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Presidential Documents

Title 3—

The President

Proclamation 7491 of October 30, 2001

Veterans Day, 2001

By the President of the United States of America

A Proclamation

Two hundred and twenty-five years ago, the signers of the Declaration of Independence declared that ''all Men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty, and the Pursuit of Happiness.''

Throughout the course of American history, courageous men and women have taken up arms to secure, defend, and maintain these core principles upon which our Nation's freedoms depend. On September 11, 2001, terrorists ruthlessly attacked our land and these freedoms. The terrorists' deluded attempt to assail our spirit failed, and our Nation's response reveals that the spirit of freedom is as strong as ever. Our troops are now fighting overseas to defeat terrorism, and, in that effort, they follow in the footsteps of the 48 million men and women who, since our Nation's founding, have stepped forward to defend our land.

Today, there are more than 25 million living veterans who served our Nation in times of peace and war. Many of them willingly entered harm's way to fight for our freedoms. These veterans have diverse religious beliefs and come from varying backgrounds and ethnicities. By their service, they kept America strong, and they have protected our way of life from tyranny's grip for over two centuries. At this moment, men and women of the Army, Navy, Air Force, Marines, and Coast Guard are serving around the world. They represent our resolute dedication to achieving a lasting peace out of the new challenges and threats of the 21st century.

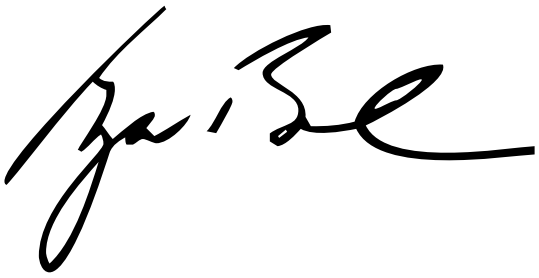
On Veterans Day, let us pause to reflect on the sacrifices of all of those who have put on the uniform to serve in the United States military. Let us honor our veterans, who proved their heroism and love of country time and again, from Yorktown and Gettysburg to Iwo Jima and the Persian Gulf. They consistently defended our ideals across the globe; and they continue to inspire those who defend America today, half a world away. More than a million have died in service to America; and more than a million and a half have been wounded. Some sustained serious injuries in combat and now live with disabilities. Our Nation will always be grateful for the noble sacrifices made by these veterans. We can never adequately repay them. But we can honor and respect them for their service.

As we consider the sacrifices and efforts of our veterans, we must never forget that freedom comes at a cost. Therefore, I ask all schools to observe November 11 through November 17, 2001, as National Veterans Awareness Week, and to invite a veteran to speak at their school. This ''Lessons in Liberty'' initiative will serve to honor America's veterans, while reminding young people of the strong principles upon which our Nation is founded. Our veterans have much to share with our young people about liberty, patriotism, democracy, and independence. They are living examples of the timeless truth that freedom is not free. I call upon our veterans to serve our country in a different way, by teaching a new generation of young Americans the importance of the liberties they helped secure.

In respect and recognition of the contributions our service men and women have made to the cause of peace and freedom, the Congress has provided (5 U.S.C. 6103 (a)) that November 11 of each year shall be set aside as a legal public holiday to honor veterans.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, do hereby proclaim November 11, 2001, as Veterans Day and urge all Americans to observe November 11 through November 17, 2001, as National Veterans Awareness Week. I urge all Americans to recognize the valor and sacrifice of our veterans through appropriate public ceremonies and private prayers. I call upon Federal, State, and local officials to display the flag of the United States and to encourage and participate in patriotic activities in their communities. I invite civic and fraternal organizations, places of worship, schools, businesses, unions, and the media to support this national observance with suitable commemorative expressions and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of October, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-sixth.



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Rules and Regulations

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

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR PART 630

RIN 3206–AJ51

Absence and Leave; Use of Restored Annual Leave

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management is issuing interim regulations to aid agencies and employees responding to the ''National Emergency by Reason of Certain Terrorist Attacks'' on the World Trade Center and the Pentagon. The regulations provide that employees who would forfeit excess annual leave because of their work to support the nation during the national emergency will be deemed to have scheduled their excess annual leave in advance. Such employees will be entitled to restoration of their annual leave under these regulations.

DATES: The interim regulations are effective on December 3, 2001. Comments must be received on or before January 2, 2002.

ADDRESSES: Comments may be sent or delivered to Donald J. Winstead, Assistant Director for Compensation Administration, Workforce Compensation and Performance Service, Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415, FAX: (202) 606–0824, or e-mail: *payleave@opm.gov*.

FOR FURTHER INFORMATION CONTACT: Sharon A. Herzberg, (202) 606–2858.

SUPPLEMENTARY INFORMATION: On September 14, 2001, President Bush declared a ''National Emergency by Reason of Certain Terrorist Attacks'' on the World Trade Center and the Pentagon. The unprecedented events of September 11, 2001, the efforts toward recovery and response, and the continuing and immediate threat of further attacks on the United States have found many Federal agencies involved in activities vital to our nation. The Office of Personnel Management (OPM) is issuing these regulations to assist Federal employees who would lose entitlement to excess annual leave because of their involvement in national emergency efforts. These interim regulations simplify the restoration of employees' forfeited annual leave and impose relaxed time limitations for using restored annual leave. The procedures established by these interim regulations are similar to those established at 5 CFR 630.309 for employees who were deemed essential to the Year 2000 (Y2K) computer conversion.

Section 6304 of title 5, United States Code, establishes limitations on the amount of annual leave an employee may carry over from one leave year to the next. Most employees can carry over no more than 240 hours of annual leave to the next leave year. However, 5 U.S.C. 6304(d)(1)(b) also provides that excess annual leave lost as a result of ''exigencies of the public business when the annual leave was scheduled in advance'' may be restored to the affected employee. For the purpose of Federal leave administration, an exigency of the public business occurs when there is a pressing need for an employee's service and his or her pre-approved annual leave must be canceled because there are no other practical alternatives available to accomplish the work by a given deadline.

Many employees in Federal agencies are essential to on-going efforts to cope with the national emergency. As a result, many of these employees will be faced with the possible forfeiture of ''use or lose'' annual leave because they must remain on the job to guarantee the fulfillment of the agencies' missions during this critical period and beyond. Under the normal rules, agencies would be faced with the administrative burden of scheduling, canceling, and restoring such leave for these employees at a time when all available attention and energy should be focused on the national emergency.

The ''National Emergency by Reason of Certain Terrorist Attacks'' constitutes an exigency of the public business under 5 U.S.C. 6304(d)(1)(b), which justifies the restoration of any forfeited annual leave in excess of the maximum allowable limits. Since it is known in advance that it is not possible for employees involved in the national emergency to be absent on leave, the scheduling and canceling of such leave places an unnecessary administrative burden on the employees and agencies involved. In support of both agencies' and employees' needs, we are simplifying the procedures for restoring annual leave forfeited as a result of the national emergency. Section 630.311(a) of title 5, Code of Federal Regulations, will deem the ''National Emergency by Reason of Certain Terrorist Attacks'' an exigency of the public business. In addition, under § 630.311(b), annual leave forfeited in a leave year as a result of the national emergency will be deemed to have been scheduled in advance for the purpose of satisfying the requirements in 5 U.S.C. 6304(d) and 5 CFR 630.308. Therefore, annual leave forfeited at the end of a leave year as a result of the national emergency will be restored under 5 U.S.C. 6304 and placed in a separate restored leave account.

Time Limit for Use of Restored Leave

Under the current § 630.306, all restored annual leave must be scheduled and used not later than the end of the leave year ending 2 years after the termination date of the exigency of the public business—i.e., the end of the national emergency or transfer of the employee to another position that is not considered essential. Employees with large restored annual leave accounts or employees remaining in positions performing work that is essential to the national emergency for an extended period of time may accrue large amounts of annual leave in their accounts. Under the current regulations, the affected employees would have to schedule and use all of the restored leave by the end of the leave year ending 2 years after the termination date of the exigency of the public business. As a result, employing agencies would have to deal with the consequence of employees using sizeable amounts of leave within 2 to 3 years after the end of the national emergency. At the same time, annual leave that accrues during that 2- to 3-year period would routinely create a ''use or lose'' situation.

To help alleviate this situation, we are providing that leave which is restored as a result of the exigency caused by the national emergency will have the same time limits for restoration as are currently used for Department of Defense employees in installations undergoing closure or realignment. (See 5 CFR 630.306(b).) A full-time employee will be required to schedule and use excess annual leave of 416 hours or less by the end of the leave year in progress 2 years after the date the employee is no longer subject to the exigency of the public business created by the national emergency. The agency will extend that period by 1 leave year for each additional 208 hours of excess annual leave or any portion thereof. A part-time employee will be required to schedule and use excess annual leave in an amount equal to or less than 20 percent of the number of hours in the employee's scheduled annual tour of duty by the end of the leave year in progress 2 years after the date the employee is no longer subject to the exigency. The agency will extend this period by 1 leave year for each additional number of hours of excess annual leave, or any portion thereof, equal to 10 percent of the number of hours in the employee's scheduled annual tour of duty.

Treatment of Current Restored Leave Accounts

Some employees currently involved in the exigency created by the national emergency have an ''active'' restored leave account—*i.e.*, an account of restored annual leave that was established under other conditions permitting restoration of annual leave under 5 U.S.C. 6304(d). Since there is no authority to restore previously restored annual leave, employees (and agencies) have little option but to use (or permit the use of) the leave in the ''active'' restored leave account to avoid the forfeiture of annual leave, even though the employees are needed for critical projects in connection with the national emergency. The interim regulations at § 630.311(d) will alleviate this problem because the time limitation for using active restored annual leave will be canceled for the entire period during which employees' services are determined to be essential for activities associated with the national emergency. At the end of the national emergency, a new time limit will be established under § 630.311(c) for using all restored leave available to the employee under 5 U.S.C. 6304(d).

Employees Who Transfer to Another Position

As noted earlier, § 630.308 currently requires that before forfeited leave may be considered for restoration, the leave must have been scheduled in writing before the start of the third biweekly pay period prior to the end of the leave year. We are concerned about the possible consequences of requiring advance scheduling for an employee who transfers from a position deemed necessary for the national emergency to another position during the latter portion of a leave year. It is possible that such employees would have leave in excess of the maximum limitation, but would still be unable to schedule it. Therefore, the interim regulations at § 630.310(e) will allow an agency to consider restoration of annual leave forfeited at the end of the leave year to an employee whose involvement in the national emergency ends during the leave year if the agency determines that there is a correlation between the lack of advance scheduling and the duties of the employee's former position.

OPM believes such annual leave may be considered for restoration. Section 630.311(e) requires affected employees to make a reasonable effort to comply with the advance scheduling requirement in § 630.308(a). However, the head of an agency may exempt an employee from the advance scheduling requirement if the employee can show that he or she was involved in activities necessary to the national emergency during the leave year and was unable to comply with the scheduling requirement due to circumstances beyond his or her control. Since the agency may determine that there was sufficient time for the employee to schedule and use annual leave before the end of the leave year, this provision does not guarantee that excess annual leave will be restored.

Waiver of Notice of Proposed Rule Making and Delay in Effective Date

In order to give practical effect to these regulations, I find that good cause exists to waive the general notice of proposed rulemaking pursuant to 5 U.S.C. 553(b)(3)(B). Also, I find that good cause exists for making this rule effective in less than 30 days. The delay in the effective date is being waived to give affected employees the benefit of these new provisions as quickly as possible.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will affect only Federal agencies and employees.

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

List of Subjects in 5 CFR Part 630

Government employees.

Office of Personnel Management.

Kay Coles James,

Director.

Accordingly, OPM is amending part 630 of title 5 of the Code of Federal Regulations as follows:

PART 630—ABSENCE AND LEAVE

1. The authority citation for part 630 continues to read as follows:

Authority: 5 U.S.C. 6311; Sec. 630.301 also issued under Pub. L. 103–356, 108 Stat. 3410; Sec. 630.303 also issued under 5 U.S.C. 6133(a); Secs. 630.306 and 630.308 also issued under 5 U.S.C. 6304(d)(3), Pub. L. 102–484, 106 Stat. 2722, and Pub. L. 103–337, 108 Stat. 2663; subpart D also issued under Pub. L. 103–329, 108 Stat. 2423; Sec. 630.501 and subpart F also issued under E.O. 11228, 30 FR 7739, 3 CFR, 1974 Comp., p. 163; subpart G also issued under 5 U.S.C. 6305; subpart H also issued under 5 U.S.C. 6326; subpart I also issued under 5 U.S.C. 6332, Pub. L. 100–566, 102 Stat. 2834, and Pub. L. 103–103, 107 Stat. 1022; subpart J also issued under 5 U.S.C. 6362, Pub. L 100–566, and Pub. L. 103–103; subpart K also issued under Pub. L. 105–18, 111 Stat. 158; subpart L also issued under 5 U.S.C. 6387 and Pub. L. 103–3, 107 Stat. 23; and subpart M also issued under 5 U.S.C. 6391 and Pub. L. 102–25, 105 Stat. 92.

Subpart C—Annual Leave

2.In § 630.308, paragraph (a) is revised to read as follows:

§ 630.308 Scheduling of annual leave.

(a) Except as provided in paragraph (b) of this section and §§ 630.310 and 630.311, before annual leave forfeited under 5 U.S.C. 6304 may be considered for restoration under that section, use of the annual leave must have been scheduled in writing before the start of the third biweekly pay period prior to the end of the leave year.

* * * * *

3. A new § 630.311 is added to read as follows:

§ 630.311 Scheduling of annual leave by employees determined necessary to respond to the ''National Emergency by Reason of Certain Terrorist Attacks.''

(a) The ''National Emergency by Reason of Certain Terrorist Attacks'' (Presidential Proclamation of September 14, 2001) is deemed to be an exigency

of the public business for the purpose of restoring annual leave forfeited under 5 U.S.C. 6304.

(b) For any employee who forfeits annual leave under 5 U.S.C. 6304 at the beginning of a leave year because the agency determined the employee's services were required in response to the national emergency, the forfeited annual leave is deemed to have been scheduled in advance for the purpose of 5 U.S.C. 6304(d)(1)(B) and § 630.308.

(c) Annual leave restored under 5 U.S.C. 6304(d) because of the national emergency must be scheduled and used within the time limits prescribed in paragraphs (c)(1) and (c)(2) of this section:

(1) A full-time employee must schedule and use excess annual leave of 416 hours or less by the end of the leave year in progress 2 years after the date the employee's services are no longer required by the national emergency. The agency must extend this period by 1 leave year for each additional 208 hours of excess annual leave or any portion thereof.

(2) A part-time employee must schedule and use excess annual leave in an amount equal to or less than 20 percent of the number of hours in the employee's scheduled annual tour of duty by the end of the leave year in progress 2 years after the date the employee's services are no longer required by the national emergency. The agency must extend this period by 1 leave year for each additional number of hours of excess annual leave, or any portion thereof, equal to 10 percent of the number of hours in the employee's scheduled annual tour of duty.

(d) The time limits established under paragraphs (c)(1) and (c)(2) of this section for using restored annual leave accounts do not apply for the entire period during which an employee's services are required for the national emergency. When coverage under paragraphs (a) and (b) of this section ends, a new time limit will be established under paragraph (c) of this section for all annual leave restored to an employee under 5 U.S.C. 6304(d).

(e) An employee whose services were determined essential during the national emergency, but who subsequently moves to a position not considered essential, must make a reasonable effort to comply with the scheduling requirement in § 630.308(a). The head of the agency or his or her designee may exempt such an employee from the advance scheduling requirement in § 630.308(a) if coverage under paragraphs (a) and (b) of this section terminated during the leave year and the employee can demonstrate that he or she was unable to comply with the advance scheduling requirement due to circumstances beyond his or her control.

