrated at least annually through an unbroken chain of comparisons starting with either an appropriate national standard established by the National Institute of Science and Technology (NIST), Gaithersburg, MD, or with a transfer standard calibrated by NIST.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–7829 Filed 3–29–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 93N–0351]

RIN 0910–AA24

Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the facility standards established in the interim regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA). This proposed rule would modify and add to the general requirements for mammography facilities, including requirements for a medical reporting and recordkeeping program, a medical outcomes audit program, special methods for examining individuals with breast implants, a consumer complaint mechanism, and a variance procedure for requesting FDA approval of alternative standards. In addition to the statutory framework and the expertise and research of FDA personnel, the agency is proposing this rule based on advice from the National Mammography Quality Assurance Advisory Committee (NMQAAC) and public comments received in response to the interim regulations. This action is being taken to ensure safe, accurate, and reliable mammography on a nationwide basis. This is the third of five related proposed rules being published concurrently.

DATES: Written comments on this proposed rule by July 2, 1996.

Written comments on the information collection requirements should be submitted by May 3, 1996. The agency is proposing that any final rule based on this proposed rule become effective 1 year after its date of publication in the Federal Register.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Regulatory Impact Study (RIS) is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This proposal is the third of five related proposed rules published in this issue of the Federal Register to amend interim regulations published on December 21, 1993 (58 FR 67558 and 58 FR 67565) implementing the MQSA (Pub. L. 102–539). The first proposed rule, ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' contains background information and a summary of the preliminary analysis of the costs and benefits of all of these proposed rules, a description of the information collection requirements, proposed revisions to § 900.1 *Scope* and § 900.2 *Definitions*, and proposed alternative approaches to mammography standards and a request for comments on the proposed alternatives.

II. Provisions of the Proposed Rule

A. Development of the Proposed Regulations

This proposed rule establishes mammography facility standards for recordkeeping and reporting, medical outcomes audit, quality assurance, imaging of examinees with breast implants, and addressing consumer complaints. The proposal also establishes general certification requirements, and a procedure for any entity regulated under this rule to request FDA approval of alternative standards. As in the development of the interim regulations, FDA has been guided by the requirements of the MQSA and its stated legislative intent to guarantee access to safe and effective mammography services for all women in the United States (Ref. 1).

In addition to the statutory framework and the expertise and research of FDA personnel, the agency relied upon two major sources of information in developing this proposed rule. The first source was the written comments received on the interim regulations. FDA received 103 comments from individuals and organizations on the interim regulations. Included among the written comments were responses from professional organizations, medical facilities, State agencies, consumer groups, manufacturers, and individual physicians, medical physicists, and radiologic technologists.

The second outside source of information used to develop the proposed regulations was the advice and recommendations of the NMQAAC. Sections of these proposed regulations were discussed at the NMQAAC meetings in February, May, July, and September 1994. All of these proposed regulations, as then drafted, were reviewed again at the January 1995 meeting of the NMQAAC. The members of the NMQAAC include interpreting physicians, medical physicists, radiologic technologists, representatives of State agencies, and consumer representatives. Consultants to the NMQAAC and guests invited to attend the meetings in recognition of their expertise in mammography also participated in the discussions.

B. Applicability

Proposed § 900.10 states that the provisions of subpart B apply to all facilities under the jurisdiction of the United States that provide mammography services, with the exception of the facilities of the Department of Veterans Affairs (DVA).

Several comments objected to the exemption of DVA facilities from the interim regulations. In response to these comments, the agency notes that the DVA facilities are excluded from the requirements of the MQSA by the statute itself (42 U.S.C. 263b(a)(3)(A)). However, since the publication of the interim regulations, DVA has voluntarily committed its facilities to a program consistent with the standards issued under the MQSA.

C. Certification Requirements

Proposed § 900.11 defines the two types of certificates, provisional and

full, that permit a mammography facility to operate lawfully after October 1, 1994. This section states the length of time the certificates will be valid and the circumstances under which the certificates may be renewed or extended. In addition, proposed § 900.11(c) outlines reinstatement procedures for a facility that has allowed its certificate to expire, has been refused a renewal of its certificate, or has had its certificate revoked by FDA. It also states that the owner or operator of a facility that has had its certificate revoked by FDA may not apply for reinstatement until at least 2 years have passed from the time of the revocation. This additional restriction is required by the statute (42 U.S.C. 263b(i)(3)).

One comment on the interim regulations requested that FDA state clearly that a provisional certificate can only be issued once.

FDA reviewed this issue in connection with implementation of the interim regulations and concluded that the statute does not limit any particular facility to receiving a provisional certificate only once.

Situations in which a subsequent provisional certificate might be issued to a facility include cases where a facility was denied an initial full certificate or renewal of its full certificate or has had its certificate revoked by FDA but subsequently has made substantial progress in correcting the problems that led to denial or revocation of the certificate. In the case of a facility that failed to achieve accreditation and certification during its initial 6-month provisional time period, the regulations permit FDA to issue a second provisional certificate if the facility applies for one after a corrective action plan has been effectively implemented. At that point, a new 6-month provisional certificate may be provided to the facility while the accreditation process is underway. In the case of a revoked certificate, as described previously, at least 2 years must pass before the owner or operator of the facility can apply for a new provisional certificate. A subsequent provisional certificate also might be issued to a facility that allowed its previous certificate to expire but later wishes to resume providing mammography services.

However, the comment is correct to the extent that FDA may not issue two sequential, uninterrupted 6-month provisional certificates to the same facility. The agency invites comments on whether its policy of permitting a facility to obtain a subsequent 6-month provisional certificate once the facility has effectively corrected its deficiencies should be included in the final regulations and, if so, what if any, conditions should be placed in the process.

The same comment expressed the opinion that provisional certificates were only intended to aid facilities in meeting the October 1, 1994, deadline.

Although it is true that the provisional certificates were valuable in helping existing facilities meet the October 1, 1994, deadline, they are also intended to provide a way for new facilities to commence operation after the date became effective. To become accredited and certified, a facility must pass clinical image review. However, without provisional certification, a new facility would be unable to perform the necessary mammographic examinations for presentation to the accreditation body for review after October 1, 1994. The provisional certificate allows such facilities lawfully to produce the images they need to achieve full accreditation and certification.

Two comments suggested that other justifications, in addition to avoiding an adverse impact on the availability of mammography, should be considered in making a determination to grant a 90-day extension of the provisional certificate.

Congress limited the possibility of a 90-day extension of a provisional certificate under the MQSA to cases in which there would be a significant reduction of access to mammography in the geographic area served by the facility (42 U.S.C. 263b(c)(2)). Provisionally certified facilities should make every effort to obtain full certification no later than 6 months from the date the provisional certificate is issued.

Other comments asked that the time periods for the provisional certificates and the 90-day extensions be increased, primarily because of the difficulty accreditation bodies experienced in meeting the timeframes.

Again, the agency notes that the MQSA established these timeframes and FDA cannot amend them. Although the number of applications for accreditation submitted to meet the October 1, 1994, deadline did cause some difficulties for accreditation bodies meeting the timeframes, the accreditation bodies have increased their staffs to match the workload. The agency believes that once the initial implementation period is over, the accreditation bodies will be fully staffed to meet these timeframes effectively and efficiently, provided that facilities promptly submit the required information for evaluation. In addition, accreditation bodies are taking steps to adjust the timeframes for renewal of accreditation so that the workload is more evenly distributed.

One comment suggested that some additional time be allowed for FDA and facilities to gain experience with the interim standards before any major changes are proposed. The comment stated that experience could then serve as a guide in determining what revisions were needed.

When Congress gave FDA interim regulation authority, it intended that FDA take prompt action to promulgate final regulations through notice and comment rulemaking. Accordingly, FDA began work on the final standards almost immediately after the interim regulations were published. Because of the deliberative nature of the rulemaking process, however, the agency will have had some experience with the interim regulations before the final regulations are published. The lessons learned during this interim period have been and will continue to be applied in the development of the final regulations.

In addition, the passage of time has helped FDA identify concerns that were not immediately apparent when the interim regulations were drafted. For example, FDA has realized that there is a possibility that, at some future time, particular facilities may not have access to an accreditation body. If this event were to occur, FDA would have to provide an alternative for accreditation or the facilities could not lawfully operate. To be prepared for this possibility, the agency has added the words ''or other entity as designated by FDA'' at every point in § 900.11, and elsewhere in the regulations, where facilities are required to take some action with respect to their accreditation body.

D. Medical Records and Mammography Reports

Proposed § 900.12(c) establishes certain requirements for the content and terminology of the mammography examination report, the manner of communicating results of the mammography examination to the examinee and to health care providers, and the duties of the facility for maintaining records of examinees.

1. Mammography Reporting

The information and assessment categories listed in proposed § 900.12(c)(1) are intended to establish a minimum national standard that will permit the results of mammography examinations to be more easily compared. This standardized format for presenting the results of the

examination will assist in preparation of the medical outcomes audit that each facility is required to perform. The standard will also facilitate communication about the risk of breast cancer from the interpreting physician to the referring health care providers. The categories proposed in the regulation are recommended by the American College of Radiology and also recommended by the Agency for Health Care Policy and Research (AHCPR) mammography practice guidelines, ''Quality Determinants of Mammography.''

During discussions with NMQAAC, certain advisory committee members suggested that FDA establish standard operating procedures that facilities should follow for the production of mammography reports. FDA believes that regulating a facility's internal procedures for generating mammography reports would be overly intrusive. Interested parties can find suggested guidelines for optimal facility operating procedures for production and dissemination of mammography results in the AHCPR's ''Quality Determinants of Mammography.''

FDA and NMQAAC discussed the collection of racial and ethnic data as part of the recordkeeping requirements. Opinions of individual committee members varied with respect to collection of such data. FDA recognizes the value of these data in addressing such important issues as the utilization and efficacy of mammography, as well as other pertinent public health research questions. However, after consultation with other Public Health Service agencies that have experience in attempting to collect racial and ethnic data from mammography facilities, FDA determined that there is currently no effective established method for collecting this information. Therefore, FDA is not at this time proposing a requirement for facilities to collect racial and ethnic data. FDA does encourage facilities to collect all information, including racial and ethnic data, that will allow facilities to better understand and serve their particular communities.

The items listed in proposed § 900.12 (c)(1) and (c)(2)(i) are minimum requirements and do not preclude the facility from including additional information in mammography reports or in notifications to examinees, including relevant public health messages to the health care provider or to the examinee.

2. Signatures

Proposed § 900.12(c)(1) would require the written mammography report to be signed by the interpreting physician. FDA views the signature on the report as an attestation of the signatory as the individual who has read the mammogram and has rendered the interpretation in the report. Therefore, in addition to handwritten signatures on the mammography reports, FDA will accept other ''signatures,'' including those that are generated from computer systems, typewritten, or name stamped, on the condition that these signatures were personally authorized by the interpreting physician.

NMQAAC advised FDA to adopt regulations to mandate that all facilities have a written policy that ensures the integrity of the signature on the mammography report as coming from the interpreting physician, or a designated interpreting physician, if the interpreting physician is unavailable. NMQAAC also encouraged FDA to mandate that facilities assure that all personnel signatures, and other legally binding equivalents in the medical record, include professional titles. FDA encourages these practices but believes that it is unnecessary to require them through regulation.

3. Communication With the Examinee and Health Care Providers

Communication responsibilities have long been a frustrating area in mammography practice. All women who have mammography need to know the results. Examinees without any health care providers need to have the actual reports to show to subsequent health care providers, especially in the case of abnormal findings. Many examinees believe no news is good news. This fallacy contributes to delays in treatment when, through communication problems, the significance of a finding is not properly communicated to the examinee.

Currently, interim regulations provide that only women who have no health care provider receive the actual medical report and a summary of the mammography results in lay language. Two comments on the interim regulations recommended that the final regulations be amended to ensure that every examinee receives a written report signed by the interpreting physician and presented in lay language. One comment on the interim regulations suggested requiring the report to include all elements previously required by the Health Care Financing Administration's (HCFA's) screening mammography program.

Proposed § 900.12(c)(2) would require that all examinees receive notification of results expressed in lay terms. Examinees without health care providers would receive the actual mammography report along with the lay notification. If there is a health care provider, the lay notification would go to the examinee and the actual report would go to the health care provider, who, in turn, could communicate with the examinee again or in greater detail, if necessary.

This proposal is in response to consumer complaints of failure to communicate abnormal and normal results to examinees. The proposed standard intends to maintain the examinee-provider relationship while ensuring that results get communicated to the examinee. The lay notification of results and recommendations vary in length and detail, but may be as simple as ''Your mammogram reveals you need further tests. Please contact your physician.'' FDA also believes that notifications to examinees should be written in a way that is not overly alarming. In addition, FDA believes that in those cases in which an examination reveals the need for followup, notification directly to the examinee is essential.

FDA recognizes there are some referring health care providers who feel that they may be placed in an uncomfortable position if an examinee is notified of results before the health care provider is notified. There is also a concern that the examinee may be unduly alarmed by the facility's notification.

In response to these concerns, the agency notes that the main purposes of the lay notification requirements are to provide another safety mechanism to help to ensure that abnormal results are followed up and to ensure that all examinees know their mammography results. If facilities notify physicians and examinees simultaneously, the referring doctor will have access to the results of the mammogram at the time an examinee calls for clarification or followup. Those physicians who prefer to handle all communication with their examinees may continue that practice if procedures are properly coordinated with the facility generating the reports. The proposed requirements would not prohibit the mammography facility from providing standard lay notifications, along with the mammography report, to a referring health care provider who has agreed to issue these notices to his or her examinees. This agreement should be documented by attestation statements from the referring provider and should be on file at the mammography facility for inspection purposes.

During discussions with NMQAAC, FDA heard diverse opinions concerning the form and content of the notification that all examinees will receive.

However, NMQAAC did favor some form of written notification to all examinees, and that recommendation has been incorporated into the proposal.

Section 900.12(e)(2)(ii)(A) of the interim regulations establishes that the written report of any mammography examination shall be sent directly to the patient if the patient's physician is not ''available'' or if the patient does not have a physician. Two comments stated that the word ''available'' in this provision is ambiguous and could be interpreted to mean that the physician will not be notified if he or she is on vacation, at a meeting, or absent. One comment suggested deleting this word. Another comment asked how one is to ascertain the availability of the examinee's physician at the time a report is generated.

FDA advises that, in the proposed regulation, communication of mammography results to examinees and communication of results to health care providers are addressed in separate sections. As with the interim regulations, the proposed regulations require a facility to provide the mammography report directly to the examinee if she does not have a health care provider (§ 900.12(c)(2)(ii)). The issue of the ''availability'' of a physician is addressed in the section of the proposed regulation that covers communications of results to health care providers, § 900.12(c)(3).

Proposed § 900.12(c)(3)(ii) is intended to address the specific concern that arises when a mammography report reveals possible malignancy. The proposed regulations would require the mammography facility immediately to make reasonable attempts to communicate a finding of possible malignancy directly to the health care provider or a responsible designee, if the health care provider is not available. ''Not available'' is intended to mean ''not on call,'' ''not able to be reached at this time,'' or other similar situations. Health care providers normally have means of handling unexpected important health matters concerning their examinees through coverage systems and the proposed regulation recognizes this practice. The regulations are intended to require reasonable attempts to notify the health care provider or the entity designated by the referring health care provider as responsible for patient care while the referring health care provider is not available.

Questions were raised by the NMQAAC about retention of lay notifications. Although the regulations do not require a facility to keep a copy of the notification in the medical record, each facility should have a system to monitor and verify that such a notice was sent out for each examinee. In addition, samples of the lay notifications which go to all examinees must be available for inspectors during annual the MQSA inspections.

The results given in the lay notification are purposely labeled as ''results'' and not as ''assessment'' to avoid facilities having to use one of the six assessment categories in proposed § 900.12(c)(1)(iii) and (c)(1)(iv). FDA encourages facilities to tailor these lay notification letters of results to their clientele's literacy level, and ethnic, cultural, and social sensibilities in order to maximize the likelihood that these examinees will understand and appropriately followup results.

Proposed § 900.12(c)(2) recognizes that assessments indicating a high probability of cancer need to be communicated with special care to examinees, especially to those examinees without health care providers. Examinees without a health care provider should receive person-to-person communication, such as a telephone call, if it is at all possible, when immediate followup is needed. In addition, in these and other circumstances, such as when there are physical findings in the absence of mammographic findings, when there are symptoms of breast disease, or when a mammography report recommends further testing, the proposed regulation requires each facility to have a formal system that can refer an examinee who is without a health care provider. FDA believes this proposed regulation codifies the role many radiologists now assume with self-referred examinees.

The interim regulations require each facility to prepare a written report of the results of each mammographic examination as soon as possible. Two comments on the interim regulations stated that it is not clear how a time limit of ''as soon as reasonably possible'' for completing a report can be enforced. The comments suggested inclusion of an actual time limit or replacing the word ''shall'' with ''should.''

FDA agrees that a timeframe should be specified. Proposed § 900.12(c)(3)(i) requires every mammography report to be prepared and communicated to the health care provider as soon as possible, but no later than 30 days from the date of the examination. Proposed § 900.12(c)(2) establishes the same timeframe for communication of results to examinees. If the facility is gathering comparison films, an initial report or notification can be sent to the examinee or health care provider indicating preliminary results with an addendum to follow.

4. Recordkeeping

One comment stated that the mammograms should be kept indefinitely, noting particularly the need for retention of baseline mammograms.

FDA believes that the 10-year time period, which is set forth in the statute itself, 42 U.S.C. 263b(f)(1)(G)(i), allows for adequate prior information to be stored and used. The proposed regulations thus adopt, in § 900.12(c)(4)(i), the same retention periods required by the interim regulations, which establish a minimum of 10 years in situations where no additional mammography examinations are done for an examinee. The time period may be longer, if required by State law.

One comment stated that the retention requirement in § 900.12(e) of the interim regulations requires facilities to retain all mammograms for 10 years, because costs of determining after 5 years whether an examinee has had additional mammograms will exceed storage costs.

FDA does not agree with this comment. One way to determine if mammograms can be discarded is during filing of each new mammogram. At that time, prior mammograms over 5 years old can be discarded if clinically appropriate and if permitted by State law. This policy allows for a case by case determination of record retention for individual examinees. A facility can keep images longer than the minimum set forth in the proposed regulations.

The same comment further requested that FDA revise the interim regulations to require that mammography records be retained for the same time periods that are otherwise required by State law, or if any State lacks such a requirement, for a period of 7 years, which is the time period specified by California.

Because the MQSA specifies minimum retention periods, the proposed change would be inconsistent with the statute. The MQSA permits States to have more stringent regulations, including requirements relating to record retention. However, the 7-year California requirement for retention of a single mammography examination would not be a more stringent requirement, because it is less than the 10 years required by the MQSA.

One comment noted that two mammography studies taken on consecutive days would allow a facility to circumvent the requirement for 10-year record retention.

FDA does not believe this comment raises a valid concern. Although the first mammograms would be exempt from the 10-year retention period, the second study would not be. It is doubtful that a facility would discard the first study while maintaining the second and highly improbable that any facility would do double studies simply to avoid retaining a set of images.

One comment suggested that examinees should only have a right to copies of mammograms, not to the originals, because of the increased risk of loss or misplacement associated with examinees permanently taking possession of their original films and reports. Another comment from an interpreting physician noted great difficulty in obtaining original mammograms for comparison purposes. This comment stated that copied films are of inadequate quality when assessing the need for surgery.

The issue of whether to require copies or originals to be sent to facilities for clinical use or for comparison studies was discussed with NMQAAC. Although NMQAAC members did acknowledge problems with loss or misplacement of original films, there was general concern that many copies were of such poor quality that they did not provide adequate information. Sometimes only original films can provide the information that will prevent a woman from undergoing unnecessary invasive procedures, or confirm the need for such procedures. Thus, the NMQAAC agreed that FDA should require that originals be sent for comparison studies, as proposed in § 900.12(c)(4)(ii). Under the proposed regulations, examinees would need to request any transfer of their films. Facilities could ask examinees to sign releases as part of the request for the transfer of originals. A copy of the film could be kept at the original facility until the original films are returned.

FDA and NMQAAC discussed the issue of facility closure and disposition of the films and mammography reports. Members of the NMQAAC advised FDA to require that facilities give the public notice of their impending closure to allow a reasonable opportunity for examinees to obtain or transfer films and reports; that facilities be required to make financial plans to fulfill this notification requirement and to transfer medical records in the event of cessation of mammography activities; that facilities be required to notify the accreditation bodies and FDA of the disposition of films and records; and that facilities establish contingency locations for the transfer of examinees' films and records.

The issue of medical record and film disposition in the event of a closure is generic to the health care system. Facilities are required under the interim and proposed regulations to report all changes in status to their accreditation bodies, including plans to close. FDA would encourage facilities to plan for an orderly transfer of records in case of closure and to comply with applicable State laws concerning record retention. However, FDA believes that additional Federal regulations on this issue would be problematic with respect to compliance and enforcement.

E. Quality Assurance—General

The MQSA requires each facility to establish and maintain a quality assurance and quality control program to ensure the reliability, clarity, and accuracy of interpretation of mammograms.

Proposed § 900.12(d) establishes general requirements for quality assurance (QA) programs.

Proposed § 900.12(d)(1) requires the facility to assign responsibility for various components of its QA program to individuals who are qualified for their assignments and who shall be given adequate time to perform their duties. Proposed § 900.12(d)(1) also establishes QA responsibilities for the lead interpreting physician, interpreting physician, medical physicist, and quality control technologist.

The agency developed these regulations in response to several comments that objected to the medical physicist having primary responsibility for the QA program under the interim regulations. The comments noted that, especially if the medical physicist is a contract employee, he or she may not have the authority to ensure that all the actions necessary for proper implementation of the QA program are carried out. In addition, NMQAAC members advised FDA that some aspects of the QA program fall outside the medical physicist's area of expertise.

The agency believes that the division of responsibility under the proposed regulations addresses these concerns and satisfies the requirements under the MQSA that certain responsibilities be assigned to the physicist.

Proposed § 900.12(d)(1)(i) states that the lead interpreting physician shall have general responsibility for assuring that all of the QA requirements are met. The regulation is intended to recognize that, in order to carry out this responsibility effectively, the lead interpreting physician must have authority to ensure that the individuals involved with the QA program are qualified for their duties and that they perform them properly.

The proposed regulation requires each facility to designate a qualified individual as lead interpreting physician for purposes of the QA program. However, the actual administrative title of the individual is left to the facility. Decisions to assign other supervisory duties, unrelated to the QA program, to the lead interpreting physician are left to the discretion of each facility.

NMQAAC felt strongly that the individual assigned overall responsibility for the QA program should be an interpreting physician. NMQAAC recognized that this may cause some difficulty for a facility whose interpreting physician is not normally at the facility. However, the committee believed, and FDA agrees, that the benefits to be gained when the individual overseeing the QA program has the skills of an interpreting physician outweighed the difficulties.

Proposed § 900.12(d)(1)(ii) establishes that all interpreting physicians have a responsibility to assist and participate in the QA program.

Proposed § 900.12(d)(1)(iii) establishes that the primary responsibility of the medical physicist in the QA program is related to mammography equipment.

Proposed § 900.12(d)(1)(iv) is intended to recognize that many aspects of the QA program should be assigned to quality control technologists. NMQAAC believed that it was essential that quality control technologists be qualified to perform diagnostic radiology examinations in order to be able to carry out adequately the responsibilities normally assigned to them, including, for example, responsibility for darkroom cleanliness, darkroom fog tests, processor quality control, analysis of fixer retention in film, and retake analysis. After some discussion, NMQAAC also concluded that the quality control technologists need not be qualified to perform mammography examinations specifically.

NMQAAC's position is reflected in the definition of quality control technologist in proposed § 900.2, published elsewhere in this issue of the Federal Register. The definition would bar biomedical engineers, manufacturer's service personnel, darkroom personnel, or individuals in other positions from serving as quality control technologists unless they were also qualified to perform diagnostic radiology examinations.

NMQAAC discussed the advisability of limiting performance of certain QA

tasks exclusively to quality control technologists. NMQAAC concluded that there might be certain situations where the absence of the technologist might require a medical physicist or interpreting physician to step in and perform these tasks in order to avoid the temporary closure of a facility. The proposed regulations, therefore, do not assign specific QA duties to particular individuals, as do the ACR manuals.

Proposed § 900.12(d)(2) outlines the necessary QA records the facility will be required to keep. These records include: A QA manual; a list assigning responsibility for the various aspects of the QA program; records to show the qualifications of the individuals involved in the program; and records that monitor the facility's implementation of its QA program and resolution of any problems that occur. FDA believes that such records are necessary to ensure that all employees are aware of their QA responsibilities and trained to perform them and that appropriate actions are taken to meet the goal of providing high quality mammography.

F. Medical Outcomes Audit

Proposed § 900.12(f) requires a mammography medical outcomes audit program to be part of each facility's QA program. A mammography medical outcomes audit is a systematic collection and analysis of mammography results and the comparison of those results with data from biopsy results.

The intent of the mammography medical audit is to provide an objective measure of the interpretive ability of the interpreting physician. This information can be useful for determining how the interpreting physician performs from year to year and in comparison with other interpreting physicians in the same facility and serving the same examinee population.

As the medical outcomes audit data are collected and analyzed, a facility should acquire information that can improve the interpretive skills of the physicians. Some examples of this type of information include: positive predictive value (PPV), cancer detection rate, and percent of minimal cancers found. The medical literature describes these and other outcome data that may prove useful in assisting the interpreting physician in assessing and continuing to develop and improve his or her interpretive skills. If one interpreting physician is not ''doing as well'' as his/her colleagues in the same practice, he/she may obtain additional training.

Although audits can be as detailed as necessary, the proposed requirements in § 900.12(f) for the medical outcomes audit program are general in nature. There are several reasons for this. In drafting the MQSA, Congress recognized that there is not consensus on the most desirable methodologies for such audit programs and provided authorization in 42 U.S.C. 263b(p) for research grants to study the most desirable methods for the collection and use of outcomes data. These research grants are administered by the National Cancer Institute (NCI). FDA believes it would be premature to require specific methodologies in the regulations before these studies are complete. In addition, some facilities may not be able to collect data that are meaningful if specific methodologies are mandated. The agency also believes that each facility should have flexibility to design an audit program that best serves its needs.

There was also concern expressed during discussion with NMQAAC that facilities may be reluctant to collect medical audit data because of concerns relating to legal liability and malpractice litigation.

In response to these concerns, FDA advises that the MQSA requires the agency to establish standards for a quality assurance and quality control program at each facility (42 U.S.C. 263b(f)(1)(A)). The agency believes that data generated and reviewed for mammography audits are to be used internally by each facility to improve individual and group performance and should not necessarily be viewed as information that is accessible to third parties.

The MQSA inspectors are trained to verify that a facility has a medical audits system that tracks positive mammograms, seeks followup results of surgical procedures, correlates those results with the mammogram, and interprets and evaluates the resulting data at least yearly for both the facility as a whole and for individual interpreting physicians. Inspectors ordinarily will not copy the data as part of the inspection and FDA has no current plans to ask facilities to provide the agency with the results of their medical audits. Accordingly, it is unlikely that the agency will have records in its possession that would be responsive to requests from the public for medical audit data.

If it does become necessary for an MQSA inspector to collect specific medical audit data, or if FDA should wish to obtain such data in the future, the agency would protect audit results from public disclosure in accordance with the Freedom of Information Act, the Trade Secrets Act, and the agency's implementing public information regulations. Aggregate data that does not identify the medical audit outcomes of any particular facility would be available to the public.

The agency recognizes that State laws with respect to medical audit information vary considerably. The 1993 ACHPR guidelines on ''Quality Determinants of Mammography'' noted that very few broadly drawn statutes protecting audit information from discovery are in place at this time. Accordingly, the agency's commitment to protect such data may not prevent disclosure in state courts through discovery or other procedures established by State law. The agency believes, however, that the medical audit requirements that are proposed in this rule are general requirements that will not increase third-party requests for medical audit data.

Proposed § 900.12(f) requires each facility to establish and maintain a mammography medical outcomes audit program that correlates the results of biopsy and cytology examinations with the interpreting physician's recommendations. A facility must correlate the biopsy or cytology results of its positive mammograms with the interpreting physician's recommendations and mammographic report. A positive mammogram includes one that has an overall assessment of findings that are suspicious or highly suggestive of malignancy, as set forth in proposed § 900.12(c)(1)(iii). The pathologist examines the tissue sample and its cellular structure to determine whether or not the tissue is cancerous.

Proposed § 900.12(f)(4) requires each facility to designate at least one interpreting physician to review the audit data at least annually. This individual shall record the dates of the audit period(s) and be responsible for identifying issues and analyzing results based on this audit. This physician will notify other interpreting physicians of these issues and results, and ensure that necessary corrective actions are taken and documented. The proposal requires evaluations to be made individually and collectively for all interpreting physicians at the facility.

One comment noted that the preamble to the interim regulations discussed preventing false negative results, but the only quality assurance issue actually addressed in the interim regulations was the tracking of positive readings.

FDA believes that it would be too burdensome to require facilities to identify all false negative exams because, at the current time, adequate methods are not available to track all negative readings. The research studies funded by NCI grants may prove helpful

in future development of adequate methods for tracking false negative results.

A related comment expressed the belief that it was imperative that FDA spell out specific audit standards in the regulations. Another comment suggested that the final regulations should include a requirement for keeping statistics on additional procedures ordered by each radiologist.

Again, NCI's research program may aid in determining whether the collection and analysis of specific statistics should be mandated. However, FDA believes that currently there is inadequate data to justify making these suggestions regulatory requirements. NMQAAC supported the agency's position at its January 1995 meeting.

One comment suggested that, instead of correlating surgical biopsy results with mammography reports, a similar result can be achieved by requiring documentation of all erroneous or indistinguishable mammography results through a complaint program.

FDA believes the complaint mechanism and audit are substantially different in intent; therefore, one cannot replace the other.

One comment did not understand how the radiology department could use outcomes data, such as pathology reports, to improve the quality of mammography or the performance of technologists.

FDA believes that an audit program helps to provide quality assurance for the interpretation component of mammography by reviewing outcome data for each interpreting physician and monitoring how that physician is performing over time with respect to other interpreting physicians in the same facility and serving the same patient population. This review and analysis provides physicians with an opportunity to evaluate and improve performance. As mentioned previously, a physician may learn from an audit that he or she needs additional training in particular skills. Technologists' performance may be better evaluated through the repeat analysis process.

One comment mistakenly perceived a deficiency in the interim audit regulations because the comment believed that the interim regulations did not require followup of positive screening examinations. In fact, the interim regulations do require the facility's medical audit to track all positive mammograms and this requirement has been maintained in the proposed regulations at § 900.12(f)(1).

One comment suggested that all mammograms should be read a second time by a second qualified physician to avoid unnecessary surgery and emotional distress that can be associated with a false positive reading, and to avoid lack of appropriate followup and treatment in the case of a false negative reading.

Although the proposed regulations do not preclude this practice, FDA has not required it due to a lack of consensus within the medical community as to whether the benefits of double reading outweigh the costs. FDA solicits further comments on this issue.

G. Mammography of Examinees With Breast Implants

The MQSA specifically requires that standards be established relating to special techniques for mammography of examinees with breast implants (42 U.S.C. 263b(f)(1)(H)). FDA interprets this requirement to mean mammography of the breast for the early detection of breast cancer, and not for imaging of the implant for rupture, leakage, or other problems. The agency recommends that women who have had breast surgery for cancer, including reconstruction with breast implants, consult with their physician as to the appropriateness of mammography for their particular situation.

Proposed § 900.12(g) requires facilities to establish procedure(s) to identify examinees with breast implants. The regulation also sets forth general techniques facilities should follow for mammographic examinations of women with breast implants. The proposed requirements are flexible enough to allow efficient adoption of newer imaging techniques as they become available.

One comment suggested that facilities should simply establish an intake procedure to identify examinees with implants and to indicate that special techniques are necessary. Another comment expressed concern that, if an examinee does not notify the technician that she has an implant, the mammogram may have to be redone.

FDA agrees with these comments and has proposed in § 900.12(g)(1) that facilities have a procedure to inquire if an examinee has a breast implant at the time of mammogram scheduling.

Another comment suggested that there be a requirement for ''Eklund'' views (four views per breast). A similar comment stated that, in order to obtain an adequate image of a breast with an implant, both the breast and implant should be carefully manipulated so that the maximum amount of breast tissue is imaged. A third comment, however, stated that FDA should not mandate medical procedures in regulations.

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. There was also recognition, however, that other methods may exist that would be preferable in particular cases.

In addition, breast implant imaging is evolving, and the agency believes that it would be premature to limit this imaging by regulation to only one technique.

However, in response to the comment that stated FDA should not require medical procedures in regulations, the agency notes that the MQSA does require FDA to establish standards and that the codification of certain procedures in regulations may be appropriate when there is consensus that such procedures are necessary to protect women and assure accurate and safe mammography.

Another comment suggested that mammography facilities provide an excellent opportunity for further data collection and health assessment of examinees with implants.

In response to this comment, FDA notes that proposed § 900.12(f) requires mammography facilities to perform mammography medical outcomes audits, and that these audits would include examinees with breast implants.

Two comments were concerned about possible harm from the compression of the implant.

To minimize this possibility, FDA has proposed in § 900.12(a)(2)(ii)(C) (published elsewhere in this issue of the Federal Register) that the technologist have at least 5 hours of training in imaging examinees with breast implants and in § 900.12(g)(3) that the supervising interpreting physician be required to have training in mammography of examinees with breast implants, including specialized mammographic techniques.

H. Facility Complaint Mechanism

In accordance with section 354(n)(3)(E) of the Public Health Service Act (the PHS Act) as amended by the MQSA (42 U.S.C. 263b(n)(3)(E)), FDA has worked with the NMQAAC to develop mechanisms to investigate consumer complaints about mammography services provided by facilities. The preamble for proposed § 900.4(g), published elsewhere in this issue of the Federal Register, provides a thorough discussion of the complaint mechanism, including the role of the accreditation body in the process. In addition, FDA received a number of written comments on the complaint

mechanism following the publication of the interim rules (58 FR 67558 and 58 FR 67565). These comments are also addressed in the preamble to proposed § 900.4(g).

While proposed § 900.4(g) focuses on the responsibility of accreditation bodies for consumer complaint processes, proposed § 900.12(h) establishes corresponding requirements for facilities to develop a system to evaluate and resolve consumer complaints about the mammography services that they provide. FDA believes that consumer complaints can be resolved most easily at the individual facilities providing the mammography services. Therefore, FDA encourages the facilities to work diligently to resolve these complaints. However, in the event that a facility is unable to resolve a complaint to the consumer's satisfaction, proposed § 900.12(h) requires the facility to provide the consumer with adequate directions to file the complaint with the facility's accreditation body.

Some members of the NMQAAC suggested that FDA require facilities to post a sign that explains how to file consumer complaints or provide a toll free telephone number for making such reports to the accreditation body.

At this time, FDA is proposing not to mandate such requirements. Instead, FDA believes facilities should have the flexibility to promote their own consumer complaint mechanism to their clientele in a manner that is most appropriate. The agency 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 the examinees.

Proposed § 900.12(h) is intended to ensure that ''serious'' complaints within the purview of the MQSA are adequately addressed. ''Serious'' complaints are defined in proposed § 900.2. FDA has worked extensively with the NMQAAC in developing the proposed consumer complaint mechanism and believes the proposed requirements meet important consumer needs without imposing an undue burden on facilities. Proposed § 900.12(h) establishes minimum requirements for facilities and provides them with the flexibility to institute their own complaint mechanism procedures. FDA encourages facilities to design their complaint mechanism procedures to be responsive to the language, ethnic, and literacy differences among consumers served by the facility.

I. Additional Clinical Image Review and Examinee Notification

Proposed § 900.12(i) requires a facility to cooperate with FDA in the investigation of concerns about the quality of the images produced by that facility and in notification of examinees or the public, should the investigation justify such notification.

Proposed § 900.12(i)(1) complements the requirements in proposed § 900.4(f) of the accreditation body regulations, which are published elsewhere in this issue of the Federal Register. Proposed § 900.4(f), among other things, would require accreditation bodies, or other entities as specified by FDA, to perform additional clinical image reviews when there are concerns or complaints about the quality of images produced at a facility. Proposed § 900.12(i)(1) requires the facility to provide the clinical images for this review.

If FDA determines that any activity related to the provision of mammography at a facility presents a serious risk to human health, proposed § 900.12(i)(2) would require a facility to notify examinees, their designees, or the public of actions that may be necessary to minimize the risk. Such notification may be used in cases where diagnoses of possible malignancy may have been missed due to the grossly inadequate performance of the facility. Examinees, their designees, health professionals, or the public may have to be notified so that they may take appropriate remedial action. For example, affected examinees may wish to repeat examinations at another facility or a member of the public may be able to contact an otherwise unreachable examinee.

J. Revocation of a Facility's Accreditation and Revocation of FDA Approval of a Facility's Accreditation Body

Proposed § 900.13 establishes procedures for revocation of facility accreditation and accreditation body approval. No comments were received on these requirements as promulgated under the interim regulations. The agency is proposing to retain these procedures with the exception of the following changes and additions:

Proposed § 900.13(a) gives FDA the discretion to revoke or suspend the certificate of a facility whose accreditation has been revoked by its accreditation body while the agency investigates what actions to take with respect to the facility as a result of the revocation.

Proposed § 900.13(b)(1) gives the agency greater flexibility with respect to facilities when FDA has revoked approval of the accreditation body that accredited the facilities. Under the proposed regulation, the certificates of the facilities would normally remain in effect for up to 1 year after the accreditation body approval was revoked. The change from the interim regulations, however, would allow the agency to shorten this period if FDA determined that a facility had been accredited fraudulently or posed a serious threat to public health or safety.

Proposed § 900.13(b)(2) incorporates the additional language the agency has proposed in § 900.11 in order to provide alternative means of accreditation if the accreditation body cannot or will not perform this function at some future date.

K. Suspension and Revocation of Certificates

FDA has revised § 900.14 to set forth the bases for agency action to suspend or revoke certificates and the procedural rights available to facilities in these circumstances.

Proposed § 900.14 tracks 42 U.S.C. 263b(i), the section of the PHS Act that establishes provisions for suspension and revocation of certificates. Proposed § 900.14(a) provides that the agency may suspend or revoke a certificate, following notice and opportunity for a hearing in accordance with part 16 (21 CFR part 16), if FDA finds 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 standards under § 900.12; (3) has failed to comply with reasonable requests for records or information; (4) has refused to permit duly authorized inspections; (5) has violated or aided and abetted violations of the MQSA or implementing regulations; or (6) has failed to comply with prior sanctions imposed under 42 U.S.C. 263b(h).