[FR Doc. 01–27518 Filed 11–1–01; 8:45 am]

BILLING CODE 6325–39–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150–AG82

List of Approved Spent Fuel Storage Casks: Westinghouse MC–10 Termination; Confirmation of Effective Date

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Nuclear Regulatory Commission (NRC) is confirming the effective date of November 5, 2001, for the direct final rule that appeared in the **Federal Register** of August 21, 2001 (66 FR 43761). This direct final rule amended the NRC's regulations revising the ''List of Approved Spent Fuel Storage Casks'' by terminating Certificate of Compliance Number 1001 for the Westinghouse MC–10 cask system. The Westinghouse MC–10 can no longer be used to store spent fuel under a general license. This document confirms the effective date.

DATES: The effective date of November 5, 2001 is confirmed for this direct final rule.

ADDRESSES: Documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. These same documents may also be viewed and downloaded electronically via the rulemaking Web site (*http://ruleforum.llnl.gov*). For information about the interactive rulemaking website, contact Ms. Carol Gallagher (301) 415–5905; e-mail *CAG@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Merri Horn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone (301) 415–8126 (E-mail: *mlh1@nrc.gov*).

SUPPLEMENTARY INFORMATION: On August 21, 2001 (66 FR 43761), the NRC published in the **Federal Register** a direct final rule amending its regulations in 10 CFR 72 revising the ''List of Approved Spent Fuel Storage Casks'' by terminating Certificate of Compliance Number 1001 for the Westinghouse MC–10 cask system. The Westinghouse MC–10 can no longer be used to store spent fuel under a general license. In the direct final rule, NRC stated that if no significant adverse comments were received, the direct final rule would become final on the date noted above. The NRC did not receive any comments that warranted withdrawal of the direct final rule. Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 29th day of October, 2001.

For the Nuclear Regulatory Commission.

Michael T. Lesar,

Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 01–27578 Filed 11–1–01; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–CE–113–AD; Amendment 39–12493; AD 2001–22–14]

RIN 2120–AA64

Airworthiness Directives; Overland Aviation Services Fire Extinguishing System Bottle Cartridges

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Overland Aviation Services (OAS) fire extinguishing system bottle cartridges that were distributed during a certain time period and are installed on aircraft. This AD requires you to remove from service any of these fire extinguishing system bottle cartridges. This AD is the result of several incidents where the fire extinguishing system bottle cartridges activated with excessive energetic force. In one instance, the discharge valve outlet screen fractured and the screen material went through the distribution manifold. The actions specified by this AD are intended to prevent damage to fire extinguishing system components caused by a fire extinguishing system bottle cartridge activating with excessive energetic force, which could result in the fire extinguishing system operating improperly.

EFFECTIVE DATE: This AD becomes effective on December 10, 2001.

ADDRESSES: You may obtain copies of the document referenced in this AD from Overland Aviation Services, 10271 Bach Boulevard, St. Louis, Missouri 63132. You may view this document at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–CE–113–AD, 901 Locust, Room 506, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Jeffrey D. Janusz, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4148; facsimile: (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD? The FAA has received reports of several incidents where fire extinguishing system bottle cartridges that were manufactured by Overland Aviation Services (OAS) activated with excessive energetic force. In one instance, the discharge valve outlet screen fractured and the screen material went through the distribution manifold.

The fire extinguishing system bottle cartridges are considered critical parts. The fire extinguishing system is only required to function after a failure or series of failures have occurred and developed into the potential for a fire. In the above-referenced incidents, the fire extinguishing system could not be relied on because of the potential for damage to the fire extinguishing system components that could result from a cartridge activating with excessive energetic force. OAS distributed fire extinguishing system bottle cartridges that could incorporate this problem from April 1, 1996, through September 15, 1997.

What is the potential impact if FAA took no action? A fire extinguishing system bottle cartridge activating with excessive energetic force could result in damage to fire extinguishing system components and cause the system to operate improperly. This could lead to passenger injury in the event of an airplane fire.

Has FAA taken any action to this point? We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to OAS fire extinguishing system bottle cartridges that were distributed from April 1, 1996, through September 15, 1997, and were installed on aircraft. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on July 12, 1999 (64 FR 37471). The NPRM proposed to require you to remove from service any of these fire extinguishing system bottle cartridges.

Was the public invited to comment? The FAA encouraged interested persons to participate in the making of this amendment. The following presents the comments received on the proposal and FAA's response to each comment:

Comment Issue No. 1: Change the Compliance Time to ''the Next Scheduled Inspection/Maintenance Interval''

What is the commenter's concern? One commenter recommends that FAA change the compliance time to the next scheduled inspection/maintenance interval. This would coincide with OAS Service Bulletin 22–09–97.

What is FAA's response to the concern? We do not concur with changing the compliance to the next scheduled inspection/maintenance interval. Operators of airplanes with the affected equipment use their airplanes in different operations, e.g., parts 121 and 135 of the Federal Aviation Regulations (14 CFR parts 121 and 135). These operations allow different inspection/maintenance intervals. The next inspection/maintenance interval for some airplanes may occur within a week after this AD becomes effective where the interval for other airplanes may occur a year after the AD becomes effective.

We have determined that the compliance time of ''180 days after the effective date of the AD'' will neither inadvertently ground any airplanes nor allow airplanes to operate with potentially defective equipment for an extended period of time.

We will consider individual extensions to the compliance times as alternative methods of compliance provided they:

—Provide a level of safety that is acceptable to FAA; and

—Are submitted using the procedures in the AD.

We are not making any changes to the final rule as a result of these comments.

Comment Issue No. 2: Re-estimate the Cost Impact

What is the commenter's concern? A commenter states that FAA's cost analysis does not account for the potential unnecessary inspection and removal of parts when you cannot identify whether one of the affected cartridges is installed. The commenter estimates this cost impact at three times more than FAA's estimate.

What is FAA's response to the concern? We based our cost analysis on operator input of the efforts to accomplish the inspection and replacement of the suspect part. Any unnecessary removal would be the result of improper identification or a lack of proper maintenance records. We have determined that, if proper maintenance was followed, the owner/operator of an airplane will maintain a direct correlation between the identity of parts on a particular airplane and that airplane's maintenance records and logbooks.

We are not making any changes to the final rule as a result of these comments.

Comment Issue No. 3: Clarify the Approved Replacement Parts

What is the commenter's concern? One commenter asks for clarification regarding whether you can use a replacement part with the same part number as those affected by this action. The commenter believes you can if the part is not of the suspect distribution date or lot number. However, the commenter feels that the current wording in the NPRM on this issue is unclear.

What is FAA's response to the concern? After re-evaluating the wording in the NPRM, we concur that the language could be more clear. To address this, we are also specifying the lot number and the distribution date in all references to part number in the AD.

Comment Issue No. 4: Explain Why FAA Uses the Distribution Date of the Cartridge Instead of the Manufacturing Date

What is the commenter's concern? One commenter asks for information regarding the requirement to use the distribution date of suspect parts instead of the manufacturing date. In particular, the commenter wants to be able to substitute the manufacturing date for the distribution date and wants information about the relationship between the two.

What is FAA's response to the concern? The manufacturer of the suspect part does not tie a single manufacturing date to a specific lot number. The lot number more directly identifies suspect components. For example, the manufacturer has produced parts with the same lot number on five different manufacturing dates.

Distribution dates are also as important as the lot numbers. Parts may have been manufactured earlier than the distribution date or the date when sent to the field or distributor.

Because of these discrepancies between the manufacturing date and the lot number and distribution dates, we

are using the part number, lot number, and distribution date as the identifying criteria for this AD action.

We are not making any changes to the final rule as a result of these comments.

Comment Issue No. 5: Extend the Compliance Time To Ensure Parts Availability

What is the commenter's concern? OAS requests FAA extend the comment period so the company can ensure that parts are available to all affected owners/operators of the aircraft with the affected cartridges installed. OAS estimates it would need approximately 210 days as of August 10, 2001.

What is FAA's response to the concern? We will increase the compliance time from 120 days to 180 days. The AD becomes effective on December 10, 2001 (122 days past August 10, 2001). This would give OAS approximately 300 days to ensure that parts are available to all affected owners/operators of the aircraft with the affected cartridges installed.

We are changing the final rule to reflect this change.

What is FAA's final determination on this issue? We carefully reviewed all available information related to the subject presented above and determined that air safety and the public interest require the adoption of the rule as proposed except for the changes discussed above and minor editorial questions. We have determined that these changes and minor corrections:

—Provide the intent that was proposed in the NPRM for correcting the unsafe condition; and

—Do not add any additional burden upon the public than was already proposed in the NPRM.

Compliance Time of This AD

Why is the compliance of this AD presented in calendar time instead of hours time-in-service (TIS)? The unsafe condition described in this AD is not a direct result of aircraft operation. The fire extinguishing system bottle cartridges could activate with excessive energetic force the first time they are used during flight. This could occur on an aircraft with 50 hours TIS or an aircraft with 10,000 hours TIS. Therefore, to ensure that the unsafe condition is corrected in a timely manner, this AD is utilizing a compliance time of 180 days after the effective date of the AD.

Cost Impact

How many airplanes does this AD impact? We estimate that this AD affects 5,128 fire extinguishing system bottle cartridges

What is the cost impact of this AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish this action:

Labor cost	Parts cost	Total cost per airplane	Total Cost on U.S. operators
8 workhours × $60 per hour=$480	OAS to provide at no charge	$480	$2,461,440

OAS reports that 2,100 parts have been removed from service. This reduces the cost impact of this AD from $2,461,440, to $1,453,440.

The number of cartridges utilized varies from airplane to airplane. The FAA has no way of determining which airplanes have the affected fire extinguishing system bottle cartridges incorporated. Therefore, FAA has presented the cost impact of this AD based upon the number of fire extinguishing system bottle cartridges manufactured instead of the number of airplanes affected.

Regulatory Impact

Does this AD impact various entities? The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new AD to read as follows:

2001–22–14 Overland Aviation Services: Amendment 39–12493; Docket No. 98–CE–113–AD.

(a) *What airplanes are affected by this AD?* This AD affects the fire extinguishing system bottle cartridges presented in paragraph (a)(1) of this AD that were distributed from April 1, 1996, through September 15, 1997, and are installed on, but not limited to, the specified aircraft:

(1) This chart presents the fire extinguishing system bottle cartridge part number, the fire extinguishing system bottle assembly basic part number, the make/model aircraft that the system could be installed on, and the cartridge lot number:

Overland Aviation Services (OAS) cartridge part numbers	Walter Kidde Aerospace (WKA) fire extinguishing system (Firex) bottle assembly basic part number	Make/model of applicable aircraft	Cartridge lot number
OA472001	472073, 472420, 472467, 897878, 897885, 899170	Aerospatiale ATR72 Series ATR42–200, –300, –320; Embraer EMB–120 Series	SBI 1–1 SBI 1–2

Overland Aviation Services (OAS) cartridge part numbers	Walter Kidde Aerospace (WKA) fire extinguishing system (Firex) bottle assembly basic part number	Make/model of applicable aircraft	Cartridge lot number
OA841155	890532, 890598, 890599, 891070, 891147, 891814, 892308, 893675, 898768	Boeing 707–100, –100B Series, –300 Series, 720B; McDonnell Douglas DC–8 and DC–8F Series; Lockheed 382, 382E, 382F, 382G; Sabreliner NA–265 Series; Bell 204B	SBI 1–3, OAS 1–2
OA873364	472049, 472162, 472389, 472390, 893456, 893523, 893524, 893572, 893726, 894703, 895353, 897770, 898006, 898066	Gulfstream G–1159, G–1159B, G–1159A; Cessna 425, 441, 550, S550, 551, 552 Fokker F.28 Series; SAAB 340 Series; Bell 412	SBI 1–3
OA873571	892807, 892857, 893244, 899827, 899927	Boeing 707–100, –100B Series, –300 Series, 720B; McDonnell Douglas DC–8, DC–8F Series; DC–9 Series; Lockheed 382, 382E, 382F, 382G	SBI 2–2
OA876296	472602, 472603, 473598, 895240, 895564, 895678, 895683, 895877, 896054, 898150	McDonnell Douglas DC–9–81, DC–9–82, DC–9–83, DC–10 Series; Airbus A300 Series	SBI 1–1, OAS 1–1
OA876299	472268, 895656, 895752, 895848, 896165, 896166, 897785, 897797, 897798	Lockheed L–1011 Series	SBI 1–1
OA897776	472258, 472428, 897775, 897869, 897885, 897899, 899066, 899074, 899170, 899486	Canadair CL–600–1A11, CL–600 –2A12, CL–600–2B16; Embraer EMB–120, EMB 120RT; Sikorsky S–76A; SAAB 340 Series	SBI 1–4, SBI 1–15, SBI 1–16, OAS 1–1

(2) OAS distributed the affected fire extinguishing system bottle cartridges from April 1, 1996, through September 15, 1997. This AD does not apply to cartridges incorporated on the aircraft prior to April 1, 1996.

(3) Procurement records may show if the owner/operator has ever bought affected parts, for spares or time replacements, for airplane installation, or to support a repair shop. These could be cross-referenced to the lots that are suspect. Additionally, a review of procurement records with respect to the part number, lot number, and distribution date of the suspect lots would also reduce the owners'/operators' workload of having to examine all applicable Air Transport Association (ATA) codes in the databases. A search of the maintenance/inspection records and logbooks of a specific airplane make and model and serial number could be beneficial.

(4) The fire extinguishing system parts are installed up to a hex wrenching flat on the cartridge body. These wrenching flats have the part number, lot number, and date of manufacture stamped on them, as well as safety wire holes. When installed, the safety wire will probably cover up at least one bit of the above information. Inspecting the wrenching flats could help determine whether the fire extinguishing system bottle cartridges contain a suspect part number with the affected distribution date or lot number.

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

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent damage to fire extinguishing system components caused by a fire extinguishing system bottle cartridge activating with excessive energetic force. This could result in the fire extinguishing system operating improperly and lead to passenger injury in the event of an airplane fire.

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

Actions	Compliance	Procedures
(1) Check the maintenance records to determine whether an extinguishing system bottle cartridge that is referenced in paragraphs (a) and (a)(1) of this AD is installed. (i) If an affected fire extinguishing system bottle cartridge was installed prior to April 1, 1996, you do not have to accomplish the removal and replacement requirements of this AD (paragraph (d)(2) of this AD); and. (ii) Make an entry into the aircraft records showing compliance with that portion of the AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).	Within the next 180 days after December 10, 2001 (the affected date of this AD).	The owner/operator holding at least a private pilot certificate as authorized by section 43.7 cartridge of the Federal Aviation Regulations (14 CFR 43.7) may accomplish this these actions.
(2) Remove from service any fire extinguishing system bottle cartridge referenced in paragraph (a) and (a)(1) of this AD). Replace that bottle cartridge with an FAA-approved fire extinguishing system bottle cartridge that is not one of the applicable OAS part numbers that was distributed from April 1, 1996, through September 15, 1997.	Within the next 180 days after December 10, 2001 (the effective dated of this AD).	OAS Service Bulletin 22–09–97, dated October 1, 2001, contains information related to this subject.
(3) Do not install, on any aircraft, any affected OAS fire extinguishing system bottled cartridge that was distributed from April 1, 1996, through September 15, 1997.	As of December 10, 2001 (the effective date of this AD).	Not Applicable.

Note 1: ''Unless already accomplished'' credit may be extended to the records check allowed by this AD provided that the records are checked to cover any time period that has elapsed since the previous check.

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

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

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

Note 2: This AD applies to each aircraft that incorporates one of the fire extinguishing system bottle cartridges identified in paragraphs (a) and (a)(1) of this AD; regardless of whether the aircraft has been modified, altered, or repaired in the area subject to the requirements of this AD. For aircraft 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.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Jeffrey D. Janusz, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4148; facsimile: (316) 946–4407.

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

(h) *How do I get copies of the documents referenced in this AD?* You may obtain copies of the document referenced in this AD from Overland Aviation Services, 10271 Bach Boulevard, St. Louis, Missouri 63132. You may view this document at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

(i) This amendment becomes effective on December 10, 2001.