Proposed § 900.14(b) sets forth the bases for FDA to suspend a certificate prior to holding a hearing. Here, too, the regulation tracks the statutory provision. FDA may dispense with a hearing if, in addition to making one of the findings listed above, the agency also determines that: (1) Failure to comply with the 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 violative acts were intentional or otherwise rise to a level that presents a threat to the public. These three aggravating factors create circumstances in which the need to protect the public health outweighs the harm to the affected facility, which will have to wait a period of time for an

opportunity to demonstrate that the agency's determinations are erroneous.

As set forth in the statute and in the proposed regulation at § 900.14(b)(1), FDA may take action before a hearing if the agency determines that a facility's failure to comply with promulgated standards presents a serious risk to human health.

FDA may also take such action following a determination that a facility has refused reasonable requests for inspection. The agency believes this provision is intended to provide discretion for the agency to suspend a certificate in circumstances where recalcitrant actions by a facility make it impossible for the agency to inspect and investigate violations in order to determine whether the public is at risk if the facility continues operation. Proposed § 900.14(b)(2) sets forth this basis for suspension prior to hearing.

The agency may also take action prior to hearing upon a determination that a facility has violated or aided and abetted in the violation of any provision of the statute or an implementing regulation. FDA has interpreted this statutory provision to mean that the agency may suspend prior to hearing when the compliance record of the facility or other evidence demonstrates that responsible persons at that facility are not disposed to comply with established standards or with representations that were made during the certifying process. Proposed § 900.14(b)(3) states that the agency may suspend a certificate prior to hearing when the agency determines that there is reason to believe that the violation, or aiding and abetting of the violation, was intentional or associated with fraud. Such behavior cannot be tolerated without undermining the entire regulatory system and is sufficiently egregious to warrant immediate action by the agency.

As required by the MQSA and proposed in § 900.14(c)(1), facilities whose certificates are suspended prior to hearing will have an opportunity for a hearing within 60 days of the suspension.

As a matter of general policy, FDA will not suspend certificates without a hearing unless the agency believes that violations at the facility or misconduct by responsible persons present a serious risk to human health. Furthermore, suspension of a certificate, with or without a hearing, is not a regulatory action FDA intends to initiate as a matter of course. The MQSA favors voluntary compliance over regulatory sanctions, and FDA is committed to working with facilities to correct deficiencies rather than eliminating services. Suspension will be necessary only in those cases where voluntary action or lesser sanctions have proven ineffective.

L. Appeals of Adverse Accreditation Decisions

The MQSA includes a provision that requires the Secretary of DHHS (the Secretary) to provide particular appeal procedures to a facility that has been denied certification. Section 263b(d)(2) of the PHS Act requires the Secretary (FDA, by delegation) to provide the facility with a statement of the grounds upon which the denial is based, and ''an opportunity for an appeal in accordance with procedures set forth in regulations published at 42 CFR 498 and in effect on the date of the enactment of [the MQSA].'' (42 U.S.C. 263b(d)(2).)

Because FDA may not certify a facility that has failed to become accredited, appeal of an FDA decision not to certify a facility will become, in actuality, a review of the accreditation body's determination that the facility did not meet necessary standards. For this reason, FDA believes that the procedural rights that are referenced in the statute should be available to the facility at the time it receives an adverse accreditation decision from the accreditation body to which it has applied.

FDA also believes that accreditation bodies should establish and implement impartial procedures for review and reconsideration of adverse accreditation decisions. As discussed elsewhere in this issue of the Federal Register, FDA is requiring each accreditation body to establish such reconsideration procedures and to inform any facility that receives an adverse accreditation decision of the opportunity to seek reconsideration by the accreditation body. Because it is the accreditation body that has the most detailed knowledge of the facts and alleged deficiencies of the facility's mammography practice, it is the accreditation body that is in the best position to make suggestions or review additional information that may result in accreditation.

FDA is proposing to require mammography facilities to seek reconsideration by the accreditation body before appealing the adverse decision to FDA. The agency believes this practice is in the best interest of the facility, the agency, and the public. As discussed above, the accreditation body will be in the best position to evaluate any additional information the facility presents for reconsideration. In addition, in order to perform an adequate evaluation of the adverse accreditation decision, FDA will request and review materials provided by the accreditation body as well as the facility. The internal reconsideration process at the accreditation body level will permit the areas of dispute to be clarified for FDA review and conserve the limited resources of agency personnel.

A facility that is not satisfied with the result of the accreditation body's reconsideration may appeal that determination to the government. The regulations set forth at 42 CFR part 498, which are referenced in the MQSA, are Health Care Financing Administration (HCFA) regulations that were promulgated for appeals of decisions that among other things deny providers of medical services the opportunity to participate in Medicare. In order to implement a certification appeals process that is in accordance with those provisions and appropriate to the review of mammography accreditation decisions, FDA has consulted with other agencies of the Department of Health and Human Services (DHHS) that utilize and apply those procedures on a regular basis. As a result of those cooperative efforts, FDA and other agencies of DHHS have agreed that FDA's Division of Mammography Quality and Radiation Programs (DMQRP) will handle all appeals for reconsideration of an accreditation body's decision to deny accreditation. Hearing officers of the DHHS' Departmental Appeals Board (DAB) will conduct formal hearings for facilities that wish to appeal the FDA's reconsideration decision, and the DAB itself will hear appeals of the hearing officer's decision.

The procedures to be followed for these various appeals are detailed in 42 CFR part 498. However, as discussed above, because those are HCFA regulations, references to HCFA should be read as FDA for purposes of the MQSA program. In addition, references to the Social Security Appeals Council in 42 CFR part 498 should be read as the DAB; although 42 CFR part 498 has not been amended to reflect the delegation of authority, administrative law judges of the DAB have been handling adversarial HCFA hearings since 1992 and the DAB itself has been handling appeals of those hearing decisions.

Although 42 CFR part 498 is referenced in the MQSA and in FDA's implementing regulations, FDA is also proposing that its MQSA regulations broadly summarize the way these HCFA regulations will be applied by FDA. The agency believes that summary of the various appeal levels will make the procedures more accessible to facilities that wish to challenge adverse

decisions. Applicable details about the various appeal procedures that are not codified in FDA's proposed regulations can be found at 42 CFR part 498.

A facility that is appealing an adverse accreditation decision, regardless of the level of appeal, may not perform mammography services until the decision has been reversed and the facility has been certified by FDA.

M. Alternative Requirements

In the interim rule published in the Federal Register of September 30, 1994 (59 FR 49808), FDA established procedures for approval 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. These procedures were developed to permit flexibility in appropriate individual circumstances and to encourage further improvement in the practice of mammography. The alternative requirement procedures will allow the agency to permit the practice of mammography to benefit rapidly from improvements and advancements without the need first to amend regulations, which is often a lengthy process. Approved alternative requirements will be made available for review in the public docket file in FDA's Dockets Management Branch (address above). In addition, notices of approved alternative requirements with wide applicability will be published in the Federal Register.

The comment period on the interim regulations ended on December 29, 1994. No comments were received on the alternative requirements or, for that matter, on any of the amendments. The agency has interpreted this lack of response to indicate that members of the public did not object to the content of the amendments.

NMQAAC discussed the alternative requirement regulation (§ 900.18) at its February 1994 meeting. The regulation was discussed again at NMQAAC's January 1995 meeting. The only suggestion for change at the latter meeting came from a Federal liaison to NMQAAC who recommended that Federal agencies be given the same opportunity as State Governments to apply for approval of alternative requirements. NMQAAC endorsed this suggestion and FDA has revised § 900.18(b)(2) accordingly.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined together the impacts of this proposed rule and the proposed rules on accreditation bodies, personnel requirements, and quality standards for mammography equipment and quality assurance, published elsewhere in this issue of the Federal Register, under Executive Order 12866, the Regulatory Flexibility Act (Pub. L. 96–354), and under the Unfunded Mandates Reform Act. The analysis has addressed the proposed requirements of these four rules as one unit for purposes of determining their economic impact. The preamble to the proposed rule ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' published elsewhere in this issue of the Federal Register, contains a brief summary of the cost and benefit determination and the Regulatory Impact Study that details the agency's calculation of these economic impacts and is available at the Dockets Management Branch (address above) for review. FDA recognized that these proposed regulations may have a disproportionate effect on small volume mammography facilities and is currently collecting additional information on the potential impact on this industry sector. The agency requests comments that will assist it in accounting for this impact.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collection are contained in the proposed rule ''Quality Mammography Standards; General Preamble and Alternative Approaches'' published elsewhere in this issue of the Federal Register with an estimate of the annual reporting and recordkeeping burden.

The agency has submitted a copy of this proposed rule to OMB for its review and approval of these information collections. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. Written comments on the information collection should be submitted by May 3, 1996.

VI. Request for Comments

Interested persons may, on or before July 2, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. Reference

The following reference has 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. ''Report on the Mammography Quality Standards Act of 1992,'' S. Rept. 102–448, October 1, 1992.

List of Subjects in 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, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 900 be amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. Section 900.10 is revised to read as follows:

§ 900.10 Applicability.

The provisions of subpart B are applicable to all facilities under the regulatory jurisdiction of the United States that provide screening or diagnostic mammography services, with the exception of the facilities of the Department of Veterans Affairs.

3. Section 900.11 is revised to read as follows:

§ 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 subpart B of this part. 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 as 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 as designated by FDA, the agency will 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) New facilities beginning operation after October 1, 1994, are eligible to apply for provisional certificates. 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) FDA will issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements of paragraph (b)(2)(i) of this section. 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 as 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) FDA will 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).

(iii) 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 revoked by FDA, may apply to have the certificate reinstated.

(1) Unless prohibited from reinstatement under paragraph (c)(4) of this section, a facility applying for reinstatement shall:

(i) Contact an FDA-approved accreditation body or other entity as designated by FDA to determine the requirements for reapplication for accreditation;

(ii) Fully document its history as a previously provisionally or fully certified mammography facility, including the following information:

(A) Name and address of the facility under which it was previously provisionally or fully certified;

(B) Name of previous owner/lessor;

(C) FDA facility identification number assigned the facility under its previous certification; and

(D) Expiration date of the most recent FDA provisional or full certificate; and

(iii) Justify application for reinstatement of accreditation by submitting to the accreditation body or other entity as 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 will issue a provisional certificate to the facility if:

(i) The accreditation body or other entity as 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 full certification.

(4) If a facility's certificate was revoked, that facility is not eligible for reinstatement until at least 2 years from the date the certificate was revoked if the facility is owned or operated by any person who owned or operated the facility at the time of revocation.

4. Section 900.12 is amended by revising paragraphs (c) and (d) and by adding new paragraphs (f), (g), (h), and (i) to read as follows:

§ 900.12 Quality standards.

* * * * *

(c) *Medical records and mammography reports.* (1) Contents and terminology. Each facility shall prepare a written report signed by the interpreting physician for each mammography examination performed under its certificate. The mammography report shall include the following information:

(i) The name of the examinee;

(ii) Date of examination;

(iii) 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, but benign finding(s) can be described at the discretion of the interpreter;

(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;

(iv) In cases where no final assessment category can be assigned due to incomplete work-up, ''Needs 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

(v) 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.

(2) Communication of mammography results to the examinee. Each facility shall maintain a system for providing written notification of results of each mammographic examination to the examinee. The written notification issued by the facility or by its designee shall be communicated to the examinee as soon as possible, but no later than 30 days from the date of the mammography examination. If assessments are ''Suspicious'' or ''Highly suggestive of malignancy'' and if the examinee has not named a referring health care provider, the facility shall make reasonable attempts to communicate results to the examinee immediately.

(i) The written notification of results provided to the examinee shall include:

(A) The date of the examination;

(B) The results of the examination in lay terms; and

(C) A recommendation to the examinee on followup actions.

(ii) Examinees 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 the written notification described in paragraph (c)(2)(i) of this section.

(iii) Each facility that accepts examinees who do not have a primary care provider shall maintain a system for referring such examinees to a health care provider when clinically indicated.

(3) Communication of mammography results to health care providers. When the examinee has a referring health care provider or the examinee 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 immediately, or if the health care provider is unavailable, to a responsible designee of the health care provider.

(4) Recordkeeping. Each facility shall maintain mammography films and reports in a permanent medical record of the examinee as follows:

(i) For a period of not less than 5 years, or of not less than 10 years if no additional mammograms of the examinee are performed at the facility, or a longer period if mandated by State or local law; or

(ii) Until requested by an examinee to transfer the original mammograms and copies of the examinee's reports to a medical institution, or to a physician or health care provider designated by the examinee, or to the examinee directly, and the records are so transferred.

(iii) Any fee charged to examinees for providing the services in paragraphs (c)(4)(ii) of this section shall not exceed the actual documented costs associated with this service.

(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 given 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 provide feedback on the quality of the mammograms they interpret to the radiologic technologists producing those mammograms and shall participate in the facility's medical outcomes audit program.

(iii) Medical physicist. Each facility shall have available the services of an individual or individuals, who meet the qualifications of paragraph (a)(3) of this section, to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility.

(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 quality control technologists.

(2) Quality assurance records. The facility shall maintain the following documents related to its quality assurance program:

(i) A quality assurance manual describing the procedures that are to be followed in meeting the requirements of paragraphs (e) and (f) of this section, including ''action levels'' for corrective actions, as defined in § 900.2. The manual shall be readily available to all staff members. It shall contain a sign-off page documenting that it has been read and approved by the lead interpreting physician and the medical physicist.

(ii) A current list of the individuals to whom quality assurance responsibilities have been assigned and the duties assigned to them. This list shall be readily available to all staff members.

(iii) Records to show that all staff members assigned responsibilities in the quality assurance program are qualified to conduct their assigned duties.

(iv) Records to show the data obtained during monitoring of the facility's 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. These records shall be kept for each test specified in paragraphs (e) and (f) of this section for a minimum of 1 year or until the test has been performed two additional times at the required frequency, whichever is longer.

* * * * *

(f) *Quality assurance—mammography medical outcomes audit.* Each facility shall establish and maintain a mammography medical outcomes audit program for followup based on mammographic assessments and to correlate biopsy or cytology results with interpreting physicians' recommendations. 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 for reviewing outcome data from all mammography performed, in order to followup on the disposition of positive mammograms and to correlate biopsy or cytology results with interpreting physician's mammography report.

(2) Data collection. Data shall be collected on an ongoing basis for all examinees with positive mammograms.

(3) Frequency of audit analysis. An initial audit analysis shall be conducted no later than 12 months after the date the facility became fully certified. Subsequent audit analyses shall be conducted at least once every 12 months from the date of the initial analysis.

(4) Reviewing interpreting physician. The facility shall designate at least one interpreting physician to review the audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for identifying issues and analyzing results based on this audit, notifying the other interpreting physicians of these issues and results, and ensuring that necessary corrective actions are taken and documented. Evaluations shall be made individually and collectively for all interpreting physicians at the facility.

(g) *Mammographic procedure and techniques for mammography of examinees with breast implants.* (1) Each facility shall have a procedure to inquire whether an examinee has a breast implant at the time of mammogram scheduling.

(2) Except where contraindicated, or unless modified by a physician's directions, examinees with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue and optimize breast cancer detection.

(3) These mammographic examinations shall be supervised by an onsite interpreting physician who is trained in mammography of examinees with breast implants, including training in specialized mammographic techniques of these examinees and training in interpreting the mammograms of these examinees.

(h) *Consumer complaint 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 the complaint 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) *Additional clinical image review and examinee notification.*

(1) If FDA believes that image quality at a facility has been severely compromised and presents a serious risk to human health, the facility shall provide clinical images, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional clinical image review will help the agency to determine whether there is a need to notify affected examinees and the public.

(2) If FDA determines that any activity related to the provision of mammography at a facility presents a serious risk to human health such that examinee notification is necessary, the facility shall notify examinees, their designees, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe specified by FDA.

5. Section 900.13 is revised to read as follows:

§ 900.13 Revocation of accreditation, and revocation of accreditation 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. If FDA determines that the revocation was justified, FDA may take action, revoke or suspend the facility's certificate, or require the submission and implementation of a corrective action plan, whichever action or combination of actions will best protect the public health.

(b) Revocation of FDA approval of an accreditation body.

(1) If FDA revokes 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 revocation, 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 revocation 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.

6. Section 900.14 is revised to read as follows:

§ 900.14 Suspension or revocation of certificates.

(a) 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 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 the 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 § 900.14(d).

(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.

7. New § 900.15 is added to subpart B to read as follows:

§ 900.15 Appeals of adverse accreditation and certification decisions.

(a) The appeals procedures described in this section are available only for adverse accreditation 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, 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 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 at 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, 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 make its request for reconsideration to 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 3 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 bases 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.

8. Section 900.18 is revised to read as follows:

§ 900.18 Alternative requirements for 42 U.S.C. 263b quality standards.

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined under paragraph (b) of this section, the Director, Division of Mammography Quality and Radiation Programs (the Director), may approve an alternative to a quality standard under § 900.12, when the Director determines that:

(1) The proposed alternative standard will be at least as effective in assuring 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, Center for Devices and Radiological Health (HFZ–240), 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 assure 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) The Director 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 will 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 will 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 will be assigned an identifying number.

(2) Notice of an approved request for an alternative standard or any amendment or extension thereof will 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 will 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, will 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 will be available for public disclosure in the Dockets Management Branch, excluding examinee 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 assure equal or greater quality of production, processing, or

interpretation of mammograms than the original standard.

(f) *Applicability of the alternative standards.* 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, except that when an alternative standard is approved for a manufacturer of equipment, any facility using that equipment will also be covered by the alternative standard. Other entities interested in similar or identical approvals must file their own application following the procedures of paragraph (c) of this section.

(g) *Withdrawal of approval of alternative requirements.* The Director shall amend or withdraw approval of an alternative standard whenever the Director 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 the Director determines that such action is necessary to prevent an imminent health hazard.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–7830 Filed 3–29–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 95N–0192]

RIN 0910–AA24

Proposed Requirements for Accreditation Bodies of Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its interim regulations for application procedures for FDA approval as an accreditation body under the Mammography Quality Standards Act of 1992 (the MQSA). FDA is proposing these amendments based on experience gained in administering the interim regulations, advice from the National Mammography Quality Assurance Advisory Committee (NMQAAC), and public comments received in response to the interim regulations. This proposal would also establish new requirements and responsibilities for accreditation bodies. This proposal is the second of five proposed rules published in this issue of the Federal Register regarding MQSA requirements applicable to mammography facilities. These proposed rules are being issued to ensure adequate and consistent evaluation of mammography facilities on a nationwide basis.

DATES: Written comments on this proposed rule by July 2, 1996. Written comments on the information collection requirements should be submitted by May 3, 1996. The agency is proposing that any final rule based on this proposed rule become effective 1 year after its date of publication in the Federal Register.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Regulatory Impact Study (RIS) is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This proposal is the second of five related proposed rules published in this issue of the Federal Register to amend interim regulations published on December 21, 1993 (58 FR 67558 and 58 FR 67565) implementing the MQSA (Pub. L. 102–539). The first proposed rule, ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' contains background information and a summary of the preliminary analysis of the costs and benefits of the proposed rules, a description of the information collection requirements, proposed revisions to §§ 900.1 *Scope* (21 CFR 900.1) and 900.2 *Definitions* (21 CFR 900.2), and proposed alternative approaches to mammography quality standards and a request for comments on the proposed alternatives.

II. Provisions of the Proposed Rule

A. Development of the Proposed Regulation

This proposed rule covers procedures for application to FDA for approval as an accreditation body and the requirements and responsibilities of such bodies. As with the interim regulations, FDA was guided in the development of this proposed rule by the intent of the legislation to guarantee access to safe and effective mammography services for all women in the United States (Ref. 1). FDA also relied upon three major sources of information, in addition to the expertise and research of FDA personnel.

First, the agency considered public comments received on the interim regulations. The agency received 103 comments from individuals and organizations, including professional organizations, medical facilities, State agencies, consumer groups, manufacturers, and individual physicians, medical physicists, and radiologic technologists. The proposed regulations were also discussed in a series of quarterly meetings with the NMQAAC. Members of the NMQAAC include interpreting physicians, medical physicists, radiologic technologists, representatives of State agencies, and consumer representatives. Consultants to the NMQAAC and guests invited to attend the committee meetings in recognition of their expertise in mammography also participated in these discussions of the proposed regulations. Finally, the agency's experience over the last year with the four accreditation bodies approved under the interim regulations also influenced the development of the proposed regulations. A discussion of the proposed amendments and a summary and analysis of both NMQAAC input and public comments regarding the regulations are provided below.

B. Application for Approval as an Accreditation Body

In § 900.3 (21 CFR 900.3) of the interim regulations, FDA established standards for approving the applications of prospective accreditation bodies. These standards are expanded in proposed § 900.3 to provide FDA with more thorough criteria for assessing a

prospective body's capabilities. FDA is also proposing regulations to establish renewable terms of authority and the scope of authority of accreditation bodies.

1. Accreditation Body Assessment Criteria

To identify more comprehensive criteria for evaluating prospective accreditation bodies, FDA researched Federal oversight of other accreditation organizations in the health care field. This included review of HCFA regulations and of an assessment of those regulations by GAO.

In the Federal Register of December 14, 1990 (55 FR 51434), HCFA published a proposed regulation entitled ''Medicare Program: Granting and Withdrawal of Deeming Authority to National Accreditation Organizations.'' GAO reviewed that proposed regulation and stated in a 1991 report that, with only one exception, the proposed regulation met all of the criteria that GAO considers important in the evaluation of an accreditation organization (Ref. 2). This regulation was finalized in the Federal Register of November 23, 1993 (58 FR 61816).

Based on GAO's review of the proposed HCFA regulation, and FDA's experience with accreditation bodies under the interim regulations, FDA considers it essential to require a complete description of a prospective accreditation body's review and decisionmaking processes, including policies and procedures used to notify facilities of deficiencies and to monitor the correction of deficiencies. In addition, FDA considers the following criteria to be important in evaluating a prospective accreditation body's application: (1) Qualifications of the body's professional staff; (2) adequacy of the body's staffing level, finances, and other resources; (3) the body's ability to provide data and reports in an electronic format compatible with FDA data systems; and (4) adequacy of the body's consumer complaint mechanism. These additional criteria, together with the interim criteria, are reflected in proposed § 900.3(b)(3).

Several comments on the interim regulations as well as members of the NMQAAC noted the importance of timely processing of accreditation applications. These comments requested that accreditation body applications include satisfactory assurances that the applicant will be able to complete the accreditation process for a given facility within 6 months if the facility submits the required information in a timely manner.

FDA agrees that timely processing of accreditation materials is necessary in order to: (1) Meet statutory requirements, that, in most cases, allow new facilities to be provisionally certified for only 6 months, and (2) ensure that reaccreditation applications will be processed before expiration of a facility's accreditation. Therefore, FDA is proposing to add a requirement in § 900.3(b)(3)(iii)(J) for prospective accreditation bodies to submit such assurances with their application for approval, along with a description of their policies and procedures for ensuring timely processing of accreditation materials.

To gain further insight regarding appropriate criteria for evaluating prospective accreditation bodies, FDA reviewed a regulation entitled ''Secretary's Procedures and Criteria for Recognition of Accrediting Agencies,'' which was finalized by the U.S. Department of Education in the Federal Register of April 29, 1994 (59 FR 22250). Based on FDA's review of that regulation, along with the agency's experience under the interim regulations and comments by NMQAAC members, FDA is proposing to add new § 900.3 (b)(3)(iii)(K), (b)(3)(viii), and (b)(3)(ix). These sections would require each prospective accreditation body to submit with its accreditation application: (1) A description of the body's appeals process for facilities contesting accreditation decisions; (2) a description of the body's mechanism for ensuring against conflicts of interest; and (3) information disclosing any commercial products used in mammography that the body develops, sells, or distributes.

2. Term Limits and Scope of Authority

In § 900.3(g), FDA is proposing to establish renewable 5-year terms of approval for accreditation bodies. The agency believes that a body should not be approved for an indefinite amount of time without undergoing periodic comprehensive reviews. Although the interim regulations addressed the possibility of withdrawing the approval of an accreditation body for unsatisfactory performance, the interim regulations did not establish a regular term limit for accreditation body approval.

FDA is proposing in § 900.3(c) a schedule and requirements for application for renewal of an accreditation body's approval. These schedule and renewal requirements would also apply to accreditation bodies approved under the interim regulations that seek to continue serving as accreditation bodies under the final regulations. FDA's intention in establishing such a schedule is to ensure sufficient time for the review and processing of applications in order to avoid interruption in the availability of the services of the accreditation body. The agency solicits comments on whether the 90-day timeframe for application is appropriate.

Proposed § 900.3(d) describes the process the agency would use for reviewing accreditation body applications and renewals. The proposed process includes a provision for extending an accreditation body's previous approval if FDA has not reached a final decision on renewal before the previous approval expires.

FDA is proposing new provisions in § 900.3 (e) and (f) requiring the accreditation body to notify facilities and FDA, and to transfer records in instances where the body: (1) Voluntarily ceases its accreditation functions before expiration of its 5-year term, (2) decides not to reapply for an additional term of approval, or (3) fails to become reapproved by FDA.

In addition to limiting the term of approval of accreditation bodies, FDA believes that the agency should be permitted to limit the scope of authority of an accreditation body (for example, geographically, for State agencies). This is proposed in § 900.3(g).

FDA plans to issue application guidance to prospective accreditation bodies to assist them in preparing materials and supporting documentation required by the revised accreditation regulations, when finalized. It is expected that for accreditation bodies applying for renewal, the supporting documentation will consist primarily of updates of information previously provided to FDA.

C. Standards for Accreditation Bodies

In § 900.4 (21 CFR 900.4), FDA is proposing expanded requirements and responsibilities for accreditation bodies. These standards are intended to ensure that accreditation bodies work together with FDA and mammography facilities to achieve and maintain high quality mammography at all facilities.

Proposed § 900.4(a) establishes a code of conduct and general responsibilities for accreditation bodies to assure the integrity and impartiality of accreditation body actions and appropriate oversight of the quality of mammography at all accredited facilities. Other proposed paragraphs in § 900.4 and the accreditation body requirements they address include: § 900.4(b)—standards that the accreditation body must apply to

accredit facilities; § 900.4 (c) and (d)—accreditation body review of facility clinical and phantom images; paragraph (e)—accreditation body review of reports of mammography equipment evaluation, physics surveys, quality control records, and personnel updates at facilities; § 900.4(f)—accreditation body onsite visits to facilities and performance of random clinical image reviews; § 900.4(g)—consumer complaint mechanisms; § 900.4(h)—other reporting and recordkeeping requirements; and § 900.4(i)—fees that accreditation bodies may charge facilities for accreditation. While most of these requirements were addressed by the interim regulations, FDA is proposing additions and modifications that are described in this preamble.

1. Code of Conduct and General Responsibilities

In § 900.4(a)(1), FDA is proposing to require an accreditation body to take certain actions if the agency believes that the clinical image quality or other aspects of a facility's practice are seriously compromised and would pose an unreasonable risk of substantial harm to the public. The agency's intention is that this authority would only be used in those situations, hopefully rare, where the mammography-specific health hazard is serious enough to warrant actions beyond the scope of those normally used to meet the facility quality standards. It is not intended to replace the normal interaction between accreditation bodies and facilities as they seek to meet the quality standards.

This section was added in response to discussions with the NMQAAC and public comments requesting additional measures to ensure timely compliance with regulatory requirements by facilities. For example, one comment questioned whether the loss of a facility's certification would assure termination of a facility's ability to provide mammography services. Another comment stated that accreditation bodies should have the authority to take action against miscreant facilities.

FDA advises that there are a number of mechanisms in place to ensure that decertified facilities no longer provide mammography services. When facilities lose their certification, they can no longer provide mammography services lawfully and are required to return their certificate to the agency. Consumers have been advised through various publicity campaigns to check for the presence of an FDA certificate when they go for a mammogram, so many consumers will be aware that they should not have a mammogram performed at a facility that does not display an FDA certificate. In addition, the statute provides for civil money penalty and injunctive sanctions against facilities that practice mammography without a certificate. Nonetheless, for circumstances where FDA believes there is a risk of substantial harm to the public, proposed § 900.4(a)(1) would provide an additional means of monitoring facility compliance with MQSA requirements and would allow FDA to require accreditation bodies to assist the agency in taking actions or requiring facilities to take actions that the agency deems necessary to prevent harm to consumers. FDA solicits comments on the nature and appropriateness of this proposed additional monitoring.

Similarly, § 900.4(a)(2) and (a)(3) propose additional steps to be taken by accreditation bodies in circumstances where a facility's operations may compromise the quality of mammography or otherwise pose a health or safety hazard that is within the scope of the MQSA but not as severe as situations addressed by § 900.4(a)(1). In accordance with these proposed paragraphs, accreditation bodies would be required to notify FDA any time the accreditation body becomes aware that there has been actual loss of life or serious injury or illness associated with facility noncompliance with MQSA requirements. Such notification would have to be provided to FDA within 5 business days of the accreditation body's learning of the event. The 5-business day interval was chosen as a compromise between the agency's need to be informed as soon as possible of serious mammography-specific health hazards and the need for the accreditation body to have sufficient time to identify and report the event. Comments are specifically invited upon the appropriateness of the allowed length of time. Accreditation bodies would also be required to obtain, review, and monitor plans of correction from facilities not in compliance with the facility standards. These provisions should further address the concerns of the comments mentioned above.

One comment requested that all time period designations related to requirements for action by accreditation bodies be specified in ''business'' days rather than ''calendar'' days.

FDA agrees that some time period designations should be specified as business days and has proposed changes to the interim regulations accordingly. Where proposed time periods are not explicitly specified as business days, they should be interpreted as calendar days. In addition, in order to afford accreditation bodies and facilities increased flexibility, FDA is proposing to eliminate some of the mandatory schedules specified under the interim regulations. For example, FDA is eliminating the interim requirement that accreditation bodies with minor deficiencies submit a plan of corrective action within 90 days. Thus, under the proposed regulations, certain schedule requirements would be left to the discretion of the accreditation body or FDA or would be subject to FDA approval during the accreditation body application process.

In § 900.4(a)(4), FDA is proposing that accreditation bodies be required to establish a quality assurance (QA) program that includes clinical and phantom image review. This QA program would establish policies and procedures to ensure consistent and accurate evaluation of facility images with respect to both methods of review. The QA program would also address training and evaluation of staff performing the reviews.

In proposed § 900.4(a)(5), FDA calls for new measures to reduce the possibility of conflict of interest or bias on the part of an accreditation body or anyone acting on an accreditation body's behalf with regard to specific facilities. NMQAAC members and consultants expressed concern about conflicts of interest or bias with regard to clinical image reviewers evaluating images from their own States or from geographically limited areas where the reviewers may know the facilities and their interpreting physicians. Also, various comments expressed concern that: (1) ''Innumerable 'non-profit' health care corporations'' could be approved as accreditation bodies and accredit their own facilities as long as clinical image reviewers had no financial interest in the facilities; (2) a professional organization serving as an accreditation body has members with ''vested interests in the outcome of the body's decisions;'' (3) individuals employed by a professional organization that is an accreditation body have a conflict of interest with regard to the establishment of standards by which their facilities would be evaluated under the MQSA; and (4) members of a professional organization that was an approved accreditation body would be prevented from conducting clinical image reviews.

The proposed code of conduct in § 900.4(a) is intended to address the various concerns raised regarding conflict of interest considerations for accreditation bodies. In addition, FDA notes that all standards used by accreditation bodies to accredit facilities

are subject to review and approval by the agency. However, neither the interim requirements nor the proposed code of conduct would preclude members of a professional organization that is designated as an accreditation body from conducting clinical image reviews for that organization solely on the basis of membership in that organization. In addition, the proposed standards include conflict of interest provisions that would preclude other situations suggested by the comments.

Several comments and presentations at the NMQAAC meetings, on behalf of a trade association of software vendors, expressed concern that a currently approved accreditation body that markets mammography reporting software might have a sales advantage because of its MQSA accreditation functions and a perceived ''imprimatur of government approval'' for its products. In particular, this trade association proposed that the following language be incorporated into FDA's standards for approval of an accreditation body:

> Satisfactory assurances that the body does not have any interest in the development, sale, promotion, or distribution of any product (including computer software) under circumstances where the product will be the subject of inspection or review by the accreditation body in facility quality assurance or quality control or other aspects of the accreditation process. This restriction does not apply to educational programs or educational material typically prepared or disseminated by an accreditation body.

Although FDA has not proposed the standard suggested by this comment, the agency specifically solicits public comment on this alternative. This issue has been raised repeatedly during the open public sessions of the NMQAAC meetings, and FDA wants to be certain that there is full opportunity for the public to comment on the underlying question: Is there an inherent conflict in an accreditation body also being a product vendor for a mammography-related product? As currently proposed, the requirements in § 900.4(a)(6) minimize the possibility of accreditation body conflict of interest with regard to the marketing of commercial products by prohibiting an accreditation body from representing in any way that the purchase of a particular product is a condition of accreditation. However, proposed § 900.4(a)(6) would not require accreditation bodies to divest all interests in commercial products. Moreover, the proposed regulation would permit an accreditation body to require the use of a product by facilities it accredits, even when there is the possibility of a conflict of interest, if FDA determines that such use is in the best interest of public health. As noted previously, FDA encourages further public comment on the conflict of interest issue, including comment on whether the outcome of any conflict of interest issue would be affected by: (1) The cost of the product sold by an accreditation body, i.e., by the magnitude of the financial interest; or (2) the number of accreditation bodies available to choose from.

Proposed § 900.4(a)(6) would require an accreditation body to state the bases for denying accreditation in a written notification to the affected facility. In accordance with proposed § 900.3(b)(3)(iii)(K), each accreditation body will establish procedures for appeal of adverse accreditation decisions to the accreditation body. The accreditation body's notification of denial of accreditation also would be required to describe the appeals process available from the body if the facility wishes to contest the adverse decision.

Proposed § 900.4(a)(8) would explicitly prohibit any State that has been approved as an accreditation body from precluding any other FDA-approved accreditation bodies from operating in that State. This amendment is intended to codify what has been FDA policy and practice under the interim regulations.

Several comments stated that FDA should allow only one accreditation body to operate in a given State or should allow only States to serve as accreditation bodies.

FDA disagrees with these comments. The statute itself does not provide for such exclusivity. The MQSA allows FDA to approve either State agencies or private nonprofit organizations to serve as accreditation bodies, as long as they meet the standards established by FDA. The agency believes that facilities, consumers, and the professional community can benefit from the existence of more than one accreditation body.

Consistent with the interim regulations, the proposed regulations would require that accreditation bodies obtain FDA authorization before changing accreditation body standards previously approved by FDA (§ 900.4(a)(9)). Several comments expressed concern that this requirement would preempt section 354(m) of the PHS Act, which permits States to enact and enforce laws that are more stringent than those mandated by the MQSA. There was also discussion during the January 1995 NMQAAC meeting as to whether accreditation bodies could have more stringent requirements than those mandated under MQSA.

FDA requires State agencies and private nonprofit organizations approved as accreditation bodies by FDA to establish and implement facility standards that have been approved by FDA. FDA will approve such standards only if FDA determines that they are substantially the same as the standards required under MQSA. In addition, all accreditation bodies, whether State agencies or private nonprofit organizations, must determine the MQSA accreditation status of a facility using only FDA-approved standards. However, accreditation bodies may use more stringent standards under other (non-MQSA) authorities for purposes other than that of determining the MQSA accreditation status of facilities. For example, a State public health agency approved as an MQSA accreditation body by FDA may require facilities in the State to meet additional standards (beyond those required by MQSA) under the body's authority as a State accreditation agency. However, the body may not require facilities to meet these additional standards in order to obtain MQSA accreditation. Similarly, a private nonprofit organization approved as an accreditation body may recommend compliance with more stringent standards than those mandated under MQSA, but may not use such standards in determining the MQSA accreditation status of a facility.

Proposed § 900.4(a)(10) states the accreditation body's obligation to protect the confidentiality of nonpublic information acquired in connection with carrying out accreditation body responsibilities. The accreditation body may not use or disclose information it receives from facilities, other than to FDA or its designated representatives, without the consent of the facility. The accreditation body must also protect the confidentiality of nonpublic information it receives from FDA or its duly designated representatives.

2. Facility Standards

In proposed § 900.4(b), FDA outlines the quality standards for mammography that accreditation bodies would have to apply to facilities they accredit (facility standards). The details of the facility standards required under the MQSA are being proposed elsewhere in this issue of the Federal Register. FDA is also proposing in § 900.4(b) actions to be required by the accreditation body with respect to facilities not in compliance with the quality standards, such as reviewing and monitoring the implementation of facility plans of correction and revoking a facility's accreditation.

One comment recommended that a single quality standard be implemented nationwide by all accreditation bodies.

FDA intends to ensure that each accreditation body's standards are substantially the same as those promulgated by the agency, in accordance with the requirements of section 354(e)(1) of the PHS Act (42 U.S.C. 263b(e)). However, FDA notes that mammography standards are unlikely to be identical across the country because the MQSA allows for both private nonprofit organizations and State agencies to serve as accreditation bodies, and also permits States to establish more stringent mammography standards under their own authority. In addition, FDA believes it is necessary to allow some flexibility in accreditation body operations in order to provide for efficient accreditation services for the more than 10,000 mammography facilities nationwide. Nonetheless, the statute and proposed regulations are intended to establish minimum nationwide facility standards, and proposed § 900.4(b) would require all accreditation bodies to adopt and apply these standards.

3. Clinical Image Review

FDA believes that effective clinical image review is essential to ensure 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 be qualified to perform that function. Accordingly, FDA is proposing to establish more specific requirements with respect to clinical image review than were established under the interim regulations. The requirements proposed are based on advice from the NMQAAC and public comments.

The areas covered by the proposed standards in § 900.4 for clinical image review are as follows: § 900.4(c)(1)—requirements for the minimum frequency of review; § 900.4(c)(2)—clinical image attributes to be evaluated (with a provision for FDA approval of alternatives, including ones that may be appropriate for new technology); § 900.4(c)(3)—scoring of clinical images; § 900.4(c)(4)—selection of clinical images for review; § 900.4(c)(5)—qualifications and procedures for clinical image reviewers; § 900.4(c)(6)—management of clinical images to ensure their timely return to facilities and the reporting of unsuspected abnormalities; and § 900.4(c)(7)—corrective measures for unsatisfactory image quality. With respect to this last paragraph, it is FDA's intent that the accreditation process be a constructive one that helps facilities improve mammography quality. Therefore, FDA is proposing that clinical image reviewers be required to provide information to facilities that can help them correct deficiencies identified from their clinical images.

Several comments as well as NMQAAC discussions concerned the interim requirements for clinical image review. Some NMQAAC members and consultants expressed uncertainty about whether States would have the expertise to perform clinical image reviews, because States had no prior experience with such reviews. Some comments called for increased standardization and the establishment of minimum requirements for clinical image review. One comment believed that all clinical images should be selected randomly in order to prevent facilities from merely selecting their best images for accreditation body review. Two comments questioned the need for clinical image review requirements at all. These two comments believed that other requirements in the interim regulations adequately addressed image quality. Another comment believed that clinical images should be independently reviewed by more than one radiologist.

In response to these comments, FDA notes first that the MQSA mandates clinical image reviews and FDA fully supports the need for such reviews. FDA does not intend to approve any entity as an accreditation body, including a State agency, without first determining that the prospective body will be capable of performing or providing satisfactory clinical image reviews. The proposed regulations concerning clinical image review add specific details and requirements that are in addition to those set forth in the interim regulations. FDA believes that these additions in the proposed regulations, as well as anticipated agency guidance, will ensure that prospective accreditation bodies understand what FDA expects of them regarding such reviews and will be prepared to establish their ability to perform or provide these reviews as part of their application to become accreditation bodies. In addition, FDA will monitor accreditation bodies' compliance with the agency's standards and expectations, including their clinical image review functions. This will be done through annual performance evaluations and other oversight mechanisms.

FDA agrees with the comment that clinical images should be independently reviewed by more than one radiologist. Although such a requirement was not explicitly established in the interim regulations, it has been the practice established by FDA and the accreditation bodies under those regulations. FDA is proposing to codify this policy in § 900.4(c)(3)(ii).

FDA disagrees with the comment that all clinical images submitted by facilities should be selected completely at random. For example, it is important in assessing the quality of a facility's mammography that accreditation bodies evaluate, for each mammography unit in a facility, mammograms for women with different types of breast composition (e.g., with predominantly glandular versus adipose tissue). FDA believes that systems for clinical image review under the MQSA can be implemented using random or nonrandom methods of image selection. FDA also notes that nonrandom methods for clinical image review were used by the ACR as part of its voluntary accreditation program before the passage of the MQSA.

4. Phantom Image Review

FDA is proposing a new requirement in § 900.4(d) for review of phantom images by the accreditation body. This is being done on the recommendation of the NMQAAC. To the extent that issues in the review of phantom images parallel issues in the review of clinical images, the requirements of this paragraph parallel those of § 900.4(c). However, a unique issue with respect to phantom images is determining what constitutes acceptable phantom characteristics for radiographically modeling aspects of breast disease and cancer.

FDA recognizes that a variety of phantoms may be useful for this purpose, and that the desirable phantom characteristics may change over time, particularly with the introduction of new technology. Consequently, FDA is not proposing that any specific attributes, such as specks, fibers, or masses, or their dimensions, be required by regulation. However, to assure the adequacy of phantoms used, FDA is proposing to require that accreditation bodies obtain FDA approval for the phantoms and methods of use that the bodies specify for facilities they accredit. This approach will provide needed flexibility for accreditation bodies and facilities and will enable FDA to respond in a timely manner to technological advances in this area.

5. Reports of Mammography Equipment Evaluation, Surveys, and Quality Control

Consistent with the interim regulations and statutory requirements, FDA is proposing to require in § 900.4(e) that accreditation bodies mandate submission of a survey by facilities in

order to obtain accreditation. ''Survey'' is defined in § 900.2 (published elsewhere in this issue of the Federal Register) as an onsite physics consultation and evaluation of a facility performed by a medical physicist. This survey would have to demonstrate the facility's compliance with the MQSA standards adopted by the accreditation body.

The statute does not require new facilities to submit a survey in order to qualify for provisional certification from FDA. Therefore, new facilities may perform mammography for up to 6 months without undergoing a survey. Both the agency and the NMQAAC believe that postponement of the survey required for full accreditation under MQSA should not be interpreted as permitting the clinical use of equipment that has not been evaluated for safety. Accordingly, FDA is proposing that all facilities, whether seeking full or provisional certification, be required to submit with their initial accreditation application a mammography equipment evaluation demonstrating that the facility's equipment is in compliance with the requirements in § 900.12(e) (21 CFR 900.12)(e)) for equipment quality assurance (published elsewhere in this issue of the Federal Register). This requirement would ensure that provisionally certified facilities verify the proper functioning of their mammography equipment prior to clinical use.

FDA will be developing a guidance document outlining the criteria for an adequate equipment evaluation. The agency invites comments on possible criteria for inclusion within this guidance document. A complete survey, which includes reviews and information in addition to equipment QA, would still have to be submitted in order for a provisionally certified facility to obtain accreditation and full certification.

There was some discussion with the NMQAAC regarding who should perform the mammography equipment evaluation that is part of the initial application for accreditation. In deference to comments from rural health care providers, FDA has decided against requiring that this evaluation be performed by a medical physicist. Rural health care providers have indicated that, because of the limited availability of medical physicists in rural areas, it might be difficult for a physicist to visit a rural facility twice over a short time period in order to perform the mammography equipment evaluation and, later, the survey required for accreditation and full certification. In addition, the agency's experience under the Radiation Control for Health and Safety Act (Pub. L. 90–602) shows that the types of measurements being requested for the mammography equipment evaluation can be performed effectively by nonphysicists. Therefore, FDA believes it would not be cost-effective or practical to require performance of the mammography equipment evaluation by a medical physicist.

FDA is proposing specific time periods for facility submission and accreditation body review of mammography equipment evaluations and surveys. These requirements are being recommended as a result of FDA's experience with MQSA over the last year and advice from the NMQAAC. In particular, both the agency and the NMQAAC believe it is important that facilities be required to submit survey and evaluation data that reflects current practice in the facility at the time of application for accreditation.

FDA is proposing to require in § 900.4(e) that accreditation bodies mandate annual submission of certain materials by the facility to the accreditation body for review. These materials would include the annual survey and quality control records, personnel updates, and other information that the body may require. This requirement is intended to assure continued compliance with the facility standards and to provide continued accreditation body oversight of facilities' quality control programs as they relate to such standards.

Several comments addressed issues related to accreditation and certification of facilities with more than one mammography unit (consisting of the x-ray generator and associated image receptor and auxiliary equipment). In particular, clarification was requested regarding the status of multiple-unit facilities that had not undergone all tests to assure compliance with standards or that had failed to meet all requirements. Some comments favored requiring the complete evaluation of all units in a facility, with measures to ensure that only equipment meeting the necessary requirements is used to perform mammography.

FDA agrees that only equipment meeting necessary requirements should be used to perform mammography. Under both the interim and proposed regulations, all units that are used for mammography in a facility must be reported to the accreditation body and meet applicable standards. As discussed previously, FDA is proposing to require that facilities submit the results of mammography equipment evaluations with their initial application for accreditation. Those evaluations will establish compliance with equipment QA standards under § 900.12(e) for every unit in the facility. In addition, surveys (§ 900.4(e)), as well as clinical (§ 900.4(c)(4)(i)) and phantom images (§ 900.4(d)(4)), would have to be submitted for each mammography unit at a facility during specified time periods. FDA is also proposing in § 900.4(c)(2)(viii)(G) that facilities with multiple units have a mechanism for identifying the unit used to produce each mammography image. This would enable inspectors and accreditation body visitors to check facility images against the compliance status of facility equipment and would facilitate problem identification and corrective measures, if necessary.

It is FDA's policy that similar requirements apply to new and repaired equipment, i.e., such equipment may be used clinically after the mammography equipment evaluation has demonstrated compliance of the equipment with the requirements in § 900.12(e). A survey and clinical and phantom image reviews may be required after the initiation of clinical use. Such image reviews and a survey are now, and would continue to be, necessary for new equipment; however, the accreditation body will specify, with FDA's approval, the circumstances under which repaired equipment will require a survey or image reviews by the accreditation body. Any facility that performs mammography with equipment the facility has reason to believe does not meet MQSA standards will be subject to sanctions under section 354(h)(2) of the PHS Act, including civil money penalties.

One comment questioned the value of requiring annual submission of all facility quality control records to both the accreditation body and FDA. The comment also suggested that quality control records may be useful for internal evaluations, but that documents that are to be submitted to the accreditation body may be screened or amended by the facility in order to avoid negative publicity or regulatory action.

FDA advises that no routine requirement exists to submit all quality control records to FDA. In addition, the use of the phrase ''quality control records'' in § 900.4(e)(2)(iii) of the interim regulations is not intended to mandate submission of all quality control records to the accreditation body every year. The records to be submitted will depend on the specific requirements established by the accreditation body, subject to FDA approval. FDA agrees that quality control records can serve as an

important internal source of information for helping facilities identify problems and appropriate solutions. However, FDA would regard any purposeful alterations of records to be acts of fraud.

6. Accreditation Body Onsite Visits and Random Clinical Image Reviews

The MQSA requires that accreditation bodies make a ''sufficient number'' of onsite visits to facilities they accredit ''to allow a reasonable estimate of the performance'' of the body (42 U.S.C. 263b(e)(4)). The MQSA 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)). These requirements are listed in § 900.4(f) of the proposed regulations (corresponding to § 900.4(e) in the interim regulations). In the proposed regulations, the word ''visits'' is substituted for the previously used word ''inspections'' in order to reduce any confusion between onsite visits by accreditation bodies and annual inspections by State or FDA inspectors.

One comment disputed the need for onsite visits by accreditation bodies and another comment questioned the need for the interim requirement that the accreditation body submit a copy of the visit report to FDA.

FDA disagrees with both of these comments. The need for onsite visits is established by the statute. The purpose of the visits is to provide a mechanism by which an accreditation body can both ensure facility compliance with quality standards and monitor its own performance of accreditation functions. The accreditation body would be able to compare the results from visits for consistency with information obtained through other accreditation body functions. Also, because FDA is required to evaluate annually the performance of each accreditation body, the reports of onsite visits would provide valuable information on which to base such evaluations. Therefore, although the agency is proposing to delete the requirement that a full copy of each onsite visit report be provided to FDA at the conclusion of the accreditation body's onsite visit, FDA would continue to require that a summary of findings obtained as a result of accreditation body visits to facilities be included in the accreditation body's annual report to FDA. As discussed previously, notification about situations involving health hazards and death or serious injury or illness cannot wait for annual reports.

Several comments addressed the selection process, number, and need for advance notification of facilities for accreditation body onsite visits. Some comments stated that the percentage of visits performed by accreditation bodies should be established by FDA (at perhaps 5 or 10 percent of accredited facilities). One comment suggested that a means be established to ensure proportionate distribution of visits to facilities with regard to facility size and geographic distribution. Several comments believed that accreditation bodies should be required to give facilities advance notice of a visit, although one comment believed that FDA should specify certain circumstances for which unannounced visits might be appropriate.

In response to these comments, FDA is proposing in § 900.4(f)(1) that accreditation bodies select some facilities for onsite visits on a random basis and select other facilities based on specific reasons for concern with those facilities, such as previous history of noncompliance with quality standards. In general, each accreditation body would have to visit annually at least 5 percent of 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.

Regarding advance notification of facilities by accreditation bodies, 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, however, for facilities selected randomly for onsite visits, FDA will encourage accreditation bodies to work with facilities to schedule visits so as to minimize examinee inconvenience and disruption to facility operations.

For random clinical image reviews, FDA is proposing that, on an annual basis, 3 percent of facilities (but no less than five facilities) accredited by an accreditation body would have to be chosen randomly to submit clinical images for review. These clinical images would be in addition to those submitted every 3 years as part of the accreditation process. As the requirements have been proposed, the accreditation body would be able to count toward this 3 percent requirement all facilities that have undergone an additional clinical image review because of random selection for the onsite visits in § 900.4(f)(1)(i)(A).

The requirement for selecting a 3 percent random sample of facilities is changed from that in the interim regulations, which required random clinical image review for each facility accredited by a body. The change in the sampling requirement is based on FDA experience with implementing 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 renewal is not an effective use of accreditation body resources. In addition, accreditation bodies should not schedule random clinical image reviews at facilities that have received their notification of their need to begin the accreditation renewal process or at facilities that have completed the accreditation renewal process within the previous 6 months.

7. Consumer Complaint Mechanism

The interim regulations required accreditation bodies to establish processes for receipt, investigation, and records maintenance of consumer complaints about facilities they accredit. In accordance with 42 U.S.C. 263(n)(3)(E), FDA has worked with the NMQAAC to develop mechanisms to investigate consumer complaints. The committee and FDA agree that the investigation of ''serious complaints'' and the correction of underlying problems that may have precipitated them can help improve the practice of mammography. The proposed role of accreditation bodies in this process is specified in § 900.4(g).

A ''serious'' complaint is defined in proposed § 900.2 (published elsewhere in this issue of the Federal Register) as a report by a consumer of: (1) A ''serious adverse event'' that significantly compromises, or has the potential to significantly compromise, clinical outcomes, or (2) an ''adverse event'' for which the facility fails to take appropriate corrective action. ''Consumer'' is defined in proposed § 900.2 as an individual who chooses to comment or complain in reference to a mammography exam. Consumers, therefore, may include the examinee or representatives of the examinee (e.g., family members or referring physicians).

In the proposed regulations, the consumer complaint mechanism focuses on serious complaints related to incidents over which FDA has regulatory authority under MQSA. FDA acknowledges that there may be additional kinds of serious complaints that are legitimate and worthy of investigation, but that do not fall under the agency's regulatory authority under MQSA (e.g., sexual harassment or discrimination). FDA encourages the channeling and resolution of such complaints through appropriate existing mechanisms, such as State oversight

organizations and professional licensing boards.

The proposed consumer complaint mechanism would set minimum requirements for facilities and accreditation bodies. FDA has worked extensively with NMQAAC in developing this mechanism and believes that the proposed requirements meet the important needs of the consumer without imposing undue burden on mammography facilities. The proposed regulations would allow facilities flexibility in instituting their own complaint resolution procedures. FDA encourages facilities to design their complaint mechanisms to be responsive to language, ethnic, and literacy differences among consumers served by the facility.

FDA believes that all comments and complaints should be directed first to the facility, where there is the greatest opportunity for resolution. FDA is proposing that facilities be required to establish and administer a documented consumer complaint mechanism that complies with standards in proposed § 900.12(h), published elsewhere in this issue of the Federal Register. However, FDA also recognizes that, under certain circumstances, consumers may want to report serious complaints that they have been unable to resolve with the facility to a more impartial organization. FDA believes that a facility's accreditation body should receive these complaints because the accreditation body has the responsibility for assuring that facilities meet quality standards. To fulfill this responsibility, accreditation bodies need data on serious complaints related to mammography quality. Therefore, FDA is proposing that the accreditation body be the second level in the complaint process to receive, investigate, and resolve serious consumer complaints.

The third level of the complaint process, should the complaint go unresolved at the accreditation body level, would be FDA. The accreditation body could recommend that FDA take regulatory action, including inspections, sanctions, or revocation of the facility's certificate. Some consumers might want to address complaints about facilities directly to FDA, and this option is also open to them.

FDA is proposing to require accreditation bodies to review and evaluate each facility's plan for handling consumer complaints. The agency is also proposing that the accreditation body be required to maintain a record of each serious complaint it receives regarding facilities it accredits, whether or not the accreditation body is able to resolve the complaint. All records of serious complaints would have to be retained for at least 3 years after the date of receipt of the complaint by the accreditation body. Accreditation bodies would also be required to submit to FDA an annual report summarizing serious complaints.

One comment on the interim regulations requested that complaint information be shared with States and the public.

The MQSA does not include a provision requiring public disclosure of individual consumer complaints or release of such information by individual facilities to State authorities. However, the MQSA does require in 42 U.S.C. 263b(l)(1) that information FDA determines to be useful in evaluating the performance of mammography facilities be made available to the general public no later than October 1, 1996, and annually thereafter. This information must include a list of facilities that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks, have been subject to sanctions, have had certificates revoked or suspended, or have had accreditation revoked.

One comment on the interim regulations noted that the mechanism for handling complaint information contains no provision for protecting confidentiality and that unsubstantiated allegations should not be made publicly available.

As discussed above, FDA does not believe the MQSA is intended to authorize public disclosure of details concerning specific complaints or allegations. FDA encourages all individuals involved in resolution of complaints to protect the confidentiality of consumers and health professionals to the full extent required by State law and professional ethics. However, knowledge of the identity of individuals involved in the complaint process may be necessary in order for the accreditation body or FDA to investigate the complaint. The agency's own regulations prohibit disclosure of information that would be an unwarranted invasion of personal privacy and FDA will not release names or personal identifiers without consent of the individuals involved (21 CFR 20.63 and 20.111).

8. Reporting and Recordkeeping

In § 900.4(h), FDA is proposing to require that accreditation body reports to FDA be submitted in the format and medium prescribed by the agency. This requirement would facilitate the use of uniform methods for efficient data management and analysis, including the use of computer-based systems by FDA.

One comment stated that the timeframes specified in the interim regulations (§ 900.4(g)) for accreditation body reporting were unreasonable.

FDA agrees that changes in this area are needed and the proposed regulations have been designed to allow greater flexibility in specifying timeframes for reports to FDA, based on FDA and accreditation body needs.

One comment expressed concern that the wording of the interim requirement in § 900.4(g)(6) might result in a request for proprietary information not specifically required by or relevant to the MQSA. Another comment indicated concern that the interim requirement in § 900.4(d)(1) for a facility to provide its accreditation body with, ''any other information the body may require, as a part of the annual report about the facility'', was excessively broad.

FDA believes that the MQSA provides the agency with the authority to determine the information that is necessary to meet the agency's statutory responsibilities under MQSA (e.g., 42 U.S.C. 263b(d)(1)(B)(iii) and (e)(1)(C)(vi)). In addition, FDA has considerable experience with receiving and protecting proprietary information. However, in response to the comments, FDA has modified the regulatory language to specify that any information collected by an accreditation body from a facility should be relevant to the MQSA. In addition, as part of FDA's approval and oversight responsibilities, the agency will review the information required by accreditation bodies with regard to its relevance to such bodies' responsibilities under MQSA.

As discussed earlier, FDA has also addressed the issue of confidentiality in the accreditation body code of conduct and general responsibilities. Proposed § 900.4(a)(9) states the obligation of the accreditation body to keep confidential all nonpublic information it acquires in connection with carrying out its accreditation body responsibilities.

9. Fees

In proposed § 900.4(i), FDA is continuing to require that accreditation body fees charged to facilities be reasonable, as in § 900.4(c) of the interim regulations.

Several comments regarding accreditation fees mentioned the relatively small amounts of various third party reimbursements for screening mammography and hoped that FDA would consider this information when establishing requirements for fees. Two comments disagreed with the interim requirements for limiting fee increases to adjustments in the consumer price index (CPI). A

few other comments raised additional issues related to determining the reasonableness of fees, including expansion costs and accreditation body activities specifically attributable to MQSA responsibilities. The latter issue was raised with respect to State agencies with multiple responsibilities in addition to those associated with MQSA.

FDA is proposing certain changes in the fee provisions in response to comments. The proposed regulations would permit variation in accreditation body fees, and adjustments would no longer be limited to changes in the CPI. However, FDA is proposing that accreditation bodies only be allowed to recover costs that are a result of MQSA-attributable functions. Consequently, fee changes might be appropriate for changes in accreditation body activities that have been approved by FDA. However, accreditation body activities that are not FDA-approved activities could not be considered in determining fees charged for MQSA accreditation functions. Consequently, the relationship of fees to costs incurred because of accreditation body responsibilities under these regulations would be an important factor in determining the reasonableness of fees.

One comment questioned whether providers would have an opportunity to question the reasonableness of fees before they are approved by FDA.

Although there is no official provision for public comment on accreditation fees, anyone who feels that fee increases are excessive may raise these concerns with FDA at any time.

D. Evaluation of Accreditation Bodies

In proposed § 900.5, FDA states that the agency will evaluate all accreditation bodies at least annually and at other times if specific circumstances warrant.

Two comments suggested the following additions to the factors specified in the interim regulations for evaluating accreditation bodies: (1) Responsiveness of the body to FDA and to complaints from other sources, and (2) compliance of the body with requirements for approval as an accreditation body. One of these comments also suggested that more detail be added related to the sample size of facilities and clinical images to be assessed by FDA as part of FDA's evaluation of accreditation bodies.

In response to these comments, FDA advises that the proposed regulations contain more extensive requirements (in § 900.3) for approval as an accreditation body than did the interim regulations. As part of its annual evaluation of accreditation bodies, FDA will consider compliance with these requirements, including the responsiveness and timeliness with which accreditation bodies meet their various responsibilities. In order to perform these evaluations, FDA will have access to the results of annual inspections of facilities by FDA or State inspectors, information from annual and other reports from accreditation bodies, and visits to facilities or accreditation bodies to evaluate their compliance with the standards specified under subparts A and B of part 900 (21 CFR part 900). FDA also will be able to request more data, such as additional clinical images, at any time the agency determines that it needs further information to complete its evaluation.

E. Withdrawal of Approval

In § 900.6, FDA has proposed certain changes to the interim criteria for withdrawal of approval of an accreditation body and the addition of certain other actions the agency may take against accreditation bodies, when warranted.

Under the interim regulations, FDA was precluded from reinstating approval of an accreditation body if withdrawal of approval was based on fraud or material false statements. FDA has reconsidered these criteria in drafting these proposed rules and in light of the agency's experience implementing the interim regulations.

FDA continues to believe that certain actions are so egregious that they should automatically preclude an accreditation body from continuing or ever resuming service as an accreditation body. The agency believes that, in addition to the commission of fraud, willful disregard of the public health constitutes an action by an accreditation body that should permanently disqualify that body from future approval. Accordingly, FDA has added willful disregard of the public health as a bar to reinstatement as an accreditation body.

However, FDA is proposing to review on a case-by-case basis applications from former accreditation bodies whose approval was withdrawn due to the submission of material false statements. The agency is persuaded that there may be instances where the submission of material false statements was unintentional or had limited consequences. FDA has drafted the proposed regulations to retain discretion to reinstate accreditation bodies if the agency determines there is evidence to demonstrate that such conduct will not recur.

The proposed regulations also clarify that FDA reserves the right to withdraw approval or place an accreditation body on probationary status, depending on the specific deficiencies involved. Unlike the interim regulations, the proposal gives FDA discretion about how to proceed, even with respect to accreditation bodies that have demonstrated major deficiencies. FDA would make these determinations on a case-by-case basis. In addition, FDA would have discretion to specify particular corrective actions that the accreditation body must take or to offer the accreditation body an opportunity to submit its own plan of corrective action (including timetables) for FDA approval.

Two comments stated that the specification in the interim regulations of a 90-day time period for submitting a corrective action plan to FDA for minor deficiencies should be shortened from 30 to 60 days, and that FDA should respond to the proposed plan within the same timeframe.

FDA has concluded that establishing fixed time periods for submission or implementation of corrective action plans does not allow the agency or accreditation bodies sufficient flexibility. Timeframes for correction of minor deficiencies should be based on the specific deficiencies that must be addressed. Therefore, the agency has not set forth specific timeframes in proposed § 900.6(b)(2). Instead, FDA will determine the necessary implementation schedules on a case-by-case basis.

F. Hearings

Under proposed § 900.7 on hearings, a facility that has been denied accreditation would be entitled to an appeals process from the accreditation body (§ 900.7(b)). The facility could then appeal the results of this process to FDA and the Department of Health and Human Services in accordance with proposed § 900.15, published elsewhere in this issue of the Federal Register.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined together the impacts of this proposed rule and the proposed rules on general facility requirements, personnel requirements, and quality standards for mammography equipment and quality assurance, published elsewhere in this issue of the

Federal Register, under Executive Order 12866, the Regulatory Flexibility Act (Pub. L. 96–354), and under the Unfunded Mandates Reform Act. The analysis has addressed the proposed requirements of these four rules as one unit for purposes of determining their economic impact. The preamble to the proposed rule ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches,'' published elsewhere in this issue of the Federal Register, contains a brief summary of the cost and benefit determination and the Regulatory Impact Study that details the agency's calculation of these economic impacts and is available at the Dockets Management Branch (address above) for review. FDA recognized that these proposed regulations may have a disproportionate effect on small volume mammography facilities and is currently collecting additional information on the potential impact on this industry sector. The agency requests comments that will assist it in accounting for this impact.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collection are contained in the proposed rule ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches,'' published elsewhere in this issue of the Federal Register, with an estimate of the annual reporting and recordkeeping burden.

The agency has submitted a copy of this proposed rule to OMB for its review and approval of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB, rm. 10235, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA. Written comments on the information collection requirements should be submitted by May 3, 1996.

VI. Comments

Interested persons may, on or before July 2, 1996, submit to the Dockets Management Branch (address above) written commentsregarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following information has 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. ''Report on the Mammography Quality Standards Act of 1992,'' U.S. Senate, Report 102–448, October 1, 1992.

2. ''Health Care: Hospitals with Quality-of-Care Problems Need Closer Monitoring,'' U.S. GAO, GAO/HRD–91–40, May 1991.

List of Subjects in 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, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 900 be amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. Sections § 900.3 through 900.7 are revised to read as follows:

§ 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 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, 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 requested scope of authority.

(2) Following receipt of the request, FDA will send application guidance to the applicant.

(3) In accordance with the guidance provided, the applicant shall furnish to FDA at the address in paragraph (b)(1) of this section three copies of an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant and evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State agency;

(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 42 U.S.C. 263b(e)(3);

(iii) Detailed description of the applicant's accreditation review and decisionmaking process, including:

(A) Procedures for performing clinical image review;

(B) Procedures for performing phantom image review;

(C) Procedures for assessing mammography equipment evaluations and surveys;

(D) Procedures for 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;

(G) Policies and procedures for notifying facilities of deficiencies;

(H) Procedures for monitoring corrections of deficiencies by facilities;

(I) Policies and procedures for revoking a facility's accreditation;

(J) Policies and procedures that will assure 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) 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;

(x) Description of the body's documented consumer complaint mechanism;

(xi) Satisfactory assurances that the applicant shall comply with the requirements of § 900.4; and

(xii) 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, an applicant for renewal shall inform FDA at the address given in paragraph (b)(1) of this section.

(2) FDA will notify the applicant of the applicable information, materials, and supporting documentation from paragraph (b)(3) of this section 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 paragraph (b)(1) of this section three copies of a renewal application containing the information, materials, and supporting documentation requested by FDA in accordance with paragraph (c)(2) of this section.

(4) No later than July 2, 1996, any accreditation body approved under the interim regulations published in the Federal Register of December 21, 1993 (58 FR 67558) that intends 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 90 days 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 will be rejected.

(3) The applicant will receive a formal notice from FDA stating whether the application has been approved or denied and a statement of 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 accreditation body 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 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 paragraph (b)(1) of this section at least 90 days 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 in accordance with §§ 900.3(d) or 900.4(a)(9), all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

(g) *Scope of authority.* The accreditation body's term of approval is for a period of 5 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) 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 an unreasonable risk of substantial harm to the public. Such reviews would be in addition to the evaluation an accreditation body performs as part of the initial accreditation or renewal process for facilities. If FDA determines that a facility's practice poses an unreasonable risk of substantial harm to the public:

(i) The accreditation body shall require the facility to take appropriate corrective actions as determined by the accreditation body or FDA, including, but not limited to, notifying examinees or referring physicians; and

(ii) The accreditation body shall monitor the facility's implementation of corrective actions in accordance with a schedule specified by FDA.

(2) The accreditation body shall provide guidance to facilities regarding reporting requirements for conditions within the scope of 42 U.S.C. 263b that arise at the facility and that pose a health hazard to examinees, personnel, or others in the facility.

(i) The accreditation body shall require that such information and a plan of correction addressing the conditions be submitted by the facility in a manner and time period specified by the accreditation body.

(ii) The accreditation body shall require the facility to cease use of any equipment or to eliminate any practices that may contribute to such potentially harmful conditions as soon as possible. In those circumstances where the accreditation body has reason to believe a hazard exists, the accreditation body shall notify the facility that use of the equipment or continuation of the practice shall stop immediately.

(iii) The accreditation body shall monitor the facility's compliance with the plan of correction and progress

toward meeting applicable standards and minimizing health hazards.

(3) The accreditation body shall inform FDA within 5 business days of becoming aware of equipment or practices that pose an unreasonable risk of substantial harm to the public.

(4) 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, evaluation, and performance improvement for clinical and phantom image reviewers, and the bases and procedures for removal of such reviewers.

(5) 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.

(6) 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 42 U.S.C. 263b, 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 42 U.S.C. 263b. Any representations about such products shall include a similar disclaimer.

(7) 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.

(8) No State agency that is approved as an accreditation body may require facilities in the State to be accredited under 42 U.S.C. 263b only by the State agency and not by other FDA- approved accreditation bodies.

(9) 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).

(10) An accreditation body shall 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, without the consent of the facility;

(ii) Nonpublic information that FDA or its duly designated representatives 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) *Facility 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 take reasonable steps to ensure that such equipment, personnel, or other aspects of the practice are not used by the facility for activities covered by 42 U.S.C. 263b.

(3) The accreditation body shall specify the actions that facilities must 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 revoke the facility's accreditation in accordance with the policies and procedures in § 900.3((b)(3)(iii)(I).

(c) *Clinical image review.* (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) Tissue exposure. Tissue exposure 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 significantly obscure breast structures or suggest the appearance of structures not actually present.

(vii) Artifacts. Artifacts due to lint, 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 and unambiguous manner and placed so as not to obscure anatomic structures:

(A) Examinee identification.

(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)(9) 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 number 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)(9) of this section. The scoring system shall include an individual scoring scale for each attribute. Each scoring scale shall cover the range from unacceptable deficiencies that markedly reduce the clinical value of an image to no significant deficiencies. Each clinical image submitted shall be scored for each attribute.

(i) The accreditation body shall establish and employ criteria for a pass-fail system for clinical image review that has been approved by FDA in accordance with § 900.3(d) or § 900.4(a)(9).

(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 normal.

(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 examinee.

(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 assure the security and return to the facility of all clinical images received and to assure 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 work with the facility to accommodate such needs.

(ii) If a clinical image reviewer identifies an abnormality on a clinical image that the facility interpreted as normal, and this finding is not clearly specified on mammography reports submitted with the clinical images, the accreditation body shall ensure that this information is provided and the clinical images returned to the facility no later than 10 business days after identification of the suspected abnormality.

(7) Corrective measures for unsatisfactory image quality. If the accreditation body determines that the clinical images from a facility it accredits are of insufficient quality, the body shall notify the facility of the nature of the problem and its possible causes. The accreditation body shall monitor facility progress in correcting the problem and take appropriate action if the necessary corrective measures are not implemented in a manner and time period satisfactory to the body.

(d) *Phantom image review.* (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)(9) 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(d) or paragraph (a)(9) 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(d) or paragraph (a)(9) 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 assure the security and return to the facility of all phantom images received and to ensure completion of all phantom image reviews by the body in a timely manner.

(7) Corrective measures for unsatisfactory image quality. If the accreditation body determines that any phantom images are of insufficient quality, the body shall notify the facility of the nature of the problem and its possible causes. The accreditation body shall monitor facility progress in correcting the problem and take appropriate action if the necessary corrective measures are not implemented in a manner and time period satisfactory to the body.

(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 performed 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) A survey which 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 assure 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 annual surveys be conducted no later than 14 months after the most recent prior survey;

(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, together with quality control records, personnel updates, and 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 determine the accreditation status of a facility and to identify necessary corrective measures for facilities.

(f) *Onsite visits to facilities 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 the facility standards imposed under § 900.3. 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, 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 visits according to a visit plan that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(9) of this section. At a minimum, such plan shall address review of the following elements during visits to facilities selected randomly and facilities selected because of previously identified concerns:

(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 examinees 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 that does not compromise care of the examinee as a result of the absence of the selected images from the facility;

(D) Review of the facility's medical audit system and assessment of correlation between film 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 of facility compliance with its consumer complaint mechanism; 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 initial and renewed accreditation for all facilities, the accreditation body shall conduct clinical image reviews annually for a randomly selected sample of 3 percent of the facilities the body accredits. However, a minimum of five facilities shall be selected for such random clinical image review. Accreditation bodies may count toward this 3 percent 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 3 percent random sample requirement any facilities selected for a visit because of previously identified concerns described in paragraph (f)(1)(i)(B) of this section.

(ii) Clinical image review. In performing clinical image reviews of the 3 percent random sample of facilities, accreditation bodies shall apply the same standards as those in paragraph (c) of this section for review of clinical images for initial and renewed accreditation.

(iii) Accreditation bodies should not schedule random clinical image reviews at facilities that have received notification of need to begin the accreditation renewal process or that have completed the accreditation renewal process within the previous 6 months.

(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)(9) of this section. Accordingly, all accreditation bodies shall:

(1) Provide a mechanism for filing a serious complaint with the accreditation body if the complaint has not been resolved at the facility;

(2) Maintain a record of every serious 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;

(3) Submit to FDA, at the address in paragraph (b)(1) of this section, in a manner and time period specified by 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.

(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 § 900.12(b)(2) 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 or revokes accreditation, or for which the accreditation body denies submission to FDA of information required from facilities for provisional certification or for extension of provisional certification, as described in paragraph (h)(3) of this section, and the reason(s) for such action;

(4) 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 will 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.

§ 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 shall initiate enforcement actions as follows:

(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 will 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 will 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 approval authority, 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 will not 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 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)(9).

(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.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–7831 Filed 3–29–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 900

[Docket No. 95N–0215]

RIN 0910–AA24

Quality Standards and Certification Requirements for Mammography Facilities; Personnel Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the mammography facility standards by modifying and adding to the personnel requirements for interpreting physicians, radiologic technologists, and medical physicists who perform mammography services. In addition to the statutory framework and the expertise and research of FDA personnel, the agency is proposing this rule based on advice provided by the National Mammography Quality Assurance Advisory Committee (NMQAAC) and public comments received in response to the interim regulations. This action is being taken to ensure that all personnel involved in mammography meet at least the minimum requirements for providing safe, accurate, and reliable mammography. This is the fourth of five proposed rules being published concurrently.

DATES: Written comments on this proposed rule by July 2, 1996.

Written comments on the information collection requirements should be submitted by May 3, 1996. The agency is proposing that any final rule based on this proposed rule become effective 1 year after its date of publication in the Federal Register.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Regulatory Impact Study (RIS) is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This proposal is the fourth of five related proposed rules published in this issue of the Federal Register to amend interim regulations published on December 21, 1993 (58 FR 67558 and 58 FR 67565), implementing the Mammography Quality Standards Act of 1992 (the MQSA). The first proposed rule entitled ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' contains background information and a summary of the preliminary analysis of the costs and benefits of all of these proposed rules, a description of the information collection requirements, proposed revisions to § 900.1 *Scope* and § 900.2 *Definitions*, and proposed alternative approaches to mammography quality standards and a request for comments on the proposed alternatives.

II. Provisions of the Proposed Rule

A. Development of the Proposed Regulation

This proposed rule establishes the personnel qualification standards that the staff of each mammography facility must meet in order to comply with requirements under the MQSA. As in the development of the interim regulations, FDA has been guided by the requirements of this statute and its stated legislative intent to guarantee access to safe and effective mammography services for all women in the United States (Ref. 1).

In addition to the statutory framework and the expertise and research of FDA personnel, the agency relied upon three major sources of information in developing this proposed rule. The first source was the written comments received on the interim regulations. FDA received 103 comments from individuals and organizations on the interim regulations. Included among the written comments were responses from professional organizations, medical facilities, State agencies, consumer groups, manufacturers, and individual physicians, medical physicists, and radiologic technologists.

Drafts of this proposed rule were also discussed with the NMQAAC, particularly at the February 1994 and January 1995 public meetings with the agency. The members of the NMQAAC include interpreting physicians, medical physicists, radiologic technologists, representatives of State agencies, and consumer representatives. Consultants to the Committee and guests invited to attend the meetings in recognition of their expertise in mammography also participated in these discussions. In the Federal Register of January 26, 1995 (60 FR 5152), the agency published a notice of availability of the draft of the proposed rule that was discussed with the NMQAAC.

Finally, the problems with the interim regulation were discussed with many of the individuals who currently perform annual inspections of mammography facilities under the MQSA to determine whether minimum quality standards are being achieved. Most of these inspectors have extensive prior experience in the inspection of radiology facilities. After the MQSA inspections began in January 1995, the agency closely monitored the process and gathered information that was valuable for developing the proposed final regulations.

B. Interpreting Physicians

The proposed regulation for interpreting physicians generally clarifies the requirements issued under the interim regulations and adds some new requirements. Although neither a national standard nor a continuing competency test for mammography interpretation currently exists, the proposed training and experience requirements for interpreting physicians will provide minimum standards to help ensure the reliability and accuracy of interpretation of mammograms for women throughout the country.

As discussed below, the quality standards proposed by FDA for interpreting physicians are divided into four general sections: Initial qualifications; continuing experience and education; exceptions; and reestablishing qualifications.

1. General Comments

Two comments expressed concern that providers in rural areas would have difficulty meeting the requirements of the interim regulations. They suggested that allowance should be made for such facilities, either through lowering the standards for rural facilities or establishing a longer phase-in period. One of these comments also stated that it would be helpful if the Department of Health and Human Services monitored the effect of the rules on rural providers.

Both FDA and NMQAAC are concerned about the impact of the MQSA on access to mammography in rural areas. However, both the agency and NMQAAC believe that the standards should not be lower for certain facilities. One of the primary goals of the MQSA is to ensure that all women receive at least the same minimum standard of care, no matter which facility they use. However, one of the specific duties that the MQSA requires of NMQAAC is to determine whether there exists a shortage of mammography facilities or health professionals in any areas and to determine the effects of the quality standards on access to mammography

services in such areas. This study already has begun and the results will be published upon completion.

2. Initial Qualifications

The first qualification for an interpreting physician under the MQSA is a State license to practice medicine (proposed § 900.12(a)(1)(i)(A)).

One comment stated that § 900.12(a)(1)(i)(A) in the interim regulations was confusing and would appear to allow a facility to license a physician. Similarly, another comment stated that the licensing requirements of physicians practicing in Federal facilities are unclear.

In response, FDA notes that a facility cannot license a physician to practice medicine. Licensing of physicians is a State function. Proposed § 900.12(a)(1)(i) simply requires the interpreting physician to have a State license to practice medicine. However, 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.

Proposed § 900.12(a)(1)(i)(B) provides two pathways to establish the second initial qualification: Board certification or documented training in interpreting mammograms. The training shall include radiation physics (including radiation physics specific to mammography), radiation effects, and radiation protection.

One comment recommended that FDA accept both American and Canadian boards as certifying bodies.

FDA does accept certification from both American and Canadian boards. Currently, FDA recognizes certification in Diagnostic Radiology and Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology (AOBR), and the Royal College of Physicians and Surgeons of Canada.

Another comment asked that two British radiology boards be added to the list of bodies designated by FDA as eligible to certify interpreting physicians: Fellow of the Royal College of Radiologists (FRCR) and, Diploma in Medical Radiodiagnosis (DMRD) from the Royal College of Physicians and Surgeons of England.