Issued in Kansas City, Missouri, on October 24, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–27412 Filed 11–1–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30277; Amdt. No. 2077]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which affected airport is located; or
3. The Flight Inspection Area Office which originated the SIAP.

For Purchase

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, US Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation's Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the Federal Register expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction of charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAMs for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been canceled.

The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S.

Standard for Terminal Instrument Procedures (TERPS). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the TERPS. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Navigation (air).

Issued in Washington, DC, on October 26, 2001.

Nicholas A. Sabatini,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120, 44701; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * Effective Upon Publication

FDC date	State	City	Airport	FDC No.	Subject
10/09/01	AR	Hot Springs	Memorial Field	1/1082	VOR RWY 5, Amdt 16.
10/09/01	TX	Temple	Temple/Draughon-Miller Central Texas Regional.	1/1101	LOC/DME BC RWY 33, Amdt 3.
10/11/01	GA	Thompson	Thompson-McDuffie County	1/1182	NDB RWY 10, Orig.
10/11/01	GA	Thompson	Thompson-McDuffie County	1/1183	ILS RWY 10, Orig.
10/17/01	FL	Punta Gorda	Charlotte County	1/1358	GPS RWY 3, Orig.
10/17/01	MI	Bellaire	Antrim County	1/1375	GPS RWY 3, Orig-B.
10/17/01	FL	Naples	Naples Muni	1/1382	VOR RWY 23, Amdt 6B.
10/17/01	MI	Gaylord	Ostego County	1/1383	VOR or GPS RWY 9, Amdt 1.
10/17/01	MI	Gaylord	Ostego County	1/1384	NDB RWY 9, Amdt 12.
10/17/01	MI	Gaylord	Ostego County	1/1385	ILS RWY 9, Orig.
10/17/01	MI	Gaylord	Ostego County	1/1386	VOR or GPS RWY 27, Amdt 1.
10/18/01	MI	Kalamazoo	Kalamazoo/Battle Creek Intl	1/1415	VOR RWY 5, Orig.
10/18/01	AK	Cold Bay	Cold Bay	[1] 1/1419	ILS RWY 14, Amdt 16A.
10/18/01	MI	Bellaire	Antrim County	1/1421	VOR RWY 2, Amdt 2.
10/18/01	MI	Bellaire	Antrim County	1/1423	NDB RWY 2, Amdt 2A.
10/22/01	AK	Barrow	Wiley Post-Will Rogers Memorial	1/1487	LOC/DME BC RWY 24, Amdt 3.
10/23/01	MS	Natchez	Hardy-Anders Field, Natchez-Adams County.	1/1547	NDB or GPS RWY 18, Amdt 4B.
10/23/01	FL	Fort Myers	Page Field	1/1552	RADAR–1, Amdt 3.
10/23/01	FL	Fort Myers	Page Field	1/1553	GPS RWY 31, Orig.

[1] 1/1419 replaces 1/8899.

[FR Doc. 01–27573 Filed 11–1–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30276 Amdt. No. 2076]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulator actions are needed because of the adoption of new or revised criteria, or because of change occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic

requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Wasington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located; or
3. The Flight Inspection Area Office which originated the SIAP.

For Purchase

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (NFDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Navigation (air).

Issued in Washington, DC, on October 26, 2001.

Nicholas A. Sabatini,

Director, Flight standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * * Effective November 1, 2001*

Palatka, FL, Kay Larkin, NDB OR GPS RWY 9, Amdt 2
Everett, WA, Snohomish County (Paine Field), ILS RWY 16R, Amdt 19

** * * Effective November 29, 2001*

Memphis, TN, Memphis, NDB RWY 9, Amdt 27
Provo, UT, Provo Muni, ILS RWY 13, Orig-A, CANCELLED
Provo, UT, Provo Muni, ILS Z RWY 13, Orig, CANCELLED
Provo, UT, Provo Muni, ILS RWY 13, Orig

** * * Effective December 27, 2001*

Iliamna, AK, Iliamna, NDB RWY 35, Amdt 1

Iliamna, AK, Iliamna, RNAV (GPS) RWY 7, Orig
Iliamna, AK, Iliamna, RNAV (GPS) RWY 17, Orig
Iliamna, AK, Iliamna, RNAV (GPS) RWY 25, Orig
Iliamna, AK, Iliamna, RNAV (GPS) RWY 35, Orig
Fayetteville/Springdale/Rogers, AR, Northwest Arkansas Regional, GPS RWY 16, Orig, CANCELLED
Fayetteville/Springdale/Rogers, AR, Northwest Arkansas Regional, GPS RWY 34, Amdt 1, CANCELLED
Fayetteville/Springdale/Rogers, AR, Northwest Arkansas Regional, RNAV (GPS) RWY 16, Orig
Fayetteville/Springdale/Rogers, AR, Northwest Arkansas Regional, RNAV (GPS) RWY 34, Orig
Santa Ana, CA, John Wayne Orange County, RNAV (GPS) RWY 1L, Orig
Santa Ana, CA, John Wayne Orange County, RNAV (GPS) RWY 19L, Orig
Kahului, HI, Kahului, RNAV (GPS) RWY 2, Orig
Algona, IA, Algona Muni, GPS RWY 30, Orig, CANCELLED
Algona, IA, Algona Muni, RNAV (GPS) RWY 30, Orig
Boone, IA, Boone Muni, RNAV (GPS) RWY 15, Orig
Boone, IA, Boone Muni, RNAV (GPS) RWY 33, Orig
Boone, IA, Boone Muni, GPS RWY 15, Amdt 1A CANCELLED
Boone, IA, Boone Muni, GPS RWY 33, Orig-A CANCELLED
Council Bluffs, IA, Council Bluffs Muni, RNAV (GPS) RWY 13, Orig
Council Bluffs, IA, Council Bluffs Muni, RNAV (GPS) RWY 31, Orig
Council Bluffs, IA, Council Bluffs Muni, GPS RWY 31, Orig CANCELLED
Monticello, IA, Monticello Regional, RNAV (GPS) RWY 15, Orig
Monticello, IA, Monticello Regional, RNAV (GPS) RWY 33, Orig
Monticello, IA, Monticello Regional, NDB–A Amdt 4
Monticello, IA, Monticello Regional, VOR/DME RNAV OR GPS RWY 31, Amdt 1B, CANCELLED
Pella, IA, Pella Muni, GPS RWY 16, Amdt 1, CANCELLED
Pella, IA, Pella Muni, RNAV Z RWY 16, Orig
Pella, IA, Pella Muni, RNAV Z RWY 34, Orig
Chicago, IL, Chicago Midway, RNAV (GPS) RWY 4R, Orig
Grand Rapids, MI, Gerald R. Ford Intl, RNAV (GPS) RWY 8L, Orig
Grand Rapids, MI, Gerald R. Ford Intl, RNAV (GPS) RWY 17, Orig
Grand Rapids, MI, Gerald R. Ford Intl, RNAV (GPS) RWY 26R, Orig
Grand Rapids, MI, Gerald R. Ford Intl, RNAV (GPS) RWY 35, Orig
Great Falls, MT, Great Falls Intl, RNAV (GPS) RWY 3, Orig
Great Falls, MT, Great Falls Intl, GPS RWY 3, Orig, CANCELLED
Albuquerque, NM, Albuquerque Intl Sunport, RNAV (GPS) RWY 3, Orig
Albuquerque, NM, Albuquerque Intl Sunport, RNAV (GPS) RWY 17, Orig
Albuquerque, NM, Albuquerque Intl Sunport, RNAV (GPS) RWY 35, Orig
Asheville, NC, Asheville Regional, RNAV (GPS) RWY 16, Orig
Asheville, NC, Asheville Regional, RNAV (GPS) RWY 34, Orig
Monroe, NC, Monroe, RNAV (GPS) RWY 5, Orig
Wilmington, NC, Wilmington Intl, NDB RWY 35, Amdt 17
St. George, UT, St. George Muni, VOR/DME RWY 34, Amdt 3
Salt Lake City, UT, Salt Lake City Muni 2, RNAV (GPS) RWY 34, Orig
Emporia, VA, Emporia-Greensville Regional, RNAV (GPS) RWY 33, Orig
Antigo, WI, Langlade County, NDB RWY 16, Amdt 5
Antigo, WI, Langlade County, RNAV (GPS) RWY 16, Orig
Antigo, WI, Langlade County, RNAV (GPS) RWY 34, Orig

[FR Doc. 01–27572 Filed 11–1–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 151, 155, 157, and 158

46 CFR Part 172

[USCG–2000–7641]

RIN 2115–AF56

Pollution Prevention for Oceangoing Ships and Certain Vessels in Domestic Service

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard amends regulations for pollution prevention from ships to align domestic requirements with international maritime pollution standards. This rule changes regulations concerning: oily-water separators, operational discharges of oil, damage and intact stability of tank vessels, period of validity for an International Oil Pollution Prevention Certificate, and garbage recordkeeping requirements. To provide consistency with industry standards and clarify U.S. oil regulations, we are also amending oily mixture discharge shore connection requirements for certain vessels and redefining certain terms dealing with oil.

DATES: This final rule is effective December 3, 2001.

ADDRESSES: Comments and materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2000–7641 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket at *http://dms.dot.gov/.*

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Bob Gauvin, Vessel and Facility Operating Standards Division, Coast Guard, 202–267–1053. If you have questions on viewing the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, at 202–366–5149.

SUPPLEMENTARY INFORMATION:

Regulatory History

On August 8, 2000, we published a notice of proposed rulemaking (NPRM) entitled ''Pollution Prevention for Oceangoing Ships and Certain Vessels in Domestic Service'' in the **Federal Register** (65 FR 48548). We received 6 letters commenting on the proposed rule. No public hearing was requested, and none was held.

Background and Purpose

This rule amends U.S. regulations for pollution prevention from oceangoing ships and certain vessels in domestic service. These amendments were adopted by the Marine Environment Protection Committee (MEPC) of the International Maritime Organization (IMO) during several sessions. MEPC adopted amendments to Annex I of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 (MARPOL 73/78) during its 32nd session (MEPC 32, March 6, 1992) and 40th session (MEPC 40, September 25, 1997). The MEPC also adopted amendments to Annex V of MARPOL, in its 37th session (MEPC 37, September 14, 1995). This rule will allow certain vessels in domestic service to use quick-connect fittings rather than international-type shore connections. We are also redefining certain terms dealing with oil in the domestic regulations for clarity.

By aligning the domestic regulations with international standards, compliant U.S. ships would encounter fewer difficulties while engaged in international trade. Under 33 U.S.C. 1902, the Coast Guard is authorized to prescribe or amend regulations necessary to implement any changes to the standards of MARPOL 73/78.

The following amendments, as provided in the NPRM, are listed below for your understanding and convenience. They have not been changed in the final rule.

Equivalent shore connections for the discharge of oily mixtures. The

amendment of 33 CFR 155.410 and 33 CFR 155.420 will allow non-oceangoing ships of 100 gross tons and above, and oceangoing ships of 100 gross tons to less than 400 gross tons operating in domestic service to use any shore connections (quick-connect fittings) that are compatible with U.S. reception facilities instead of an international-type connection.

Definitions. We are redefining for clarity those words throughout 33 CFR parts 151, 155, 157, and 158 dealing with oil. Those words are: ''oily mixtures,'' ''oil,'' ''oil cargo residues,'' and ''oil residues.'' We are removing all conflicting and duplicative terms.

Amendments to Annex I of MARPOL are described in a **Federal Register** document published on November 12, 1993 (58 FR 60080). These amendments established more stringent criteria for controlling the discharge of oil and oily-water from vessels' machinery space bilges and cargo tanks of tank vessels.

Rate of discharge of oil. This rule amends 33 CFR 157.37(a) by reducing the allowable rate from 60 liters per nautical mile to 30 liters per nautical mile to align with the international standard set by MARPOL 73/78.

Controlling discharge from space bilges and tank vessels' cargo tanks. This rule amends 33 CFR 151.10(a)(5), 33 CFR 155.360(a), 33 CFR 155.370(a), and 33 CFR 157.39(b)(3) (redesignated as (b)(2)) by reducing the allowable oil content in effluent from oil tanker bilges and other ships of 400 gross tons and above from 100 parts per million (ppm) to 15 ppm.

Automatic stoppage of a discharge. This rule amends 33 CFR 155.370(a) to require ships of 400 gross tons to less than 10,000 gross tons that are carrying ballast water in their fuel oil tanks, and for ships over 10,000 gross tons, to have a means for automatically stopping discharges that exceed 15 ppm.

Discharge equipment. This rule amends 33 CFR 155.370(a), which requires all ships to comply with the oil filtering equipment, alarms, and automatic stop requirements by the rule's effective date.

International Oil Pollution Prevention (IOPP) Certificates. This rule sets the maximum term of validity for International Oil Pollution Prevention (IOPP) Certificates at 5 years to coincide with the International Maritime Organization's (IMO's) Harmonized System of Surveys and Certification, and MARPOL 73/78 standards.

Damage stability of tank vessels. This rule amends 33 CFR part 157, appendix B, and 46 CFR 172.065, table 172.065(a), to require oil tankers over 20,000 deadweight tons (DWT) to be designed to survive potential raking damage caused by grounding.

Intact stability of tankships. This rule adds two new sections—33 CFR 157.22 and 46 CFR 172.070—which require tankships over 5,000 DWT contracted after this rule's effective date to be designed to prevent lolling.

Garbage discharge records. This rule aligns U.S. garbage recordkeeping requirements with those in Regulation 9, Annex V of MARPOL. Oceangoing ships less than 400 gross tons and greater than 40 feet in length engaged in commerce are no longer required to carry garbage discharge records. Additionally, this rule requires every manned ship engaged in an international voyage that is certified to carry 15 passengers or more to carry garbage discharge records. These amendments do not change how vessel garbage is handled nor does it change the requirement to maintain a plan describing vessel waste management.

Note: A copy of MARPOL 73/78 is available from the International Maritime Organization, 4 Albert Embankment, London, SE1 7SR, England. It is also available online at *http://www.imo.org/.*

Discussion of Comments and Changes

We received 6 letters containing 11 specific comments in response to our NPRM. The information in this section discusses the comments we received, provides the Coast Guard's responses, and explains any changes we are making to the regulation.

1. Seven of the comments supported sections of the Coast Guard's proposed rule as written, and they generally supported the alignment of domestic regulations with international standards. These seven comments stated support for—

- Maintaining requirements for refuse logs on vessels of 400 gross tons and above, and those carrying 15 or more passengers on international voyages;
- The establishment of an equivalency for shore connections for vessels on domestic voyages; and
- An interpretation that fixed or floating production platforms would be excluded from oily-water separating equipment requirements with a valid NPDES permit issued under section 402 of the Clean Water Act and 40 CFR chapter I.

2. Three comments did not support the addition of 33 CFR 158.415, the proposed posting of placards for reporting inadequate port waste reception facilities. These comments discussed that posting these placards was impractical and costly and would not be helpful for reporting inadequate waste facilities to the Coast Guard. The Coast Guard agrees with these comments. Significant regulations are already in place that support the spirit of the proposed requirements and allow the Coast Guard to adequately police port reception facilities and permit anyone to report inadequacies. Therefore, we have removed proposed 33 CFR 158.415 from this final rule.

3. One comment proposed expanding the harmonization of U.S. regulations with MARPOL 73/78 to incorporate vessels below the 400 gross tonnage threshold for specific U.S. requirements on waste management plans. The Coast Guard does not agree with this comment as such a proposal is outside the scope of this rulemaking. Therefore, no change was made to the final rule.

4. In addition to the changes discussed in this section that were made in response to the comments, the Coast Guard is making an administrative edit to update a reference table's note within 33 CFR 151.26, ''Shipboard oil pollution emergency plans.'' As IMO resolution A.648(16) has been superceded by IMO resolution A.851(20), the reference to resolution A.648(16) in the note to table 151.26(b)(3)(iii) is changed to A.851(20).