NMQAAC discussed but did not recommend including other bodies to certify interpreting physicians at this time because there was insufficient information about the procedures and requirements for obtaining board certification from other bodies. FDA has not added additional bodies to its list of certifying bodies because FDA agrees that it has insufficient information at this time.

One comment stated that certifying bodies for interpreting physicians should be listed in the regulations. Another comment noted that the interim regulations do not indicate the particular bodies that have or will be designated by FDA as eligible to certify interpreting physicians and noted that approval of inappropriate certifying bodies could result in poorly qualified physicians reading and interpreting mammograms. The comment suggested that guidelines are needed regarding the certification of interpreting physicians.

FDA believes that it is best not to codify the list of eligible certifying bodies in the regulation in order to be able to make changes to the list of certifying bodies in a timely manner each time a body must be added to or deleted from the list. FDA will add or delete names based upon the agency's determination that the body has in place and implements procedures and requirements that are adequate to ensure that interpreting physicians certified by the body are capable of satisfying the MQSA needs. Whenever possible, FDA intends to consult with the NMQAAC before making a determination about adding or removing a body from the list of those eligible to certify physicians. The list of currently eligible certifying boards is based upon FDA evaluation and consultation with NMQAAC, as described above. FDA will follow a similar policy with respect to its determination of eligibility for boards or organizations that certify radiologic technologists and medical physicists.

One comment noted that his State's requirements for interpreting physicians are more stringent than the interim requirements and suggested that FDA may want to include the following language in the regulation (sic): ''require A.B.R. or A.O.B.R. certification or has successfully completed and graduated from an accredited radiology residency within the past 24 months.'' Another comment stated that FDA should give careful consideration before approving either the ABR or the AOBR to certify interpreting physicians. The comment further explained that if the ABR or AOBR certifies physicians based on ''board certification,'' many physicians who are not adequately trained in mammography automatically would be allowed to interpret mammograms.

FDA recognizes that some earlier board examinations may not have included testing in mammography. FDA also recognizes that board certification that includes mammography cannot by itself ensure the accuracy of outcomes in clinical mammography practices. However, board certification is evidence that the physician is knowledgeable in the basics of diagnostic radiology and board certification serves as a foundation for the additional requirements specific to mammography that interpreting physicians must meet under FDA's interim and proposed regulations.

Alternatively, proposed § 900.12(a)(1)(i)(B) would permit 3 months of documented formal training in mammography, including the interpretation of mammograms and other topics related to mammography, in place of board certification in diagnostic radiology. The other topics related to mammography include, but are not limited to: Radiation physics, including radiation physics specific to mammography; radiation effects; and radiation protection. The interim regulations require 2 months of documented full-time training. The agency is proposing an additional month of required training to reflect the increased emphasis that has been placed on mammography in residency programs.

During discussions at an NMQAAC meeting, it was recommended that FDA require training in radiation physics specific to mammography instead of training in general radiation physics as the training required by the alternative pathway in proposed § 900.12(a)(1)(i)(B). FDA agrees that mammography specific training is necessary, but also believes that general training in radiation physics is important for basic principles and should be retained as part of the requirements for the alternative pathway provided by proposed § 900.12(a)(1)(i)(B). NMQAAC also suggested that all required training in physics be obtained from a physicist. However, the agency believes that this suggestion is too restrictive and would limit the availability of adequate training opportunities.

The agency is proposing that the training in interpretation required for the alternative pathway be performed under the direct supervision of an interpreting physician who meets the MQSA requirements for an interpreting physician. It was recommended during NMQAAC discussions that there be additional qualifications for the

supervising physician beyond those required of an interpreting physician. For example, FDA could require supervising physicians to be qualified to offer continuing medical education (CME) credits. Again, the agency believes that this suggestion would be too restrictive and reduce the availability of effective training opportunities.

One comment suggested having an alternative method for allowing a physician who is not a radiologist but who is experienced in interpreting film mammography to be certified and allowed to continue to interpret mammograms.

The agency agrees and has proposed § 900.12(a)(1)(i)(B) in order to provide an alternative to board certification for radiologists and physicians who are not radiologists, but who otherwise qualify.

One comment stated that the alternate pathway to board certification in the interim regulations, requiring 2 months of training in the interpretation of mammograms, is not adequate. The comment stated that some type of board certification is necessary to ensure that women are receiving high quality interpretation of mammograms. Another comment advocated the addition of a proficiency examination, which would require a physician to demonstrate his or her ability to interpret mammograms, both at the point of the physician's initial certification and at periodic intervals to maintain that certification. The latter comment noted that academic achievement, although important, is not sufficient to ensure high quality mammography.

The NMQAAC discussed the possibility of requiring that interpreting physicians undergo proficiency testing in mammography, but did not recommend such testing at this time. To date, sufficient data have not been compiled on existing levels of interpretive skills for interpreting physicians to determine whether there is a general need for proficiency testing. With respect to the adequacy of the training required under the alternate pathway, FDA is proposing to increase that requirement from 2 to 3 months of documented training in the interpretation of mammograms.

Proposed § 900.12(a)(1)(i)(C) requires 60 hours of documented continuing medical education credits in mammography for all interpreting physicians, including instruction in the interpretation of mammograms and training appropriate to each mammographic modality used in the interpreting physician's practice. At least 40 of these hours must be Category I CME credits and, to ensure that the physician has recent mammography education, at least 15 of these 40 Category I CME hours must have been acquired within the 3 years immediately preceding 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 the appropriate representative of the training institution.

One comment stated that the interim regulations, which require 40 hours of documented CME in mammography, are quite adequate to ensure that interpreting physicians have the training, expertise, and experience necessary to do mammographic interpretations.

The agency believes that an increase to 60 hours is in keeping with current training trends and the emergence of new technologies.

Proposed § 900.12(a)(1)(i)(C) requires training in each mammographic modality employed in the interpreting physician's practice. FDA added this requirement because of the differences among imaging modalities (e.g., film screen and xeromammography) currently in use and emerging technologies, such as digital mammography. The agency believes that, before a physician begins to interpret images produced by a particular modality, he or she should have specific training in the interpretation of such images. FDA is proposing that at least 8 hours of Category I CME credit be related to each mammographic modality used by the interpreting physician.

FDA has also proposed, with the concurrence of NMQAAC, that the interpreting physician must have education in each of the following: basic breast anatomy; breast pathology and physiology; technical aspects of mammography (e.g., exposure factors, compression, positioning); quality assurance and quality control in mammography.

One comment questioned whether ABR certified physicians are required to document 40 hours of initial education under the interim regulations.

The interim regulations require this documentation from physicians using either of the two pathways and proposed § 900.12(a)(1)(i)(C) would continue this requirement for the 60 hours of required initial training.

Two comments asked what FDA will consider to be adequate documentation of the radiologist's training.

A variety of documentation has and will be accepted (e.g., copy(s) of the license(s) to practice medicine, copy(s) of the certificate issued by certifying board(s), CME credit certificates). The agency previously issued guidance on adequate documentation under the interim regulations that will be revised, as needed, and made available when the final regulations are published. Such guidance does not bind the agency or the facility and facilities may choose to accept documentation that is not discussed in FDA guidance. However, FDA encourages facilities that plan to accept alternate documentation to discuss the matter in advance with FDA in order to avoid potential loss of time and resources. Upon inspection of the facility, in any situation in which documentation appears inadequate, the burden will be upon the employee and the facility to provide additional evidence to demonstrate the qualifications of personnel employed by the facility.

One comment suggested that time spent in a residency program devoted to mammography should be documented by the residency program.

FDA agrees and is proposing that the resident's training be documented in writing by the appropriate representative of the training institution.

Proposed § 900.12(a)(1)(i)(D) requires the qualifying physician to interpret at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician within the 6 months immediately prior to fulfilling the initial qualifications as an interpreting physician. The intent of this requirement is to demonstrate recent supervised experience before the physician begins to interpret mammograms independently. Proposed § 900.12(a)(1)(iii)(B) provides an exception from this prior 6-month timeframe for diagnostic radiology residents who become board certified at the first allowable time, as defined by the eligible certifying body of their choice. Such residents must still interpret at least 240 mammographic examinations in the last 2 years of residency under the direct supervision of a qualified interpreting physician.

One comment expressed concern that the volume of films that must be read to achieve and maintain certification may have an unintended, negative impact on a physician working on a locum tenens basis, that is, a physician serving as a temporary replacement for another physician.

In response, FDA notes that proposed § 900.12(a)(1)(i)(D) is an initial requirement that need only be met once if the interpreting physician maintains his or her continuing experience requirements under proposed § 900.12(a)(1)(ii).

3. Continuing Qualifications

Proposed § 900.12(a)(1)(ii)(A) is the first of the requirements established to ensure that interpreting physicians maintain their qualifications. Under this requirement, in order to continue to qualify under the MQSA, interpreting physicians must have read an average of at least 40 mammographic examinations a month during the previous 24 months. Although the wording has changed somewhat from the interim rule, the proposed regulation is not substantially different from the interim requirement.

There were numerous comments on this requirement in the interim regulations. Comments expressed concern about the difficulty in meeting this requirement in rural areas due to lack of volume at the facility. One comment expressed concern that the requirement may have a negative impact on physicians serving as temporary replacements for other physicians (i.e., on a locum tenens basis). Two comments suggested allowing the substitution of continuing education for this experience requirement, and one of these comments suggested that the physician be allowed to submit interpretations on a specified number of test mammograms in lieu of the 40 per month average and that the requirements could also be modified slightly to focus on the number of mammograms read per year, instead of per month. Another comment requested that rural x-ray departments be exempted from this requirement.

As previously stated, FDA believes that all women, including those in rural areas, are entitled to the same quality of care, and the agency cannot support lower standards for particular facilities. The agency also believes, as discussed below, that it will not be difficult for most physicians to meet this continuing qualification, even for those in rural areas.

The monthly average is to be maintained over a 24-month period. FDA selected 24 months to allow interpreting physicians a reasonable chance to maintain the required average. Physicians who are absent for a period of time, due to sabbaticals or other reasons, or who only read mammographic images during selected periods, because of their facility rotation schedule or employment on a locum tenens basis, will have the opportunity to read enough images during some portions of the 24-month period to maintain the required average. The agency also wants to clarify that this is a physician requirement, not a facility requirement. Interpreting physicians who provide services to low workload facilities can read films at more than one facility to attain the required average. Double reading of images (2 or more physicians interpreting the same mammogram) is also accepted as a way of meeting this requirement. However, the agency excludes from its definition of double reading the interpretation of the same mammogram more than once by a same physician. For all of these reasons, the agency believes there will not be widespread difficulty in meeting this requirement.

One comment suggested that the agency develop something besides an artificial number to tell whether or not a radiologist is able to do a good job.

FDA recognizes that numbers alone cannot guarantee competency, but believes that the experience a radiologist accumulates through interpreting a certain minimum number of films is a necessary aspect of the qualification process. Elsewhere in this issue of the Federal Register, FDA is proposing requirements for the establishment and implementation of a medical outcomes' audit for individual physicians. This type of monitoring can further improve the reliability, clarity, and accuracy of interpretation of mammograms.

One comment suggested that FDA establish a maximum number of images that the interpreting physician would be allowed to read in a given period of time.

FDA does not believe there is any evidence to support a need to establish such a limit.

Proposed § 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 3 years. 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.

The interim regulations require interpreting physicians to participate in education programs, either by teaching or completing an average of at least five CME credits in mammography per year. There were numerous comments on this requirement in the interim regulations, most of which focused on the lack of a specified average period. Some comments suggested that it should be 15 hours over a 3-year period.

Proposed § 900.12(a)(1)(ii)(B) addresses these concerns by establishing a 3-year period of time for determining the yearly average. FDA has proposed that the credits be in category I CME in order to ensure that continuing education is more formal and contributes to the development of the physician. The section also requires that at least 6 of the CME hours be in each mammographic modality used in the interpreting physician's practice. Therefore, the CME hours required for an interpreting physician who practices in a facility that employs more than 2 modalities will be in excess of the minimum requirement of 15 hours of category I CME.

Proposed § 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 modality. This education requirement is a logical parallel to the requirement in proposed § 900.12(a)(1)(i)(C) that the physician must have at least 8 hours of training in each modality used in his or her practice when the initial qualifications are first met.

4. Exceptions

Proposed § 900.12(a)(1)(iii) would allow exceptions to some of these requirements in certain specific cases. In order to ensure continuing and uninterrupted availability of mammography services, FDA is proposing to permit those interpreting physicians who have qualified under the interim regulations to continue to interpret mammograms, provided that they maintain the continuing experience and education requirements in proposed § 900.12(a)(1)(ii)(A) through (a)(1)(ii)(C). Proposed § 900.12(a)(1)(iii)(A) would exempt these physicians from the new and additional initial requirements proposed in § 900.12(a)(1)(i). The additional month of training in proposed § 900.12(a)(1)(i)(B) for physicians using the alternative pathway, the additional 20 hours of CME in proposed § 900.12(a)(1)(i)(C), the 8 Category I CME credits in new modalities in proposed § 900.12(a)(1)(i)(C), and the requirement that 15 Category I CME credits must have been acquired in the 3 years immediately before qualifying as an interpreting physician in proposed § 900.12(a)(1)(i)(C).

Proposed § 900.12(a)(1)(iii)(B) allows another exception in response to NMQAAC's concern that the initial experience requirement in proposed § 900.12(a)(1)(i)(D) may pose a problem in some diagnostic residency programs that schedule mammography rotations in the first 6 months of the last year. This exception permits a resident to satisfy the requirement of proposed § 900.12(a)(1)(i)(D) by having interpreted at least 240 mammographic examinations under the direct supervision of a qualified interpreting

physician during the last 2 years of the residency. FDA has included this exception only for the diagnostic radiology resident who successfully becomes board certified at the earliest opportunity provided by an eligible certifying board (''first allowable time'').

For the physician who qualifies for the exception under proposed § 900.12(a)(1)(iii)(B), the continuing education and experience requirements of proposed § 900.12(a)(1)(ii)(A) through (a)(1)(ii)(C) would begin from 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, then this physician must interpret 240 mammographic examinations under the direct supervision of a qualified interpreting physician within a period of 6 months immediately prior to initial qualification as an interpreting physician. The ''first allowable time'' means 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 becomes eligible to take the boards may vary with the certifying body, that term is not defined further in the regulations. If the physician wishes to use this exemption, 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.

5. Reestablishment of Qualifications

Proposed § 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. Proposed § 900.12(a)(1)(iv)(A) requires the physician who fails to meet the continuing experience requirements to interpret at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician within a period of 6 months immediately before reestablishing qualifications and resuming independent interpretation.

Proposed § 900.12(a)(1)(iv)(B) requires physicians who do not maintain the continuing education requirements 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 3 years. 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.

C. Radiologic Technologists

FDA's interim regulations for radiologic technologists performing mammography sought to ensure that: (1) The technologists possessed adequate general qualifications for performing radiologic examinations; (2) the technologists possessed adequate specific qualifications for performing mammography examinations; and (3) the technologists maintained these qualifications over time. The proposed regulations are intended to achieve the same goals. They are primarily clarifications of the interim regulations with some added requirements to address concerns that developed as the interim regulations were implemented.

The first clarification is in response to a number of comments received by FDA asking whether all of the radiologic technologists who perform mammography at the facility had to meet the requirements or if it would be sufficient if only some of them did. These questions may have been generated from experience with a previous voluntary system for accreditation.

All radiologic technologists who perform mammography must meet the requirements. The plain language of the statute clearly states that personnel who perform mammography must meet the minimum training and experience requirements and either be licensed by a State or certified to perform radiological procedures by an organization designated by the Secretary of HHS (42 U.S.C. 263b(f)(1)(C)). The statute does not provide, nor does the legislative history indicate, that Congress intended any of the individuals who perform mammography to be exempt from minimum quality standards. Exempting some radiologic technologists from compliance with the personnel standards required under the act would increase, not diminish, the possibility that an incipient cancer might be misdiagnosed because of a poorly produced mammogram. FDA has revised § 900.12(a)(2) to read ''All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements.'' Similar revisions were included in other paragraphs of § 900.12(a) to clarify the requirement that all physicians and medical physicists must also meet the personnel qualifications specific to their areas of practice.

Several comments expressed concern that the interim regulations would allow technologists with ''partial'' or ''special'' licenses to perform mammography. States that issue such licenses usually limit their holders to the performance of certain narrow types of examinations (e.g., extremities or dental x-rays) or particular medical practices (e.g., podiatry).

The intent of the licensure requirement under the MQSA is to ensure that the radiologic technologist has a broad background in radiologic technology as a basis for his or her specific work in mammography. FDA does not believe that partial or special licenses demonstrate this necessary background. The provisions set forth in proposed § 900.12(a)(2)(i)(A) require the State license to be a general license to perform radiologic procedures. As an alternative to obtaining such a State license, proposed § 900.12(a)(2)(i)(B) would recognize a general certification by one of the bodies designated by FDA to certify radiologic technologists as adequate evidence that a technologist satisfies the general radiologic technology requirements.

The license required by proposed § 900.12(a)(2)(i)(A) must be a State license but need not be from the State in which the technologist currently practices, as some States do not have a licensing requirement. For States that do have their own licensing requirements, the technologists practicing in these States are responsible for meeting those licensing requirements as well as the requirements under the MQSA.

One comment suggested that FDA amend the language of the interim regulations at § 900.12(a)(2)(i)(B) to indicate that certification by an eligible body is an alternative that is available only when the State in which the radiologic technologist is practicing has no licensure procedures or requirements.

Proposed § 900.12(a)(2)(i) requires the technologist to become licensed or certified to perform general radiological procedures. The license may be obtained from a State under § 900.12(a)(2)(i)(A) or the certificate can be obtained from an eligible certification body under § 900.12(a)(2)(i)(B). If the technologist is certified by an eligible certifying body and practices in a State that has its own licensing requirement, the technologist must still become licensed under State law, unless otherwise exempted by the State.

Although such individuals would be in compliance with Federal requirements under the MQSA, a technologist that is not licensed in accordance with the requirements of the

State in which he or she practices will be in violation of the State law.

Several comments on the interim regulations stated that FDA should clarify the initial requirements that a radiological technologist must satisfy to demonstrate specific mammography training.

After seeking and obtaining the advice of the NMQAAC, the agency has proposed more specific requirements for this training in § 900.12(a)(2)(ii). Under the proposed regulation, training specific to mammography includes the performance of a minimum of 50 examinations under the direct instruction of a qualified individual. After the effective date of these regulations, only individuals meeting the requirements of § 900.12(a)(2) for radiologic technologists will be considered qualified to provide this supervision.

The NMQAAC has discussed the option of recognizing the American Registry of Radiologic Technologists' (ARRT) special certification in mammography as fulfilling, at least in part, the training requirement under § 900.12(a)(2)(ii). At its February 1994 meeting, the NMQAAC advised against reducing the training required based on the ARRT special certification. However, at its subsequent meeting in May 1994, members reconsidered this possibility and discussed how much credit might reasonably be allocated for an ARRT special certification and for which aspects of the training requirements. Suggestions were made by some NMQAAC committee members that this special certificate be accepted in lieu of 20 of the required 40 contact hours, but that the certificate not be a substitute for any part of the required performance of 50 examinations under the direct supervision of a qualified radiologic technologist.

After further consideration, FDA has decided not to propose recognition of the special certificate as a partial fulfillment of the training requirement. FDA does not want to incorporate into its regulations a training requirement that specifically relies on a particular certification program by a private group. If, in the agency's view, subsequent changes in the certification program diminished the certificate's value in assuring properly trained radiologic technologists, the agency might, nevertheless, be bound to continue to accept the certificate until the regulations could be amended through notice and comment rulemaking to remove the recognition of the certificate as a substitute for training. On the other hand, the agency believes that the training that is required to earn the certificate can fulfill part of the proposed training requirements, even if the program is not mentioned explicitly in the regulations. In fact, when evaluating technologists' training under the interim regulations, the agency has recognized the value of training hours required for AART special certification as well as training hours required by other programs. The agency intends to continue to do so, as long as it believes such recognition is warranted. Agency guidance on this subject is available for review. As mentioned earlier, guidance represents the agency's best thinking at the current time and does not bind either the facility or FDA.

The NMQAAC did recommend that there be a requirement that all technologists have the equivalent of at least five continuing education units (CEU) of initial training in imaging examinees with breast implants. NMQAAC recognized that many technologists rarely conduct examinations of individuals with breast implants. However, the committee recommended that this training be required of all technologists so that all examinees with breast implants can use any certified facility with assurance that there will be technologists trained to perform these examinations.

FDA agrees and has included this requirement in proposed § 900.12(a)(2)(ii)(C).

The interim regulations permit a technologist to have all of his or her training in mammography, both initial and continuing, related to one modality (e.g., film screen, xerography), even if the radiologic technologist uses other modalities to perform mammography. However, the agency and the NMQAAC believe that education and training should be required for each modality performed by the technologist. Proposed § 900.12(a)(2)(ii)(B) and (a)(2)(iii)(B) would correct this shortcoming in the interim regulations by requiring both the initial training and the continuing education requirements to include training in each modality used by the technologist.

Several comments on the interim regulations objected to the use of an undefined overall averaging period for the requirement that the radiologic technologist earn at least five CEU's per year in mammography.

Although the use of an undefined time period has provided a flexibility that is advantageous under the interim regulations, FDA agrees that more specific requirements are desirable. Therefore, proposed § 900.12(a)(2)(iii) requires that, on any given date, each technologist must have earned at least 15 CEU's in mammography in the 3 years immediately preceding that date. To be fair to technologists who have just completed their initial training in mammography, proposed § 900.12(a)(2)(iii) would not apply this requirement immediately. Technologists will have up to 3 years after completing their initial training to earn at least 15 CEU's related to mammography. After the end of the initial 3-year period, all technologists would have to be able to demonstrate, on any subsequent date, that they had earned at least 15 CEU's in mammography in the 3 previous years.

Proposed § 900.12(a)(2)(iii)(C) describes the actions that must be taken by technologists who fail to meet the continuing education requirement in order to reestablish their qualifications. Until these actions are taken, such technologists cannot perform mammographic examinations without supervision.

In recognition of the fact that unused skills may deteriorate, proposed § 900.12(a)(2)(iv) establishes a continuing experience requirement corresponding to the continuing experience requirement for interpreting physicians found in both the interim and proposed regulations. This requirement is based upon the advice of NMQAAC that performance of 100 or more mammography examinations a year represents a reasonable level of experience. Proposed § 900.12(a)(2)(iv)(B) permits radiologic technologists who fail to meet this continuing requirement to reestablish their qualification through performance of 50 examinations (a number suggested by NMQAAC) under the direct supervision of a qualified radiologic technologist before resuming independent performance of mammography examinations.

One comment on the interim regulations questioned the use of October 1, 1996, for changing certain requirements for radiologic technologists while a date of October 27, 1997, was used for similar changes for medical physicists. The comment suggested that the dates should be the same.

FDA notes that the MQSA established these dates and FDA cannot modify them. It is likely that the differences in these provisions is the result of congressional concern about the availability of medical physicists.

Another comment suggested that a training and experience alternative to the licensure or certification requirement be made available to radiologic technologists similar to the alternative available to medical physicists.

FDA disagrees, Congress specified the alternative route for medical physicists in the statute. The MQSA did not provide a similar alternative for technologists.

D. Medical Physicists

Proposed requirements for medical physicists are set forth in § 900.12(a)(3). FDA recognizes that the medical physicist plays a pivotal role in assuring the overall quality of mammography and, therefore, seeks to emphasize, in the proposed regulations, the need for uniform national minimum requirements for medical physicists working in mammography facilities.

In developing the proposed qualifications for medical physicists, the agency has considered: (1) The requisite amount of prior knowledge and experience to evaluate mammography equipment; (2) the level of performance of individuals currently providing mammography physics support; (3) the concern over the supply of qualified medical physicists; and (4) the recommendations from members of the NMQAAC and comments from the Conference of Radiation Control Program Director's Task Force on Medical Physics Criteria. The issue of qualifications for medical physicists was discussed extensively at several NMQAAC meetings. Earlier draft regulations on this subject were shared with the NMQAAC and made available to the public.

The MQSA provides two alternative pathways for medical physicists to demonstrate minimum qualifications after October 27, 1997. These alternative pathways, set forth in the statute and codified in proposed § 900.12(a)(3)(i)(A), are: (1) State licensure or approval or (2) certification by a board approved by FDA. However, the NMQAAC expressed concern during the February 1994 meeting that not all States have adequate minimum qualification standards. Concern has also been expressed that some board certified physicists do not have adequate experience with mammography equipment. Therefore, FDA proposes to add additional requirements for all physicists, regardless of which initial route they follow to become qualified under the MQSA. After October 27, 1997, or the effective date of the regulation, whichever is later, only those medical physicists who meet the initial additional education and experience requirements proposed in § 900.12(a)(3)(i)(B) or (a)(3)(ii)(B) will be qualified to perform surveys under the MQSA.

FDA believes that ongoing developments in imaging technology, including the development of new technologies, such as digital mammography, will require medical physicists to have increased understanding of science and technology in order to apply these scientific advances to the practice of mammography. Proposed § 900.12(a)(3)(i)(B) addresses this need by requiring medical physicists who enter the field after October 27, 1997, to hold at least a master's degree in a physical science, including a minimum of 20 semester credit hours or equivalent of college level physics, to have specialized training in conducting mammography surveys, and to have actual experience conducting surveys of at least 5 mammography facilities and a total of at least 10 mammography units. The experience in conducting surveys must be acquired under the direct supervision of a medical physicist who has fulfilled all of the requirements of § 900.12(a)(3)(i) and (a)(3)(iii). This requirement is intended to ensure that medical physicists who serve as supervisors will have an adequate educational background to train new physicists in new imaging technologies.

The advisory committee recommended that FDA require the 20 semester credit hours of physics be specific to imaging physics.

FDA agrees that courses in imaging physics would be desirable. However, the agency does not have enough information about the number of imaging physics courses offered in different curricula to be certain that these courses would be available nationwide. Therefore, the agency has not proposed limiting the physics credit hours to imaging physics at this time. The agency is soliciting public comment on this issue.

Although FDA believes that future changes in technology will require an enhancement of the educational qualifications of medical physicists, the agency also recognizes that currently there are a number of medical physicists with bachelor's degrees and substantial experience who are performing medical physics surveys of mammography facilities with care and competence. These physicists provide valuable physics support to facilities. The agency believes that it would be unjust to these physicists and potentially detrimental to the facilities that they serve to bar them from continuing to provide this physics support to mammography facilities in the absence of any evidence to show that the services that they currently offer are inadequate. Accordingly, proposed § 900.12(a)(3)(ii) provides an opportunity for those individuals who are lawfully practicing medical physics under the interim regulations (21 CFR 900.12(a)(3)) to continue their practice after October 27, 1997.

Proposed § 900.12(a)(3)(ii) has been modified from the draft proposal discussed at the January 1995 meeting with the NMQAAC. During this meeting, the NMQAAC recommended that the opportunity to continue services as a mammography physicist because of prior experience should be open only to physicists with bachelor's degrees and 5 years of experience in conducting surveys of mammography facilities by October 27, 1997.

However, upon further consideration, FDA believes that the fundamental requirement of this alternative pathway is the quality and depth of the survey experience itself, and not the number of years it has taken the individual to acquire that experience. Therefore, proposed § 900.12(a)(3)(ii) requires those physicists who intend to qualify because of prior experience to have performed surveys of at least 10 facilities and a total of at least 20 units by October 27, 1997, or the effective date of these regulations, whichever date is later. This change has been made in order to give all medical physicists who are currently eligible to practice under the interim rules a reasonable opportunity to acquire the requisite experience before this alternative pathway closes.

Proposed § 900.12(a)(3)(ii) further requires that the bachelor's degree and specific training requirements be completed before any physics survey or unit evaluations may be counted toward satisfying the experience requirement under this provision. During a presentation at the January 1995 NMQAAC meeting, a representative of the medical physics community, speaking on behalf of the professional medical physicists who are members of the American College of Radiology, the American College of Medical Physics, and the North American Association of Physicists in Medicine, expressed the view that any mammography medical physics experience obtained prior to obtaining a basic understanding of fundamental principles through education is of little value. The NMQAAC also strongly recommended that the degree requirement must be a prerequisite to the experience requirement. The agency's proposal, therefore, establishes that the initial education and training qualifications must be met before any experience can be considered for purposes of satisfying the initial experience qualifications. The

agency is soliciting public comment on this requirement.

Under proposed § 900.12(a)(3)(iii), medical physicists will be required to maintain their education and experience qualifications, as are radiologic technologists and interpreting physicians.

Proposed § 900.12(3)(iv) establishes the requirements that medical physicists who fail to maintain their qualifications must meet to reestablish their eligibility to perform mammography facility surveys.

At its February 1994 meeting, the NMQAAC members raised the concern that medical physicists who meet the qualifications requirement may nevertheless delegate the onsite survey work to less qualified personnel.

FDA shares this concern and, therefore, is proposing in § 900.12(e)(9), published elsewhere in this issue of the Federal Register, that the medical physicist who signs the facility survey report must be present at the facility during the survey and must meet the requirements of proposed § 900.12(a)(3).

Physicists in training may perform surveys in order to meet the experience requirement described in these standards, but they must do so under the direct supervision of a qualified medical physicist. ''Direct supervision'' is defined in proposed § 900.2(k)(2), also published elsewhere in this issue of the Federal Register, to mean: ''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.''

E. Retention of Personnel Records

Under the interim regulations, FDA is often asked how long records demonstrating personnel qualifications must be kept after an individual is no longer employed by the facility.

Proposed § 900.12(a)(4) requires that records be retained for all individuals employed in mammography by the facility from: (1) The date of the last inspection or (2) the effective date of the final regulations, whichever is later. Because inspections are required annually under the MQSA, records of individuals no longer employed by the facility typically would be retained less than a year after the individual's employment ends. The agency believes that this requirement will allow FDA adequately to assess whether personnel requirements are being met without putting an undue paperwork burden on the facility. Facilities should also become familiar with any State regulations that are applicable to personnel records because these State laws may require retaining the records for a longer period of time.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined together the impacts of this proposed rule and the proposed rules on accreditation bodies, general facility requirements, and quality standards for mammography equipment and quality assurance, published elsewhere in this issue of the Federal Register, under Executive Order 12866, the Regulatory Flexibility Act (Pub. L. 96–354), and under the Unfunded Mandates Reform Act. The analysis has addressed the proposed requirements of these four rules as one unit for purposes of determining their economic impact. The preamble to the proposed rule ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'', published elsewhere in this issue of the Federal Register, contains a brief summary of the cost and benefit determination and the Regulatory Impact Study that details the agency's calculation of these economic impacts and is available at the Dockets Management Branch (address above) for review. FDA recognized that these proposed regulations may have a disproportionate effect on small volume mammography facilities and is currently collecting additional information on the potential impact on this industry sector. The agency requests comments that will assist it in accounting for this impact.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collection and an estimate of the annual reporting and recordkeeping burden are contained in the proposed rule entitled ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' published elsewhere in this issue of the Federal Register.

The agency has submitted a copy of this proposed rule to OMB for its review of these information collections. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. Written comments on the information collection should be submitted by May 3, 1996.

VI. Request for Comments

Interested persons may, on or before July 2, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. Reference

The following reference has 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. ''Report on the Mammography Quality Standards Act of 1992,'' S. Rept. 102–448, October 1, 1992.

List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 900 be amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. Section 900.12 is amended by revising paragraph (a) to read as follows:

§ 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. 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 must include: Instruction in the interpretation of mammograms; at least 8 hours of Category I continuing medical education credits in each mammographic modality used in the interpreting physician's practice; and education in basic breast anatomy, pathology, and physiology; technical aspects of mammography, and quality assurance and quality control in mammography. At least 40 of these hours must be Category I and at least 15 of the Category I hours must 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) Have interpreted at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician within the 6-month period immediately prior to fulfilling the requirements of paragraph(a)(1)(i) of this section.

(ii) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

(A) At all times following the second anniversary date of completion of the requirements of paragraph (a)(1)(i) of this section, the interpreting physician shall have interpreted an average of at least 40 mammographic examinations a month during the previous 24 months;

(B) At all times following the third anniversary date of completion of the requirements of paragraph (a)(1)(i) of this section, the interpreting physician shall have taught or completed at least 15 Category I continuing medical education credits in mammography in the previous 3 years. This training must 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 modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new modality.

(iii) Exceptions. (A) Those physicians who previously qualified as interpreting physicians under FDA's interim regulations at § 900.12(a)(1) 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 continuing experience and education requirements of paragraph (a)(1)(ii) of this section.

(B) Physicians who have interpreted at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician 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 interpret at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician, within a period of 6 months immediately prior to reestablishing their qualifications as an interpreting physician.

(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 3 years before resuming independent reading.

(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 undergone 40 contact hours of documented training specific to mammography under the supervision of a qualified individual. A qualified individual is one that has met all the requirements of paragraph (a)(2) of this section. The 40 hours of documented training shall include:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques;

(B) The performance of a minimum of 50 examinations under the direct supervision of a qualified individual; and

(C) At least 5 hours of training in imaging examinees with breast implants and at least 8 hours of training in each imaging modality to be used by the technologist in performing mammography exams.

(iii) Continuing education requirements. (A) At all times following the third anniversary date of completion of the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section or (insert effective date of the final regulation), whichever date is later, the radiologic technologist shall have taught or completed at least 15 continuing education units related to mammography in the previous 3 years.

(B) At least six of these continuing education units shall be related to each

modality used by the technologist in mammography.

(C) Requalification. Following any 3-year period in which a radiologic technologist fails to meet the continuing education requirements under paragraphs (a)(2)(iii)(A) through (a)(2)(iii)(B) of this section, that technologist shall obtain a sufficient number of continuing education units in mammography to bring the 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.

(D) Before a radiologic technologist may begin independently performing mammographic examinations using a 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) In each 12-month period after completion of the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section or (effective date of the final rule), whichever date is later, the radiologic technologist shall perform a minimum of 100 mammography examinations.

(B) Requalification. Following any 12-month period in which a radiologic technologist fails to perform at least 100 mammography examinations, that technologist shall perform a minimum of 50 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 42 U.S.C. 263b 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 surveys; and

(B)(*1*) Have a master's degree or higher in a physical science from an accredited institution, including at least 20 semester hours or equivalent (e.g., 30 quarter hours) of college (graduate or undergraduate) 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 5 mammography facilities and a total of at least 10 mammography units. After the later date of October 27, 1997, or the effective date of these regulations, 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 the interim regulations at § 900.12(a)(3) and maintained the active status of any qualifying licensure, approval, or certification required under the interim regulations; and

(B) By October 27, 1997, or [Date 1 year after date of publication of the final rule] regulations, whichever is later, 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 level physics,

(*2*) Forty contact hours of documented specialized training in conducting surveys of mammography facilities and,

(*3*) The experience of conducting surveys of at least 10 mammography facilities and a total of at least 20 mammography units. The training and experience requirements must be met after fulfilling the degree requirement.

(iii) Continuing qualifications. (A) Continuing education. At all times after the third anniversary of completion of the initial requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section, the medical physicist shall have taught or completed at least 15 continuing education units in mammography over the preceding 3 years. This continuing education shall include training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs.

(B) Continuing experience. At all times after the first anniversary of completion of the initial requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section, the medical physicist shall have surveyed at least three mammography facilities within the preceding 12 months.

(C) Before a medical physicist may begin independently performing mammographic examinations using a new modality, that is, a 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 with the new 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 satisfactory survey of three mammography facilities under the direct supervision of a medical physicist who meets the qualifications of paragraphs (a)(3)(i) and (a)(3)(iii) of this section.

(4) Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel employed by the facility in the production, processing, and interpretation of mammographic images. These records must be available for review by the MQSA inspectors and should not bediscarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.

* * * * *

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–7832 Filed 3–29–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 95N–0195]

RIN 0910–AA24

Proposed Quality Standards for Mammography Equipment and Quality Assurance

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations for facility standards established in the interim regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA). This proposed rule will establish additional performance standards for mammography equipment and equipment-related quality assurance practices currently required of mammography facilities. FDA is proposing these amendments based on advice from the National Mammography Quality Assurance Advisory Committee (NMQAAC), mammography equipment manufacturers, and public comments received in response to the interim regulations. This proposed rule is intended to assure safe, accurate, and reliable mammography on a nationwide basis. This document is the fifth of five related proposed rules that FDA is publishing concurrently in this issue of the Federal Register.

DATES: Written comments by July 2, 1996. The agency is proposing that any final rule based on this proposed rule become effective 1 year after its date of publication in the Federal Register, except where otherwise indicated.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. The Regulatory Impact Study (RIS) is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This proposal is the fifth of five related proposed rules published in this issue of the Federal Register to amend interim regulations published on December 21, 1993 (58 FR 67558 and 58 FR 67565), implementing the MQSA (Pub. L. 102–539). The first proposed rule, ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' contains background information and a summary of the preliminary analysis of the costs and benefits of the proposed rules, a description of the information collection requirements, proposed revisions to § 900.1 *Scope* and § 900.2 *Definitions* (21 CFR 900.1 and 900.2), and proposed alternative approaches to mammography quality standards and a request for comments on the proposed alternatives.

II. Provisions of the Proposed Rule

A. Development of the Proposed Regulation

As with the interim regulations, FDA was guided in the development of this proposed rule by the intent of the legislation to guarantee access to safe and effective mammography services for all women in the United States (Ref. 1). FDA also relied upon three major sources of information, in addition to the expertise and research of FDA personnel.

First, the agency considered public comments received on the interim regulations. The agency received 103 comments from individuals and organizations, including: Professional organizations, medical facilities, State agencies, consumer groups, manufacturers, and individual physicians, medical physicists, and radiologic technologists. The proposed regulations were also discussed in a series of quarterly meetings with the NMQAAC. Members of the NMQAAC include interpreting physicians, medical physicists, radiologic technologists, representatives of State agencies, and consumer representatives. Consultants to the NMQAAC and guests invited to attend the committee meetings in recognition of their expertise in mammography also participated in these discussions of the proposed regulations. Finally, the agency obtained input through discussions with various professional and trade organizations and individuals with expertise related to mammography equipment, quality assurance, and infection control. Preliminary drafts of the proposed regulations were made generally available at the NMQAAC meetings and through notices of availability published in the Federal Register on December 30, 1994 (59 FR 67710) and January 26, 1995 (60 FR 5152).

Organizations participating in discussions of the regulations included the National Electrical Manufacturers Association (NEMA), the Conference of Radiation Control Program Directors (CRCPD), and four national medical physicist organizations: The American Association of Physicists in Medicine, the American Academy of Health Physics, the American College of Medical Physicists, and the Health Physics Society.

A discussion of the proposed amendments and a summary and analysis of NMQAAC input and public comments regarding the regulations is provided below.

B. Equipment Regulations

In § 900.12(b) of the interim regulations, performance standards were established for equipment used in the production of mammograms. These standards were substantially harmonized with existing standards, such as those established by the Health Care Financing Administration (HCFA), the American College of Radiology (ACR), and some States. This interim approach was consistent with the legislative intent of the MQSA (Ref. 1) and enabled FDA to certify the thousands of facilities that already met voluntary accreditation standards prior to publication of the interim regulations. This approach also allowed the agency to concentrate its initial resources on facilities with no such prior accreditation. Now that additional input regarding the equipment standards has been obtained from the NMQAAC, equipment manufacturers, and the public, FDA is proposing additional requirements in § 900.12(b) for radiographic, processing, and ancillary equipment used in mammography.

In developing the proposed equipment standards, FDA recognized the need to balance the economic impact of new standards against the associated gains to the public health. It was also necessary for FDA to consider the availability (initially, and over time) of mammography equipment meeting the new requirements. This was necessary because, for some requirements, considerable time might be needed to allow for redesign, production, purchase, and installation of new equipment, or for retrofitting of the installed equipment base. The amount of time needed would depend on the nature of the requirement, the capacity of manufacturers, and the number of facilities already meeting the requirement. In consideration of these factors, the agency is proposing to phase in the equipment standards in proposed § 900.12(b) over the next 1 to 10 years.

In accordance with guidance from the NMQAAC, three effective dates are being proposed for different phases of implementation. Requirements to be implemented during the first phase would have an effective date of 1 year after the date of publication of the final rule. Such requirements would cover aspects of equipment performance that the NMQAAC considered fundamental to the delivery of quality mammography. Requirements to be

implemented during the second and third phases would have effective dates of 5 and 10 years after the date of publication of the final rule, which FDA estimates would correspond to approximately October 1, 2000, and October 1, 2005, respectively. Although these dates have been used for the purpose of this proposal, the final effective dates will be modified to correspond to the dates 5 and 10 years after the publication date of the final rule. The agency believes that this advance guidance to the industry regarding upcoming changes in requirements and the phasing in of such requirements will minimize the economic impact of implementing improvements in mammography.

Several comments received on the interim regulations indicated a lack of awareness of agency plans for notice-and-comment rulemaking in promulgating final regulations, or listed specific recommendations for changes or additions. Most of the recommendations for specific equipment requirements have been incorporated into the proposed standards. A summary of these comments and the FDA responses follow:

1. General

One comment disagreed with the prohibition in the interim regulations against performance of mammography using a conventional x-ray system with device modifications or options specifically designed to enable use of the system for mammography. The comment stated that allowing use of such systems for mammography would represent an economical source of equipment that should not be problematic as long as the systems can produce quality images without compromising examinee safety or dosage considerations.

In response to this comment, FDA notes that the MQSA expressly states that equipment standards must ''require use of radiological equipment specifically designed for mammography'' (42 U.S.C. 263b(f)(1)(B)). Therefore, FDA is continuing the prohibition against use of nonmammography x-ray equipment for the production of mammograms.

One comment supported the interim requirements in § 900.12 (b)(2)(i) to (b)(2)(iii) but requested the addition of two subsections requiring: (1) Cassettes of appropriate size, to allow the technologist to obtain a complete breast image on a single film, and (2) grids specifically designed for mammography for each size of cassette.

FDA agrees with these comments and has included such requirements in proposed § 900.12(b)(4).

Three comments suggested that the provision in § 900.12(b)(2)(iii), requiring mammography equipment to have a removable grid, be expanded to require a reciprocating removable grid. A reciprocating (moving) grid would avoid grid lines often seen with a stationary grid. One comment did not understand the requirement in § 900.12(b)(2)(iv), and in particular the phrase ''removable grid.'' The comment stated that, if the intent is not to reduce radiation dose, the appropriate word would be ''moving,'' rather than ''removable,'' because moving the grid improves image quality. Also, the comment questioned whether this standard refers to regular view or magnification mode.

FDA believes that all equipment should be provided with reciprocating (moving) grids and that these grids should be removable for all systems providing magnification capability. These grid requirements have been proposed in § 900.12 (b)(4)(ii) and (b)(4)(iii). The intent is that the grid be removable so that magnification procedures can be completed properly without increasing the radiation dose to the examinee.

Discussions with the NMQAAC indicated considerable concern that radiographic equipment be equipped to enable a number of routine views for all examinees. Of specific concern were the mediolateral oblique, caudo-cranial, and cranio-caudal views, and the need to ensure that each facility has equipment that allows for variation in individual body habitus.

Under § 900.12(b)(3) (ii) and (iii), FDA has proposed specific requirements related to the motion capability of the gantry assembly that the NMQAAC believes will achieve this goal.

The NMQAAC also strongly recommended that all mammography systems be required to have a light field that approximates the x-ray field and passes through the collimation system. This configuration would assist in positioning and allow visual verification that the radiographic view of the breast remains unobstructed. In response to this NMQAAC recommendation, FDA received comments from a major trade association representing manufacturers of mammography x-ray equipment indicating that a significant portion of the installed equipment base would not meet these requirements. This association further indicated that there may be significant costs associated with retrofitting existing equipment to comply with this recommendation.

FDA is proposing to require in § 900.12(b)(5) that all mammography systems have the light field recommended by the NMQAAC, effective October 1, 2000. FDA is requesting public comment on this proposed requirement and its likely impact on the cost and availability of mammography services.

Proposed § 900.12(b)(11)(i) references the requirements in § 1020.30(m)(l) (21 CFR 1020.30(m)(1)) for minimum beam quality (half-value layer (HVL)) for mammography x-ray systems. FDA realizes that this reference is redundant with proposed § 900.12(b)(2), but believes that it is necessary to clarify the requirements stated in proposed § 900.12(b)(11)(i).

One comment stated that, in addition to requiring the incorporation of a breast compression device, the regulation should mandate use of this device (at least for screening mammography), because compression enables better visualization of the breast and permits lower radiation dose to be used.

FDA recognizes that use of a breast compression device is considered by professionals to be essential for proper imaging of the breast. By requiring that each system be equipped with a breast compression device, FDA has attempted to ensure that this feature is always available to the technologist. However, because the requirement that the compression device always be used would be extremely difficult to enforce, such a requirement has not been proposed.

In § 900.12(b)(12), FDA is proposing that all mammography systems be equipped with both foot-controlled power driven and fine adjustment controls (either manual or power driven). The intent of this requirement is to allow the technologist to use both hands to position the examinee under foot regulated power control, and to make final adjustments to the compression under the increased control provided by the fine adjustment mechanism. FDA is specifically requesting additional comments on this proposed requirement. For example, would a power-only system that provided a slower, more controlled, final application of power driven compression be as useful as a combination of power and manual compression?

One comment suggested requiring that all compression equipment allow for automatic release of compression in case of power or mechanical failure.

FDA recognizes that some facilities consider an automatic compression release desirable, and the proposed regulations permit this. However, under

some conditions, an automatic release may represent a physical hazard to the examinee. Therefore, under § 900.12(b)(12)(ii), FDA is proposing certain restrictions on systems that provide an automatic decompression feature.

Two comments noted that the interim regulations do not require that the breast compression device be parallel to the imaging plane, thus potentially allowing unequal compression to occur.

FDA agrees and the proposed regulations contain a requirement under § 900.12(b)(12)(iii)(B) to address this concern. FDA notes, however, that there is one manufacturer that does not meet this proposed requirement because it claims that the nonparallel design of its device provides uniform compression. FDA requests comments (and supporting data) regarding whether the agency should: (1) Modify the proposed regulations to accommodate this alternative design, or (2) retain the requirement as proposed and allow manufacturers to obtain variances to market alternative devices, in accordance with the alternative equipment provision in proposed § 900.18 (published elsewhere in this issue of the Federal Register).

Seven comments recommended that FDA require automatic exposure control (AEC) capability on all systems. One comment suggested that the equipment requirements should be more specific to address phototimers, acceptable operating energies, radiation output, and milliampere (mA) requirements.

FDA agrees and has included requirements for each of these areas in proposed § 900.12 (b)(13), (b)(14), and (b)(15). These requirements were supported by the NMQAAC.

One comment suggested that all mammography systems installed or transferred following implementation of the interim regulations should provide for milliampere second (mAs) readout following each exposure.

FDA agrees that mAs readout is important and under proposed § 900.12(b)(13)(iv), all equipment that automatically selects the mAs will be required to indicate the mAs value used following the exposure.

Two comments suggested a number of technical requirements that all mammography equipment should be required to meet.

The recommended requirements are supported by FDA and the NMQAAC and have been included in proposed § 900.12 (b)(4), (b)(5), (b)(8), (b)(11), (b)(14), and (b)(15), or were already covered under the diagnostic x-ray system performance standard in §§ 1020.30 and 1020.31 (21 CFR 1020.31), with the exception of the following:

(1) One comment suggested that a tungsten target tube should never be used for screen-film mammography.

FDA disagrees with this comment. The agency believes there is no evidence to support prohibiting the use of tungsten target tubes and has not included this limitation in the proposed regulations.

(2) One comment stated that the nominal focal spot size should be regulated in conjunction with the system source-image receptor distance (SID).

FDA is proposing to address the issue of focal spot size through the proposed requirement for system resolution in § 900.12(b)(8). The intent of this requirement (which has been adopted by the ACR), is to provide a test for system resolution that is easier to perform than a focal spot size determination.

(3) One comment stated that the SID should not be less than 50 centimeters (cm).

FDA is proposing to adopt the ACR's minimum requirement for SID, which is 55 cm.

2. Xeromammography

Three comments requested FDA to prohibit use of xeromammography, which the comments believed produces lower quality mammograms at a higher dose of radiation than screen-film modalities.

FDA is aware of the controversy regarding use of xeromammography, but the agency believes that, with respect to certain diagnostic applications, the modality may still be equal to screen-film systems. At the same time, the virtual disappearance of xeromammography units from the marketplace indicates that the mammography community itself is discontinuing the general use of this modality. Both the interim and proposed regulations place a maximum limit on the dose that can be delivered to an examinee using xeromammography. In proposed § 900.12(c), published elsewhere in this issue of the Federal Register, the dose that may be delivered by xeromammography has been reduced from the interim requirement of 4.0 milliGray (mGy) to 3.0 mGy. This decision was based on communication from the manufacturer of xeromammography systems informing FDA that properly adjusted and maintained xeromammography systems could meet such a requirement. Under the proposed regulations, therefore, the dose limits for screen-film and xeromammography would be the same.

One comment questioned whether xeromammography will continue to be considered inadequate for screening purposes, in accordance with HCFA regulations.

FDA regulations replace those issued by HCFA concerning mammography facilities and FDA regulations do not prohibit the use of xeromammography for screening.

3. Operator Protection

Two comments expressed concern that no regulations addressed the protection of the operator by requiring radiation protective barriers or anchored exposure switches.

FDA believes that specific operator safety requirements remain the responsibility of State and local authorities regulating the use of diagnostic x-ray equipment. Therefore, FDA has not proposed any requirements relating to this aspect of the facility operation.

4. Examinees With Disabilities

In addition to meeting the specific requirements listed in this regulation, it was the opinion of the NMQAAC that each facility has the responsibility to accommodate examinees with physical disabilities and to provide such examinees with access to the same quality mammography provided to other examinees. The NMQAAC further believed that facilities that could not provide such special services should be required to screen prospective examinees during the appointment scheduling process and refrain from scheduling disabled examinees who cannot be accommodated.

FDA has included a requirement in proposed § 900.12(b)(16) reflecting this recommendation. The agency also encourages facilities that cannot accommodate disabled individuals to refer these individuals to a facility that is equipped to provide mammography services for them. FDA encourages comments regarding the necessity and appropriateness of this section in light of the requirements currently imposed by the Americans with Disabilities Act of 1990.

5. Interventional Mammography

Five comments indicated that standards and test methods are needed for stereotactic units and dedicated biopsy-type machines.

FDA agrees with these comments. However, the agency believes that no consensus exists in the mammography community regarding appropriate standards for such equipment and

procedures. Various public and private organizations are working to develop such standards and FDA will propose requirements some time in the future.

6. International Harmonization

In the Federal Register of November 28, 1994 (59 FR 60870), FDA published an agency policy on international harmonization of regulatory requirements. In accordance with that policy, the agency requests comments regarding the implications of the proposed equipment standards on any related international harmonization efforts for mammography equipment.

C. Quality Assurance (QA)—Equipment

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. To achieve this, the performance parameters of the equipment must be tested at appropriate frequencies, the test results must be promptly analyzed to determine if the performance of the equipment is satisfactory, and any identified problems must be corrected as soon as possible. In addition, followup tests must be conducted to determine whether the corrective actions were effective. Requirements for these types of tests are proposed in § 900.12(e).

1. Testing of Screen-Film Systems

Proposed § 900.12 (e)(1) through (e)(5) establish the minimum performance tests to be conducted on screen-film systems. The agency has decided not to propose extensive detailed requirements in order to provide facilities with the flexibility to use alternative methods that might be equally satisfactory or to add other tests. Under the interim regulations, FDA adopted the ACR's relatively detailed QA requirements (Ref. 2). However, the NMQAAC has advised FDA that these ACR requirements were intended to be used as guidelines, not in a prescriptive manner.

Therefore, the agency is proposing to limit the quality assurance requirements for equipment to a more general listing of the required tests, establishment of the required test frequencies, definition of action limits, and, in some cases, specification of critical test conditions.

At the July 1994 NMQAAC meeting, an additional daily total system test was discussed, which read as follows:

Total System Test:

(A) The optical density (OD) of the film at the center of an image of a uniform phantom when exposed in AEC mode shall not change by more than ± 0.20 from the established operating level. The OD of the established operating level shall be above 1.20. The mAs shall not change by more than 10 percent from the established value corresponding to the operating level OD.

(B) The film shall be examined for system artifacts.

The agency believes that this total system test, in conjunction with the processor performance test set forth in proposed § 900.12(e)(1), should be performed daily before the first examinee is examined. The performance of these two tests will assure the overall quality of the x-ray machine, processor, and films. The records of the tests will also enable a medical physicist to quickly detect the source of a problem when it occurs. The above described system test takes only a few minutes to perform and can be performed by a quality control technologist.

The NMQAAC suggested that more data about the usefulness of the total system test should be gathered before this test is introduced as a required daily test. The NMQAAC also agreed that the image quality evaluations described in proposed § 900.12(e)(2) should be performed weekly if the total system test is not required.

The agency is proposing system testing requirements in accordance with the NMQAAC's advice. Although FDA is not proposing to require the daily total system test at this time, the agency requests comments regarding the utility of this test. If the total system test were introduced, FDA would revise the regulations to require monthly, rather than weekly, performance of the image quality evaluations in proposed § 900.12(e)(2).

Several comments on the interim regulations raised concern about basing the quality control requirements on a single manual, such as the ACR manual (Refs. 2 and 3).

In the proposed regulations, no manual has been referenced. A facility may consult any appropriate manual or rely on agency guidance to meet the requirements in proposed § 900.12(e)(1) through (e)(5).

One comment requested that any standard that is developed be achievable with current technology. As an example of a test that the comment believed could not be achieved using current technology, the comment cited ACR's criteria for passing the screen-film contact test, as described in the 1992 ACR manual (Ref. 2).

The agency is convinced, based on the expertise of its staff and experience with the interim regulations, that the requirements and action limits proposed in this regulation can be met with current technology.

One comment suggested that a minimum allowable dose should be specified for a 4.5-cm compressed breast composed of 50 percent glandular tissue and 50 percent adipose tissue. Also, one comment suggested that the mean glandular dose should not exceed 1.0 mGy for screen-film systems without grids.

FDA believes that placing a lower limit on dose may hamper further technological advancement of systems that may reduce the dose without compromising image quality. In addition, the agency has decided to use only one upper dose limit for all systems.

Several comments stated that FDA's data indicate that an accepted phantom simulates a 4.2-cm thick compressed breast, not 4.5 cm. Therefore, the regulations should use a 4.2-cm thickness. One comment stated that the dose should be determined using clinically employed technique factors for a 4.5-cm thick compressed breast composed of 50 percent glandular tissue and 50 percent adipose tissue, instead of using the phantom technique factors promulgated in the interim regulations. Two comments noted that, in many cases, the technique factors used by a facility to produce phantom images do not reflect the technique factors actually used on examinees. This could result in examinees receiving doses exceeding the limits specified in the regulations, even though the facility technically passed the compliance test by using their phantom image technique factors. One comment stated that the dose should be determined under the facility's proposed technique factors for a 4.2-cm thick compressed 50 percent glandular/50 percent adipose breast.

After review of these comments, FDA is proposing to require clinical technique factors and a phantom simulating a 4.2-cm thick compressed 50 per cent glandular/50 per cent adipose tissue breast to be used during dose measurements. Although FDA has data to show that an accepted phantom simulates the attenuation properties of 4.2 cm of 50/50 compressed breast tissue, the agency recently has developed additional data indicating that the phantom may be equivalent in attenuation properties to approximately 4.0-cm of 50/50 compressed breast tissue, as per the dose model used to convert skin exposure to dose. The agency, therefore, is soliciting more information and comments on the appropriate equivalent thickness of the phantom for dose calculation.

One comment requested an explanation of the methods for obtaining FDA certification of QA phantoms. Another comment suggested that the regulations should specify one, and only one phantom, and should specify the minimum acceptable performance, rather than leaving this to the discretion of accreditation bodies.

The agency continues to believe that accreditation bodies should establish phantom specifications and related performance criteria. However, as part of it responsibilities for accreditation body approval and oversight, FDA will examine each body's phantom specifications and performance requirements, which will have to be substantially the same among different accreditation bodies.

One comment recommended that FDA publish some type of voluntary form(s) for maintaining appropriate records.

FDA believes it is inadvisable for the agency to generate sample forms because such forms may be unnecessarily restrictive. Facilities that do not want to generate their own forms may adopt forms that are provided in various manuals, as appropriate.

2. Systems With Other Modalities

Proposed § 900.12(e)(6) would require that the facility quality assurance program for systems with image receptor modalities other than screen-film (e.g., xeromammography) be substantially the same as that recommended by the image receptor manufacturer. This section would also require that such systems meet the same dose limits as screen-film systems.

3. Mobile Units

Proposed § 900.12(e)(7) would establish additional quality assurance requirements for mobile mammography units. These mobile units are operated in a variety of environments and undergo the stress of frequent movements, often over rough surfaces. In view of this, a number of comments on the interim regulations urged FDA to require that a phantom image quality test be performed after every move, before any additional examinations are conducted at the new site. These comments stated that if a problem occurs after a move which could compromise the quality of clinical images, this problem should be detected and corrected before any further clinical use of the equipment. These comments believe this additional testing is necessary for mobile units in order to minimize the need for repeat examinations, which would result in additional radiation exposure and expense and might result in some cancers going undetected if it is not possible to get examinees to return to the facility.

In contrast, other comments noted that a requirement for a post-move, pre-examination image quality test would pose great difficulties to mobile services that are some distance from their home base and do not have access to adequate processing at the test site. These comments expressed concern that such a requirement would cause some mobile services to cease operation and would significantly reduce access to mammography in rural and inner city areas. Several comments cited their own experience in stating that image quality tests conducted after moves rarely or never show that a problem has occurred because of the move. The preliminary results of a survey of mobile facilities conducted by the ACR found that nearly 90 percent of the facilities rarely found problems after a move. However, the remaining facilities found problems as often as daily or weekly.

The 1992 edition of the ACR QA manual (Ref. 2) recommended that an image quality test be conducted after every move, but was somewhat ambiguous regarding when the processing and analysis of the images should occur. However, the agency has been informed by members of the ACR committee who were responsible for the manual that they did not intend to require processing before further examinations were conducted. The 1994 edition of the ACR QA manual (Ref. 3) completely dropped the requirement for conducting image quality testing after every move. Under this revised ACR requirement, therefore, mobile units are required to undergo image quality testing at the same frequency as fixed units, which ordinarily is monthly.

At its September 1994 meeting, the NMQAAC discussed this issue and recommended that post-move, pre-examination testing of mobile units be required in the final regulations. FDA agreed with this recommendation and has incorporated it in proposed § 900.12(e)(7).

The NMQAAC further recommended allowing use of a method of testing based on post-exposure mAs readout values in place of phantom image testing. FDA has decided not to require a particular method of testing at this time. Instead, the agency is proposing to require each facility to adopt a test method that will verify the adequacy of image quality following a move, but to leave the choice of test method to the facility. The agency believes that this approach will give individual facilities maximum flexibility. FDA will issue guidance documents that reflect the agency's current thinking about test methods that are appropriate. At this time, FDA expects those methods to include the method recommended by the NMQAAC as well as the traditional phantom image quality test.

Including these methods of testing in guidance rather than in regulations has the advantage of increased speed and flexibility. As the agency becomes aware of new test methods of proven value, the agency's evaluation of such methods can be publicized through modification of guidance materials much more rapidly than through amendment of regulations. In addition, mobile units will have the option of using post-move pre- examination image quality test methods that are different from those described in guidance. Testing methods described in these materials will guide inspectors as they evaluate the adequacy of an individual facility's testing methods. Although the methods described in guidance will represent the agency's most current thinking about appropriate testing for this purpose, such guidance will not bind the facility or the agency. If a facility chooses alternative procedures, FDA encourages the facility to discuss the choice in advance in order to prevent expenditure of efforts and resources on testing that may later be determined to be unacceptable because it does not establish the adequacy of image quality following a move.

4. Use of Test Results

Proposed § 900.12(e)(8) describes how results from the tests specified in paragraphs (e)(1) through (e)(7) would be used to ensure that problems are detected and corrected before they adversely affect the quality of examinations.

5. Survey

Proposed § 900.12(e)(9) describes the activities that would have to be carried out by the medical physicist as part of the annual evaluation of facility equipment performance and quality assurance programs. A concern raised at the February 1994 NMQAAC meeting and elsewhere was that qualified medical physicists might delegate the onsite survey work to less qualified personnel and merely review and sign the survey report.

Because FDA is also concerned about such delegation occurring, the agency is proposing in § 900.12(e)(9)(i) that only qualified medical physicists be authorized to conduct the surveys. The agency is further proposing to require in § 900.12(e)(9)(V) that the report be signed and dated by the individual who

performs the survey. As is the case with the signature of the interpreting physician on the mammography report (see discussion of § 900.12(c)(1) published elsewhere in this issue of the Federal Register), the purpose of the signature requirement is to identify the individual who performed or provided direct supervision of the work. Therefore, in addition to handwritten signatures, FDA will accept ''signatures'' that are generated from computer systems, typewritten, name stamped, and possibly provided in other ways. These requirements would not prohibit physicists-in-training from performing surveys to gain experience, but would require that such surveys be done under the direct supervision of a fully qualified medical physicist, who would have to sign the report as the responsible physicist. If another individual performs any part or all of the survey under the direct supervision of a medical physicist, that person and the part of the survey that person performed must also be identified on the survey report.

6. Mammography Equipment Evaluation

Proposed § 900.12(e)(10) would require a mammography equipment evaluation to be performed whenever a mammography unit or image processor is installed or major components of that unit or processor are changed. This requirement was added to ensure that the performance of new or significantly changed equipment is evaluated, and problems corrected, before such equipment is used during examinations. FDA believes mammography equipment evaluation, rather than a complete survey of the facility as described in § 900.12(e)(9), is adequate for this purpose because not all aspects of the facility operation which are checked during a survey would be affected by the installation of new equipment or the modification of old equipment.

The agency will describe its current thinking about appropriate procedures for carrying out these evaluations in guidance documents and will update that guidance, when warranted, to reflect scientific and professional developments. Similarly, the agency will describe in guidance its current thinking about appropriate qualifications for persons doing this work. As discussed previously with respect to agency guidance for testing mobile units, facilities will have the option of using procedures other than those described in guidance or employing individuals with qualifications different than those listed in guidance, assuming such alternative procedures or qualifications are adequate to examine equipment for such purposes. The guidance issued by FDA will not be binding on either the facility or the agency. Once again, however, FDA encourages facilities that choose alternative personnel or procedures, to discuss the choice in advance in order to prevent expenditure of efforts and resources on evaluations that may later be determined to be inadequate.

FDA realizes that § 900.12(e)(10), as presently proposed, raises the question as to what constitutes a ''major component'' of the equipment, i.e., what components would have a significant impact on the performance of the equipment if their repair or replacement were done improperly. The agency specifically requests comments on this issue.

7. Housekeeping and Maintenance Tasks

At its July 1994 meeting, the NMQAAC stressed the importance of carrying out regular maintenance and housekeeping activities as well as properly storing film and processing chemicals. However, the agency decided, for two reasons, not to propose detailed and comprehensive requirements for such activities.

First, failure to follow proper maintenance and housekeeping activities at a facility will be revealed through failure of the tests outlined in § 900.12(e)(1) through (e)(6) and through adverse findings in the physicist's survey. Additional detailed requirements would be redundant.

Second, there are a wide variety of effective maintenance and housekeeping activities. The agency believes that it would be overly prescriptive to limit facilities to one set of activities in this area by regulation.

At its January 1995 meeting, the NMQAAC agreed that the details of these activities could be incorporated into guidance materials rather than regulatory requirements. However, the members believed that general requirements should be established for certain especially important activities. Therefore, FDA is proposing to require in § 900.12(e)(11) that facilities establish and follow protocols for the maintenance of darkroom, screen, and view box cleanliness.

8. Calibration of Exposure Measuring Instruments

In order to have reliable uniform dose measurements in facilities all across the United States, it is important to have proper traceability of the instruments used to measure x-ray exposure. The agency is proposing to add in § 900.12(e)(12) a requirement for annual calibration of such instruments, which must be traceable to a national standard.

9. Infection Control

Concern was expressed during the open public portion of several NMQAAC meetings and by one comment on the interim regulations that, because of the possibility of nipple discharge during mammography, FDA should mandate the use of universal precautions during all mammography examinations to protect examinees and health care workers from possible transmission of bloodborne pathogens. The comment also expressed concern that present procedures used to disinfect mammography equipment between examinations are inadequate to prevent disease transmission.

FDA notes that the concept of ''universal precautions'' is an approach to infection control stipulating that all human blood and certain human body fluids should be treated as if known to be infectious for human immunodeficiency virus (HIV), hepatitis B and C viruses (HBV, HCV), and other bloodborne pathogens. The Occupational Safety and Health Administration (OSHA) already mandates the use of universal precautions for all situations where occupational exposure can reasonably be anticipated (29 CFR 1910.1030). Although staff at the Centers for Disease Control (CDC) have advised FDA that there have been no reported cases of transmission of HIV, HBV, or HCV to examinees or health care workers during mammography, such transmission is theoretically possible (if no infection control precautions are taken). Therefore, the OSHA regulations are applicable to the practice of mammography, and it would be redundant for FDA to issue a universal precautions requirement under the MQSA authority.

With respect to appropriate decontamination practices, members of the NMQAAC noted during an advisory committee meeting that guidelines and regulations addressing infection control practices relevant to mammography are available from CDC (Ref. 4) and OSHA (29 CFR 1910.1030(d)(4)). These guidelines and regulations specifically address the decontamination of medical equipment and working surfaces after contact with blood or other potentially infectious materials. Local infection control policies are also in effect in many locations.

In addition, the Association for the Advancement of Medical Instrumentation (AAMI) recently published a technical information report on reprocessing of reusable medical

devices (Ref. 5). Several other national and international standards setting organizations are developing guidance in this area as well. However, these guidelines, regulations, reports, and standards do not completely cover all aspects of reprocessing mammography equipment, because they may not address the special concerns of disinfecting electrical equipment, and may not consider the effect of the disinfecting agent upon the equipment. For these reasons, FDA is developing a guidance document regarding labeling of reusable medical devices for reprocessing in health care facilities (Ref. 6). A notice of availability requesting comments on this guidance document was published in the Federal Register on June 15, 1995 (60 FR 31484). FDA and industry will utilize this document to ensure appropriate labeling for new devices as well as for improving labeling for currently marketed devices.

FDA believes that the concern raised by the comment transcends the issue of reuse of mammography devices and addresses the broader general issue of safe reuse of any reusable medical device. Therefore, it is an issue to be resolved under the agency's general medical device authority, rather than under the authority of the MQSA. In light of the concerns raised, however, FDA is reviewing current guidance and regulations, as well as additional guidance under development by the agency, to determine whether new labeling information or accessories are necessary with respect to reuse of mammography devices. FDA encourages interested parties to communicate to the agency any concerns and proposed solutions in this area.

To ensure that the practice of mammography benefits from infection control guidance already available, FDA is proposing to require that facilities establish, adhere to, and document their compliance with a system of infection control. In addition to requiring compliance with any applicable infection control regulations, each facility's system would have to require adherence to infection control recommendations provided by the manufacturer(s) of the mammography equipment used in the facility, or, if adequate manufacturer's recommendations are not available, adherence to generally accepted guidance on infection control (e.g., Refs. 4 and 5), until such recommendations become available.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined together the impacts of this proposed rule and the proposed rules on accreditation bodies, general facility requirements, and personnel, published elsewhere in this issue of the Federal Register, under Executive Order 12866, the Regulatory Flexibility Act (Pub. L. 96–354), and under the Unfunded Mandates Reform Act. The analysis has addressed the proposed requirements of these four rules as one unit for purposes of determining their economic impact. The preamble to the proposed rule ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches,'' published elsewhere in this issue of the Federal Register, contains a brief summary of the cost and benefit determination and the Regulatory Impact Study that details the agency's calculation of these economic impacts and is available at the Dockets Management Branch (address above) for review. FDA recognized that these proposed regulations may have a disproportionate effect on small volume mammography facilities and is currently collecting additional information on the potential impact on this industry sector. The agency requests comments that will assist it in accounting for this impact.

V. Paperwork Reduction Act of 1995

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995.

VI. Comments

Interested persons may, on or before July 2, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets at the heading of this document. Information submitted in response to this notice may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following information has 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. ''Report on the Mammography Quality Standards Act of 1992,'' U.S. Senate, Report 102-448, October 1, 1992.

2. American College of Radiology, ''Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual,'' February, 1992.

3. American College of Radiology, ''Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual,'' 1994.

4. Centers for Disease Control, ''Recommendations for Prevention of HIV Transmission in Health-Care Settings,'' *Morbidity and Mortality Weekly Report*, 36(2S):3S-18S, 1987.

5. AAMI TIR No. 12-1994, ''Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers,'' Association for the Advancement of Medical Instrumentation, 3330 Washington Blvd., suite 400, Arlington, VA 22201-4598, 1995.

6. Food and Drug Administration, ''Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance,'' Rockville, MD, March, 1995.

List of Subjects in 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, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 900 be amended to follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. Section 900.12 is amended by revising paragraphs (b) and (e) to read as follows:

§ 900.12 Quality standards.

* * * * *

(b) *Equipment*—(1) Prohibited equipment. Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This 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) Gantry assembly motion.

(A) The gantry assembly shall be capable of being rigidly fixed in any position where it is designed to operate. Once fixed in any such position, the gantry shall not move without operator intervention.

(B) The mechanism assuring compliance with paragraph (b)(2)(A) of this section shall not fail in the event of power interruption.

(ii) Effective October 1, 2000, the gantry assembly shall allow continuous rotation of at least 180° from vertical (cranio-caudal position) in one direction and of at least 105° from vertical in the other direction.

(iii) Effective October 1, 2005, the gantry assembly shall allow continuous rotation of at least 180° from vertical (cranio-caudal position) in one direction and of at least 135° from vertical in the other direction.

(iv) Effective October 1, 2005, the system shall provide visual indication of the gantry angle to within ± 5°.

(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.

(iv) Grid motion shall not be impeded when a breast is subjected to compression during mammography. For each size of breast support device provided with the system, compliance shall be determined by applying compression to, and exposing, a 12-cm diameter acrylic disk, 1.5 cm-thick, placed with its center located 4 cm in from the center of the chest wall edge of the breast support surface. A 4-cm thick homogeneous acrylic attenuator with rounded edges shall be located in the beam between the source and the compression paddle during the exposure. A film exposed at 28 kilovoltage peak (kVp) to obtain an optical density as close to 1.3 as possible shall be examined for grid-related artifacts. For equipment provided with automatic exposure control (AEC), the test shall be performed in the AEC mode. The compression to be applied during these tests shall be determined as follows:

(A) Before October 1, 2000, for systems meeting the requirements in paragraph (b)(12)(i)(C) of this section, the maximum attainable power driven compression shall be used; and for systems not meeting the requirements in paragraph (b)(12)(i)(C) of this section, the compression applied shall be as close to 200 newtons (45 pounds) as possible, using manual compression or a combination of manual and power driven compression.

(B) Effective October 1, 2000, the maximum attainable power-drive compression shall be used to determine compliance.

(5) Beam limitation and light fields. (i) All systems shall have beam limitation devices that provide means to restrict the useful beam so that the x-ray field can be adjusted to extend beyond the chest wall edge of the image receptor.

(ii) Any mammography system with a light field that passes through the beam-limiting device shall meet the following requirements:

(A) The light field shall be aligned with the x-ray field so that the total 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 shall not exceed 2 percent of the distance from the source to the midpoint of the chest wall edge of the image receptor support device.

(B) The light field shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

(iii) Effective October 1, 2000, all mammography systems shall be equipped with light fields that pass through the beam-limiting device and approximate the x-ray field.

(iv) Effective October 1, 2005, all systems shall be interlocked to prevent exposure unless appropriate combinations of beam limitation and image receptor size are selected.

(v) Effective October 1, 2005, all systems shall be interlocked to prevent exposure with an x-ray field that extends beyond the nonchest wall edges of the image receptor support device.

(6) Source-image receptor distance (SID). Effective October 1, 2000:

(i) Systems designed solely for contact mammography shall have a minimum SID of at least 55 cm.

(ii) All systems shall provide visual indication of the selected SID to within 2 percent of its actual value.

(7) Magnification. (i) Systems used for diagnostic procedures shall have magnification capability available for use by the operator at any time.

(ii) Systems designed for magnification procedures shall provide at least one magnification setting within the range of 1.4 to 2.0.

(8) System resolution. (i) The focal spot shall be such that, with the mammography screen-film combination used in the facility, the system will provide a minimum resolution of 11 line-pairs/mm when the high contrast resolution bar pattern is oriented with the bars perpendicular to the anode-cathode axis, and 13 line-pairs/mm when the bars are parallel to that axis.

(ii) Effective October 1, 2005, for those systems providing magnification capability, a focal spot that meets the following requirements shall be provided:

(A) The resolution provided by the magnification focal spot shall meet, at a minimum, the requirements of paragraph (b)(8)(i) of this section. Compliance shall be determined with the test pattern placed 4.5 cm above the magnification breast support, under the conditions of system magnification providing a magnification factor as close to 1.5 as can be achieved with the system.

(B) When more than one target material is provided, the measurement in paragraph (b)(8)(ii)(A) of this section shall be made using the appropriate focal spot for each target material.

(C) The grid shall be removed from the imaging chain during these measurements.

(9) 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 is selected by the system algorithm, based on the exposure or a test exposure, the system shall display the target material selected after the exposure.

(iv) When the selected target is related to the kVp, the system shall prevent exposure unless the correct combination of target and kVp is selected.

(10) Focal spot location. (i) The focal spot shall be located so that the ray falling on the mid-point of the chest wall edge of the image receptor is within ± 5° of perpendicular to the image receptor.

(ii) Compliance shall be determined for each focal spot provided.

(11) Filtration. (i) General. Each system shall comply with the beam quality requirements of § 1020.30(m)(1)

of this chapter for the minimum half-value layer (HVL).

(ii) Variable filtration. (A) Effective October 1, 2000, systems with variable filtration type or thickness shall be interlocked to prevent exposure if the selected filtration material is inappropriate for the target chosen or is outside the allowable range specified in paragraph (b)(11)(i) of this section.

(B) If different types of filtration materials are available, the system shall display the type of filtration in use prior to exposure.

(C) Effective October 1, 2000, if the filtration is automatically selected based on a test exposure, the system shall visually indicate the filtration that was actually used after the exposure is completed.

(12) Compression. All mammography systems shall incorporate a compression device.

(i) Application of compression. Effective October 1, 2000:

(A) Power driven compression activated by foot controls operable from both sides of the examinee shall be provided.

(B) Fine adjustment compression controls operable from both sides of the examinee shall be provided.

(C) The compression device shall provide a maximum compression for the power drive between 111 newtons (25 pounds) and 200 newtons (45 pounds).

(ii) Decompression. (A) 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 also provide an override capability to allow maintenance of compression and shall continuously display the override status.

(B) Each system shall provide a manual emergency compression release that can be activated in the event of power or automatic release failure.

(C) If a system is equipped with a remote compression release control for the operator, the release control shall be located in a position that allows the operator to observe the examinee during activation of the release control.

(iii) Compression paddle. (A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-sized image receptors provided. 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)(12)(iii)(B) and (b)(12)(iv)(A) of this section.

(B) When compression is applied, 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. Compliance shall be determined by applying maximum system power compression to a 12-cm diameter acrylic disk 1.5-cm thick placed with its center located 4 cm in from the center of the chest wall edge of the breast support surface for each full size compression paddle provided. For systems without power driven compression, or for systems which, before October 1, 2000, do not meet the requirements in paragraph (b)(12)(i)(C), compliance shall be determined by applying compression at as close to 200 newtons (45 pounds) as achievable using manual or a combination of manual and power driven compression. Vertical measurements shall be made between the breast support surface and the compression paddle at each of the four corners of the image receptor and shall be compared to each other and to the 1.5-cm thickness of the test device. The maximum difference between any two values shall not exceed 1.0 cm.

(C) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(D) The chest wall edge should be bent upward, forming a lip to allow for examinee comfort, but shall not interfere with the image at the chest wall.

(iv) Compression paddle alignment. (A) Effective October 1, 2000, when compression is applied, a line constructed perpendicular to the flat surface of the compression paddle through the vertex of the angle formed by the flat surface and the lip of the compression paddle and extending to the plane of the image receptor, shall intercept that plan within a distance no greater than ± 1 percent of the SID from the useful edge of the image receptor at the chest wall side (see Figure 1).

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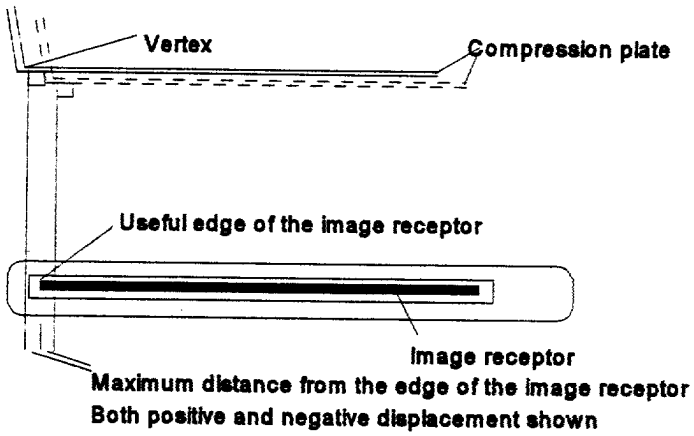

Figure 1

(B) Effective October 1, 2005, when compression is applied, a line constructed perpendicular to the flat surface of the compression paddle through the vertex of the angle formed by the flat surface and the lip of the compression paddle and extending to the plane of the image receptor, shall pass within ±2 millimeters of the useful

edge of the image receptor at the chest wall side.