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget (OMB) has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). A final Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT follows:

Costs

The total present value costs for this rule during the 10-year period of analysis will approximate $3,037. The costs arise from the following requirements:

(a) *Oily-water or bilge monitors.* Based on the policies established in Navigation Vessel Inspection Circular (NVIC) No. 6–94, we estimate that at least 90 percent of the 131 affected tank vessels are currently operating within policy guidelines by automatically or manually setting the oil or oily-water discharge rate to not exceed 30 liters per nautical mile. The other 10 percent will simply upgrade their existing monitoring systems with new components that meet the new requirement. The estimated equipment costs to upgrade the components of an

existing bilge monitor average $250, making the one-time cost of this requirement approximately $3,250. When valued in year 2000 dollars, the cost will be $3,037. A copy of NVIC No. 6–94 is available in the docket where indicated under **ADDRESSES.**

(b) *Oil-filtering equipment.* We estimate that requiring oil-filtering equipment will affect 650 vessels, all of which are currently practicing the policies established in NVIC No. 6–94 and currently have oil-filtering equipment that complies with the 15 ppm oil content of the effluent discharged. Therefore, this requirement does not impose additional costs.

(c) *Automatic shut-off device/alarm.* We estimate that requiring automatic shut-off devices/alarms will affect 396 ships, all of which already practice the policies established in NVIC No. 6–94. Therefore, this requirement does not impose additional costs.

(d) *Damage stability for tank vessels.* We estimate that the damage stability requirements will affect 650 vessels. Based on trend data from the Coast Guard's Marine Safety Management System (MSMS) database (1992–1996), we estimate that 13 U.S.-flag tank vessels of 20,000 deadweight tons (DWT) and above will be built each year. For every single-hull tank vessel that is phased out before 2015, a double-hull tank vessel may be built as its replacement. Currently, 54 single-hull tankships and 160 single-hull tank barges will be phased out over the next 16 years. For the 10-year period of analysis for the damage stability requirements, approximately 3 tankships and 10 tank barges will be built annually to meet demand and to replace phased-out tank vessels (130 tank vessels over the 10-year period). We expect the affected tank vessel fleet to incur minimal costs to comply with these requirements. The U.S. international fleet currently complies with the damage stability requirements in MARPOL 73/78. Also, vessels in the U.S. domestic fleet that hold IOPP Certificates currently meet the additional design and engineering calculation requirements for design stability. Moreover, under section 4115(a) of the Oil Pollution Act of 1990 (OPA 90), these single-hull tank vessels are required to be retrofitted with double hulls or phased out of service by the year 2015. For vessels being retrofitted, there will be nominal additional costs during the design process for additional stability analyses. The requirement entails fitting the vessel with U-shaped ballast tanks, instead of J-shaped (or other) ballast tanks, and relocating cargo tank boundaries.

(e) *Intact stability for tank vessels.* We assume that all tank vessels of 5,000 DWT and above will be constructed so that they are capable of engaging in international commerce. Therefore, we assume that, in order to participate in international commerce, currently operating tank vessels affected by the intact stability requirements already meet the requirements in MARPOL 73/78. No additional costs are incurred by these requirements.

(f) *Equivalent shore connections.* Certain U.S. ships that are used only for domestic voyages will be required to use shore connections that are compatible with U.S. reception facilities. Although these ships will not be in compliance with the international-type standard, they will meet the intent of the standard by having a connector that is compatible with discharge facilities in their area of operation. Because these ships currently have connections that are compatible with the facilities used, this requirement imposes no additional cost on these ships.

Benefits

(a) *Industry benefits.* The total present value of industry benefits for this rule during the 10-year period of analysis will be approximately $164.1 million. The industry benefits arise from the following requirements: IOPP Certificates ($3,715); garbage discharge records ($163.5 million); and compliance with international oil discharge limitations ($632,122).

(1) *IOPP Certificates.* Changing the term of the IOPP Certificate from 4 to 5 years for both inspected and uninspected vessels creates a benefit by reducing the costs incurred due to recertification. The costs for this change are included under the approved collection OMB 2115–0518. By aligning U.S. regulations with international standards, the annual paperwork burden cost will be reduced by $530. The 10-year accumulated present value of the recurring benefit is approximately $3,715.

(2) *Refuse discharge.* The refuse discharge requirement applies to each oceangoing ship of 400 gross tons and above engaged in commerce and documented under the laws of the United States or numbered by a State, each vessel certified to carry 15 passengers or more on international voyages, and each fixed or floating platform subject to the jurisdiction of the United States. We use these garbage discharge records to determine how ship-generated waste is handled (i.e., incinerated, discharged at sea, or off-loaded at a shore reception facility). Since all of these vessels currently maintain these records, this requirement imposes no additional information-collection burden.

Instead, this requirement creates an annual benefit for those vessels no longer required to maintain garbage discharge records. The total annual cost (burden) for this information-collection is estimated in revised OMB collection 2115–0613 to be $2.6 million, and it applies to 1,296 vessels. The previous requirement imposed an annual cost (burden) of $25.9 million on 16,878 vessels. This rule saves industry $23.3 million annually. Therefore, the accumulated present value for the 10-year period of this benefit is $163.5 million.

(3) *Compliance with international oil discharge limitations.* Complying with international oil discharge limitations will enable U.S. vessels to engage in international trade with minimal interruption. Vessels that are not in compliance with this requirement could be denied entry into ports of countries party to MARPOL 73/78 or could experience detention in these ports. These actions could result in a substantial monetary loss due to the vessel's inability to engage in trade. Assuming non-compliance with the international oil discharge limitations, resulting in one U.S. vessel being detained each year, we estimate the avoided cost (savings) of complying with this rulemaking will be $90,000 per year. The accumulated present value for the 10-year period of this benefit will be $632,122.

Small Entities

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

In terms of costs, the oily-water or bilge monitors requirement will impose a $250 cost per tank vessel. This is a one-time cost, and in our view a very small additional cost to tank vessel owners, considering that the cost of a tank vessel, depending on its size, may be $100 million or more.

As for cost savings, the Coast Guard proposes removing from the CFR the requirement for garbage discharge records for ships of 12.2 meters (40 ft.) or more in length and less than 400

gross tons. These ships are most likely owned by the small entities in this industry and are no longer required to keep garbage disposal records. Therefore, the small entities that own these vessels benefit from the new regulation. We estimate that 15,582 oceangoing vessels will no longer need to meet that requirement, and the average annual avoided costs (savings) to each vessel will be $1,494 ($23.3 million/15,582 vessels). The accumulated present value of these avoided costs (savings) for the 10-year period of analysis will be $10,491 per vessel (163.5 million/15,582 vessels).

In addition, vessels of less than 400 GT that might be owned or operated by small entities will not be required to install oily-water separators, associated monitors, and alarms. Under § 155.350, these vessels will only need to comply with the existing requirement for retaining oily mixtures on board.

Also, under § 155.410(a)(3), U.S. non-oceangoing vessels between 100 GT and 400 GT will be allowed to install shore connections that are compatible with U.S. reception facilities. This rule allows vessels of less than 400 GT operating only in domestic service to use any shore connection that is compatible with U.S. reception facilities, rather than one that meets the international standard.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), the Coast Guard offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking.

Small entities, as well as the general public, were provided an opportunity to comment on the notice of proposed rulemaking published on August 8, 2000. No requests for assistance or for a public hearing were received.

This rule assists small entities by making the following changes to requirements: removing requirements for garbage disposal records from ships that are usually owned by small entities; removing requirements for oily-water separators, associated monitors, and alarms; and removing the requirement for certain vessels to install shore connections that meet the international standard. These actions provide cost savings to small entities.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule amends two collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Refuse discharge. This requirement mandates that vessel owners develop and maintain garbage discharge records on board their vessels if those vessels are either oceangoing ships of 400 gross tons and above, or their vessels are certified to carry 15 or more passengers and are engaged in international voyages. Oceangoing vessels less than 400 gross tons will no longer be required to maintain garbage discharge records—with the exception of vessels certified to carry 15 passengers or more on international voyages. The burden for this requirement is included in a revised OMB collection 2115–0613. As required by 44 U.S.C. 3507(d), we submitted a copy of this rule to OMB for its review of the collection of information. OMB has approved the collection. The section number is 33 CFR 151.55, and the corresponding approval number from OMB is OMB Control Number 2115–0613, which expires on April 30, 2004.

IOPP Certificates. Changing the term of the IOPP Certificate from 4 to 5 years will decrease the information-collection burden on ship owners. The information-collection burden of the IOPP Certificate is included under the previously approved OMB collection 2115–0518. As required by 44 U.S.C. 3507(d), we submitted a copy of this rule to OMB for its review of the collection of information. OMB has approved the collection. The section number is 33 CFR 151.19, and the corresponding approval number from OMB is OMB Control Number 2115–0518, which expires on February 29, 2004.

You are not required to respond to a collection of information unless it displays a currently valid OMB control number.

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them.

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

It is well settled that States may not regulate in categories reserved for regulation by the Coast Guard. It is also well settled, now, that all of the categories covered in 46 U.S.C. 3306, 3703, 7101, and 8101 (design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels), as well as the reporting of casualties and any other category in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, are within the field foreclosed from regulation by the States. (See the decision of the Supreme Court in the consolidated cases of *United States* v. *Locke and Intertanko* v. *Locke,* 529 U.S. 89, 120 S.Ct. 1135 (March 6, 2000).

This rule concerns requirements for the construction (damage and intact stability), operation (operational discharges of oil, IOPP Certificates, and garbage recordkeeping requirements), and equipping (oily-water separators) of tank vessels or other oceangoing vessels. It also implements and allows the use of an optional type of shore connection equipment for domestic vessels discharging oily mixtures at shoreside facilities. This entire rule falls within the preempted categories listed above, which, as we have long held, apply to both inspected vessels as well as tank vessels. For this reason, preemption is not an issue in this rulemaking.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their regulatory actions not specifically required by law. In particular, the Act addresses actions that may result in the expenditure of $100 million or more in any one year by a State, local, or tribal government, in the aggregate, or by the private sector. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive

Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that Order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph (34)(d) and (34)(e), of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation.

The rule aligns certain U.S. regulations with the international standards introduced in the amendments to MARPOL 73/78. These regulations fall under categorical exclusions 34 (d) and (e) regarding vessel equipment and approval. Therefore, this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket where indicated under **ADDRESSES.**

List of Subjects

33 CFR Part 151

Administrative practice and procedure, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

33 CFR Part 155

Hazardous substances, Incorporation by reference, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 157

Cargo vessels, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 158

Administrative practice and procedure, Harbors, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

46 CFR Part 172

Cargo vessels, Hazardous materials transportation, Incorporation by reference, Marine safety.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR parts 151, 155, 157, and 158 and 46 CFR part 172 as follows:

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE, MUNICIPAL OR COMMERCIAL WASTE, AND BALLAST WATER

1. The authority citation for part 151, subpart A, continues to read as follows:

Authority: 33 U.S.C. 1321 and 1903; Pub. L. 104–227 (110 Stat. 3034), E.O. 12777, 3 CFR, 1991 Comp. p. 351; 49 CFR 1.46.

§ 151.01 [Amended]

2. In § 151.01, remove the note.

3. In § 151.05, revise the definitions of the terms ''MARPOL 73/78'', ''oil'', and ''operational waste'' and add, in alphabetical order, the definitions of ''oil residue'', ''oil cargo residue'', ''fuel oil'', ''oily rags'', and ''operational waste'' to read as follows:

§ 151.05 Definitions.

* * * * *

Fuel oil means any oil used to fuel the propulsion and auxiliary machinery of the ship carrying the fuel. The term ''fuel oil'' is also known as ''oil fuel.''

* * * * *

MARPOL 73/78 means the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating to that Convention. A copy of MARPOL 73/78 is available from the International Maritime Organization, 4 Albert Embankment, London, SE1, SR7, England.

* * * * *

Oil means petroleum whether in solid, semi-solid, emulsified, or liquid form, including but not limited to, crude oil, fuel oil, sludge, oil refuse, oil residue, and refined products, and, without limiting the generality of the foregoing, includes the substances listed in Appendix I of Annex I of MARPOL 73/78. ''Oil'' does not include animal and vegetable based oil or noxious liquid substances (NLS) designated under Annex II of MARPOL 73/78.

Oil cargo residue means any residue of oil cargo whether in solid, semi-solid, emulsified, or liquid form from cargo tanks and cargo pump room bilges, including but not limited to, drainages, leakages, exhausted oil, muck, clingage, sludge, bottoms, paraffin (wax), and any constituent component of oil. The term ''oil cargo residue'' is also known as ''cargo oil residue.''

Oil residue means—

(1) Oil cargo residue; and

(2) Other residue of oil whether in solid, semi-solid, emulsified, or liquid form, resulting from drainages, leakages, exhausted oil, and other similar occurrences from machinery spaces.

Oily mixture means a mixture, in any form, with any oil content. ''Oily mixture'' includes, but is not limited to—

(1) Slops from bilges;

(2) Slops from oil cargoes (such as cargo tank washings, oily waste, and oily refuse);

(3) Oil residue; and

(4) Oily ballast water from cargo or fuel oil tanks.

Oily rags means rags soaked with oil.

Operational waste means all cargo-associated waste, maintenance waste, and cargo residues other than oil residues and NLS cargo residues. ''Operational wastes'' includes ashes and clinkers (i.e., a mass of incombustible matter fused together by heat) from shipboard incinerators and coal-burning boilers but does not include plastic clinkers, which are treated as an Annex V waste, or oily rags, which are treated as an Annex I waste.

* * * * *

§ 151.08 [Amended]

4. In § 151.08(a), remove the words ''oil or oily residues and mixtures'' and add, in their place, the phrase ''oil, oil residue, or oily mixtures''.

5. In § 151.10—

a. Revise the section heading to read as follows;

§ 151.10 Control of oil discharges.

* * * * *

b. In paragraph (a)(5), remove the number ''100'' and add, in its place, the number ''15'';

c. In the note to paragraph (f), remove the words ''residues and mixtures containing oil'' and add, in their place, the words ''oil residues and oily mixtures''; and

d. Revise paragraph (c), paragraph (f) introductory text, and paragraphs (f)(2)(i) through (f)(2)(iii) to read as follows:

(c) The overboard discharge of any oil cargo residues and oily mixtures that include oil cargo residues from an oil tanker is prohibited, unless discharged in compliance with part 157 of this chapter.

* * * * *

(f) The person in charge of an oceangoing ship that cannot discharge oily mixtures into the sea in compliance with paragraphs (a), (b), (c), or (d) of this section must ensure that those oily mixtures are—

* * * * *

(2) * * *

(i) The estimated time of day the ship will discharge oily mixtures;

(ii) The type of oily mixtures to be discharged; and

(iii) The volume of oily mixtures to be discharged.

* * * * *

6. In § 151.13, revise paragraph (b)(3) to read as set forth below and, in paragraph (f), remove the words ''oil residues'' and add, in their place, the words ''oily mixtures'':

§ 151.13 Special areas for Annex I of MARPOL 73/78.

* * * * *

(b) * * *

(3) All ships operating in the Antarctic area must have on board a tank or tanks of sufficient capacity to retain all oily mixtures while operating in the area and arrangements made to discharge oily mixtures at a reception facility outside the Antarctic area.

* * * * *

7. In § 151.19, revise paragraph (e) introductory text to read as follows:

§ 151.19 International Oil Pollution Prevention (IOPP) Certificates.

* * * * *

(e) The IOPP Certificate for each inspected or uninspected ship is valid for a maximum period of 5 years from the date of issue, except as follows:

* * * * *

§ 151.25 [Amended]

8. In § 151.25—

a. In paragraph (d)(2), remove the words ''dirty ballast'' and add, in their place, the words ''ballast containing an oily mixture'';

b. In paragraph (d)(3), remove the words ''oily residues (sludge)'' and add, in their place, the words ''oil residue''; and

c. In paragraph (e)(10), remove the word ''residues'' and add, in its place, the words ''oil residue''.

§ 151.26 [Amended]

9. In § 151.26—

a. In paragraphs (b)(3)(i)(A) and (b)(3)(i)(B), after the words ''A discharge of oil'', add the words ''or oily mixture'';

b. In paragraph (b)(3)(ii), in the note to table 151.26(b)(3)(ii), remove the phrase ''resolution A.648(16)'' and add in its place ''resolution A.851(20)''; and

c. In paragraph (b)(3)(iii)(B), after the words ''For actual or probable discharges of oil'', add the words ''or oily mixtures''.

10. In § 151.55, revise paragraphs (a)(1) and (a)(2), add a new paragraph (a)(3), and revise paragraph (b) introductory text to read as follows:

§ 151.55 Recordkeeping requirements.

(a) * * *

(1) Every manned oceangoing ship (other than a fixed or floating platform) of 400 gross tons and above that is engaged in commerce and that is documented under the laws of the United States or numbered by a State.

(2) Every manned fixed or floating platform subject to the jurisdiction of the United States.

(3) Every manned ship that is certified to carry 15 passengers or more engaged in international voyages.

(b) The master or person in charge of each ship under paragraph (a)(1), (a)(2), or (a)(3) of this section shall ensure that a written record is maintained on the ship of each of the following garbage discharge or disposal operations:

* * * * *

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

11. The authority citation for part 155 continues to read as follows:

Authority: 33 U.S.C. 1231, 1321(j); 46 U.S.C. 3715, 3719; sec. 2, E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; 49 CFR 1.46, 1.46(iii). Sections 155.100 through 155.130, 155.350 through 155.400, 155.430, 155.440, 155.470, 155.1030(j) and (k), and 155.1065(g) also issued under 33 U.S.C. 1903(b); and §§ 155.1110 through 155.1150 also issued under 33 U.S.C. 2735.

§ 155.330 [Amended]

12. In § 155.330, in the section heading, remove the phrase ''Bilge slops/fuel oil'' and add, in its place, the phrase ''Oily mixture (bilge slops)/fuel oil'' and, in paragraph (b), remove the words ''oily residue'' and add, in their place, the words ''oil residue''.

13. In § 155.350, revise the section heading and paragraph (a)(2) to read as follows and, in paragraph (b), remove the words ''oily residue'' and add, in their place, the words ''oil residue'':

§ 155.350 Oily mixture (Bilge slops)/fuel oil tank ballast water discharges on oceangoing ships of less than 400 gross tons.

(a) * * *

(2) Has approved oily-water separating equipment for processing oily mixtures from bilges or fuel oil tank ballast and discharges into the sea according to § 151.10 of this chapter.

* * * * *

14. In § 155.360—

a. Revise the section heading to read as set forth below;

b. In paragraph (a), remove the number ''100'' and add, in its place, the number ''15'' and remove the words ''oily bilge slops or oily'' and add in their place ''oily mixtures from bilges or'';

c. In paragraph (b), introductory text remove the phrase ''oily residues (sludges)'' and add, in its place, the words ''oil residue'';

d. In paragraph (b)(2), remove the words ''oily wastes'' and add in their place ''oily mixtures''; and

e. Revise paragraph (e) to read as follows:

§ 155.360 Oily Mixture (Bilge slops) discharges on oceangoing ships of 400 gross tons and above but less than 10,000 gross tons, excluding ships that carry ballast water in their fuel oil tanks.

* * * * *

(e) This section does not apply to a fixed or floating drilling rig or other platform, except as specified in § 155.400(a)(2).

* * * * *

15. In § 155.370—

a. Revise the section heading and paragraph (a) to read as set forth below;

b. In paragraph (b) introductory text, remove the phrase ''oily residues (sludges)'' and add, in its place, the words ''oil residue'';

c. In paragraph (b)(1), remove the words ''oily residues'' and add, in their place, the words ''oil residue'';

d. In paragraph (b)(2), remove the words ''oily wastes'' and add, in their place, the words ''oily mixtures'';

e. Remove paragraph (d);

f. Redesignate paragraphs (e) and (f) as paragraphs (d) and (e), respectively; and

g. Revise newly redesignated paragraph (e) to read as follows:

§ 155.370 Oily mixture (bilge slops)/fuel oil tank ballast water discharges on oceangoing ships of 10,000 gross tons and above and oceangoing ships of 400 gross tons and above that carry ballast water in their fuel oil tanks.

(a) No person may operate an oceangoing ship of 10,000 gross tons and above, or any oceangoing ship of 400 gross tons and above, that carries ballast water in its fuel oil tanks, unless it has—

(1) Approved 15 ppm oily-water separating equipment for the processing of oily mixtures from bilges or fuel oil tank ballast;

(2) A bilge alarm; and

(3) A means for automatically stopping any discharge of oily mixture when the oil content in the effluent exceeds 15 ppm.

* * * * *

(e) This section does not apply to a fixed or floating drilling rig or other platform, except as specified in § 155.400(a)(2).

§ 155.380 [Amended]

16. In § 155.380, remove paragraph (c) and redesignate paragraph (d) as paragraph (c).

17. In § 155.410, revise paragraph (a)(3) to read as set forth below and, in paragraph (b), remove the words ''oily bilge slops or oily'' and add, in their place, the words ''oily mixtures from bilges or'':

§ 155.410 Pumping, piping, and discharge requirements for non-oceangoing ships of 100 gross tons and above.

(a) * * *

(3) Each outlet required by this section has a shore connection that is compatible with reception facilities in the ship's area of operation; and

* * * * *

18. In § 155.420—

a. In paragraph (a)(3), remove the words ''The outlet'' and add, in their place, the phrase ''For a ship on an international voyage, the outlet'';

b. Redesignate paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively;

c. Add new paragraph (a)(4) to read as follows;

d. In newly designated paragraph (a)(5), remove the word ''wastes'' and add, in its place, ''mixtures''; and

e. In paragraph (b), remove the words ''oily bilge slops or oily'' and add, in their place, the words ''oily mixtures from bilges or'':

§ 155.420 Pumping, piping, and discharge requirements for oceangoing ships of 100 gross tons and above but less than 400 gross tons.

(a) * * *

(4) For a ship not on an international voyage, the outlet required by this section has a shore connection that is compatible with reception facilities in the ship's area of operation;

* * * * *

19. In § 155.430, revise paragraph (a) introductory text to read as set forth below:

§ 155.430 Standard discharge connections for oceangoing ships of 400 gross tons and above.

(a) All oceangoing ships of 400 gross tons and above must have a standard shore connection for reception facilities to discharge oily mixtures from machinery space bilges or ballast water containing an oily mixture from fuel oil tanks. The discharge connection must have the following dimensions:

* * * * *

§ 155.440 [Amended]

20. In § 155.440, in the section heading, remove the words ''water ballast'' and add, in their place, the words ''ballast water''.

21. Revise § 155.810 to read as follows:

§ 155.810 Tank vessel security.

Operators of tank vessels carrying more oil cargo residue than normal in any cargo tank must assign a surveillance person or persons responsible for maintaining standard vessel security.

§ 155.1015 [Amended]

22. In § 155.1015, in paragraphs (a) and (c)(2), before the words ''cargo residue'', add the word ''oil''.

23. In § 155.1020, revise the definition of ''petroleum oil'' to read as follows:

§ 155.1020 Definitions.

* * * * *

Petroleum oil means petroleum in any form, including but not limited to, crude oil, fuel oil, sludge, oil residue, and refined products.

* * * * *

PART 157—RULES FOR THE PROTECTION OF THE MARINE ENVIRONMENT RELATING TO TANK VESSELS CARRYING OIL IN BULK

24. The authority citation for part 157 continues to read as follows:

Authority: 33 U.S.C. 1903; 46 U.S.C. 3703, 3703a (note); 49 CFR 1.46. Subparts G, H, and I are also issued under section 4115(b), Pub. L. 101–380, 104 Stat. 520; Pub. L. 104–55, 109 Stat. 546.

§ 157.03 [Amended]

25. In § 157.03—

a. In the definitions of ''lightweight'', ''oil fuel'', and ''segregated ballast'', remove the words ''oil fuel'' and add, in their place, the words ''fuel oil'';

b. In the definition of ''slop tank'', remove the words ''oil mixtures'' and add, in their place, the words ''oily mixtures'';

c. Add, in alphabetical order, the definitions of the terms ''MARPOL 73/78'', ''oil cargo residue'', ''oil residue'' and ''oily mixture'';

d. Remove the definition of ''MARPOL Protocol''; and

e. Revise the definition of ''petroleum oil'' to read as follows:

§ 157.03 Definitions.

* * * * *

MARPOL 73/78 means the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating to that Convention. A copy of MARPOL 73/78 is available from the International Maritime Organization, 4 Albert Embankment, London, SE1 7SR, England.

* * * * *

Oil cargo residue means any residue of oil cargo whether in solid, semi-solid, emulsified, or liquid form from cargo tanks and cargo pump room bilges, including but not limited to, drainages, leakages, exhausted oil, muck, clingage, sludge, bottoms, paraffin (wax), and any constituent component of oil. The term ''oil cargo residue'' is also known as ''cargo oil residue.''

Oil residue means—

(1) Oil cargo residue; and

(2) Other residue of oil whether in solid, semi-solid, emulsified, or liquid form, resulting from drainages, leakages, exhausted oil, and other similar occurrences from machinery spaces.

Oily mixture means a mixture, in any form, with any oil content. ''Oily mixture'' includes, but is not limited to—

(1) Slops from bilges;

(2) Slops from oil cargoes (such as cargo tank washings, oily waste, and oily refuse);

(3) Oil residue; and

(4) Oily ballast water from cargo or fuel oil tanks, including any oil cargo residue.

* * * * *

Petroleum oil means petroleum in any form, including but not limited to, crude oil, fuel oil, sludge, oil residue, and refined products.

* * * * *

§ 157.04 [Amended]

26. In § 157.04(b), remove the words ''MARPOL Protocol'' and add, in their place, ''MARPOL 73/78''.

§ 157.07 [Amended]

27. In § 157.07, remove the phrase ''MARPOL Protocol'' and add, in its place, the phrase ''MARPOL 73/78''.

§ 157.11 [Amended]

28. In § 157.11(a), remove the words ''cargo residues and other''.

§ 157.12 [Amended]

29. In § 157.12(b)(2), remove the phrase ''MARPOL Protocol'' and add, in its place, the phrase ''MARPOL 73/78''.

30. Revise § 157.15(b) introductory text to read as follows:

§ 157.15 Slop tanks in tank vessels.

* * * * *

(b) *Capacity.* Slop tanks must have the total capacity to retain oily mixtures from cargo tank washings, oil residue, and ballast water containing an oily mixture of 3 percent or more of the oil carrying capacity. Two percent capacity is allowed if there are—

* * * * *

§ 157.17 [Amended]

31. In § 157.17—

a. In the section heading and in paragraphs (b) and (c), remove the words ''oily residue'' and add, in their place, the phrase ''oil residue (sludge)''; and

b. In paragraph (a), remove the words ''oily residue'' and add, in their place, the words ''oil residue''.

32. Add § 157.22 to read as follows:

§ 157.22 Intact stability requirements.

All tank ships of 5,000 DWT and above contracted after December 3, 2001 must comply with the intact stability requirements of Regulation 25A, Annex I MARPOL 73/78.

§ 157.24 [Amended]

33. In § 157.24(c)(2), remove the words ''MARPOL Protocol'' and add, in their place, ''MARPOL 73/78''.

§ 157.24a [Amended]

34. In § 157.24a(b)(2), remove the words ''MARPOL Protocol'' and add, in their place, ''MARPOL 73/78''.

§ 157.33 [Amended]

35. In § 157.33, remove the words ''oil fuel'' and add, in their place, the words ''fuel oil''.

36. In § 157.37—

a. In paragraph (a)(3), remove the number ''60'' and add, in its place, the number ''30'';

b. In paragraph (a)(7), remove the phrase ''MARPOL Protocol'' and add, in its place, the phrase ''MARPOL 73/78'';

c. In paragraph (b), remove the word ''residues'' and add, in its place, the words ''oil cargo residues''; and

d. Revise the section heading and paragraph (e) introductory text to read as follows:

§ 157.37 Discharge of oily mixtures from oil cargoes.

* * * * *

(e) Ballast water containing an oily mixture may be discharged below the waterline at sea by gravity if—

* * * * *

§ 157.39 [Amended]

37. In § 157.39—

a. In paragraph (a) and the introductory text of paragraph (b), remove the words ''oil cargo mixture'' and add, in their place, the words ''oil cargo residue'';

b. Remove paragraph (b)(1);

c. Redesignate paragraphs (b)(2), (b)(3), and (b)(4) as paragraphs (b)(1), (b)(2), and (b)(3), respectively;

d. In newly designated paragraph (b)(2), remove the number ''100'' and add, in its place, the number ''15''.

§ 157.43 [Amended]

38. In § 157.43(b) introductory text, remove the words ''oil mixture'' and add, in their place, the words ''oily mixture''.

§ 157.118 [Amended]

39. In § 157.118(a)(1)(ii) and (a)(2)(i), remove the phrase ''MARPOL Protocol'' and add, in its place, the phrase ''MARPOL 73/78''.

§ 157.138 [Amended]

40. In § 157.138(a)(1), remove the phrase ''MARPOL Protocol'' and add, in its place, the phrase ''MARPOL 73/78''.

§ 157.140 [Amended]

41. In § 157.140(a)(1), remove the phrase ''oil clingage or deposits of oil, or both'' and add, in its place, the words ''oil residues''.

§ 157.160 [Amended]

42. In § 157.160(a)(2) and (b)(3), remove the word ''sludge'' and add, in its place, ''oil cargo residue''.

§ 157.216 [Amended]

43. In § 157.216(a)(1)(ii) and (a)(2)(i), remove the phrase ''MARPOL Protocol'' and add, in its place, the phrase ''MARPOL 73/78''.

§ 157.224 [Amended]

44. In § 157.224(a), remove the phrase ''MARPOL Protocol'' and add, in its place, the phrase ''MARPOL 73/78''.

§ 157.302 [Amended]

45. In § 157.302, paragraphs (b)(3) and (b)(6), remove the words ''cargo residues'' and add, in their place, the words ''oil cargo residues''.

§ 157.304 [Amended]

46. In § 157.304(a), remove the words ''cargo residues'' and add, in their place, ''oil cargo residues''.

§ 157.310 [Amended]

47. In § 157.310(c), remove the words ''cargo residues'' and add, in their place, the words ''oil cargo residues''.

§ 157.400 [Amended]

48. In § 157.400(b)(2), remove the words ''cargo residue'' and add, in their place, the words ''oil cargo residue''.

49. In part 157, appendix B, add paragraph 3(f) to read as follows:

Appendix B—Subdivision and Stability Assumptions

* * * * *

3. * * *

(f) For oil tankers of 20,000 DWT and above, the damage assumptions must be supplemented by the following assumed bottom raking damage:

(1) Longitudinal extent:

(i) For ships of 75,000 DWT and above, 0.6L measured from the forward perpendicular.

(ii) For ships of less than 75,000 DWT, 0.4L measured from the forward perpendicular.

(2) Transverse extent: B/3 anywhere in the bottom.

(3) Vertical extent: Breach of the outer hull.

Appendix D [Amended]

50. In part 157, appendix D, paragraph 2(a)(1), remove the word ''slop'' and add, in its place, the words ''oily mixtures''.

PART 158—RECEPTION FACILITIES FOR OIL, NOXIOUS LIQUID SUBSTANCES, AND GARBAGE

51. The authority citation for part 158 continues to read as follows:

Authority: 33 U.S.C. 1903(b); 49 CFR 1.46.

§ 158.100 [Amended]

52. In § 158.100(b)(1), remove the words ''Residues and mixtures containing oil'' and add, in their place, the words ''Oily mixtures''.

§ 158.110 [Amended]

53. In § 158.110(a)(1), remove the words ''residues and mixtures containing oil'' and add, in their place, the words ''oily mixtures''.