(C) When the system is configured without magnification capability, compliance shall be determined with the bottom surface of the compression paddle placed at a distance within the range of 2.0 to 6.0 cm above the breast support.

(D) When the system is configured for magnification procedures, compliance shall be determined with the bottom surface of the compression paddle placed at a distance within the range of 2.0 to 6.0 cm above the breast support of the magnification device.

(v) Display of compressed breast thickness. Effective October 1, 2005, the compressed breast thickness shall be displayed and visible to the operator during positioning.

(A) The compressed breast thickness shall be displayed to within ±0.5 cm.

(B) Compliance shall be determined at the maximum attainable power compression using a flat sheet of rigid material with known thickness placed between the examinee support and the compression device. This sheet shall be placed in flat contact with the top surface of the breast support. If the support is uneven or has projections around the edges, the sheet shall be in contact with that part of the surface that actually supports the breast. This test shall be performed using sheets of the following thicknesses: 3 cm, 4.5 cm, and 6 cm.

(13) Technique factor selection and display. (i) Manual selection of milliampere seconds (mAs) shall be available.

(ii) All technique factors shall be clearly displayed at the control panel prior to exposure.

(iii) When operating in AEC mode, the system shall indicate initial technique factors prior to exposure.

(iv) Following AEC mode use, the system shall indicate the actual kVp and mAs used during the exposure.

(v) All indications of kVp shall be within ±5 percent of the actual kVp.

(vi) Effective October 1, 2005:

(A) Each system shall provide, at a minimum, for the selection of tube potentials of between 22 and 34 kVp.

(B) Selection of kVp shall be available in increments no greater than 1 kilovolt each over the entire range provided.

(C) Adjacent mAs settings shall differ by no more than 26 percent of the lower of the adjacent settings.

(D) Combinations of exposure time and tube current (mAs) shall be available over the range of at least 5 mAs to 300 mAs.

(14) Radiation output. (i) The system shall be capable of producing a minimum output of 1.29×10^{-4} coulomb/kilogram (C/kg) per second (500 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography mode at any SID where the system is designed to operate. Effective October 1, 2000, the system shall be capable of producing a minimum output of 2.06×10^{-4} C/kg per second (800 mR per second) when operating at 28 kVp in the standard mammography mode at any SID where the system is designed to operate.

(ii) The system shall be capable of maintaining the required minimum radiation output for at least 3.0 seconds.

(iii) Compliance shall be determined with the center of the detector located 4.5 cm above the breast support device used for contact mammography and centered on the breast support 4 cm in from the chest wall edge of the support with the compression paddle in place between the source and the detector.

(15) Automatic exposure control. (i) Each system shall provide an AEC mode which is operable in all combinations of equipment configuration provided, i.e. grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The AEC shall be capable of providing automatic mAs selection.

(iii) The AEC shall provide reproducible radiation exposures with a coefficient of variation not to exceed 0.05.

(iv) The positioning or selection of the active 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 input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated and visible from both sides of the examinee.

(v) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

(vi) Effective October 1, 2005, the system shall provide means for the operator to vary the optical density a minimum of 4 steps above and 4 steps below the normal (zero) setting of optical density. These steps shall vary in optical density increments of between 10 to 20 percent of the difference between adjacent mAs settings;

(vii) The system shall meet, at a minimum, the following requirements at all detector positions and for thicknesses of 2, 4, and 6 cm of homogeneous breast tissue-equivalent material. Compliance shall be determined using the screen-film and processing combination used at the facility when the mean optical density is at least 1.20.

(A) Effective October 1, 2000, equipment shall produce images with optical densities that vary from the mean optical density by no more than 0.30.

(B) Effective October 1, 2005, equipment shall produce images with optical density that varies from the mean optical density by no more than 0.15.

(16) Disabled examinees. Each facility scheduling disabled individuals shall have equipment and established protocols to ensure the facility's capability to perform mammography adequately on such individuals.

(17) X-ray film. The facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(18) Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall match them to the spectral sensitivity specified by the manufacturer of the film used.

(19) Film processing solutions. For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used in a manner equivalent to the minimum requirements specified by the film manufacturer.

(20) Lighting. The facility shall provide a special light with variable luminance capable of producing light levels greater than that provided by the view box.

(21) Film Masking Devices. (i) All facilities shall have film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film.

(ii) Facilities using x-ray collimation that provides nonrectangular exposed areas on the film shall provide masking devices appropriate to these fields.

(iii) Facilities shall make devices meeting the requirements of paragraphs (b)(21)(i) and (b)(21)(ii) of this section available to the interpreting physician.

(22) Film processors. Film processors used to develop mammograms shall meet the following requirements:

(i) The processor shall be adjusted and maintained to meet the technical development specifications for the mammography film in use.

(ii) Effective October 1, 2000, the processor shall indicate the selected time cycle reflecting the time from leading edge entry into the developer to leading edge entry into the fixer.

(iii) Effective October 1, 2000, the processor shall be capable of maintaining the developer temperature to within ±0.3° Celsius (±0.5 °F). Compliance measurements for immersion tank type processors shall be taken at the center of the surface of the developer solution and 7.5 cm (3 inches) below the surface when the developer is at the proper operating level.

(iv) Effective October 1, 2005, the processor shall clearly display the actual developer temperature to within ±0.1 °C (±0.2 °F) of the actual temperature.

(v) Effective October 1, 2005, for processors with variable cycles, the selectable parameters shall be interlocked to prevent any initiation of changes in the parameters until any film in process is completed, and to prevent any new film from entering the process cycle until the variables are properly stabilized at the new cycle parameters. If the unit is equipped with an override of this interlock for maintenance procedures, the override status shall be clearly indicated to the operator.

* * * * *

(e) *Quality assurance—equipment*—(1) Daily quality control tests. Facilities with screen-film systems shall perform a processor performance test on each day that examinations are performed before any examinations are performed 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 of no less than 1.20 optical density (OD).

(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 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 acceptable to FDA in accordance with § 900.3(d) or § 900.4(a)(9).

(iv) The image contrast between the background of the phantom and an added test object, used to assess density difference, 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 and any corrective actions and their results shall be recorded.

(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. If the darkroom has a safelight, it shall be on during this test.

(ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh screen.

(iii) Compression. The compression device shall meet the specifications described in § 900.12(b)(12).

(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 phantom thickness is varied over a range of 2 to 6 cm and the kVp is varied over the kVp range used in the facility for such thicknesses.

(B) The operating optical density of the film in the center of the phantom image shall not be less than 1.20.

(C) If the requirement of paragraph (e)(5)(i)(A) of this section 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.

(ii) Kilovoltage peak (kVp) accuracy and reproducibility.

(A) At the lowest and highest clinical values and at any other commonly used clinical settings of kVp, the kVp shall be accurate to within ± 10 percent, 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) System Resolution. The limiting spatial resolution shall not be less than 13 line-pairs/mm parallel to the anode-cathode axis of the x-ray tube and 11 line-pairs/mm perpendicular to the anode-cathode axis.

(iv) Beam quality and half-value layer (HVL). The HVL shall meet the specifications in paragraph (b)(11) of this section.

(v) Breast entrance exposure and AEC reproducibility. The coefficient of variation for both exposure 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 4.2-cm thick, compressed breast consisting of 50 percent glandular and 50 percent adipose tissue, shall not exceed 3.0 milliGray (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a 4.2-cm, 50 percent glandular/50 percent adipose tissue compressed breast.

(vii) X-ray field/light field/image receptor/compression paddle alignment. The x-ray field/light field/image receptor alignment shall meet the specifications of paragraph (b)(5) of this section and § 1020.31(f)(3) of this chapter. In addition, the chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one per cent of the SID.

(viii) Screen speed uniformity. Screen speed uniformity 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 phantom large enough to cover the mammography cassette.

(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 additional 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 non screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, pre-examination testing of mobile units, to the limits established in the test method used by the facility. The applicable tests shall be repeated immediately for any parameters found to be beyond the specified acceptable ranges.

(ii) If the repeated tests continue to produce unacceptable results, the source of the problem shall be identified and corrective actions shall be taken before any further examinations are performed.

(9) Surveys. (i) At a frequency of no less than 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 in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test 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, or major components of a mammography unit or processor equipment are changed. 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. The mammography equipment evaluation shall be performed by an individual whose qualifications are adequate to examine equipment for this purpose and in accordance with procedures that are adequate to ensure that the examination is complete and accurate.

(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 exposure measuring instruments. (i) Instruments used to measure the exposure or exposure rate from a mammography unit shall be traceable to a national standard.

(ii) Effective October 1, 2005, the manufacturers calibrating instruments to measure exposure or exposure rate from mammography units shall meet the requirements of a recognized quality assurance program. A calibration laboratory calibrating instruments to measure exposure or exposure rate from mammography units must be accredited by a recognized national program or an equivalent international program which requires continuing participation with NIST in measurements and testing for maintaining quality assurance appropriate for mammography.

(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.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 25

National Environmental Policy Act: Proposed Revision of Policies and Procedures; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 96N–0057]

National Environmental Policy Act; Proposed Revision of Policies and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing compliance with the National Environmental Policy Act of 1969 (NEPA) as implemented by the regulations of the Council on Environmental Quality (CEQ). The primary purpose of this proposed rule is to increase the efficiency of FDA's implementation of NEPA and reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an environmental impact statement (EIS) nor an environmental assessment (EA) is required. FDA is also proposing to amend its regulations to make its NEPA procedures more concise and understandable to the public and to reflect current FDA policy with respect to environmental considerations. This proposed rule is in response to initiatives announced in the President's National Performance Reports, ''Reinventing Drug and Medical Device Regulations,'' April 1995, and ''Reinventing Food Regulations,'' January 1996.

DATES: Submit written comments on the proposed rule by July 2, 1996. Submit written comments on the information collection requirements by May 3, 1996.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn.: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: For information regarding human drugs: Nancy Sager, Center for Drug Evaluation and Research (HFD–357),Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6740.

For information regarding biologics: Nancy Roscioli, Center for Biologics Evaluation and Research (HFM–205), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3031.

For information regarding veterinary medicines: Charles E. Eirkson, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1683.

For information regarding foods: Buzz L. Hoffmann, Center for Food Safety and Applied Nutrition (HFS–246), Food and Drug Administration, 200 C St. SW.,Washington, DC 20204, 202–418–3005.

For information regarding medical devices and radiological health: Mervin Parker,Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

NEPA requires all Federal agencies to assess the environmental impact of their actions and to ensure that the interested and affected public is informed of environmental analyses. CEQ is responsible for overseeing Federal efforts to comply with NEPA. Both CEQ and FDA have issued regulations governing agency obligations and responsibilities under NEPA. In the Federal Register of March 15, 1973 (38 FR 7001), FDA issued its first regulations to implement NEPA. FDA amended these regulations in the Federal Register of April 15, 1977 (42 FR 19986), based on consideration of revised guidelines for preparing EIS's issued by CEQ. In 1978, CEQ replaced its guidelines with regulations implementing the procedural requirements of NEPA (40 CFR parts 1500 to 1508). To comply with CEQ regulations, in the Federal Register of April 26, 1985 (50 FR 16636), FDA revised its NEPA policies and procedures in part 25 (21 CFR part 25).

The CEQ regulations, which are binding on all Federal executive agencies, establish formal guidance on the requirements of NEPA. Agencies must adopt procedures to supplement them. In adopting NEPA-implementing procedures, Federal agencies are directed by CEQ to reduce paperwork (40 CFR 1500.4 and 1500.2(b)) and to reduce delay (40 CFR 1500.5) by using several means including the use of categorical exclusions. CEQ defines categorical exclusions as categories of actions which do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required (40 CFR 1508.4). The CEQ regulations also state that agencies shall continue to review their policies and procedures and, in consultation with CEQ, revise them as necessary to ensure full compliance with the purpose and provisions of NEPA (40 CFR 1507.3).

II. Overview of the Proposed Rule

Since FDA's NEPA policies and supplemental procedures were published in 1985, the agency has prepared EA's for many agency-initiated actions and has reviewed hundreds of EA's for a variety of industry requests for agency action. Based on FDA's experience reviewing EA's and on its evaluation and knowledge of other relevant environmental science, FDA has determined that certain classes of actions normally do not cause significant environmental effects, and therefore, should be added to the list of actions that are excluded from the requirement to prepare an EA or an EIS. Some of these actions had already been identified by FDA as unlikely to cause significant environmental effects, as evidenced by the fact that the agency has been requiring less information to support these actions, i.e., an abbreviated EA rather than a full EA (see § 25.31a(b)).

Thus, in response to the President's reinventing Government initiatives announced in the President's National Performance Reports, ''Reinventing Drug and Medical Device Regulations,'' April 1995, and ''Reinventing Food Regulations,'' January 1996, FDA, in consultation with CEQ, is now proposing to increase the efficiency of FDA's implementation of NEPA and to substantially reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant impact on the human environment and for which, therefore, neither an EA nor an EIS is required. This proposal would substantially reduce the number of EA's required to be submitted by industry and reviewed by FDA and, consequently, reduce the number of findings of no significant impact (FONSI's) the agency would be required to prepare. Furthermore, the proposal will not compromise the environment because the excluded actions have been found not to have a significant effect on the environment, and the proposed rule would continue

to provide for the preparation of an EA under extraordinary circumstances in which a categorically excluded action may have a significant environmental impact. This proposal would enable FDA to focus its resources in the environmental area on situations likely to have an effect on the environment.

The agency is also proposing to revise its environmental regulations to make them more concise and useful to the public and regulated industry by reorganizing, simplifying, and eliminating unnecessary and duplicative language. The proposed rule would reorganize and renumber various sections so that information on certain topics is grouped together. The agency solicits comments on and suggestions for further improvement in these regulations.

III. Specific Proposed Changes

A. General Provisions

The proposed rule would eliminate unnecessary language in current subpart A of part 25 by deleting the reference to the environmental statutes listed in current § 25.5 *Policies*, amending § 25.15 Terminology (proposed § 25.5), and making other minor revisions, including combining § 25.5 Policies and § 25.10 NEPA planning into proposed § 25.10 *Policies* and *NEPA planning.*

In proposed § 25.5 *Terminology*, FDA is proposing to remove definitions listed in current § 25.15 that are not used in part 25, and add new definitions for ''active moiety'' and ''increased use'' of a drug. ''Increased use'' of a drug will occur if the drug will be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect, or if the drug is a new molecular entity. ''Increased use'' encompasses consideration of FDA-regulated articles that are disposed of by consumers.Eric Flamm suggests wording: ''Increased use'' encompasses consideration of disposal of FDA regulated articles by consumers. ''Active moiety'' has been previously defined in FDA regulations (21 CFR 314.108(a)).

B. Agency Actions Requiring Environmental Consideration

Proposed § 25.15 would contain the general procedural information now found in current §§ 25.20 and 25.22.

The proposed rule would create new § 25.l6 *Public health and safety emergencies* using revised language now contained in current § 25.40(b).

Actions requiring preparation of an EA (proposed § 25.20) would remain essentially the same as current § 25.22, except that: (1) Current § 25.22(a)(13), promulgation and enforcement of FDA regulations relating to the control of communicable disease and to interstate conveyance sanitation, has been deleted and is covered by proposed § 25.20(g); and (2) actions relating to approval of new drug applications (NDA's) and abbreviated applications, actions on investigational new drug applications (IND's) (current § 25.22(a)(14)), issuance of licenses for biologic products (current § 25.22(a)(16)), and approval of supplements to existing approvals of FDA-regulated articles (§ 25.22(a)(8)) have been combined into one provision (proposed § 25.20(l)) and revised to reflect current terminology.

The proposed regulations include new § 25.21 Extraordinary circumstances, which addresses circumstances under which categories of actions that would ordinarily be categorically excluded would require preparation of environmental documents. Proposed § 25.21 incorporates current § 25.23(b) and includes two examples of circumstances under which an action would require the preparation of environmental documents because it might have the potential to significantly affect the environment. The examples of circumstances that will cause an action not to qualify for categorical exclusion are: (1) Actions for which data available establish that, at the expected level of exposure, there is the potential for serious harm to the environment (proposed § 25.21(a)); and (2) actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened, or wild flora or fauna that are entitled to special protection under some other Federal law (proposed § 25.21(b)). In addition, the proposed rule references the CEQ regulations at 40 CFR 1508.27, which provide examples of circumstances in which significant effects may occur. Extraordinary circumstances may be shown by either data available to the agency or data available to the applicant or petitioner and may be based on production, use, or disposal from use.

The two examples of extraordinary circumstances in proposed § 25.21 reflect Are they really disqualification criteria? If the criteria are met, the exclusion is warranted. See 25.24(c)(1). Gail concurs with this.criteria that appear in some of the categorical exclusions listed in current § 25.24. The language in the first example, proposed § 25.21(a), is derived from but differs slightly from current § 25.24 language relating to toxicity (see, e.g., § 25.24(a)(10), (b)(2), and (c)(6)). The extraordinary circumstance example in proposed § 25.21(a) would revise the language in current § 25.24, ''the substance may be toxic to organisms in the environment'' to read ''there may be harm to the environment.'' FDA is revising this language to reflect that possible adverse environmental effects other than toxicity should be considered. For example, some biological agents that may be released may not be toxic to indigenous organisms, but could have lasting effects on ecological community dynamics.

FDA considers a substance to be toxic if it is harmful to some biological mechanism or system. Although FDA recognizes that any substance may produce damage to biological mechanisms or systems under specific conditions, for the purposes of these regulations, FDA considers a substance to be toxic if it is harmful to appropriate test organisms at the expected level of exposure even though it may be without effect in humans or other organisms at these concentrations, and may even be used by humans because of its toxic properties.

As a result of the new language in proposed § 25.21(a), the words ''toxic'' and ''toxic substance'' are no longer used in the proposed regulation. Therefore, FDA is proposing to remove the definition of ''toxic substance'' at current § 25.15(b)(6). Furthermore, FDA no longer believes that the second part of the current definition relating to toxicity of a substance is appropriate for the following reasons: (1) Evaluation of the toxicity of a substance based only on the concentration at the point of entry or point of highest concentration ignores factors such as instantaneous dispersion that typically takes place as a result of processes such as river flow and wind, and that not all substances bioaccumulate. Consideration of such dilution processes may be reasonable and scientifically sound in estimating environmental concentrations for certain purposes; and (2) the use of a factor of 1/100 of the concentration that causes 50-percent mortality in a test organism to assess the toxicity of a substance is not appropriate in all cases. The factors used to assess toxicity should be directly related to the amount of valid ecotoxicity data available. Although a factor of 1/100 may be appropriate in some instances, it may be too much or too little in others. In evaluating whether extraordinary circumstances exist, FDA will take into account any ecotoxicity data relevant to the issue.

The second example of extraordinary circumstances relates to instances in which the proposed action could adversely affect an endangered or threatened species, or a species entitled to protection under some other Federal law. FDA intends to closely examine proposed actions that involve FDA-regulated articles obtained from wild flora and fauna and will use the extraordinary circumstances provision to require at least an EA in any instance in which it appears from an examination of the proposed action that the action may cause a species to become endangered or threatened.

In addition, the agency notes that the language in proposed § 25.21(a) includes the indirect effects as well as direct effects of agency actions. For example, when the agency takes action to prohibit or restrict the use of an FDA-regulated product, the agency may consider whether the increased use of substitutes for the prohibited or restricted product might, at the expected level of exposure, result in harm to the environment.

FDA is proposing to remove current § 25.25 (Retroactive environmental consideration), because any request by FDA to an applicant to submit additional information to an existing FDA approval will be made under authority granted to FDA by the Federal Food, Drug, and Cosmetic Act (the act) or the Public Health Service Act (the PHS Act).

C. Categorical Exclusions

1. General

The proposed rule would increase the number of categorical exclusions and reorganize the categorical exclusions into the following five sections in proposed subpart C of part 25: Section 25.30 *General*; § 25.31 *Human drugs and biologics*; § 25.32 *Foods, food additives, and color additives*; § 25.33 *Animal drugs*, and § 25.34 *Devices and electronic products*. The agency is also proposing to delete the general introductory language from current § 25.24 because it is unnecessary to include this information in the regulation.

The agency is proposing to retain most of the general categorical exclusions listed in current § 25.24(a) (proposed § 25.30) and to make certain revisions described below:

Current § 25.24(a)(4) categorically excludes destruction or disposition of any FDA-regulated article condemned after seizure, following detention or recall at agency request, or the distribution or use of which has been enjoined. In proposed § 25.30(d), FDA is proposing to revise the criteria for the categorical exclusion from ''if the method of destruction or disposition of the article, including packaging material, will not result in the release of a toxic substance into the environment'' to ''if the waste is disposed of in compliance with all Federal, State, and local requirements.'' The agency is proposing this revision to reflect current agency practice and because the previous criterion is covered under paragraph (a) of proposed § 25.21 Extraordinary circumstances.

The agency is proposing to revise the categorical exclusion for current good manufacturing practice (CGMP) regulations (§ 25.24(a)(10), proposed § 25.30(j)) to include regulations based on the hazard analysis critical control points (HACCP) principles. The HACCP concept is a systematic approach to the identification, assessment of risk, and control of the biological, chemical, and physical food safety hazards associated with a particular food production process. The HACCP system is based upon the implementation of a control plan developed by a food producer that analyzes significant food safety hazards, identifies the points in the production process where a hazard can be prevented, and determines the preventive measures that are necessary for proper control.

The agency has recently issued regulations (60 FR 65096, December 18, 1995) that use HACCP principles to ensure the safe processing and importing of seafood. The agency is also considering developing HACCP regulations for other regulated food industries (59 FR 39888, August 4, 1994). FDA has found that the environmental considerations based on HACCP principles are essentially identical to the environmental considerations of regulations based on CGMP's. Neither type of regulation is likely to have significant environmental impacts. Therefore, the agency believes that it is appropriate to incorporate into the categorical exclusion for CGMP regulations an exclusion of the HACCP regulations.

FDA also is proposing to add a categorical exclusion (proposed § 25.30(m)) for actions relating to the disposal of the hazardous laboratory waste materials generated in FDA laboratories (low-level radioactive waste and chemical waste). Today, all of this hazardous waste is disposed of under contract with a hazardous waste management firm.We don't mention what the waste is—even though it is in the codified part. The contractor is responsible for the collection, handling, storage, packing, and ultimate disposal of the waste materials at facilities permitted by the U.S. Environmental Protection Agency (EPA) and/or facilities licensed by the Nuclear Regulatory Commission (NRC). In awarding contracts, FDA takes into consideration whether a prospective contractor has all applicable licenses, permits, and insurance necessary to perform the work and transport the waste as required under the contract. The contractor and all disposal facilities must certify that they are in full compliance with all applicable Federal, State, and local requirements, before FDA will award the contract. Further, FDA requires the contractor to present a comprehensive operational plan. FDA reviews this plan to determine if the contractor's approach is complete, safe, appropriate, and responsive to, among other things, FDA's requirements for waste disposal. Further, the contractor must operate in full compliance with appropriate regulations issued by EPA (Title 40), the Department of Transportation (Title 49), the Department of Labor (Title 29), NRC (Title 10), and with relevant State and local regulations governing the disposal of hazardous and nonhazardous waste. Therefore, FDA is proposing in § 25.30(m) to categorically exclude disposal of low-level radioactive waste materials and chemical waste materials generated in laboratories serviced by FDA-administered contracts.

2. Human Drugs and Biologics

In the National Performance Report, ''Reinventing Drug and Medical Device Regulations,'' April 1995, the President announced FDA's proposal to reduce the number of EA's submitted by industry under NEPA by increasing the number of categorical exclusions for those actions relating to drugs and biologics that, as a class, have no individual or cumulative significant effect on the environment. As described below, in fulfillment of this commitment, FDA is proposing additional categorical exclusions for classes of actions on drugs and biologic products that, based on experience in reviewing these types of actions, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have concluded do not have significant effects on the human environment. All of the environmental reviews of these categories of actions performed under the current regulations have resulted in FONSI's.

The proposed new categorical exclusions in § 25.31(a) and (b) apply to actions on an NDA, abbreviated application or a supplement to such

applications, or action on an over-the-counter (OTC) monograph. They are divided into two sections: (1) Proposed § 25.31(a), which applies if FDA's action does not increase the use and disposal of the drug; and (2) proposed § 25.31(b), which applies if FDA's action does increase the use and disposal of the drug. This is similar to the distinction drawn in the existing regulations between actions that increase use and actions that do not. Proposed § 25.31(a) and (b) use the term ''active moiety'' rather than substance, drug product, or other terminology to clarify the exact focus of the environmental review.

The categorical exclusion in proposed § 25.31(a) is based on the categorical exclusions in current § 25.24(c)(1) and (c)(2) and the fact that, if the action does not increase the use of a drug, there is no change in the level of the substance in the environment. FDA has defined ''increased use'' of a drug to include those circumstances currently listed in § 25.24(c)(1) and (c)(2). Because the environmental effects, if any, associated with the use and disposal of the drug were incurred when it was first approved, actions to approve additional products may be categorically excluded if they do not increase the use of the drug. Among the actions covered under this categorical exclusion may be approvals of new dosage forms, prodrugs, generic drug products, and manufacturing supplements that may change the method or site of manufacture of a drug but not its use.

Actions under proposed § 25.31(b) that may increase the use or disposal of a drug product may be categorically excluded if the concentration of the substance in the environment will be below 1 part per billion (ppb), the level that FDA has found, based on past experience, will not significantly affect the aquatic environment. This reflects a change from current regulations that require an environmental assessment in any case in which an action may increase the use of a drug. The basis for this change is described below.

CDER performed a retrospective review of available toxicity information from EA's that were previously submitted in support of NDA's and NDA supplements. This information, which includes data from each review division that are representative of pharmacological drug classifications, has routinely demonstrated that there are no significant observed effects on relevant standard test organisms in the aquatic environment at concentrations below 1 ppb.

Based on the method of entry into the environment from use and their physical and chemical characteristics (e.g., water solubility), human drugs would be expected predominantly to enter the aquatic environment, and the data submitted in EA's reviewed by CDER have routinely supported this hypothesis. Human drugs and their metabolites enter the environment from use by excretion from patients. The majority of hospitals, clinics, and homes in the United States are serviced by a wastewater treatment facility where compounds are subjected to some form of aerobic and anaerobic decomposition. Drug and/or metabolites that are not degraded in the wastewater treatment facility may be discharged into surface water or removed from the wastewater treatment plant in sludge.

The data also have routinely shown that in those cases in which an applicant has provided toxicity results for terrestrial organisms in addition to acute toxicity results for aquatic organisms, the drugs are toxic to aquatic organisms at lower levels than they are to terrestrial organisms, suggesting that the use of aquatic organisms is a conservative approach.

CDER evaluates the potential for significant environmental effects by relating the concentrations determined to have toxic effects on relevant standard test organisms to the level of the substance expected in the environment. CDER's retrospective review shows that drugs at concentrations less than 1 ppb in the aquatic environment have no significant effect on relevant standard test organisms and, therefore, are unlikely to have a significant effect on the environment. The vast majority of actions taken by CDER result in the substance being in the aquatic environment at concentrations less than 1 ppb because the majority of drugs are produced and used at low levels, and the use of drugs is not typically localized but rather is spread throughout the United States.

One of the criteria for determining that a drug is safe for human use is consideration of its potential to bioaccumulate. The vast majority of drugs do not have the physical or chemical characteristics that would allow them to bioaccumulate in tissue because this would raise safety concerns for use in humans. If a drug does have the physical or chemical characteristics that would allow it to bioaccumulate, there has to be a mechanism for the human body to metabolize the compound to a substance that has lower bioaccumulation potential so that it is cleared from the body. In the environmental assessments that CDER reviewed, bioaccumulation has not been an issue.

Thus, FDA has determined that actions that may increase the use or disposal of a drug should be categorically excluded if the concentration of the substance in the environment from use will be less than 1 ppb and no extraordinary circumstances exist. For example, even under conditions in which an action would increase the use of a drug, such as an efficacy supplement adding a new indication, the proposed action may be categorically excluded under this proposal if the substance in the environment will be below 1 ppb. CDER has provided guidance on appropriate calculations for estimating environmental concentrations (Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements, November 1995).

CDER will continue to critically review the environmental toxicity information submitted for those actions requiring an EA. As additional data become available to CDER, the agency may propose to modify the 1 ppb environmental concentration cut-off through notice and comment rulemaking.

Proposed § 25.31(a) and (b) include actions on NDA's. Under the current regulations (§ 25.24(c)(1) and (c)(2)), abbreviated new drug applications (ANDA's) and supplements may be categorically excluded, but NDA's for the same type of action may not. Sometimes an applicant has a choice whether to submit a proposed action as an NDA or ANDA (e.g., a new dosage form may be submitted as an ANDA with a suitability petition or as an NDA). Thus, the applicant's choice of submission would determine whether an EA would need to be submitted. Proposed § 25.31(a) and (b) would permit FDA to treat NDA's, abbreviated applications, and supplements alike based on the type of action being affected by the application.

Current § 25.24(c)(6) categorically excludes actions on OTC monographs if the product is already marketed for the proposed use. FDA is proposing to add OTC monographs to proposed § 25.31(a) and (b) because, by action on an OTC monograph, FDA permits the manufacture and marketing of OTC drugs that meet the monograph. It should be noted that actions to switch drugs from prescription to OTC use that are submitted in an NDA or supplement would also be covered under these provisions.

Proposed § 25.31(a) and (b) would also delete any reference to ''actions on amendments'' to clarify that the agency

does not take actions on amendments. Amendments are merely changes to a pending application that are incorporated into the application. The action the agency takes is on the application as a whole, not on the amendment.

Proposed § 25.31(a) and (b) applies to drugs regulated by CDER. FDA is proposing a new categorical exclusion in § 25.31(c) for substances that occur naturally in the environment, that would apply to both drugs and biologics. Proposed § 25.31(b) would apply to actions on an NDA, abbreviated application, application for marketing approval of a biologic product, a supplement to such applications, or action on an OTC monograph when the action is not expected to alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. Under the current regulations, FDA requires an abbreviated EA for a drug that occurs naturally in the environment. These abbreviated EA's require information about the production site and about whether the use of the product will significantly alter the concentration, distribution, and effect of the natural substance in the environment.

Since the publication of the NEPA regulations in 1985, FDA has reviewed abbreviated EA's for substances that are naturally occurring. FDA has found that actions on submissions for these substances will not affect the environment if the action will not significantly alter the concentration or distribution of the natural substance in the environment. Under these circumstances, the agency has prepared FONSI's. Both CDER and CBER routinely include in safety evaluations evidence that a product and/or living system used to produce the product are inactivated following production and prior to release into the environment, if there is a reasonable possibility that the product or living system may be harmful to the environment. Therefore, there are not likely to be any environmental effects. The proposed regulations would categorically exclude an action for a substance that occurs naturally in the environment when the action will not alter significantly the concentration or distribution of the substance in the environment. FDA has access to information regarding metabolites and degradation products to aid in determining if the categorical exclusion request is appropriate.

When an action does alter significantly the concentration or distribution of a naturally occurring substance, its metabolites, or degradation products in the environment, e.g., when the use and disposal will occur in a geographic area where the substance is not naturally occurring, an EA may be required.

FDA is proposing in § 25.31(d) to expand the categorical exclusion provision for the withdrawal of approval of an NDA or abbreviated application. The agency is proposing that all types of withdrawals of approval, whether requested by industry or initiated by the agency, be categorically excluded because, based on CDER's experience, these types of actions will not result in the production or distribution of any substances and, therefore, will not result in the introduction of any substance into the environment.There would be no increase in use of substitutes? See line 21 on page 38 (of 1/26 draft). EIS considered increase of hydrocarbon propellants in anti-perspirant aerosols.

Proposed § 25.31(e) would revise the categorical exclusions for actions on an IND. Current § 25.24(c)(4) categorically excludes actions on IND's if the drug shipped under such notice is intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic. Under proposed § 25.31(e), FDA would categorically exclude all IND's. In many cases, FDA's actions on IND's do not significantly increase the use of the drug or the amount of drug introduced into the environment because the drug is being tested in few patients or is already being marketed for another use. Therefore, no changes in environmental effects will occur. In those cases in which an increase in the use of the drug may occur as a result of an investigation under an IND, CDER's experience in reviewing actions on IND's indicates that significant environmental effects will not occur because the use of such drugs is limited and controlled.

The agency is proposing to delete the language ''if the drug shipped * * * may reasonably be expected to be nontoxic'' because an action that results in waste that is expected to be toxic would require an EA under proposed § 25.21 Extraordinary circumstances.Is that what 25.21(a) means—that if waste is toxic, there may be harm and an EA will be required?

Proposed § 25.31(g) would add a categorical exclusion for the testing and release by CBER of lots or batches of a licensed biologic product. The effects on the environment of licensed biologic products are evaluated during the safety evaluation and approval of the license application. Therefore, conducting a separate NEPA review for the testing and release by CBER of individual lots or batches is unnecessary.

Proposed § 25.31(i) would permit a categorical exclusion for the establishment of a comparability determination for a biologic product subject to licensing. Establishment of a comparability determination does not result in introduction of a substance into the environment. A substance will be introduced into the environment only when CBER has made a comparability determination and subsequently approves a license application for a specific biologic product. The environmental considerations will be made in connection with the review of individual license applications that meet the comparability criteria.

Proposed § 25.31(j) incorporates current § 25.24(c)(10), the categorical exclusion for promulgation, amendment, or revocation of a standard for a licensed biologic product, and would eliminate the current requirement that there be no increased use of the product. The standards normally explain how the product is to be manufactured and any additional requirements for approval and marketing. Therefore, the increased use criterion is unnecessary.

Proposed § 25.31(k), regarding revocation of a biologic product, would eliminate the current criteria in § 25.24(c)(9) that the biological product ''is no longer being marketed'' or that the action is ''at the request of the license holder. The agency is proposing to delete these criteria as unnecessary because revocation of a license for a biologic product means that the product can no longer be marketed. Marketing of the product after license revocation must cease regardless of whether the revocation was at the request of the license holder or initiated by the agency. Revocation of a license for a biologic product under any circumstances will not result in the introduction of any substance into the environment and, therefore, will not significantly affect the environment.

The agency is also proposing other minor, nonsubstantive amendments to delete unnecessary language, improve the accuracy and clarity of the categorical exclusions, and reflect current terminology.

3. Foods, Food Additives, and Color Additives

In the President's National Performance Report, ''Reinventing Food Regulations,'' January 1996, the President announced that FDA proposed to reduce the number of EA's

submitted by industry under NEPA by increasing the number of categorical exclusions for food and color additives and generally recognized as safe (GRAS) substances based on little or no impact on the environment from the use and disposal of these products. As described below, in fulfillment of this commitment, FDA is proposing additional categorical exclusions for actions on foods, food additives, color additives, and GRAS substances which, based on experience in reviewing these types of actions, the Center for Food Safety and Applied Nutrition (CFSAN) has concluded will not significantly affect the human environment.

As was explained previously, FDA is proposing to remove criteria from certain exclusions in current § 25.24. For actions involving foods, food additives, color additives, and GRAS substances, the criteria for the exclusions in current § 25.24(a)(10), (b)(2), (b)(3), (b)(7), (b)(8), and (b)(9) have been removed. These exclusions can be located in proposed §§ 25.30(j), and 25.32(b), (c), (f), (g), and (h). This change is being made because the provisions in proposed § 25.21 Extraordinary circumstances could apply to any of the agency's exclusions, making certain criteria for individual exclusions unnecessary.

In addition, to reflect current FDA policy, the agency is removing from part 25 the environmental review requirements for the establishment of action levels for unavoidable poisonous or deleterious substances in food or food packaging, and for natural or unavoidable defects in food that present no health hazard. This change is discussed below.

For the classes of actions proposed for categorical exclusion in § 25.32(i), (j), (k), (l), (o), (q), and (r), FDA has traditionally required certain information to assess the potential environmental impact of the production of the food additive, color additive, or GRAS substance. In all cases, FDA has found in its reviews that the production of these substances did not significantly affect the environment. The agency has determined that FDA ordinarily will not consider potential impacts at sites of production of FDA-regulated products, as discussed in section III.D of this document.

a. *Proposed § 25.32(f).* Currently, FDA's NEPA procedures in § 25.24(b)(7) provide for a categorical exclusion for actions relating to the affirmation of a food substance as GRAS if the substance is already marketed for the use for which affirmation is sought. FDA is proposing to expand this categorical exclusion in proposed § 25.32(f) to include actions to establish and amend regulations under part 181 (21 CFR part 181) for prior-sanctioned ingredients that are already marketed in the United States. Actions involving prior-sanctioned ingredients are similar to certain GRAS affirmation actions in that the food substance is likely to be already marketed in the United States for the proposed use at the time the action is being considered and will continue to be marketed after the regulation is published. As defined in § 170.3(l) (21 CFR 170.3(l)) and § 181.5(a), a prior sanction shall exist only for a specific use of a substance for which there was explicit approval by FDA or the U.S. Department of Agriculture (USDA) before September 6, 1958. Actions to affirm substances as GRAS or prior-sanctioned for the specific uses for which they were already marketed in the United States create little or no change in the introduction of the substance into the environment. Therefore, such actions have no significant effect on the environment.

b. *Proposed § 25.32(i).* FDA is proposing to amend its NEPA procedures to categorically exclude from the requirement to prepare an EA actions to approve a food additive petition or grant a request for exemption from regulation as a food additive under § 170.39 (21 CFR 170.39) (threshold of regulation) when a food additive is a functional component of finished food-packaging materials present at not greater than 5 percent-by-weight. FDA based this proposed exclusion on its review of 95 petitions for food additives in this class, all of which resulted in FONSI's, and on the evaluation of the potential for future petitions in this class to have significant environmental effects. FDA has had limited experience in considering the environmental impact of threshold of regulation submissions because the regulations establishing a threshold of regulation policy were recently issued (60 FR 36582, July 17, 1995). However, because the information currently required for such submissions is identical to the information required for the food-packaging class of indirect food additives discussed in this section, the agency believes that its experience with the 95 food additive petitions is relevant to these threshold of regulation submissions and that these submissions also warrant a categorical exclusion.

The agency's evaluation of functional components of food-packaging materials present at not greater than 5 percent-by-weight has traditionally included consideration of potential impacts relating to the disposal of food-packaging materials containing the additive and the use of natural resources and energy.

To determine the potential for significant introductions of substances into the environment at the site of disposal of food-packaging materials, i.e., municipal solid waste landfill or combustion sites, the agency currently requires an estimate of the maximum yearly market volume for the proposed use of the food additive and the percent of that amount that will become a component of the finished food-packaging material. To determine the potential for significant introductions at landfill sites, FDA estimated the concentration of the additive that could be present in landfill leachate for each of the 95 petitions it reviewed for additives used as functional components of food-packaging materials. FDA found that in virtually all cases, the concentration of the additives in landfill leachate was less than 50 ppb. The concentration of the additives in surface or ground water receiving landfill leachate was expected to be substantially less, taking into consideration the mobility and degradation of the additives in landfills and their dilution in receiving waters.

Consequently, FDA determined in all cases that these extremely low levels would not have significant environmental impacts at landfill sites. The agency believes that approvals of future petitions in this class are even less likely to result in significant introductions of substances at landfill sites because EPA published new landfill regulations in the Federal Register of October 9, 1991 (56 FR 50978), that require new and expanded landfills to have leachate collection systems and liners to prevent leachate from entering surface or groundwater. Although operators of existing landfills are not required to retrofit liner systems, they are required to monitor groundwater adjacent to existing landfills and to take corrective action as appropriate.

The agency's evaluation of petitions for additives used as functional components of food-packaging materials has also shown that there is little potential for significant introductions from the combustion of packaging materials containing the additives. These types of additives are used at low levels in the packaging materials, <5 percent by weight, and, therefore, the additional amounts of combustion products emitted were found to be insignificant compared to the levels already being generated during municipal solid waste combustion. Because FDA's experience shows that the use levels for additives used as

functional components of food-packaging materials are low, the agency believes that future approvals will also result in insignificant introductions into the environment at municipal solid waste combustor sites.

Under current part 25, FDA requires no documentation to assess potential impact on energy and resource use if the proposed additive is intended for the same use as another additive already in use and will not materially change the potential uses of the packaging materials to which it is added. The agency has required sponsors to provide information in an abbreviated EA showing that these criteria are met. Based on FDA's experience in reviewing petitions for functional components of food-packaging materials, the agency has found that petitioners generally were able to demonstrate that a proposed additive would compete with and replace other, already regulated additives and that approval would not change the uses of the packaging materials to which they were added. In cases where a proposed additive did not compete with and replace an already regulated additive, the agency was still able to conclude that there would not be a significant impact on energy and natural resource use largely because use of the additive in food-contact articles represented a very small fraction of total usage.

Thus, based on the low levels of use of these functional components of food-packaging materials and on FDA's experience reviewing abbreviated EA's for these functional components, the agency believes that approvals of future submissions for such additives are highly unlikely to have significant effects on the environment. Therefore, under proposed § 25.32(i) a requestor need not ordinarily submit an EA.

c. *Proposed § 25.32(j).* FDA is proposing to categorically exclude actions to approve a food additive and to grant a request for exemption from regulation as a food additive under § 170.39 when the additive is a component of food-contact surfaces of permanent or semipermanent equipment or of other food-contact articles intended for repeated use (proposed § 25.32(j)). This proposed exclusion is based on FDA's experience with 43 petitions for additives used as components of repeat-use food-contact articles, all of which resulted in a FONSI. FDA has had limited experience in considering the environmental impact of threshold of regulation submissions for components of repeat-use, food-contact articles because the regulations establishing a threshold of regulation policy were recently issued. However, because the information currently required for such submissions is identical to the information required for food additive petitions for these types of indirect food additives used in repeat-use, food-contact articles, the agency believes that its experience with the 43 food additive petitions is relevant to these threshold of regulation submissions and that approval of these submissions warrants a categorical exclusion.

In reviewing the petitions for components of repeat-use, food-contact articles, the agency's evaluation of environmental impact has traditionally included consideration of potential impacts relating to the disposal of the food-contact articles containing the additive. To determine the potential for significant introductions of substances into the environment at the sites of disposal of food additives that are used as components of the food-contact surfaces of permanent or semipermanent equipment, or of other repeat-use articles, the agency currently requires an estimate of the maximum yearly market volume for the proposed use of the additive. In reviewing abbreviated EA's for these additives, FDA found that these additives ordinarily have limited potential for causing significant environmental effects as a result of their use and disposal. The potential for significant introductions of substances to the environment due to disposal is, in fact, very low because of the long service life of the food-contact equipment or other repeat-use articles, of which additives in this class are components, and the limited market volumes of the additives as estimated by the petitioners. Because its actions on these petitions and requests will not significantly affect the environment, FDA will not ordinarily require the preparation of an EA.

d. *Proposed § 25.32(k).* FDA is proposing to categorically exclude actions to approve food additive, color additive, and GRAS affirmation petitions for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food. This proposed exclusion is based on FDA's experience reviewing 21 petitions in this class, all of which resulted in a FONSI. Examples of the types of additives and GRAS substances that belong to this class are the color additives added to foods listed in 21 CFR parts 73 and 74, most of the direct food additives listed in part 172 (21 CFR part 172), and certain GRAS substances listed in part 184 (21 CFR part 184). Examples of substances that are not included in the class for which this categorical exclusion is being proposed are the substances intended to replace macronutrients in food (such as sweetening agents intended to replace sugar, e.g., see §§ 172.800 and 172.804, and fat substitutes, e.g., § 184.1498).

The agency's evaluation of the environmental effects of substances added directly to food has included consideration of the potential for impacts from the disposal of human waste products containing the petitioned substance and/or its products of digestion and metabolism, and from the use of natural resources and energy.

The substances added directly to food considered here will be ingested by consumers as components of food containing these substances. After ingestion, these substances are either digested and/or metabolized to other substances or excreted largely intact. In all cases, the agency's review of past actions on substances added directly to food resulted in decisions to issue FONSI's. To address the potential for environmental impacts from disposal of this class of substances, the agency's FONSI's relied on one or more of the following scenarios: (1) The agency's approval of the petition resulted in very low levels (in the low ppb range or lower) of the substances in either effluents and/or sewage sludge from publicly owned wastewater treatment plants and these levels were determined not to be toxic to organisms in the environment; (2) the petitioned substance was digested and/or metabolized by¶humans such that only products of digestion and metabolism were expected to be excreted and these products were the same as (or very similar to) the products of digestion and metabolism resulting from human food; such products should have no potential for significant environmental effects because wastewater treatment facilities are already designed to handle them; or (3) the petitioned substance was excreted largely intact but was rapidly degraded into nontoxic products either in wastewater treatment plants or in the environment.

FDA's experience shows that substances added directly to food and intended to remain with food through ingestion that are the subject of new petitions will have use and disposal patterns similar to those described above and will not be toxic to organisms in the environment at the expected levels of exposure. Thus, use and disposal of such substances are not expected to result in significant environmental effects.

The agency has also found, as a result of its review of petitions for substances in the class being considered here, that

in no case was there potential for significant impacts on energy and natural resources. These findings relied on one or more of the following scenarios: (1) The substances were expected to compete with and replace other already regulated substances with no significant change in the overall use of natural resources or energy, (2) the substances are also used in nonfood contact situations and the food-contact usage represented a small increase in the overall production and usage of the substance such that the small increase in the uses of natural resources and energy was not significant, or (3) the predicted market volumes for the petitioned substances were very small so that the use of natural resources and energy for the petitioned substances was very limited. In no case did the agency find that there would be any effects on threatened or endangered species. Because the use and disposal of substances added directly to foods and intended to remain with foods through ingestion has no significant effect on the environment and has very limited potential for significant effects on energy and natural resources, EA's for these substances will not ordinarily be required.

e. *Proposed § 25.32(l).* FDA is proposing to categorically exclude actions to approve color additives used in contact lenses, sutures, polymethylmethacrylate filaments used in supporting haptics for intraocular lenses, bone cement, and in other FDA-regulated products that involve similar low levels of use. The agency reviewed EA's for 20 color additive petitions for these types of uses and found that all proposed uses involve small amounts of color additives. Because of the nature of these uses, the highest annual market volume encountered for any of these color additives was 12 kilograms (kg), while most of the petitioned uses involved considerably less than 5 kg. Consequently, the environmental introduction levels of the color additives from manufacture, use, and disposal would be exceedingly small. FDA's experience shows that petitions for color additives in these types of applications will have very low market volumes such that only extremely low levels of substances will be introduced into the environment and will not cause significant environmental effects. Therefore, FDA is proposing to categorically exclude actions on such petitions from the requirement to prepare an EA.

f. *Proposed § 25.32(m).* FDA is proposing to categorically exclude actions to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics, e.g., the withdrawal of approval for the use of a food or color additive, removal of the use of a substance from a GRAS list (21 CFR parts 182, 184, and 186), or prohibition of the use of a prior-sanctioned substance (defined under §§ 170.3(l) and 181.5(a)). The agency has prepared EA's for 12 actions to withdraw approval for the use of a food or color additive or to prohibit the use of a substance in food. The agency has prepared only one EIS for the withdrawal of approval of a food additive. In 1978, the agency prepared an EIS for its action to prohibit the use of certain chlorofluorocarbons in food, food additive, drug, animal food, animal drug, cosmetic, and medical device products as propellants in self-pressurized containers (43 FR 11301, March 17, 1978). The specified chlorofluorocarbons were prohibited because their continued use was predicted to result in the depletion of the stratospheric ozone layer. FDA prepared the EIS as part of an interagency effort to address this problem. CEQ determined that an EIS was necessary for this particular action because of the controversy surrounding the scientific issues associated with the potential effects of these chemicals on stratospheric ozone. The agency considers its action on chlorofluorocarbons to be an exception. It is the only action of this type that involved potentially significant effects on the environment.

The effect of withdrawing approval or prohibiting the use of a substance is to reduce or eliminate environmental exposure to that substance. Thus, no potential exists for direct adverse environmental effects from the agency's prohibition of the use of a substance. It may sometimes be necessary, however, to consider the potential indirect environmental effects that would result from increased use of substitutes for the prohibited substance. Since the agency began considering the environmental impact of its actions under NEPA, it has not found that significant adverse environmental effects would result from the increased use of a substitute for a food or color additive or other food substance that was being restricted. In the agency's evaluation of past actions in this class, the agency has found that there are frequently a number of substitutes for the prohibited substance. Thus, the increase in production, use, or disposal of substitutes is spread among a number of substances. Further, environmental exposure to any one substitute is minimal. In some cases, the agency has found that substitutes have been previously subjected to environmental review under NEPA by the agency, and that this review encompassed the use of the substitute as a replacement for the prohibited substance and resulted in an EA and FONSI being prepared. Any new food or color additive that may be developed to replace a prohibited one would undergo environmental review during the premarket approval process.

g. *Proposed § 25.32(n).* FDA is proposing to categorically exclude actions to issue, amend, or revoke regulations pertaining to infant formulas. FDA is proposing to exclude actions on infant formulas because they have little or no potential for adverse environmental effects. The preparation, distribution, and directions for use of infant formulas are carefully controlled by regulations in 21 CFR parts 106 and 107 and, along with other foods, by the CGMP regulations in 21 CFR part 110. In addition, the nature of this product, a food designed for infants, means that the product itself is very unlikely to cause adverse environmental impacts. Infant formulas are expected to be used and disposed of in a manner similar to other human food, but infant formulas form only a small fraction of the total human food supply since they are used only in the first year or 2 of human life. Therefore, it is unlikely that future actions on infant formulas will have potential for significant environmental effects, and thus, FDA is proposing to exclude them from the requirement to prepare an EA.

h. Proposed § 25.32(o). FDA is proposing to exclude actions to approve a food additive petition when an additive is the intended expression product(s) present in food derived from new plant varieties. The proposed exclusion is based on our determination that the USDA Animal and Plant Health Inspection Service (APHIS) has lead responsibility, under the Federal Plant Pest Act (7 U.S.C. 150aa *et seq.*), to prevent the movement and dissemination in the United States of plant pests. Under that authority, USDA APHIS addresses the potential of new plant varieties to pose a plant pest risk in accordance with the requirements mandated under NEPA. USDA considers the potential for risk in a very broad context, so that not only is direct disease or damage to plants and plant materials considered as a component of plant pest risk, but indirect effects on beneficial or other organisms in the agronomic context are also addressed. Before issuing a determination of nonregulated status for an organism that has been subject to USDA oversight because it was considered to present a

potential risk of being a plant pest, USDA conducts an environmental analysis in compliance with its NEPA requirements that addresses plant pest risk characteristics, disease and pest susceptibilities, expression of any introduced gene products and effects thereof, new enzymes, or changes to plant metabolism, weediness of the plant, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the plant on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information believed to be relevant to a determination. The issues considered by FDA are the same or a subset of the issues that USDA addresses as part of its NEPA review. Therefore, a NEPA review by FDA would be redundant.

i. *Proposed § 25.32(p).* FDA is proposing to categorically exclude actions under part 101 (21 CFR part 101) to issue, amend, or revoke a regulation in response to a reference amount petition (§ 101.12(h)), a nutrient content claim petition (§ 101.69), a health claim petition (§ 101.70), or a petition pertaining to the label declaration of ingredients (§ 101.103). The agency has regulations pertaining to various aspects of food labeling in part 101. These regulations include provisions that enable interested persons to petition the agency to issue regulations on several subjects related to labeling, listed above. These petitions must include, under current regulations, either a claim for categorical exclusion under current § 25.24 or an EA under current § 25.31.

Current § 25.24(a)(11) contains an exclusion for the establishment or repeal by regulation of labeling requirements for marketing articles, ''if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.'' The criteria are intended to ensure that the excluded labeling actions will not cause significant environmental effects. This exclusion can be used with petitions of the type listed above, if petitioners demonstrate that the criteria are met. For those actions that would not qualify for exclusion under current § 25.24(a)(11) because there will be an increase in the use of the product, FDA now believes that this increased use will not have significant environmental effects. Thus, the agency has determined that a specific unqualified categorical exclusion for petitions related to food labeling is appropriate.

When changes in the labeling on food products are allowed, there is a potential for changes in the levels of use, and in the intended uses, of such products or their substitutes. In fact, nutrient content claims and health claims are generally intended to increase the use of the labeled product. However, the changes that will result from FDA's actions on the types of petitions listed above will be modifications of the purchasing and consumption habits of consumers. A food labeled in the newly allowed manner will be purchased and consumed instead of another food that, for a variety of reasons, will not be labeled in this new manner. The net result will be the substitution of one food for a similar food. Thus, no significant adverse effects on the environment will result. Therefore, the agency is proposing that its future actions on petitions for the issuance, amendment, or revocation of regulations on reference amounts customarily consumed per eating occasion (§ 101.12(h)), on nutrient content claims (§ 101.69), on health claims (§ 101.70), and on the label declaration of ingredients (§ 101.103) be categorically excluded from the preparation of an environmental assessment.

j. *Proposed § 25.32(q).* FDA is proposing in § 25.32(q) to categorically exclude from the requirement to submit an EA actions to approve food additive petitions for substances registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.) for the same use requested in the petition. FDA has had limited experience in considering the environmental impact of threshold of regulation submissions for substances registered by EPA under FIFRA because the regulations establishing threshold of regulation policy were recently issued. However, because the information currently required for such submissions is identical to the information required for food additive petitions for these types of substances, the agency believes that its experience with food additive petitions is revelant. This proposed exclusion is based on FDA's experience reviewing 12 petitions in this class, all of which resulted in a FONSI. All of these petitions were for antimicrobial substances used either in the processing of food or in food-packaging materials.

FDA's evaluation of the potential environmental effects of antimicrobial substances has included consideration of potential impacts at the site of use and disposal of the antimicrobial substance, and from the use of natural resources and energy. Currently, for the use sites of antimicrobial substances, petitioners are directed to rely on information in studies submitted to EPA for registration of the product under FIFRA, and to describe any potential adverse environmental effects determined by EPA. Petitioners may submit a brief description and summary of results of EPA studies in lieu of the complete test reports. For use sites, FDA has based its environmental decision on a prediction of exposure levels, using introduction and fate information, that is compared with relevant toxicological data to determine the potential for significant environmental effects.

The agency's experience with antimicrobial petitions has been that, before an antimicrobial product can be used in food-contact situations, EPA will have already examined the environmental risks and benefits of registering the product under FIFRA. The parallel between EPA's review and FDA's environmental review is illustrated by FDA's finding that it has not had to require environmental testing for antimicrobial products because such tests were already conducted as part of EPA's review. In addition, antimicrobial substances that are used and discharged at point sources within the United States are subject to the requirements of National Pollution Discharge Elimination System (NPDES) permits under the Clean Water Act (33 U.S.C. 1251 et seq.). In registering a product under FIFRA, EPA requires the label to state that: (1) The product is not to be discharged into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of an NPDES permit and unless the permitting authority has been notified in writing prior to discharge; and (2) the product is not to be discharged to sewer systems without previously notifying the local sewage treatment plant authority. EPA also requires, if necessary, that labels contain information such as a warning of toxicity to fish and/or wildlife, as specified in 40 CFR 156.10(h)(2)(ii). Thus, FDA has found that its assessment of the fate and effects of antimicrobial substances essentially duplicates the review by EPA under FIFRA and, to some extent, the review by NPDES permitting authorities under the Clean Water Act.

Currently, petitioners must address the potential for impact on the use of natural resources and energy as required in an EA by specifying the natural resources and energy required to produce, transport, use, and/or dispose of a given amount of the product that is the subject of the action. FDA's experience with this area of potential impacts is that these types of substances almost always compete with and replace other similar substances so that there is

little or no change in the use of natural resources and energy. Thus, FDA believes that future food additive petitions for the same use as pesticides approved by EPA under FIFRA will have little or no potential for significant environmental impacts and that FDA's actions on these petitions warrant exclusion from the requirement to prepare an EA.

k. *Removal of action levels.* At the time the current environmental regulations were issued, the agency believed that the establishment of an action level required environmental review. Thus, the agency included a paragraph for the establishment of action levels in current § 25.22(a)(11) and specified an EA format in current § 25.31d. FDA also provided a categorical exclusion in current § 25.24(b)(6) for action levels for natural or unavoidable defects in food for humans or animals if these defects presented no health hazard.

In 1987, in a limited holding, the Court of Appeals for the D.C. Circuit in *Community Nutrition Institute* v. *Young*, 818 F.2d 943 (D.C. Cir. 1987), found that FDA was treating its action levels as substantive, legislative rules and, thus, action levels were subject to the notice-and-comment requirements of the Administrative Procedure Act (5 U.S.C. 551 et seq.). The court recognized, however, that FDA could proceed by action levels that are not binding rules. Since the court's holding, FDA has followed this approach. Under its statutory authority under 21 U.S.C. 342(a)(1), (a)(2)(A), and 346 to limit the amount of poisonous or deleterious substances in food, FDA establishes ''action levels'' to inform food producers of the level of contaminants in food that may result in regulatory action. Action levels are not intended to bind the public, or FDA, or to create or confer any rights, privileges, immunities, or benefits on or for any private person, but are intended merely for internal FDA guidance for deciding whether to bring an enforcement action. The establishment of an action level is not agency action and is not subject to NEPA.

Moreover, under CEQ regulations (40 CFR 1508.18(a)), bringing judicial, administrative, civil, or criminal enforcement actions is not major Federal action. Because establishment of action levels is intended merely for internal guidance for deciding whether to bring an enforcement action, establishment of an action level is not major Federal action.

Therefore, FDA is proposing to remove all references to action levels from part 25. The agency will continue to apply these regulations to the establishment of tolerances for poisonous or deleterious substances in food for human or animal consumption or in packaging materials intended for use with human food and animal feeds.

l. *Proposed § 25.32(r).* FDA is proposing to categorically exclude actions to approve a food additive, a color additive, or a GRAS affirmation petition for a substance that occurs naturally in the environment, when the action is not expected to alter significantly the concentration or distribution of the substance, its metabolites, or degradation products. This proposed exclusion is based on FDA's review of 19 petitions for substances in this class, all of which resulted in a finding of no significant impact.

The agency currently requires limited information for substances that occur naturally in the environment, as specified in the abbreviated EA format in current § 25.31a(b)(5). This format focuses on whether the use of the substance can reasonably be expected, on the basis of all available evidence, to alter significantly the concentration and distribution of the substance, its metabolites, or degradation products in the environment and on information about the environmental effects of substances expected to be emitted into the environment. From its review of 19 petitions, the agency has found that the use of naturally occurring substances as food additives, color additives, or GRAS substances did not alter significantly the concentration and distribution of the substance, its metabolites or degradation products in the environment, and therefore, substances emitted into the environment did not have adverse environmental effects.

Among the 19 petitions for naturally occurring substances reviewed by the agency were several petitions for substances intended to replace macronutrients in food. In § 25.32(k), FDA is not proposing to exclude from the requirement to prepare an EA petitions for substances intended to replace macronutrients. However, when a macronutrient replacement is also a substance that occurs naturally in the environment, the categorical exclusion proposed here will apply, unless the agency finds that extraordinary circumstances exist, as delineated in proposed § 25.21.

4. Veterinary Drugs and Feed Additives

The National Performance Report, ''Reinventing Food Regulations,'' January 1996, announced FDA's proposal to reduce the number of EA's submitted by industry under NEPA by increasing the number of categorical exclusions for actions relating to animal drugs, animal feeds, and food and color additives, which as a class have no individual or cumulative significant effects on the environment. As described below, in fulfillment of this commitment, FDA is proposing additional categorical exclusions for actions on animal drugs and feed additives that, based upon its experience in reviewing these types of actions, the Center for Veterinary Medicine (CVM) has concluded will not significantly affect the human environment.

Under proposed § 25.33(a), actions relating to new animal drug applications (NADA's), abbreviated applications, and supplements to such applications that do not increase the use and disposal of the substances are categorically excluded.

Proposed § 25.33(a) includes the categorical exclusions listed in current § 25.24(d)(1) and (d)(2), and broadens the categorical exclusion to allow FDA to categorically exclude other actions that do not result in increased use of a drug and, consequently, do not result in an increase in the expected level of environmental exposure. For example, the approval of a supplement for a new manufacturing site is not specifically listed but may be categorically excluded if it is not expected to result in increased use of the substance for which the supplement was submitted. Proposed § 25.33(a)(7) for animal drugs used in feeds is the same as current § 25.24(d)(2) but has been revised for clarity because FDA approves animal drugs for use in animal feeds.What about 512(m) and proposed 25.24(e)?

The categorical exclusions in proposed § 25.33(a) include actions relating to abbreviated new animal drug applications (ANADA's) in recognition of the creation of ANADA's under the 1988 Generic Animal Drug and Patent Term Restoration Act (GADPTRA) (21 U.S.C. 301 note). An ANADA is merely an abbreviated form of an NADA and seeks to effectuate the same action, approval of an animal drug. Therefore, the nature of environmental considerations is similar. For animal drugs not otherwise excluded in § 25.33(a), the agency is reserving § 25.33(b) to provide for a categorical exclusion analogous to that contained in proposed § 25.31(b) for human drugs. The categorical exclusion would be for actions that increase the use of an animal drug in the instance that the agency determines a level at or below which the concentration of the substance in the environment does not significantly affect the environment.

FDA recognizes that proposed § 25.31(b) for human drugs allows for a categorical exclusion for increased uses of human drugs if the concentration of the substance in the aquatic environment will be at or below 1 ppb. At this time, FDA is not adopting a specific environmental concentration from use of animal drugs because the agency is still conducting a retrospective review of environmental assessments for these products and a review of revelant environmental science. The Animal Health Institute and FDA/CVM held an Environmental Risk Assessment Workshop on February 20 and 21, 1996, to establish a comprehensive ecological risk assessment process for the evaluation of animal health products. Following this opportunity for public debate, and for drugs not otherwise excluded, FDA will adopt a risk assessment paradigm for determining environmental introductions for animal drugs and an environmental concentration at or below which no meaningful environmental effects are expected to occur.

Proposed 25.33(c) would categorically exclude any action on an NADA, abbreviated application, or a supplement to such actions for substances that occur naturally in the environment, when the action is not expected to alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. Currently, FDA's regulations require an abbreviated EA for an animal drug substance that occurs naturally in the environment. These abbreviated EA's require information about the production site and about whether the use of the product will significantly alter the concentration, distribution, and effect of the natural substance in the environment.

Since the publication of the NEPA regulations in 1985, FDA has reviewed abbreviated EA's for substances that are naturally occurring. FDA has found that actions on submissions for these substances will not affect the environment if the action will not significantly alter the concentration or distribution of the natural substance in the environment. Under these circumstances, the agency has prepared FONSI's.

Therefore, the proposed regulations would categorically exclude actions on an NADA, abbreviated application, or a supplement to such applications for substances that occur naturally in the environment when the action is not expected to alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. FDA has access to information regarding metabolites and degradation products to aid in determining if the categorical exclusion request is appropriate. Neither an EA nor an EIS would be required for such actions. When an action does alter significantly the concentration or distribution of the products, its metabolites, or degradation products in the environment, e.g., when the use and disposal will occur in a geographic area where the substance is not naturally occurring, an environmental assessment may be required.

Proposed § 25.33(d) includes categorical exclusions for actions relating to approval of applications for animal drugs intended for use in nonfood animals, for local or general anesthesia, for ophthalmic or topical applications, for the treatment of a disease occurring in minor species animals, as defined in § 514.1(d)(1)(i) (21 CFR 514.1(d)(1)(i)), and for use under prescription or veterinarian's order. Under current § 25.31a(b)(4), FDA requires abbreviated EA's to be submitted as part of any request for such approvals. These abbreviated EA's require environmental information for production sites. Since the publication of the NEPA regulation in 1985, CVM has reviewed many abbreviated EA's for these types of products. In every instance, the agency has prepared a FONSI because the manufacturing was determined to be in compliance and would remain in compliance with the Federal, State, and local environmental requirements that apply to the site of manufacturing, and the market volume for such products was so low that FDA found, based on its experience, the drugs would not significantly affect the environment. Furthermore, as the agency explains in section III.D. of this document, the agency has determined that ordinarily FDA will not consider potential impacts at the site of production.

The categorical exclusion for local and general anesthetic products applies only to those products that are administered individually. Some anesthetic products may be intended to be administered to many animals or in significant quantities. In these instances, potential environmental effects exist that require environmental analysis. The exclusion for ophthalmic and topical products is limited to those products intended for nonsystemic use. Products used systemically could result in greater environmental introductions that could potentially affect the environment and, therefore, require further environmental analysis. Furthermore, FDA is clarifying that the categorical exclusion for drugs for minor species applies only to those animal drugs that have been previously approved for use in another or the same species when similar animal management practices are used. When management practices are different, environmental introductions and impacts may also be different and require environmental analyses. Minor species include wildlife and endangered species (§ 514.1(d)(1)(ii)).

The categorial exclusion for animal drugs used under prescription or veterinarian's order applies only to animal drugs for therapeutic uses as defined in section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)). Based on its experience in reviewing EA's for these products, FDA has found that prescription products are generally administered individually to a limited number of animals for a limited amount of time. Therefore, there are no significant environmental effects. However, FDA may require an EA if the agency determines that there are extraordinary circumstances associated with the use of such a product.

Current § 25.24(d)(4) categorically excludes actions on an investigational new animal drug application (INAD) if the drug to be shipped under such notice is intended to be used for clinical studies or research in which wastes will be controlled or the amount of wastes expected to enter the environment may reasonably be expected to be nontoxic. Under proposed § 25.33(e), FDA would categorically exclude all actions on INAD's. In many cases, FDA's actions on INAD's do not significantly increase the use of the drug and, thus, the amount of drug introduced into the environment. Therefore, no changes in environmental effects will occur. In those cases where an increase in use of a drug may occur as a result of an investigation under an INAD, FDA's experience from reviewing many actions on INAD's shows that significant environmental effects will not occur because the use of such drugs is limited and controlled.

Proposed § 25.33(f) would categorically exclude actions on applications submitted under section 512(m) of the act (21 U.S.C. 360b(m)). FDA is proposing to exclude actions on such applications because they permit feed manufacturers to manufacture animal feed bearing or containing new animal drugs previously approved for use in feeds. The potential for environmental effects to occur is considered at the time the new animal drug is approved for use in feed. Therefore, there is no need to require an

additional EA each time the agency considers approval of an application submitted under section 512(m) of the act.

Current § 25.24(d)(3) categorically excludes withdrawals of approval of NADA's when the drug is no longer marketed or at the request of the application holder. Under proposed § 25.33(g), FDA would categorically exclude withdrawals of approval of ANADA's, as well as withdrawals of approval of NADA's, without conditions. FDA has determined that withdrawal of an NADA or ANADA approval does not significantly affect the environment because any change in introduction of the drug will generally be a decrease.

Under proposed § 25.33(h), FDA would categorically exclude actions to withdraw the approval for uses of food additives in animal feeds or to remove substances for use in animal feeds from the GRAS list or to remove substances from the GRAS list (parts 182, 184, or 186). Withdrawal or removal of a food additive substance that reduces or eliminates animal feed use will not significantly affect the environment because any change in introduction of the substance to the environment will generally be a decrease.

In those cases where the withdrawal of the NADA, ANADA, or FAP, or GRAS substance has resulted in the use of a substitute product, the agency has found in all instances that the increased use of the substitutes will not significantly affect the environment.

FDA is proposing to eliminate the categorical exclusions under current § 25.24(d)(5) and (d)(6) because FDA does not do testing and certification of batches of antibiotics for animal use, and FDA does not use monographs for animal drugs. FDA is proposing to eliminate current § 25.24(d)(7). This action takes place under an INAD, and its effect is to set the standard for approving ANADA's. FDA will determine whether it needs to consider environmental effects when it approves individual ANADA's.

5. Devices and Electronic Products

The agency is proposing to redesignate current § 25.24(e) as proposed § 25.34 and to remove criteria in § 25.24(e)(4) and (e)(7), now incorporated in proposed § 25.21 *Extraordinary circumstances*.

D. Subpart D—Preparation of Environmental Documents

The proposed rule would reorganize current subpart C of part 25 to improve the usefulness and readability of the current regulations.

Proposed § 25.40(b) would eliminate the EA and abbreviated EA formats and delete any reference to formats. After consultation with CEQ, the agency has decided to remove the standard formats from part 25, and to provide appropriate formats in guidance documents. Guidance documents, which do not bind the agency or the public, are more easily revised. Use of such documents will give FDA greater flexibility to tailor environmental documents to reflect state-of-the-art developments in environmental analysis and to assist companies in focusing on important environmental issues. Information/guidance concerning the nature and scope of information that an applicant or petitioner should submit in an EA may be obtained from the center responsible for the action subject to environmental evaluation (proposed § 25.40(c)).

In the Federal Register of January 11, 1996, FDA announced the availability of a guidance document entitled, ''Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements'' (61 FR 1031). The guidance, prepared by CDER, is intended to assist industry by providing guidance on how to prepare EA's for submission to CDER as part of NDA's, antibiotic applications, ANDA's, abbreviated antibiotic applications, and IND's. This guidance will be amended to reflect the final regulations and categorical exclusions and to include biologic products subject to licensure under the PHS Act. The guidance document employs a tiered approach to testing and accepts the use of test methods recognized and recommended by competent authorities such as FDA (see e.g., FDA's EA Technical Assistance Handbook), EPA (see 40 CFR parts 796 and 797) and the Organization for Economic Co-operation and Development. Under the proposed rule, this approach will continue to be acceptable.

The current formats in part 25 focus the environmental analysis on the use and disposal from use of FDA-regulated articles but also address production impacts. FDA proposes to maintain this focus in the proposed revised regulations, but, for the following reasons, is proposing to change the way it addresses production impacts. To address the potential environmental impacts from production of FDA-regulated articles, FDA currently requires a limited amount of information to make sure that the article will be produced in compliance with applicable emissions requirements. Specifically, the agency requires that the following information be included in an EA: A list of the substances expected to be emitted, the controls exercised, a citation of applicable emissions requirements and statement of compliance with these requirements, and a discussion of the effect the approval of the petition will have on compliance with these requirements.

FDA recognizes, however, that Federal, State, and local environmental protection agencies have the responsibility for issuing regulations, permitting and licensing facilities, and enforcing compliance with the requirements that these agencies have determined are necessary to ensure adequate protection of the environment from emissions from production operations. Regulating emissions from production sites requires balancing between air, water, and solid waste emissions for all production operations carried out at a production site and in the region with consideration of the costs of compliance and available technology that requires expertise found primarily in Federal, State, and local environmental agencies. As required by environmental regulations and/or as conditions of retaining licenses and permits, manufacturers must obtain or modify permits and provide information to these agencies when production operations are initiated or changed. The information required to be provided to FDA regarding production impacts and compliance with emission requirements is information that is generally required to be provided to or is known by other agencies whose responsibility is to monitor compliance.

FDA has reviewed hundreds of EA's in which information regarding the manufacturing site, such as emitted substances and emission controls, was provided. As a result of this review, FDA has found that FDA-regulated articles produced in compliance with all applicable emission requirements (e.g., Clean Air Act, Clean Water Act, Occupational Safety and Health Act) will not significantly affect the environment. Based on these findings, FDA has determined that it is no longer necessary to review a company's compliance with Federal, State, and local environmental laws and FDA is proposing to delete the requirements for the submission of emission information for production sites. Accordingly, under the proposed regulations, FDA will continue to focus its environmental reviews on the use and disposal from use of FDA-regulated articles, and FDA will no longer routinely require submission of information regarding manufacturing sites or a certification of compliance with Federal, State, and

local emission requirements. However, if information available to the agency or the applicant establishes that the general or specific emission requirements promulgated by Federal, State, or local environmental protection agencies do not address unique emission circumstances and the emissions may harm the environment, this would be sufficient grounds for requesting manufacturing information in an EA. FDA generally requires manufacturing information to be submitted as part of applications or petitions for FDA-regulated articles. This information will aid FDA in determining if a categorical exclusion request is appropriate.

Proposed § 25.40(a) includes additional information found in the CEQ regulations to clarify that the EA shall include brief discussions of the need for the proposal, alternatives, environmental impacts of the proposed action, and a listing of agencies and persons consulted, and include additional information to clarify the scope and focus of an EA. Environmental documents shall concentrate on timely and significant issues, not amass needless detail. To that end, the agency has included some general information regarding the acceptability of using a tiered testing scheme. A tiered testing scheme results in test termination when sufficient data are available to assess the potential environmental fate and effects of an FDA-regulated article in the environment. Specific information regarding tiered testing will be provided in guidance documents. Although the number of pages for any EA may vary in relation to the complexity of the issues, generally they should not exceed 30 pages, not including test reports and data.

The agency is proposing to add § 25.40(b) to clarify that CEQ regulations (40 CFR 1506.5(b)) place ultimate responsibility on FDA for the scope and content of environmental analyses. Thus, FDA may require additional information from applicants or may itself include additional information in environmental documents (EA's, FONSI's, or EIS's) when warranted. Proposed § 25.40(c) would include information found in current § 25.30(a) and encourages applicants or petitioners who submit EA's to FDA to consult with FDA regarding the appropriate scope and content for EA's for the requested action. Proposed § 25.40(d) discusses incorporation of information in an EA by reference.

Proposed § 25.41 would include information on FONSI's that is found in current § 25.32(a) and (c). The agency is proposing to delete the language on notices of intent and draft, final, and supplemental EIS's, found in current §§ 25.33 and 25.34, because the CEQ regulations describe the process for determining the scope of an EIS and provide detailed requirements for the preparation of draft and final EIS's. Thus, this information is duplicative and unnecessary in FDA regulations (40 CFR 1501.7 and part 1502).

Proposed § 25.42 would describe the subject matter that needs to be discussed in an EIS and references the CEQ regulations governing the requirements for preparation of an EIS. Proposed § 25.42(c) fulfills the CEQ requirement under 40 CFR 1502.9(c) that FDA adopt procedures for introducing a supplement into its administrative record.

The agency is proposing to add new § 25.43 to clarify the agency's existing responsibility under the CEQ regulations to prepare a concise public record of decision for cases requiring EIS's (40 CFR 1505.2).

Proposed § 25.44 would include information found in current § 25.10(b), describing the responsibilities of lead and cooperating agencies. The agency is proposing to delete duplicative and unnecessary information on lead and cooperating agencies that is already found in the CEQ regulations, and to delete the first sentence in current § 25.10(b) because it is self-evident that FDA will be the lead agency for programs administered by FDA.

Proposed § 25.45 would include information from current § 25.42, describing who the responsible agency official will be and his or her responsibilities. The agency is proposing to remove information in current § 25.42 that is duplicative of requirements already found in CEQ regulations.

E. Subpart E—Public Participation and Notification of Environmental Documents

The proposed rule would improve the usefulness and readability of the regulations by reorganizing current subpart D of part 25, ''agency decisionmaking'' (now proposed ''Public Participation and Notification of Environmental Documents'') by deleting unnecessary information that is duplicative of requirements found in the CEQ regulations, and, as discussed above, moving information to other relevant sections. Proposed subpart E would now address public participation in the NEPA process and clarify circumstances under which environmental documents will publicly be disclosed. These revisions are consistent with our responsibilities under the CEQ regulations and under Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations, February 11, 1994.

CEQ regulations require that agency procedures ensure full compliance with NEPA to the extent possible, unless existing law applicable to the agency's operations expressly prohibits or makes compliance impossible (40 CFR 1500.6). Proposed § 25.50 clarifies that laws governing public disclosure may limit FDA's ability to comply with NEPA and CEQ regulations.

Proposed § 25.51(a) and (b), public disclosure of FONSI's and EA's, would include the public disclosure information found in current § 25.30(b) and 25.41(b). The proposed rule would move the information relating to statutory time frames from current § 25.40(c) to proposed § 25.51(b)(1).

Proposed § 25.52 would add new information relating to the public disclosure of EIS's.

F. Subpart F—Other Requirements

Current subpart E will be renumbered as subpart F. The agency is not proposing to amend this subpart.

IV. Environmental Impact Considerations

The agency has determined under current 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an EA nor an EIS is required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96–354), 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 proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in

the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation). That act also requires (in section 205) that the agency identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost effective, or least burdensome alternative that achieves the objective of the rule. The following analysis demonstrates that this proposed rule is consistent with the principles set forth in the Executive Order and in these two statutes. The proposed rule is not an economically significant regulatory action under Executive Order 12866.

Based on the approximate number of EA's that FDA currently receives each year and the resources needed to prepare them, the agency estimates that the proposed reduced requirements for submitting EA's will result in an annual cost savings to industry of approximately $15.7 million. The basis for this estimate is as follows:

Human pharmaceuticals: Approximately 125 EA's related to human pharmaceuticals would be eliminated annually under the proposal. About one-half of these are abbreviated EA's; the remainder are full assessments. FDA assumes that the average cost of preparing an abbreviated assessment was approximately $40,000, while the average cost of a full assessment was approximately $200,000. These assumptions yield a cost savings of about $2.5 million for abbreviated EA's and $12.5 million for full EA's, for a total savings to industry from the reduced requirements of EA's relating to human pharmaceuticals of approximately $15 million per year.