54. In § 158.120—

a. Revise the section heading;

b. Remove the definition of ''MARPOL Protocol'';

c. Revise the definition of ''oil'';

d. In the definition of ''reception facility'', remove the words ''residues and mixtures containing oil'' and add, in their place, the words ''oily mixtures''; and

e. Add, in alphabetical order, the definitions of the terms ''MARPOL 73/78'', ''oil cargo residue'', ''oil residue'', and ''oily mixtures'' to read as follows:

§ 158.120 Definitions.

* * * * *

MARPOL 73/78 means the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating to that Convention. A copy of MARPOL 73/78 is available from the International Maritime Organization, 4 Albert Embankment, London, SE1 7SR, England.

* * * * *

Oil means petroleum whether in solid, semi-solid, emulsified, or liquid form, including but not limited to, crude oil, fuel oil, sludge, oil refuse, oil residue, and refined products, and, without limiting the generality of the foregoing, includes the substances listed in Appendix I of Annex I of MARPOL 73/78. ''Oil'' does not include animal and vegetable based oil or noxious liquid substances (NLS) designated under Annex II of MARPOL 73/78.

Oil cargo residue means any residue of oil cargo whether in solid, semi-solid, emulsified, or liquid form from cargo tanks and cargo pump room bilges, including but not limited to, drainages, leakages, exhausted oil, muck, clingage, sludge, bottoms, paraffin (wax), and any constituent component of oil. The term ''oil cargo residue'' is also known as ''cargo oil residue.''

Oil residue means—

(1) Oil cargo residue; and

(2) Other residue of oil resulting from drainages, leakages, exhausted oil, and other similar occurrences from machinery spaces.

Oily mixture means a mixture, in any form, with any oil content. ''Oily mixture'' includes, but is not limited to—

(1) Slops from bilges;

(2) Slops from oil cargoes (such as cargo tank washings, oily waste, and oily refuse);

(3) Oil residue; and

(4) Oily ballast water from cargo or fuel oil tanks.

* * * * *

§ 158.133 [Amended]

55. In § 158.133(a), remove the words ''residues and mixtures containing oil'' and add, in their place, the words ''oily mixtures''.

§ 158.135 [Amended]

56. In § 158.135(a), remove the words ''residues and mixtures containing oil'' and add, in their place, the words ''oily mixtures''.

57. Revise the heading of subpart B to read as follows:

Subpart B—Criteria for Reception Facilities: Oily Mixtures

§ 158.200 [Amended]

58. In § 158.200(a)(2), (a)(3)(i), (a)(3)(iii), and (b), remove the words ''residues and mixtures containing oil'' and add, in their place, the words ''oily mixtures''; and, in (a)(3)(ii), remove the words ''oily ballast'' and add, in their place, the words ''ballast water containing oily mixtures''.

§ 158.210 [Amended]

59. In § 158.210—

a. In paragraph (a), remove the word ''Sludge'' and add, in its place, the words ''Oil residue'';

b. In paragraph (b), remove the words ''Oily bilge water'' and add, in their place, the words ''Bilge water containing oily mixtures''; and

c. In paragraph (c), remove the words ''Oily ballast'' and add, in their place, the words ''Ballast water containing oily mixtures''.

§ 158.220 [Amended]

60. In § 158.220—

a. In paragraph (a), remove the word ''Sludge'' and add, in its place, the words ''Oil residue'';

b. In paragraph (b), remove the words ''Oily bilge water'' and add, in their place, the words ''Bilge water containing oily mixtures'';

c. In paragraph (c), remove the words ''Oily ballast'' and add, in their place, the words ''Ballast water containing oily mixtures''; and

d. In paragraph (d), remove the words ''Cargo residue'' and add, in their place, the words ''Oil cargo residue''.

§ 158.230 [Amended]

61. In § 158.230—

a. In paragraph (a), remove the word ''Sludge'' and add, in its place, the words ''Oil residue''; and

b. In paragraph (b), remove the words ''Oily bilge water'' and add, in their place, the words ''Bilge water containing oily mixtures''.

62. In § 158.240, revise paragraphs (a) and (b), and the introductory text to paragraphs (c) and (d), to read as follows:

§ 158.240 Ship repair yards.

* * * * *

(a) An amount of ballast from bunker tanks, and the wash water and oil residue from the cleaning of bunker tanks and oil residue (sludge) tanks, equal to 8 percent of the bunker capacity of the largest oceangoing ship serviced;

(b) An amount of solid oil cargo residues from cargo tanks equal to 0.1 percent of the deadweight tonnage of the largest oceangoing tanker serviced;

(c) An amount of ballast water containing oily mixtures and wash water from in-port tank washing equal to—

* * * * *

(d) An amount of liquid oil cargo residue based on the following percentages of deadweight tonnage of the largest oceangoing tanker serviced:

* * * * *

§ 158.250 [Amended]

63. In § 158.250, remove the words ''oily bilge water''and add, in their place, the words ''bilge water containing oily mixtures''.

46 CFR PART 172—SPECIAL RULES PERTAINING TO BULK CARGOES

64. The authority citation for part 172 continues to read as follows:

Authority: 46 U.S.C 3306, 3703, 5115; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

65. Add § 172.048 to read as follows:

§ 172.048 Definitions.

As used in this subpart—

MARPOL 73/38 means the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating to that Convention

66. In § 172.065, in table 172.065(A), revise the heading of the table and, at the end of the table, immediately preceding footnote 1 to the table, add a new undesignated heading and entry for ''GROUNDING PENETRATION FOR RAKING DAMAGE''; and, in table 172.065(B), revise the heading of the table to read as follows:

§ 172.065 Damage stability.

* * * * *

TABLE 172.065(A)—EXTENT OF DAMAGE

* * * * * * *	
GROUNDING PENETRATION FOR RAKING DAMAGE	
For tank vessels of 20,000 DWT and above, the following assumed bottom raking damage must supplement the damage assumptions:	
Longitudinal extent	For vessels of 75,000 DWT and above, 0.6L measured from the forward perpendicular. For vessels of less than 75,000 DWT, 0.4L measured from the forward perpendicular.
Transverse extent	B/3 anywhere in the bottom.
Vertical extent	Breach of the outer hull.
* * * * * * *	

TABLE 172.065(B)—PERMEABILITY

* * * * *

68. Add § 172.070 to read as follows:

§ 172.070 Intact stability.

All tank vessels of 5,000 DWT and above contracted after the effective date of this rulemaking must comply with the intact stability requirements of Regulation 25A, annex I of MARPOL 73/78.

Dated: June 25, 2001.

Paul J. Pluta,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 01–27256 Filed 11–01–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–01–198]

RIN 2115–AA97

Security Zone; Verrazano Narrows Bridge, New York

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary emergency security zone around the Verrazano Narrows Bridge, New York that will restrict vessel traffic in a portion of The Narrows, between Staten Island and Brooklyn, NY. This action is necessary to ensure public safety, and protect the Port of NY/NJ from sabotage or terrorist acts, accidents, or other causes of a similar nature during the New York City Marathon. Entry into or movement within this zone by any vessel or person, of any description without the express authority of the Captain of the Port, New York, or his authorized patrol representative is strictly prohibited.

DATES: This rule is effective from 9:20 a.m. until 12:20 p.m. on November 4, 2001.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket (CGD01–01–198) and are available for inspection or copying at Coast Guard Activities New York, 212 Coast Guard Drive, room 204, Staten Island, New York 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant M. Day, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4012.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(3), the Coast Guard finds that good cause exists for not publishing an NPRM. This rulemaking is urgently required to prevent terrorist strikes within and adjacent to the Port of NY/NJ. The delay inherent in the NPRM process is contrary to the public interest as it may render individuals, vessels and facilities within the Port vulnerable to subversive activity, sabotage or terrorist attack. Commercial vessels may still transit through the Port via Long Island Sound, the East River, the Kill Van Kull, and the Arthur Kill.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The measures contemplated by the rule are intended to prevent future terrorist attacks. Immediate action is needed to accomplish these objectives. Any delay in the effective date of this rule is impractical and contrary to the public interest.

Background and Purpose

Terrorist attacks against the World Trade Center in Manhattan, New York on September 11, 2001 inflicted catastrophic human casualties and property damage. Federal, state and local agencies are engaged in ongoing efforts to recover the victims and secure other potential terrorist targets from attack. The Coast Guard is establishing this security zone to ensure the security of the Port of NY/NJ against terrorism, sabotage, or other subversive acts and incidents of a similar nature prior to and during the start of the New York City Marathon, a widely publicized event that draws large numbers of spectators and participants.

This regulation establishes a temporary security zone in all waters of The Narrows within 500 yards of the Verrazano Narrows Bridge. The security zone is in effect from 9:20 a.m. until 12:20 p.m. on Sunday, November 4, 2001. The security zone prevents vessels from transiting a portion of The Narrows between Staten Island and Brooklyn, NY.

This security zone is based on the security needs for the Port of NY/NJ. It has been narrowly tailored to impose the least impact on maritime interests yet provide the level of security deemed necessary. Entry into or movement within this security zone is prohibited unless authorized by the Coast Guard Captain of the Port, New York. Public notifications will be made prior to the event via the Local Notice to Mariners and Marine Information Broadcasts.

Regulatory Evaluation

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

The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory

Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This finding is based on the minimal time that vessels will be restricted from the zone, that vessels may still transit through the Port via Long Island Sound, the East River, Kill Van Kull, and the Arthur Kill, and advance notifications which will be made. The U.S. Coast Guard in consultation with local, state, and federal law enforcement agencies determined the size of this security zone.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit a portion of The Narrows between Staten Island and Brooklyn, NY during the times this zone is activated.

This security zone will not have a significant economic impact on a substantial number of small entities for the following reasons. Vessel traffic may still transit through the Port via Long Island Sound, the East River, the Kill Van Kull, and the Arthur Kill. Before the effective period, public notifications will be made via the Local Notice to Mariners and Marine Information Broadcasts, which are widely available to users of the Port of NY/NJ.

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this rule and concluded that under figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1D, this rule is categorically excluded from further environmental documentation. This rule fits paragraph 34(g) as it establishes an emergency security zone. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Regulation

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. Add temporary § 165.T01–198 to read as follows:

§ 165.T01–198 Security Zone: Verrazano Narrows Bridge, New York.

(a) *Location.* The following area is a security zone: All waters of The Narrows within 500 yards of the Verrazano Narrows Bridge.

(b) *Effective period.* This section is effective from 9:20 a.m. until 12:20 p.m. on November 4, 2001.

(c) *Regulations.* (1) The general regulations contained in 33 CFR 165.33 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene-patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: October 25, 2001.

P.A. Harris,

Captain, U.S. Coast Guard, Captain of the Port, New York, Acting.

[FR Doc. 01–27607 Filed 10–30–01; 3:45 pm]

BILLING CODE 4910–15–U

POSTAL SERVICE

39 CFR Part 960

Implementation of the Contract With America Advancement Act

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service is amending the rules implementing the Equal Access to Justice Act in Postal Service proceedings to reflect the statutory increase in the amount of the hourly fees payable.

EFFECTIVE DATE: November 2, 2001.

FOR FURTHER INFORMATION CONTACT: Diane M. Mego, (703) 812–1905.

SUPPLEMENTARY INFORMATION: The Contract with America Advancement Act of 1996 (Pub. L. 104–121, 110 Stat. 857 (1996)) increased the maximum amount of attorney fees under the Equal Access to Justice Act from $75 per hour to $125 per hour. This rulemaking amends 39 CFR part 960 to conform with the statutory change. In addition, language specifying the allowable fees for expert witnesses is being deleted.

These are statutorily mandated changes in agency rules of procedure before the Judicial Officer and, therefore, it is appropriate for their adoption by the Postal Service to become effective immediately.

List of Subjects in 39 CFR Part 960

Administrative practice and procedure, Equal access to justice, Postal Service.

Accordingly, the Postal Service adopts amendments to 39 CFR part 960 as specifically set forth below:

PART 960—[AMENDED]

1. The authority citation for part 960 continues to read as follows:

Authority: 5 U.S.C. 504 (c) (1); 39 U.S.C. 204, 401 (2).

§ 960.6 [Amended]

2. Section 960.6(b) is amended by removing ''$75.00 per hour'' and adding $125.00 per hour, or such rate as prescribed by 5 U.S.C. 504''.

3. Section 960.6(b) is further amended by removing '', which is generally $50.00 per hour''.

§ 960.7 [Amended]

4. Section 960.7(a) is amended by removing ''$75 per hour'' and adding ''$125.00 per hour, or such rate as prescribed by 5 U.S.C. 504,''.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 01–27626 Filed 11–1–01; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–7096–1]

RIN 2060–AC28

Ethylene Oxide Emissions Standards for Sterilization Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; amendments.

SUMMARY: This action finalizes amendments to the emissions standards for sterilization facilities by eliminating maximum achievable control technology (MACT) requirements for chamber exhaust vents. This action reduces safety problems associated with the existing requirements. This action also amends testing and monitoring requirements for sterilization chamber, aeration, and chamber exhaust vents to correct technical problems associated with the existing requirements.

EFFECTIVE DATE: November 2, 2001.

ADDRESSES: Docket No. A–88–03 contains supporting information used in developing the standards for the ethylene oxide commercial sterilization source category. The docket is located at the U.S. EPA, 401 M Street, SW., Washington, DC 20460 in Room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. David W. Markwordt, Policy, Planning, and Standards Group, Emission Standards Division (MD–13), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0837, facsimile (919) 541–0942, electronic mail address: *markwordt.david@epa.gov.*

SUPPLEMENTARY INFORMATION: *Docket.* The docket is an organized and complete file of all the information considered by EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(7)(A) of the Clean Air Act (CAA).) The regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be mailed on request from the Air Docket by calling (202) 260–7548. A reasonable fee may be charged for copying docket materials.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of today's final rule amendments will also be available on the WWW through the EPA's Technology Transfer Network (TTN). Following signature, a copy of the rule amendments will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules, *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

Regulated Entities. Categories and entities regulated by this action include:

Category	SIC [a]/NAICS [b]	Examples of regulated entities
Industry	3841, 3842 ...	Medical suppliers.
	2834, 5122, 2831, 2833	Pharmaceuticals.
	2099, 5149, 2034, 2035, 2046	Spice manufacturers.
	7399, 7218, 8091	Contract sterilizers.

[a] Standard Industrial Classification Code.
[b] North American Information Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility is regulated by this action, you should examine the applicability criteria in § 63.2131 of the final rule.

Judicial Review. Under section 307(b) of the CAA, judicial review of this final rule is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by January 2, 2002. Under section 307(d)(7)(B) of the CAA, only an objection to these rule amendments which was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section

307(b)(2) of the CAA, the requirements established by today's final action may not be challenged separately in any civil or criminal proceeding we bring to enforce these requirements.

I. Background

On July 11, 1997, we learned of reports of explosions at several ethylene oxide sterilization facilities. Some of the explosions occurred at facilities affected by the ethylene oxide emissions standards. As a result, we took immediate steps to suspend the rule until December 1998 pending an investigation of the explosions and to notify facility owners.

We completed our investigation in 1998 to determine if the emission control equipment mandated by the emissions standards was in any way associated with the problems at these facilities. We agreed with industry that, in the cases where explosions occurred, the catalytic oxidizer units were overfed with ethylene oxide in concentrations above the safe operations limit due to abnormal activation of the chamber exhaust (backvent). In June 1998, the Ethylene Oxide Sterilization Association (EOSA) recommended ''additional time to consider safe and economical control, installation, operation, and maintenance alternatives applicable to aeration and chamber exhaust (backvent) emissions.'' The EOSA provided a time line of approximately 12 months beyond December 1998 to enable implementation of the appropriate changes to ensure safe operation. We agreed with EOSA's recommendation and further extended the compliance date for chamber exhaust and aeration room vents for all sources affected by the ethylene oxide emissions standards by 1 year, until December 8, 1999. The two affected emission points, the chamber exhaust and aeration room vent, represent approximately 1 and 3 percent of the uncontrolled emissions, respectively.