Veterinary products: The proposed changes would eliminate approximately 37 abbreviated EA's for veterinary products each year, at an average cost of approximately $5,000 each. About 77 brief submissions, which currently require categorical exclusion criteria review, would also be eliminated; these cost an estimated $300 each to prepare. Total cost savings to the veterinary products industry under the proposal would thus be approximately $208,000 per year.

Food products: About 36 EA's per year received by CFSAN would be eliminated under the proposal. Approximately 28 of these would have been abbreviated EA's and 8 would have been full assessments under current rules. FDA estimates that the cost of producing most abbreviated EA's for CFSAN is approximately $2,500 and the average cost of producing a full EA is approximately $50,000. These assumptions imply an annual cost savings of approximately $70,000 for abbreviated EA's and $400,000 for full EA's, for a total annual savings to the foods industry of approximately $470,000.

In addition to these savings to industry, the proposed changes would improve FDA efficiency by eliminating agency review costs of approximately $1 million per year.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule of small entities. Because these regulations will not impose significant new costs on any firms, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

This proposed rule contains reporting requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 and 3507). Therefore, in accordance with 5 CFR part 1320, a description of reporting requirements with an estimate of the annual collection of information burden is given below by cross reference to existing FDA clearance submissions previously approved by OMB which this proposed rule affects.

FDA is soliciting comments 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 proposed collection of information; (3) evaluate 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.

Title: National Environmental Policy Act; Policies and Procedures.

Description: FDA has previously issued regulations that implement NEPA (part 25). The proposed rule would reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EIS nor an EA is required. FDA is also proposing to amend these regulations to ensure that the NEPA procedures are more concise and understandable to the public and to reflect current FDA policy with respect to environmental considerations. This proposed rule is in response to initiatives announced in the President's National Performance Reports, ''Reinventing Drug and Medical Device Regulations,'' April 1995, and ''Reinventing Food Regulations,'' January 1996.

Description of Respondents: Persons and businesses, including small businesses.

Estimated Annual Reporting and Recordkeeping Burden. The estimated burden associated with the information collection requirements for this proposed rule will be recognized in the individual FDA clearances where NEPA considerations apply. Listed below are those clearances affected by this regulation, including the section of title 21 CFR, the title, and the OMB approval number:

Section 10.30, Citizen Petitions, 0910–0183; § 71.1, Color Additive Petitions, 0910–0185; § 170.35, Affirmation of Generally Recognized As Safe (GRAS) Status, 0910–0132; § 101.12, Reference amounts customarily consumed per eating occasion, 0910–0286; § 101.69, Petitions for nutrient content claims, 0910–0288; § 101.70, Petitions for health claims, 0910–0287; § 170.39, Threshold of regulation for substances used in food-contact articles, 0910–0298; § 171.1, Food Additive Petitions, 0910–0016; § 312.23, Conditions for Exemption of New Drugs for Investigational Use, 0910–0014; § 511.1, New Animal Drugs for Investigational Use Exempt From Section 512(a) of the Act, 0910–0117; § 514.1, New Animal Drug Applications, 0910–0032; § 514.8, Supplemental New Animal Drug Applications, 0910–0032; § 571.1, Food Additive Petitions, 0910–0016; § 601.2 Product Licenses-Procedures for Filing, 0910–0124; § 812.20, Investigational Device Exemptions Application, 0910–0078.

The proposed rule would reduce these information collections that have already been reviewed and approved by the OMB.Reporting burdens imposed by current part 25 are approved by OMB through December 31, 1997 (see OMB control number 0910–0190, ''National Environmental Policy Act; Policy and Procedures—21 CFR Part 25'').

The agency has submitted copies of the proposed rule to OMB for its review of these reporting requirements. Interested persons are requested to send comments regarding information collection by May 3, 1996, to the Office of Information and Regulatory Affairs, OMB (address above).

List of Subjects in 21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 25 be revised to read as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

Subpart A—General Provisions

Sec.

Subpart B—Agency Actions Requiring Environmental Consideration

Subpart C—Categorical Exclusions

Subpart D—Preparation of Environmental Documents

Subpart E—Public Participation and Notification of Environmental Documents

Subpart F—Other Requirements

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 351, 354–361 of the Public Health Service Act (42 U.S.C. 262, 263b–264); 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 3 CFR, 1966-1970 Comp., p. 902, as amended by E.O. 11991, 3 CFR, 1977 Comp., p. 123; E.O. 12114, 3 CFR, 1979 Comp., p. 356.

Subpart A—General Provisions

§ 25.1 Purpose.

The National Environmental Policy Act of 1969 (NEPA), as amended, directs that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA. All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements. The regulations in this part implement section 102(2) of NEPA in a manner that is consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. This part also supplements the regulations for implementing the procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in 40 CFR Parts 1500 through 1508 and the procedures included in the ''HHS General Administration Manual, Part 30: Environmental Protection'' (45 FR 76519 to 76534, November 19, 1980).§ 25.5 *Terminology*.

(a) Definitions that apply to the terms used in this part are set forth in the CEQ regulations under 40 CFR part 1508. The terms and the sections of 40 CFR part 1508 in which they are defined follow:

(1) Categorical exclusion (40 CFR 1508.4).

(2) Cooperating agency (40 CFR 1508.5).

(3) Cumulative impact (40 CFR 1508.7).

(4) Effects (40 CFR 1508.8).

(5) Environmental assessment (EA) (40 CFR 1508.9).

(6) Environmental document (40 CFR 1508.10).

(7) Environmental impact statement (EIS) (40 CFR 1508.11).

(8) Federal agency (40 CFR 1508.12).

(9) Finding of no significant impact (40 CFR 1508.13).

(10) Human environment (40 CFR 1508.14).

(11) Lead agency (40 CFR 1508.16).

(12) Legislation (40 CFR 1508.17).

(13) Major Federal action (40 CFR 1508.18).

(14) Mitigation (40 CFR 1508.20).

(15) NEPA process (40 CFR 1508.21).

(16) Notice of intent (40 CFR 1508.22).

(17) Proposal (40 CFR 1508.23).

(18) Scope (40 CFR 1508.25).

(19) Significantly (40 CFR 1508.27).

(b) The following terms are defined solely for the purpose of implementing the supplemental procedures provided by this part and are not necessarily applicable to any other statutory or regulatory requirements:

(1) *Abbreviated application* applies to an abbreviated new drug application, an abbreviated antibiotic application, and an abbreviated new animal drug application.

(2) *Active moiety* means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex chelate or clathrate) of the molecule responsible for the physiological or pharmacological action of the drug substance.

(3) *Agency* means the Food and Drug Administration (FDA).

(4) *Increased use* of a drug or biologic product may occur if the drug will be administered at higher dosage levels, for longer duration or for different indications than were previously in effect, or if the drug is a new molecular entity. New molecular entity means a drug for which the active moiety (present as the unmodified (parent) compound, or an ester or a salt, clathrate, or other noncovalent derivative of the base (parent) compound) has not been previously approved or marketed in the United States for use in a drug product, either as a single ingredient or as part of a combination product or as part of a mixture of stereoisomers. The term ''use'' also encompasses disposal of FDA-regulated articles by consumers.

(5) *Responsible agency official* means the agency decisionmaker designated in part 5 of this chapter.

(c) The following acronyms are used in this part:

(1) CEQ—Council on Environmental Quality.

(2) CGMP—Current good manufacturing practice.

(3) EA—Environmental assessment.

(4) EIS—Environmental impact statement.

(5) The act—Federal Food, Drug, and Cosmetic Act.

(6) FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act.

(7) FONSI—Finding of no significant impact.

(8) GLP—Good laboratory practice.

(9) GRAS—Generally recognized as safe.

(10) HACCP—Hazard analysis critical control point.

(11) IDE—Investigational device exemption.

(12) IND—Investigational new drug application.

(13) INAD—Investigational new animal drug application.

(14) NADA—New animal drug application.

(15) NDA—New drug application.

(16) NEPA—National Environmental Policy Act of 1969.

(17) PDP—Product development protocol.

(18) PMA—Premarket approval application.

§ 25.10 Policies and NEPA planning.

(a) All FDA's policies and programs will be planned, developed, and implemented to achieve the policies declared by NEPA and required by CEQ's regulations to ensure responsible stewardship of the environment for present and future generations.

(b) Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time to ensure that planning and decisions reflect environmental values, to avoid delays later in the process, and to avoid potential conflicts.

(c) For actions initiated by the agency, the NEPA process will begin when the agency action under consideration is first identified. For actions initiated by applicants or petitioners, NEPA planning begins when FDA receives a submission from an applicant or petitioner seeking action by FDA. FDA may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potential significant environmental effects.

(d) Environmental documents shall concentrate on timely and significant issues, not amass needless detail.

(e) If a proposed action for which an EIS will be prepared involves possible environmental effects that are required to be considered under statutes or Executive Orders other than those referred to under ''AUTHORITY'' in this part, these effects shall be considered in the NEPA review, consistent with 40 CFR 1502.25 and the Department of Health and Human Services' General Administration Manual, part 30.

Subpart B—Agency Actions Requiring Environmental Consideration

§ 25.15 General procedures.

(a) All applications or petitions requesting agency action require the submission of an EA or a claim of categorical exclusion. A claim of categorical exclusion shall include a certification of compliance with the categorical exclusion criteria and shall certify that to the applicant's knowledge, no extraordinary circumstances exist. Failure to submit an adequate EA for an application or petition requesting action by the agency of a type specified in § 25.20, unless the agency can determine that the action qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34, is sufficient grounds for FDA to refuse to file or approve the application or petition.

(b) The responsible agency officials will evaluate the information contained in the EA to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS will be prepared. If significant effects requiring the preparation of an EIS are identified, FDA will prepare an EIS for the action in accordance with the procedures in subparts D and E of this part. If significant effects requiring the preparation of an EIS are not identified, resulting in a decision not to prepare an EIS, the responsible agency official will prepare a FONSI in accordance with § 25.41.

(c) Classes of actions that individually or cumulatively do not significantly affect the quality of the human environment ordinarily are excluded from the requirement to prepare an EA or an EIS. The classes of actions that qualify as categorical exclusions are set forth in §§ 25.30, 25.31, 25.32, 25.33, or 25.34.

(d) A person submitting an application or petition of a type subject to categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34, or proposing to dispose of an article as provided in §§ 25.30(d) or 25.32(h), is not required to submit an EA if the person certifies that the action requested qualifies for a categorical exclusion, citing the particular categorical exclusion that is claimed, and certifies that to the applicant's knowledge, no extraordinary circumstances exist.

§ 25.16 Public health and safety emergencies.

There are certain regulatory actions that, because of their immediate importance to the public health or safety, may make adherence to the procedural provisions of NEPA and CEQ's regulations impossible. For such actions, the responsible agency official shall consult with CEQ about alternative arrangements before the action is taken, or after the action is taken, if time does not permit prior consultation with CEQ.

§ 25.20 Actions requiring preparation of an environmental assessment.

Any proposed action of a type specified in this section ordinarily requires at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34:

(a) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved.

(b) Destruction or other disposition of articles condemned after seizure or whose distribution or use has been enjoined, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(c) Destruction or other disposition of articles following detention or recall at agency request, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(d) Disposition of FDA laboratory waste materials, unless categorically excluded in § 25.30(m).

(e) Intramural and extramural research supported in whole or in part through contracts, other agreements, or grants, unless categorically excluded in § 25.30(e) or (f).

(f) Establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in §§ 25.30(k) or 25.31(a), (b), (c), (h), (i), or (j), or 25.32(a) or (p).

(g) Issuance, amendment, and enforcement of FDA regulations, or an exemption or variance from FDA regulations, unless categorically excluded in §§ 25.30(h), (i), or (j), or 25.32(e), (g), (n), or (p).

(h) Withdrawal of existing approvals of FDA-approved articles, unless categorically excluded in §§ 25.31(d) or (k), 25.32(m), or 25.33(g) or (h).

(i) Approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, and granting of requests for exemption from regulation as a food additive, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

(j) Establishment of a tolerance for unavoidable poisonous or deleterious substances in food or in packaging materials to be used for food.

(k) Affirmation of a food substance as GRAS for humans or animals, on FDA's initiative or in response to a petition, under part 182, 184, 186, or 582 of this chapter and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, unless categorically excluded in § 25.32(f), (k), or (r).

(l) Approval of NDA's, abbreviated applications, applications for marketing approval for marketing of a biologic product, supplements to such applications, and actions on IND's, unless categorically excluded in § 25.31(a), (b), (c), (e), or (l).

(m) Approval of NADA's, abbreviated applications, supplements, and actions on INAD's, unless categorically excluded under § 25.33(a), (c), (d), or (e).

(n) Approval of PMA's for medical devices, notices of completion of PDP's for medical devices, authorizations to commence clinical investigation under an approved PDP, or applications for an

IDE, unless categorically excluded in § 25.34.

§ 25.21 Extraordinary circumstances.

As required under 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (see 40 CFR 1508.27 for examples of significant impacts). Examples of such extraordinary circumstances include:

(a) Actions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment; and

(b) Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law.

§ 25.22 Actions requiring the preparation of an environmental impact statement.

(a) There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS.

(b) EIS's are prepared for agency actions when evaluation of data or information in an EA or otherwise available to the agency leads to a finding by the responsible agency official that a proposed action may significantly affect the quality of the human environment.

Subpart C—Categorical Exclusions

§ 25.30 General.

The classes of actions listed in this section and §§ 25.31 through 25.34 are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Routine administrative and management activities, including inspections, and issuance of field compliance programs, program circulars, or field investigative assignments.

(b) Recommendation for an enforcement action to be initiated in a Federal court.

(c) Agency requests for initiation of recalls.

(d) Destruction or disposition of any FDA-regulated article condemned after seizure or the distribution or use of which has been enjoined or following detention or recall at agency request if the method of destruction or disposition of the article, including packaging material, is in compliance with all Federal, State, and local requirements.

(e) Extramural contracts, other agreements, or grants for statistical and epidemiological studies, surveys and inventories, literature searches, and report and manual preparation, or any other studies that will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment.

(f) Extramural contracts, other agreements, and grants for research for such purposes as to develop analytical methods or other test methodologies.

(g) Activities of voluntary Federal-State cooperative programs, including issuance of model regulations proposed for State adoption.

(h) Issuance, amendment, or revocation of procedural or administrative regulations and guidelines, including procedures for submission of applications for product development, testing and investigational use, and approval.

(i) Corrections and technical changes in regulations.

(j) Issuance of CGMP regulations, HACCP regulations, establishment standards, emergency permit control regulations, GLP regulations, and issuance or denial of permits, exemptions, variances, or stays under these regulations.

(k) Establishment or repeal by regulation of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.

(l) Routine maintenance and minor construction activities such as:

(1) Repair to or replacement of equipment or structural components (e.g., door, roof, or window) of facilities controlled by FDA;

(2) Lease extensions, renewals, or succeeding leases;

(3) Construction or lease construction of 10,000 square feet or less of occupiable space;

(4) Relocation of employees into existing owned or currently leased space;

(5) Acquisition of 20,000 square feet or less of occupiable space in a structure that was substantially completed before the issuance of solicitation for offers; and

(6) Acquisition of between 20,000 square feet and 40,000 square feet of occupiable space if it constitutes less than 40 percent of the occupiable space in a structure that was substantially completed before the solicitation for offers.

(m) Disposal of low-level radioactive waste materials (as defined in the Nuclear Regulatory Commission regulations at 10 CFR 61.2) and chemical waste materials generated in the laboratories serviced by the contracts administered by FDA, if the waste is disposed of in compliance with all applicable Federal, State, and local requirements.

§ 25.31 Human drugs and biologics.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NDA, abbreviated application, or a supplement to such application, or action on an OTC monograph, if the action does not increase the use of the active moiety.

(b) Action on an NDA, abbreviated application, or a supplement to such application, or action on an OTC monograph, if the action increases the use of the active moiety, but the concentration of the substance in the environment will be below 1 part per billion.

(c) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such application, or action on an OTC monograph, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Withdrawal of approval of an NDA or an abbreviated application.

(e) Action on an IND.

(f) Testing and certification of batches of an antibiotic or insulin.

(g) Testing and release by the Center for Biologics Evaluation and Research of lots or batches of a licensed biologic product.

(h) Issuance, revocation, or amendment of a monograph for an antibiotic drug.

(i) Establishment of bioequivalence requirements for a human drug or a comparability determination for a biologic product subject to licensing.

(j) Issuance, revocation, or amendment of a standard for a biologic product.

(k) Revocation of a license for a biologic product.

(l) Action on an application for marketing approval for marketing of a biologic product for transfusable human blood or blood components and plasma.

§ 25.32 Foods, food additives, and color additives.

The classes of actions listed in this section are categorically excluded and,

therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Issuance, amendment, or repeal of a food standard.

(b) Action on a request for exemption for investigational use of a food additive if the food additive to be shipped under the request is intended to be used for clinical studies or research.

(c) Approval of a color additive petition to change a provisionally listed color additive to permanent listing for use in food, drugs, devices, or cosmetics.

(d) Testing and certification of batches of a color additive.

(e) Issuance of an interim food additive regulation.

(f) Affirmation of a food substance as GRAS for humans or animals on FDA's initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter, and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, if the substance or food ingredient is already marketed in the United States for the proposed use.

(g) Issuance and enforcement of regulations relating to the control of communicable diseases or to interstate conveyance sanitation under parts 1240 and 1250 of this chapter.

(h) Approval of a request for diversion of adulterated or misbranded food for humans or animals to use as animal feeds.

(i) Approval of a food additive petition or the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter when the additive is present in finished food-packaging material at not greater than 5 percent-by-weight and is also a functional component of the finished packaging material.

(j) Approval of a food additive petition or the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter when the additive is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

(k) Approval of a food additive, color additive, or GRAS petition for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.

(l) Approval of a petition for color additives used in contact lenses, sutures, filaments used as supporting haptics in intraocular lenses, bone cement, and in other FDA-regulated products having similarly low levels of use.

(m) Action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics.

(n) Issuance, amendment, or revocation of a regulation pertaining to infant formulas.

(o) Approval of a food additive petition for the intended expression product(s) present in food derived from new plant varieties.

(p) Issuance, amendment, or revocation of a regulation in response to a reference amount petition as described in § 101.12(h) of this chapter, a nutrient content claim petition as described in § 101.69 of this chapter, a health claim petition as described in § 101.70 of this chapter, or a petition pertaining to the label declaration of ingredients as described in § 101.103 of this chapter.

(q) Approval of a food additive petition or the granting of a request for an exemption from regulation as a food additive under § 170.39 of this chapter for a substance registered by the Environmental Protection Agency under FIFRA for the same use requested in the petition.

(r) Approval of a food additive, color additive, or GRAS affirmation petition for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

§ 25.33 Animal drugs.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NADA, abbreviated application, or supplement to such applications, if the action does not increase the use of the drug. Actions to which this categorical exclusion applies include:

(1) An animal drug to be marketed under the same conditions of approval as a previously approved animal drug;

(2) A combination of previously approved animal drugs;

(3) A new premix or other formulation of a previously approved animal drug;

(4) Changes specified in § 514.8(a)(5), (a)(6), or (d) of this chapter;

(5) A change of sponsor;

(6) A previously approved animal drug to be contained in medicated feed blocks under § 510.455 of this chapter or as a liquid feed supplement under § 558.5 of this chapter; or

(7) Approval of a drug for use in animal feeds if such drug has been approved under § 514.2 or 514.9 of this chapter for other uses.

(b) [Reserved]

(c) Action on an NADA, abbreviated application, or a supplement for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Action on an NADA, abbreviated application, or a supplement to such applications, for:

(1) Drugs intended for use in nonfood animals;

(2) Anesthetics, both local and general, that are individually administered;

(3) Nonsystemic topical and ophthalmic animal drugs;

(4) Drugs for minor species, including wildlife and endangered species, when the drug has been previously approved for use in another or the same species where similar animal management practices are used; and

(5) Drugs intended for use under prescription or veterinarian's order for therapeutic use.

(e) Action on an INAD.

(f) Action on an application submitted under section 512(m) of the act.

(g) Withdrawal of approval of an NADA or an abbreviated NADA.

(h) Withdrawal of approval of a food additive petition that reduces or eliminates animal feed uses of a food additive.

§ 25.34 Devices and electronic products.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on a device premarket notification submission under subpart E of part 807 of this chapter.

(b) Classification or reclassification of a device under part 860 of this chapter.

(c) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard.

(d) Approval of a PMA or a notice of completion of a PDP or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device.

(e) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(f) Issuance of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(g) Action on an application for an IDE or an authorization to commence a clinical investigation under an approved PDP.

(h) Issuance of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

Subpart D—Preparation of Environmental Documents

§ 25.40 Environmental assessments.

(a) As defined by CEQ in 40 CFR 1508.9, an EA is a concise public document that serves to provide sufficient evidence and analysis for an agency to determine whether to prepare an EIS or a FONSI. The EA shall include brief discussions of the need for the proposal, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted. An EA shall be prepared for each action not categorically excluded in §§ 25.30, 25.31, 25.32, 25.33, or 25.34. The EA shall focus on relevant environmental issues and shall be a concise, objective, and well-balanced document that allows the public to understand the agency's decision. If potentially adverse environmental impacts are identified for an action or group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The use of a scientifically justified tiered testing approach, in which testing may be stopped when the results suggest that no significant impact will occur, is an acceptable approach.

(b) Generally, FDA requires an applicant to prepare an EA and make necessary corrections to it. Ultimately, FDA is responsible for the scope and content of EA's and may include additional information in environmental documents when warranted.

(c) Information concerning the nature and scope of information that an applicant or petitioner shall submit in an EA may be obtained from the center or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA EA guidance documents, which provide additional advice on how to comply with FDA regulations.

(d) Consistent with 40 CFR 1500.4(j) and 1502.21, EA's may incorporate by reference information presented in other documents that are available to FDA and to the public.

(e) The agency evaluates the information contained in an EA and any public input to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS or FONSI will be prepared. The responsible agency official designated in part 5 of this chapter as responsible for the underlying action examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action.

§ 25.41 Findings of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a FONSI is a document prepared by a Federal agency stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) The agency official(s) responsible for approving the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusion not to prepare an EIS for the action under consideration.

§ 25.42 Environmental impact statements.

(a) As defined by CEQ regulations (40 CFR 1508.11) and section 102(2)(C) of NEPA, an EIS should be a clear, concise, and detailed written statement describing:

(1) The environmental impacts of a proposed action;

(2) Any adverse effects that cannot be avoided if the action is implemented;

(3) Alternatives to the action;

(4) The relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity; and

(5) Any irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented.

(b) The CEQ regulations (40 CFR 1501.7 and part 1502) describe the process for determining the scope of an EIS and provide detailed requirements for the preparation of draft and final EIS's. CEQ format and procedures for preparing EIS shall be followed.

(c) Under the conditions prescribed in 40 CFR 1502.9, the agency will prepare a supplement for a draft or final EIS and introduce the supplement into the administrative record.

§ 25.43 Records of decisions.

(a) In cases requiring environmental impact statements, at the time of its decision, the agency shall prepare a concise public record of decision.

(b) The record of decision shall:

(1) State what the decision was;

(2) Identify and discuss alternatives considered by the agency in reaching its decision;

(3) State whether all practicable means to avoid or minimize environmental harm have been adopted, and if not, why not; and

(4) Discuss and implement any monitoring and enforcement program necessary to affect mitigation.

§ 25.44 Lead and cooperating agencies.

For actions requiring the preparation of an EIS, FDA and other affected Federal agencies will agree which will be the lead agency and which will be the cooperating agencies. The responsibilities of lead agencies and cooperating agencies are described in the CEQ regulations (40 CFR 1501.5 and 1501.6, respectively). If an action affects more than one center within FDA, the Commissioner of Food and Drugs will designate one of these units to be responsible for coordinating the preparation of any required environmental documentation.

§ 25.45 Responsible agency official.

(a) The person designated in part 5 of this chapter as the responsible agency official for the underlying action is responsible for preparing environmental documents or ensuring that they are prepared.

(b) The responsible agency official will weigh any environmental impacts of each alternative course of action, including possible mitigation measures, and will balance environmental impacts with the agency's objectives in choosing an appropriate course of action. The weighing of any environmental impacts of alternatives in selecting a final course of action will be reflected in the agency's record of formal decisionmaking as required by 40 CFR 1505.2.

Subpart E—Public Participation and Notification of Environmental Documents

§ 25.50 General information.

(a) To the extent actions are not protected from disclosure by existing law applicable to the agency's operation, FDA will involve the public

in preparing and implementing its NEPA procedures and will provide public notice of NEPA-related hearings, public meetings, and the availability of environmental documents.

(b) Many FDA actions involving investigations, review, and approval of applications, and premarket notifications for human drugs, animal drugs, biologic products, and devices are protected from disclosure under the Trade Secret Act, 18 U.S.C. 1905, and 301(j) of the act. These actions are also protected from disclosure under FDA's regulations including part 20, §§ 312.130(a), 314.430(b), 514.11(b), 514.12(a), 601.50(a), 601.51(a), 807.95(b), 812.38(a), and 814.9(b) of this chapter. Even the existence of applications for human drugs, animal drugs, biologic products, and devices is protected from disclosure under these regulations. Therefore, unless the existence of applications for human drugs, animal drugs, biologic products, or premarket notification for devices has been made publicly available, the release of the environmental document before approval of human drugs, animal drugs, biologic products, and devices is inconsistent with statutory requirements imposed on FDA. Appropriate environmental documents, comments, and responses will be included in the administrative record to the extent allowed by applicable laws.

§ 25.51 Environmental assessments and findings of no significant impact.

(a) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in the portion of environmental documents that is made public. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner shall submit such data and information separately in a confidential section We have spend 20 years trying to keep confidential information out of Eas. I suggest the preceding revision. Gail said she prefers confidential appendix to the EA.and shall summarize the confidential data and information in the EA to the extent possible.

(b) FONSI's and EA's will be available to the public in accordance with 40 CFR 1506.6 as follows:

(1) When the proposed action is the subject of a notice of proposed rulemaking or a notice of filing published in the Federal Register, the notice shall state that no EIS is necessary and that the FONSI and the EA are available for public inspection at FDA's Dockets Management Branch. If the responsible agency official is unable to complete environmental consideration of the proposed action before a notice of filing of a food or color additive petition is required to be published under the act, and if the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the Federal Register document publishing the final regulation rather than the notice of filing shall state that no EIS is necessary and that the FONSI and the EA are available upon request and filed in FDA's Dockets Management Branch.

(2) For actions for which notice is not published in the Federal Register, the FONSI and the EA shall be made available to the public upon request according to the procedures in 40 CFR 1506.6.

(3) For a limited number of actions, the agency may make the FONSI and EA available for public review (including review by State and areawide information clearinghouses) for 30 days before the agency makes its final determination whether to prepare an EIS and before the action may begin, as described in 40 CFR 1501.4(e). This procedure will be followed when the proposed action is, or is closely similar to, one that normally requires an EIS or when the proposed action is one without precedent.

§ 25.52 Environmental impact statements.

(a) If FDA determines that an EIS is necessary for an action involving investigations or approvals for drugs, animal drugs, biologic products, or devices, an EIS will be prepared but will become available only at the time of the approval of the product. Disclosure will be made in accordance with 40 CFR 1506.6 and part 20 of this chapter. The EIS will in all other respects conform to the requirements for EIS's as specified in 40 CFR part 1502 and 1506.6(f).

(b) Comments on the EIS may be submitted after the approvalof the drug, animal drug, biologic product, and device. Those comments can form the basis for the agency to consider beginning an action to withdraw the approval of applications for a drug, animal drug, biologic product, or to withdraw premarket notifications or premarket approval applications for devices.

(c) In those cases where the existence of applications and premarket notifications for drugs, animal drugs, biologic products, or devices has already been disclosed before the agency approves the action, the agency will make diligent effort (40 CFR 1506.6) to involve the public in preparing and implementing the NEPA procedures for EIS's while following its own disclosure requirements including those listed in part 20, §§ 312.130(b), 314.430(d), 514.11(d), 514.12(b), 601.51(d), 807.95(e), 812.38(b), and 814.9(d) of this chapter.

(d) Draft and final EIS's, comments, and responses will be included in the administrative record and will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

Subpart F—Other Requirements

§ 25.60 Environmental effects abroad of major agency actions.

(a) In accordance with Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions'' of January 4, 1979 (44 FR 1957, January 9, 1977), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

(1) Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere.

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine in accordance with section 2–3 of the Executive Order whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine in accordance with section 2–4(a) and (b) of the Executive Order, whether the subject action calls for:

(1) An EIS;

(2) A bilateral or multilateral environmental study; or

(3) A concise environmental review.

(d) In preparing environmental documents under this subpart, the responsible official shall:

(1) Determine, as provided in section 2–5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and

modification in contents, timing, and availability of documents.

(2) Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.

Dated: March 19, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–8090 Filed 4–2–96; 8:45 am]

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Federal Register

Wednesday
April 3, 1996

Part IV

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Part 15, et al.
Federal Acquisition Regulations (FAR): Withdrawal of Proposals; Proposed Rule

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 15, 17, 31, and 52

[FAR Cases 90–52, 91–018, 95–008, and 92–024]

RINs 9000–AE21, 9000–AE65, 9000–AG67, and 9000–AG53

Federal Acquisition Regulation; Withdrawal of Proposals

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council have decided to withdraw four proposed rules published in the Federal Register as follows:

FAR Case 90–52, Evaluation Factors (55 FR 46930, November 7, 1990). This rule proposed an amendment to the Federal Acquisition Regulation (FAR) to state, among other things, that quality must be considered in planning every source selection and, if appropriate, included as an evaluation factor. A final rule, 93–002, Past Performance Information, was published in the Federal Register at 60 FR 16718, March 31, 1995. The final rule revised the FAR in a manner which meets the intent of the proposed rule concerning evaluation factors, by allowing ''quality'' to be addressed through inclusion in one or more of the non-cost evaluation factors or subfactors (i.e., past performance). Therefore, the proposed rule is withdrawn.

FAR Case 91–018, Special Contracting Methods (Multiyear Contracting) (56 FR 20507, May 3, 1991). This rule proposed amendments to the FAR concerning multiyear solicitations and contracts. The case has been superseded by FAR Case 94–712, Multiyear Contracting, which implements Sections 1022 and 1072 of the Federal Acquisition Streamlining Act of 1994 (Pub. L. 103–355). Therefore, the proposed rule is withdrawn.

FAR Case 95–008, Competitive Range (60 FR 56035, November 6, 1995). This rule proposed an amendment to the FAR to delete the statement that a proposal should be included in the competitive range. Section 4203 of the 1996 DoD Authorization Act. (Public Law 104–106) contains authority for establishing more flexibility in determining competitive ranges. The Councils believe that the DOD Procurement Process Reform Process Action Team's recommended FAR change would not be best addressed under the more general revisions that will arise from implementation of the acquisition reform provisions of the 1996 DOD Authorization Act. Therefore, the proposed rule is withdrawn.

FAR Case 92–024, Employee Stock Ownership Plans (60 FR 56216, November 7, 1995). This rule proposed revisions to the FAR to ensure uniform treatment on the allowability of costs of all employee stock ownership plans (ESOPs), irrespective of whether the ESOP is structured as a pension plan or as deferred compensation,including making the interest costs of leveraged ESOPs expressly unallowable.

The respondents expressed concerns that the rule, as currently written, would (1) inhibit the establishment of new ESOPs and the expansion of existing ESOPs by Government contractors, and (2) adversely impact the financial condition of Government contractors with existing ESOPs. Therefore, this rule has been withdrawn.

FOR FURTHER INFORMATION CONTACT: Ms. Beverly Fayson, FAR Secretariat, Room 4037, GS Building, Washington, DC 20405 (202) 501–4755.

List of Subjects in 48 CFR Parts 15, 17, 31, and 52

Government procurement.

Dated: March 27, 1996.

Edward C. Loeb,

Director, Federal Acquisition Policy Division.

[FR Doc. 96–8016 Filed 4–2–96; 8:45 am]

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Federal Register

Wednesday
April 3, 1996

Part V

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Parts 9, 35, and 37
Federal Acquisition Regulation; OFPP Policy Letter 93–1, Management Oversight of Service Contracting; Proposed Rule

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 9, 35, and 37

[FAR Case 94–008]

RIN 9000–AG86

Federal Acquisition Regulation; OFPP Policy Letter 93–1, Management Oversight of Service Contracting

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council are proposing amendments to the Federal Acquisition Regulation to provide agency guidance on the management of service contracts. This regulatory action was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

DATES: Comments should be submitted on or before June 3, 1996 to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets, NW, Room 4037, Washington, DC 20405. Please cite FAR case 94–008 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: Mr. Peter O'Such at (202) 501–1759 in reference to this FAR case. For general information, contact the FAR Secretariat, Room 4037, GS Building, Washington, DC 20405 (202) 501–4755. Please cite FAR case 94–008.

SUPPLEMENTARY INFORMATION:

A. Background

On May 24, 1994, the Office of Federal Procurement Policy (OFPP) reissued, as a final policy letter, and published in the Federal Register (59 FR 26818), Policy Letter 93–1, entitled ''Management Oversight of Service Contracting''. The policy letter provides Governmentwide guiding principles which are intended to improve the acquisition, management, and administration of service contracts.

The proposed FAR rule removes references to advisory and assistance services at 9.505–3; removes the reference to OMB Circular No. A–120, ''Guidelines for the Use of Advisory and Assistance Services'' from 35.017–2(i); clarifies 37.000; adds paragraphs (d) through (g) to 37.102 to address additional agency responsibilities concerning service contracts in general; and adds a new Subpart 37.5, Management Oversight of Service Contracts, to address FAR implementation of OFPP Policy Letter 93–1.

B. Regulatory Flexibility Act

The proposed changes may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because it implements OFPP Policy Letter 93–1, Management Oversight of Service Contracting, which establishes Governmentwide policies concerning contracting for services. These changes will affect the manner in which Federal agencies will develop requirements for, award, manage, and administer contracts for services which, in turn, will affect each small entity which is awarded a contract for services. An Initial Regulatory Flexibility Analysis (IRFA) has been prepared and will be provided to the Chief Counsel for Advocacy for the Small Business Administration. A copy of the IRFA may be obtained from the FAR Secretariat. Comments are invited. Comments from small entities concerning the affected FAR subpart will be considered in accordance with 5 U.S.C. 610. Such comments must be submitted separately and should cite 5 U.S.C. 601, *et seq.* (FAR Case 94–008), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed changes to the FAR do not impose recordkeeping or information collection requirements, or collections of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 9, 35, and 37

Government procurement.

Dated: March 26, 1996.

Edward C. Loeb,

Director, Federal Acquisition, Policy Division.

Therefore, it is proposed that 48 CFR Parts 9, 35, and 37 be amended as set forth below:

1. The authority citation for 48 CFR Parts 9, 35, and 37 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 9—CONTRACTOR QUALIFICATIONS

2. Section 9.505–3 is revised to read as follows:

9.505–3 Providing evaluation services.

Contracts for the evaluation of offers for products or services shall not be awarded to a contractor that will evaluate its own offers for products or services, or those of a competitor, without proper safeguards to ensure objectivity to protect the Government's interests.

PART 35—RESEARCH AND DEVELOPMENT CONTRACTING

3. Section 35.017–2 is amended by revising paragraph (i) to read as follows:

35.017–2 Establishing or changing an FFRDC.

* * * * *

(i) Quantity production or manufacturing is not performed unless authorized by legislation.

* * * * *

PART 37—SERVICE CONTRACTING

4. Section 37.000 is revised to read as follows:

37.000 Scope of part.

This part prescribes policy and procedures which are specific to the acquisition and management of services by contract. This part applies to all contracts for services regardless of the type of contract or kind of service being acquired. Additional guidance for research and development services is in part 35; architect-engineering services is in part 36; information resources is in part 39; and transportation services is in part 47. Parts 35, 36, 39, and 47 take precedence over this part in the event of inconsistencies. This part includes, but is not limited to, contracts for services to which the Service Contract Act of 1965, as amended, applies (see subpart 22.10).

5. Section 37.102 is amended by adding paragraphs (d) through (g) to read as follows:

37.102 Policy.

* * * * *

(d) Agency program officials are responsible for accurately describing the need to be filled, or problem to be resolved, through service contracting in a manner that assures full understanding and responsive performance by contractors and in so doing, should obtain assistance from contracting officials, as needed;

(e) Agencies shall establish effective management practices in accordance with the OFPP Policy Letter 93–1, Management Oversight of Service Contracting, to prevent fraud, waste, and abuse in service contracting.

(f) Services are to be obtained in the most cost-effective manner, without barriers to full and open competition, and free of any potential conflicts of interest.

(g) Agencies shall ensure that sufficiently trained and experienced officials are available within the agency to manage and oversee the contract administration function.

6. Subpart 37.5 is added to read as follows:

Subpart 37.5—Management Oversight of Service Contracts

Sec.
37.500 Scope of subpart.
37.501 Definition.
37.502 Exclusions.
37.503 Agency-head responsibilities.
37.504 Contracting officials responsibilities.

37.500 Scope of subpart.

This subpart establishes responsibilities for implementing Office of Federal Procurement Policy (OFPP) Policy Letter 93–1, Management Oversight of Service Contracting.

37.501 Definition.

Best practices, as used in this subpart, means techniques that agencies may use to help detect problems in the acquisition, management and administration of service contracts. Best practices are practical techniques gained from experience that agencies may use to improve the procurement process.

37.502 Exclusions.

(a) This subpart does not apply to services that are (1) obtained through personnel appointments and advisory committees; (2) obtained through personal service contracts authorized by statute; (3) for construction as defined in FAR 36.102; or (4) obtained through interagency agreements where the work is being performed by in-house Federal employees.

(b) Services obtained under contracts below the simplified acquisition threshold and services incidental to supply contracts are excluded from coverage of this subpart. Good management practices and contract administration techniques should be used regardless of the contracting method.

37.503 Agency-head responsibilities.

The agency head or designee should ensure that—

(a) Requirements for services are clearly defined and appropriate performance standards are developed so that the agency's requirements can be understood by potential offerors and that performance in accordance with contract terms and conditions will meet the agency's requirements.

(b) Service contracts are awarded and administered in a manner that will provide the customer its goods and services within budget and in a timely manner.

(c) Specific procedures are in place before contracting for services to assure compliance with OFPP Policy Letters 92–1, Inherently Governmental Functions, 91–2, Service Contracting, and 89–1, Conflicts of Interest Policies Applicable to Consultants.

(d) Strategies are developed and necessary staff training is initiated to assure effective implementation of the policies in FAR 37.102.

37.504 Contracting officials responsibilities.

Contracting officials should ensure that ''best practices'' techniques are used when contracting for services and in contract management and administration (see OFPP Policy Letter 93–1).

[FR Doc. 96–8015 Filed 4–2–96; 8:45 am]

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