In June 1999, the EOSA requested elimination of the requirement for chamber exhaust vent controls. In December 1999, we again suspended the compliance dates for chamber exhaust and aeration room vents. A 1-year suspension of control requirements for aeration room vents was based on the fact that many facilities are routing chamber exhaust emissions to the emission control device for aeration room vents. Since control of the aeration room vent by itself does not pose any known safety problems, we did not anticipate any further suspensions of requirements for aeration room vents beyond December 6, 2000. We provided a 2-year suspension of control requirements for chamber exhaust vent emissions based on the anticipated time required to propose and promulgate changes in the **Federal Register**. We committed to reconsidering the original MACT determination for chamber exhaust vents and proposing a course of action in the near future.

The use of existing technology by some sources in the relevant industry category presumes the ability to operate that technology in a proven safe manner. Nonetheless, at the time of promulgation (December 1994), state-of-the-art control technology for chamber exhaust vent emissions apparently involved safety hazards not known at that time. To date, solutions to the safety problems have not been developed, and there is no indication that resolution of the safety issues is forthcoming. Consequently, on March 6, 2001, we proposed eliminating the MACT requirements for chamber exhaust vents (66 FR 13464). We also proposed amendments to testing and monitoring requirements for sterilization chamber, aeration, and chamber exhaust vents.

II. What Are the Final Rule Amendments?

A. Chamber Exhaust Vents

We have removed the requirement to control the ethylene oxide emissions from the chamber exhaust vents. See the March 6, 2001 proposal preamble for the detailed reasons for this change. For all facilities (i.e., both major and area sources), we have removed the 5,300 parts per million per volume (ppmv) concentration limit requirement for chamber exhaust vents.

B. Catalytic Oxidizer Monitoring

We have removed the requirement to operate at the average temperature to demonstrate continuous compliance. We are now requiring facilities to maintain a minimum temperature for catalytic oxidizers based on manufacturer design and perform a work practice. Facilities can do either of the following work practices: periodically replace catalyst, or annually test control device performance and if necessary restore the catalyst.

We have made changes to the monitoring requirements to provide facilities an alternative to continuous catalyst temperature monitoring. Facilities can monitor either temperature or ethylene oxide concentration for catalytic oxidizers. In the final rule, we have added several additional test method to measure ethylene oxide concentration.

III. What Major Changes Have We Made to the Rule Since Proposal?

In response to comments received on the proposed amendments, we made several changes for the final rule. While some of the changes we made were clarifications designed to make our intentions more clear, some of the changes do alter the requirements as proposed. The substantive comments and/or changes and responses made since the proposal are summarized in the following sections. Our complete responses to public comments are contained in a memorandum that can be obtained from docket A–88–03.

A. Elimination of 5,300 ppmv Concentration Requirement

To ensure that the current amount of ethylene oxide being evacuated via the sterilization pump continues to be routed to a control device rather than exhausted via an uncontrolled vent, we proposed a concentration-based limit on emissions from major source chamber exhaust vents. In the original, existing rule, this requirement currently applies to area sources but not to major sources.

Comments: Commentors questioned ''the Agency's reliance on the 5,300 ppmv empty chamber concentration as a suitable limitation when such test conditions have zero connection to the reality of operations in a commercial sterilization facility.'' The commentor also stated that their research showed ''no reliable justification for the 5,300 ppmv MACT and we are convinced from our own experience that this level, however determined, was unfounded at the time the regulation was originally drafted.''

One commentor stated that industry does not have knowledge of any proven instrumentation it could employ to comply with the proposed requirement to determine the concentration of ethylene oxide in the sterilization chamber immediately prior to the operation of the chamber exhaust. The commentor stated it is universally known and understood that a safe, reliable and accurate technology capable of providing a determination of the exhaust vent concentration is not available. The commentor also stated that a separate system (suitable for small exhaust, high concentration, for a short time period of 5 minutes or less) would be needed, probably for each chamber. If gas chromatography (GC)-based systems are used, costs are $60,000–$100,000 per chamber, provided some existing system could somehow be made safe, reliable, and accurate. Also,

units for area and process control are not satisfactory because they are set up differently and measure different concentration levels.

Response: As stated previously, the Agency is removing the control requirement for the major source chamber exhaust vent as proposed. The Agency had also proposed a 5,300 ppmv concentration limit on the chamber exhaust vent for larger facilities (i.e., major sources). The 5,300 ppmv concentration limit was required in the original rule for smaller facilities (i.e., area sources with 1 to 10 tons of ethylene oxide use) which were not required to control chamber exhaust vent emissions.

We agree with the commentor that the 5,300 ppmv concentration limit was based on ''Agency modeling, not actual operating conditions.'' We also agree with the commentor that there is no proven instrumentation which could be employed to comply with the proposed requirement to determine the concentration of ethylene oxide in the sterilization chamber immediately prior to the operation of the chamber exhaust. For these reasons, we have reconsidered the proposed and existing concentration limit requirement.

The sterilization chamber vent emissions are currently controlled with add-on control devices; these devices are required to reduce inlet emissions by 99 percent. For small facilities, under the existing rule the MACT floor for new and existing source chamber exhaust vents requires no reduction in emissions from these vents. The purpose of the existing rule's 5,300 ppmv limitation on the small chamber exhaust vents is to ensure that the current amount of ethylene oxide being evacuated via the sterilization pump continues to be routed to a control device rather than exhausted via an uncontrolled vent. The 5,300 ppmv requirement maintained the status quo for emissions from the chamber exhaust vent, and did not require the use of any control technologies. In promulgating the existing rule, the Administrator determined that the use of this limit did not constitute measures beyond the MACT floor for these sources (59 FR 10591). The chamber exhaust concentration limit was added to the rule as a precautionary measure; the Agency did not know of any plant operators by-passing main sterilization vent control devices.

Comment: One commentor recommended a 7,500 ppmv limit (25 percent of the lower explosive limit); the limit would be determined based on empty chamber cycle calculations for all cycles. This approach does not require test equipment. The commentor stated that it is common industry practice to analyze the safety of a sterilization cycle by calculating the residual sterilant in an empty sterilizer at the completion of the process. Most sterilization facilities require that the safety analysis be performed on every new sterilization cycle. The intent of the safety analysis is to demonstrate that the concentration of ethylene oxide gas in the sterilizer at the end of processing is below 1 percent (10,000 ppmv). This ensures that during routine processing the sterilizer environment is non-flammable when the door is opened and the exhaust vent is activated. The determination of this empty chamber concentration relies on simple dilution formulas and the ideal gas laws. Using partial pressure data of ethylene oxide in the sterilizer following the initial charge, one can determine concentration through the subsequent evacuation and purging sequences. The commentor stated that sterilization cycles in question are generally validated to meet the requirements of the Food and Drug Administration (FDA).

Another commentor believes the present regulations provide adequate assurance to ensure that ethylene oxide from the sterilization chamber vent continues to be routed through a control device. The EPA specifically defines sterilization chamber vent as ''* * * the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.'' The rule also specifically requires that sources using greater than 1 ton per year of ethylene oxide ''* * * shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.''

Rerouting sterilization chamber vents to exhaust out the uncontrolled chamber exhaust vent would be in direct violation of the present regulation.

Response: After considering the comments and additional information, we decided that the concentration limit approach is not feasible because there is no known way to safely measure concentration. A gas chromatograph is a logical testing approach but it includes a flame source which introduces a safety issue.

Today, we have less concern regarding by-passing the main sterilization control equipment by routing ethylene oxide to the chamber exhaust vent. As stated previously, there were no data suggesting plant operators were by-passing the main control device. Since initial work on the rule in the 1980's, significant regulatory changes have occurred which have affected the sterilization industry. In response to the phase-out of chlorofluorocarbon production, industry switched from a mixture of chlorofluorocarbons and ethylene oxide to pure ethylene oxide for processing. The Occupational Safety and Health Administration (OSHA) tightened workplace ethylene oxide concentration exposure limits, and on October 7, 1996, the FDA revised the Current Good Manufacturing Practice (CGMP) requirements for medical devices and incorporated them into a quality system regulation.

Now that the use of pure ethylene oxide dominates industry practice, there are serious safety issues associated with by-passing the main control device. Venting pure ethylene oxide to the atmosphere could cause an explosion. Additionally, it is probable that venting would result in workplace exposure concentrations which would violate the OSHA limits. Industry is very aware of these safety concerns.

The FDA quality system regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. The action was necessary to add preproduction design controls and to achieve consistency with quality system requirements worldwide. The regulation sets forth the framework for device manufacturers to follow and gives them greater flexibility in achieving quality requirements (61 FR 52601).

These requirements apply to contract sterilization and specify quality system requirements including management controls, design controls, material controls, equipment controls, production and process controls, corrective and preventive action, and documentation. For sterilization operations, the objectives of the quality system regulation apply only to the safety and effectiveness of medical devices following sterilization. However, compliance with its requirements may also provide an assurance that processing will be performed in a way which meets concerns regarding vent emissions. For example, in meeting the requirement in the quality system regulation for a definition of specifications for all steps of the process, a sterilizing facility must specify the number of air washes in the ethylene oxide sterilization process. By meeting the requirements for documentation to demonstrate that each process step has been performed as specified, the facility will establish

procedures to document performance of the air washes. The requirements of the quality system are already in place; compliance with the quality system regulation will ensure that specifications for process steps are defined and met.

The Agency believes there are sufficient practical reasons (i.e., safety considerations as well as existing OSHA and FDA regulatory requirements) for eliminating our original presumptive need for the chamber exhaust emission limit. The Agency sees no practical benefit to adding additional requirements to accomplish the same thing. Therefore, because the concentration cannot be measured and there is now little or no value to the requirement, we are not promulgating the chamber exhaust concentration limit for large facilities and are withdrawing the requirement for small facilities.

B. Alternative to Catalyst Replacement Requirement

We proposed a requirement to replace catalytic oxidizer catalyst every 2 years to ensure that the catalyst remains active and in continuous compliance with the control device performance requirement. The proposed replacement of catalyst every 2 years was opposed by commentors because the practice was believed to be wasteful and costly. Some commentors stated that the compliance test should suffice to indicate compliance.

We agreed with the commentors that performance testing is a viable alternative to routine replacement of catalyst in ensuring continuous compliance. Therefore, we have added a test alternative to the rule. If test results show the control efficiency is below the performance standard, the facility will have to restore the catalyst as soon as practicable but no later than 180 days after the performance test.

IV. Summary of Environmental, Energy and Economic Impacts

There are negligible environmental, energy, and economic impacts associated with these amendments. Ethylene oxide emissions from the chamber exhaust vent comprise less than 1 percent of the uncontrolled emissions from the sterilization process.

V. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), we 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. The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that these rule amendments are not a ''significant regulatory action'' under the terms of Executive Order 12866. Consequently, this action was not submitted to OMB for review under Executive Order 12866.

B. Paperwork Reduction Act

The information collection requirements of the ethylene oxide national emission standards for hazardous air pollutants (NESHAP) were submitted to and approved by OMB. A copy of the Information Collection Request (ICR) document (OMB control number 2060–0283) may be obtained from Ms. Sandy Farmer by mail at the U.S. EPA, Office of Environmental Information, Collection Strategies Division (2822), 1200 Pennsylvania Avenue, Washington, DC 20460, by e-mail at *farmer.sandy@epa.gov*, or by calling (202) 260–2740. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr.*

Today's action has little or no impact on the information collection burden estimates made previously. Today's action eliminates requirements for chamber exhaust vents and clarifies testing and monitoring requirements for sterilization and aeration room vents. These changes revise existing requirements and do not impose new additional burdens; consequently, the ICR has not been revised.

C. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' Policies that have federalism implications is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

These final rule amendments will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The final rule is mandated by statute and does not impose requirements on States; however, States will be required to implement the rule by incorporating the rule into permits and enforcing the rule upon delegation. States will collect permit fees that will be used to offset the resource burden of implementing the rule. Thus, the requirements of section 6 of the Executive Order do not apply to this rule. Although section 6 of Executive Order 13132 does not apply to this rule, the EPA did consult with State and local officials in developing these rule amendments.

D. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

These final rule amendments do not have tribal implications. They will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. This is because no tribal governments own or operate an ethylene oxide sterilization facility. Thus, Executive

Order 13175 does not apply to these rule amendments.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in aggregate, or by the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows the EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation as to why that alternative was not adopted. Before the EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule amendments contain no Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. These amendments eliminate existing requirements. Thus, today's final rule amendments are not subject to the requirements of sections 202 and 205 of the UMRA. In addition, the EPA has determined that these amendments contain no regulatory requirements that might significantly or uniquely affect small governments because it contains no regulatory requirements that apply to such governments or impose obligations upon them. Therefore, today's final rule amendments are not subject to the requirements of section 203 of the UMRA.

Because these final rule amendments do not include a Federal mandate and are estimated to result in expenditures less than $100 million in any 1 year by State, local, and tribal governments, the EPA has not prepared a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative. In addition, because small governments will not be significantly or uniquely affected by these rule amendments, the EPA is not required to develop a plan with regard to small governments. Therefore, the requirements of the UMRA do not apply to this action.

F. Regulatory Flexibility Act (RFA) as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's final rule amendments on small entities, small entity is defined as: (1) A small business according to the Small Business Administration (SBA) size standards by NAICS code ranging from 500 to 1,000 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule amendments on small entities, EPA has concluded that this action will not have a significant impact on a substantial number of small entities. We believe there will be little or no impact on any small entities because these amendments do not impose additional requirements but instead either eliminate or streamline some existing requirements of the ethylene oxide NESHAP. Based on the foregoing, the EPA concludes that these rule amendments will not have a significant impact on a substantial number of small businesses.

Although these final rule amendments will not have a significant impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact on small entities by providing alternatives to compliance and monitoring requirements.

G. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Public Law 104–113; 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in their regulatory and procurement activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices) developed or adopted by one or more voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through annual reports to OMB, with explanations when an agency does not use available and applicable voluntary consensus standards.

These final rule amendments provide technical corrections and minor technical amendments to the Ethylene Oxide Emissions Standards for Sterilization Facilities (40 CFR part 63, subpart O). These amendments include two technical standards: EPA Method 25A and PS–8. Consistent with the NTTAA, the EPA conducted searches to identify voluntary consensus standards in addition to these EPA methods and performance specifications. No voluntary consensus standards were identified for PS–8. The search and review results have been documented and are placed in the Docket No. A–88–03 (see **ADDRESSES** section) for these rule amendments.

The search for emissions monitoring procedures identified two voluntary consensus standards, both for EPA Method 25A. The EPA determined that these two standards identified for measuring emissions of hazardous air pollutants or surrogates subject to emission standards in the final rule would not be practical due to lack of equivalency, detail, and/or quality assurance and/or quality control requirements. Therefore, we did not use this voluntary consensus standard in this rulemaking.

The two voluntary consensus standards, EN 12619:1999 ''Stationary Source Emissions—Determination of the Mass Concentration of Total Gaseous

Organic Carbon at Low Concentrations in Flue Gases—Continuous Flame Ionization Detector Method'' and ISO 14965:2000(E) ''Air Quality—Determination of Total Nonmethane Organic Compounds—Cryogenic Preconcentration and Direct Flame Ionization Method,'' are impractical alternatives to EPA Method 25A for the purposes of this rulemaking because the standards do not apply to solvent process vapors in concentrations greater than 40 ppm (EN 12619) and 10 ppm carbon (ISO 14965). Methods whose upper limits are this low are too limited to be useful in measuring source emissions, which are expected to be much higher.

Section 63.365 of the NESHAP lists the EPA test methods and performance standards included in this rulemaking. Under 40 CFR 63.7(f) of the General Provisions, a source may apply to EPA for permission to use alternative test methods in place of any of the EPA testing methods.

H. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be ''economically significant,'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned rule is preferable to other potentially effective and reasonable alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. These final rule amendments are not subject to Executive Order 13045 because they are based on technology performance and not on health or safety risks. No children's risk analysis was performed because no alternative technologies exist that would provide greater stringency at a reasonable cost. Furthermore, these rule amendments have been determined not to be ''economically significant'' as defined under Executive Order 12866.

I. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing these rule amendments and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). These amendments will be effective November 2, 2001.

J. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This rule is not subject to Executive Order 13211 (66 FR 28355 May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 24, 2001.

Christine Todd Whitman,

Administrator.

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

PART 63—[AMENDED]

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

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

Subpart O—[Amended]

2. Section 63.360 is amended:

a. In Table 1 by revising the entry for ''63.7(a)(2)'';

b. Removing and reserving paragraphs (g)(7) through (10).

The revision reads as follows:

§ 63.360 Applicability.

(a) * * *

TABLE 1 OF SECTION 63.360.—GENERAL PROVISIONS APPLICABILITY TO SUBPART O

Reference	Applies to sources using 10 tons in subpart O [a]	Applies to sources using 1 to 10 tons in subpart O [a]	Comment
* * *	Yes	*	* *
63.7(a)(2).			
* * *	*	*	* *

[a] See definition.

* * * * *

3. Section 63.361 is amended by removing the definition for ''Parametric monitoring,'' revising the definition for ''Baseline temperature,'' and adding a definition for ''Thermal oxidizer'' and ''Deviation'' in alphabetical order to read as follows:

§ 63.361 Definitions.

* * * * *

Baseline temperature means a minimum temperature at the outlet from the catalyst bed of a catalytic oxidation control device or at the exhaust point from the combustion chamber of a thermal oxidation control device.

* * * * *

Deviation means any instance in which an affected source, subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limitation (including any operating limit) or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

* * * * *

Thermal oxidizer means all combustion devices except flares.

4. Section 63.362 is amended by:

a. Revising Table 1 of paragraph (a);

b. Removing and reserving paragraph (e).

The revision reads as follows:

§ 63.362 Standards.

(a) * * *

TABLE 1 OF SECTION 63.362.—STANDARDS FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND FUMIGATORS

Existing and new sources	Source type	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent
Source size	<907 kg (<1 ton)	No control required; minimal recordkeeping requirements apply (see § 63.367(c)).		
	≥907 kg and <9,070 kg (≥1 ton and < 10 tons).	99% emission reduction (see § 63.362(c)).	No control	No control.
	≥9,070 kg (≥10 tons)	99% emission reduction (see § 63.362(c)).	1 ppm maximum outlet concentration or 99% emission reduction (see § 63.362(d)).	No control.

* * * * *

(e) [Reserved]

5. Section 63.363 is revised (including the section heading) to read as follows:

§ 63.363 Compliance and performance provisions.

(a)(1) The owner or operator of a source subject to emissions standards in § 63.362 shall conduct an initial performance test using the procedures listed in § 63.7 according to the applicability in Table 1 of § 63.360, the procedures listed in this section, and the test methods listed in § 63.365.

(2) The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in § 63.360(g).

(b) The procedures in paragraphs (b)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(c), the sterilization chamber vent standard and to establish operating limits for the control devices:

(1) The owner or operator shall determine the efficiency of control devices used to comply with § 63.362(c) using the test methods and procedures in § 63.365(b).

(2) For facilities with acid-water scrubbers, the owner or operator shall establish as an operating limit either:

(i) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1); or

(ii) The maximum liquor tank level using the procedures described in § 63.365(e)(2).

(3) For facilities with catalytic oxidizers or thermal oxidizers, the operating limit consists of the recommended minimum oxidation temperature provided by the oxidation unit manufacturer for an operating limit.

(4) Facilities with catalytic oxidizers shall comply with one of the following work practices:

(i) Once per year after the initial compliance test, conduct a performance test during routine operations, i.e., with product in the chamber using the procedures described in § 63.365(b) or (d) as appropriate. If the percent efficiency is less than 99 percent, restore the catalyst as soon as practicable but no later than 180 days after conducting the performance test; or

(ii) Once per year after the initial compliance test, analyze ethylene oxide

concentration data from § 63.364(e) or a continuous emission monitoring system (CEMS) and restore the catalyst as soon as practicable but no later than 180 days after data analysis; or,

(iii) Every 5 years, beginning 5 years after the initial compliance test (or by December 6, 2002, whichever is later), replace the catalyst bed with new catalyst material.

(c) The procedures in paragraphs (c)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(d), the aeration room vent standard:

(1) The owner or operator shall comply with either paragraph (b)(2) or (3) of this section.

(2) Determine the concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with § 63.362(d)) using the methods in § 63.365(c)(1); or

(3) Determine the efficiency of the control device used to comply with § 63.362(d) using the test methods and procedures in § 63.365(d)(2).

(d) [Reserved]

(e) For facilities complying with the emissions limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator of the facility shall provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in § 63.365(g), the owner or operator shall determine the site-specific operating limit(s)for the operating parameters approved by the Administrator.

(f) A facility must demonstrate continuous compliance with each operating limit and work practice standard required under this section, except during periods of startup, shutdown, and malfunction, according to the methods specified in § 63.364.

6. Section 63.364 is amended by:

a. Revising paragraph (b) introductory text;

b. Adding a sentence to the end of paragraph (b)(2);

c. Revising paragraph (c) introductory text;

d. Removing and reserving paragraphs (c)(1), (2) and (3);

e. Adding a sentence to the end of paragraph (c)(4);

f. Revising paragraph (d);

g. Revising paragraph (e); and

h. Removing and reserving paragraph (f).

The additions and revisions read as follows:

§ 63.364 Monitoring requirements.

* * * * *

(b) For sterilization facilities complying with § 63.363(b) or (d) through the use of an acid-water scrubber, the owner or operator shall either:

* * * * *

(2) * * * Monitoring is required during a week only if the scrubber unit has been operated.

(c) For sterilization facilities complying with § 63.363(b) or (c) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall either comply with § 63.364(e) or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.

(1) [Reserved]

(2) [Reserved]

(3) [Reserved]

(4) * * * As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(d) For sterilization facilities complying with § 63.363(b) or (c) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Administrator using the methods and procedures in § 63.365(g).

(e) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere after any control device according to the procedures specified in § 63.365(c)(1). The owner or operator shall compute and record a 24-hour average daily. The owner or operator will install, calibrate, operate, and maintain a monitor consistent with the requirements of performance specification (PS) 8 or 9 in 40 CFR part 60, appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS 9 or section 2.3 of PS 8 are required only on days when ethylene oxide emissions are vented to the control device.

(f) [Reserved]

7. Section 63.365 is amended by:

a. Revising paragraph (b)(1) introductory text;

b. Revising paragraph (b)(1)(iv)(B);

c. Removing and reserving paragraph (b)(1)(iv)(C);

d. Removing and reserving paragraph (b)(2);

e. Revising paragraph (c);

f. Revising paragraph (d);

g. Removing and reserving paragraph (f);

h. Revising paragraph (h).

The revisions read as follows:

§ 63.365 Test methods and procedures.

* * * * *

(b) * * *

(1) *First evacuation of the sterilization chamber.* These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

* * * * *

(iv) * * *

(B) Test Method 18 or 25A, 40 CFR part 60, appendix A (hereafter referred to as Method 18 or 25A, respectively), shall be used to measure the concentration of ethylene oxide.

(*1*) Prepare a graph of volumetric flow rate versus time corresponding to the period of the run cycle. Integrate the area under the curve to determine the volume.

(*2*) Calculate the mass of ethylene oxide by using the following equation:

$$W_o = C \times V \times \frac{MW}{SV} \times \frac{1}{10^6}$$

Where:

Wo = Mass of ethylene oxide, g (lb)

C = concentration of ethylene oxide in ppmv

V = volume of gas exiting the control device corrected to standard conditions, L (ft^3)

$1/10^6$ = correction factor $L_{EO}/10^6\ L_{TOTAL\ GAS}$ ($ft^3_{EO}/10^6\ ft^3_{TOTAL\ GAS}$)

(*3*) Calculate the efficiency by the equation in paragraph (b)(1)(v) of this section.

(C) [Reserved]

* * * * *

(2) [Reserved]

* * * * *

(c) *Concentration determination.* The following procedures shall be used to determine the ethylene oxide concentration.

(1) *Parameter monitoring.* For determining the ethylene oxide concentration required in § 63.364(e), follow the procedures in PS 8 or PS 9 in 40 CFR part 60, appendix B. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS–8.

(2) *Initial compliance.* For determining the ethylene oxide concentration required in § 63.363(c)(2), the procedures outlined in Method 18 or Method 25 A (40 CFR part 60, appendix A) shall be used. A Method 18 or Method 25A test consists of three 1-hour runs. If using Method 25A to determine concentration, calibrate and report Method 25A instrument results using ethylene oxide as the calibration gas. The arithmetic average of the ethylene oxide concentration of the three test runs shall determine the overall outlet ethylene oxide concentration from the control device.

(d) *Efficiency determination at the aeration room vent (not manifolded).* The following procedures shall be used to determine the efficiency of a control device used to comply with § 63.362(d), the aeration room vent standard.

(1) Determine the concentration of ethylene oxide at the inlet and outlet of the control device using the procedures in Method 18 or 25A in 40 CFR part 60, appendix A. A test is comprised of three 1-hour runs.

(2) Determine control device efficiency (% Eff) using the following equation:

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

Where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_O = mass flow rate out of the control device

(3) Repeat the procedures in paragraphs (d)(1) and (2) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

* * * * *

(f) [Reserved]

* * * * *

(h) An owner or operator of a sterilization facility seeking to demonstrate compliance with the requirements of § 63.363 or § 63.364, with a monitoring device or procedure other than a gas chromatograph or a flame ionization analyzer, shall provide to the Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would demonstrate continuous compliance with each operating limit. The Administrator may request further information and will specify appropriate test methods and procedures.

8. Section 63.366 is amended by revising paragraph (a)(3) to read as follows:

§ 63.366 Reporting requirements.

(a) * * *

(3) Content and submittal dates for deviations and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per § 63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate (see § 63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in Table 1 of § 63.360, and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

* * * * *

9. Section 63.367 is revised to read as follows:

§ 63.367 Recordkeeping requirements.

(a) The owner or operator of a source subject to § 63.362 shall comply with the recordkeeping requirements in § 63.10(b) and (c), according to the applicability in Table 1 of § 63.360, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.

(b) The owners or operators of a source using 1 to 10 tons not subject to § 63.362 shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to § 63.362).

(c) The owners or operators of a source using less than 1 ton shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to § 63.362).

(d) The owners or operators complying with § 63.363(b) (4) shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

[FR Doc. 01–27594 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301185; FRL–6806–4]

RIN 2070–AB78

Methoxyfenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of methoxyfenozide in or on field corn grain, stover and oil, aspirated grain fractions and soybean forage, hay, oil, and seed. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on field corn and soybeans. This regulation establishes a maximum permissible level for residues of methoxyfenozide in these food commodities. The tolerances will expire and are revoked on December 31, 2003.

DATES: This regulation is effective November 2, 2001. Objections and requests for hearings, identified by docket control number OPP–301185, must be received by EPA on or before January 2, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301185 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide

Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6463; and e-mail address: Madden.Barbara@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at *http://www.epa.gov/*. To access this document, on the homepage select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html*, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301185. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the insecticide methoxyfenozide, benzoic acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide, in or on field corn grain at 0.02 part per million (ppm), field corn forage at 10 ppm, field corn stover at 75 ppm, corn oil at 0.1 ppm, aspirated grain fractions at 20 ppm, soybean seed at 0.04 ppm, soybean forage at 10 ppm, soybean hay at 75 ppm and soybean oil at 1.0 ppm. These tolerances will expire and are revoked on December 31, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of August 3, 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Methoxyfenozide on Field Corn and Soybeans and FFDCA Tolerances

Field Corn - The southwestern corn borer (Pyralidae: *Diarrhea grandiosella*) is one of several major corn pests in the southern United States. There are usually three generations per year. First generation larvae feed in the whorl, where it is susceptible to foliar insecticide applications. Second and third generation larvae bore into the stalk, where they are protected from insecticide applications. Larvae tunnel down the main stem to the base of the plant and overwinter in the crown of the corn stalk, just below soil surface, where they are susceptible to death by freezing, drowning, or mechanical destruction.

The Mississippi University Cooperative Extension Service recommends the following chemicals for southwestern corn borer control: Carbaryl, carbofuran, chlorpyrifos, cyhalothrin, esfenvalerate, and permethrin. According to the Mississippi application frequent summer rains have affected the effectiveness of the registered pesticides, most of which have short residual lives, resulting in poor southwestern corn borer control and

increasing the need for repeated applications. Furthermore, corn farmers in Mississippi, mostly small farmers who also grow catfish in ponds and handle and apply pesticides themselves, avoid using carbofuran, which is perceived as hazardous to themselves and their catfish. Methoxyfenozide, an IGR specific to lepidopteran larvae, was identified as a suitable alternative because of its moderate residual life and low risk to humans and most non-target organisms.

Transgenic Bt corn is an effective alternative, but is limited to 50% of the acreage planted due to resistance management compliance. Natural enemies destroy a portion of the southwestern corn borer population, but not at levels necessary to prevent economic losses. In the past, destruction of corn stubble by shredding, disking, or deep tillage was an effective cultural control method. However, under the present no-till conservation practices, larger numbers of overwintering larvae survive and infest the next year's crop.

The request indicates that yield reductions associated with southwestern core borer infestations have been reported in the range of 10% to 50%.

Soybean - Saltmarsh caterpillars (often called ''woolly worms'') feed in the larval stage in groups on soybean foliage. It feeds on the leaves on the upper third of the soybean canopy. The saltmarsh caterpillar has historically been only an occasional pest of soybeans in Arkansas and Mississippi. Although it is usually present in soybean fields, it is rarely at population densities to cause economic damage. However, due to favorable conditions, population densities of the saltmarsh caterpillar have been increasing over the last few years.

While environmental conditions played a role in the recent saltmarsh caterpillar outbreaks, the inability to control the pest with currently registered insecticides was the primary cause for yield loss. Control of the pest with currently registered insecticides (thiodicarb, esfenvalerate, and spinosad) was seldom greater than 50%. This required multiple, short interval, high rate insecticide applications with associated increase in cost. Soybeans which suffered the greatest impact were the late maturing varieties.

EPA has authorized under FIFRA section 18 the use of methoxyfenozide on field corn for control of Southwestern corn borer in Mississippi and for use on soybeans to control Saltmarsh caterpillars in Arkansas and Mississippi. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of methoxyfenozide in or on field corn and soybeans. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on field corn and soybeans after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether methoxyfenozide meets EPA's registration requirements for use on field corn and soybeans or whether a permanent tolerance for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of methoxyfenozide by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Arkansas and Mississippi to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for methoxyfenozide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of methoxyfenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of methoxyfenozide in or on field corn grain at 0.02 ppm, field corn forage at 10 ppm, field corn stover at 75 ppm, corn oil at 0.1 ppm, aspirated grain fractions at 20 ppm, soybean seed at 0.04 ppm, soybean forage at 10 ppm, soybean hay at 75 ppm and soybean oil at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the

appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for methoxyfenozide used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METHOXYFENOZIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13–50 years of age and the general population including infants and children	none	none	No appropriate endpoint was identified in the oral toxicity studies including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits.
Chronic dietary all populations	NOAEL= 10.2 mg/kg/day UF = 100 Chronic RfD = 0.10 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.10 mg/kg/day	2–Year combined chronic feeding/carcinogenicity, rats LOAEL = 411 mg/kg/day based on hematological changes (decreased RBC, hemoglobin and hematocrit), liver toxicity (increased weights, hypertrophy), histopathological changes in thyroid (increased follicular cell hypertrophy, altered colloid), possible adrenal toxicity (increased weights).
Short-term, intermediate-term, and long-term dermal and inhalation	None	None	No systemic toxicity was seen at the limit dose following repeated dermal application to rats. Based on low vapor pressure, the low acute toxicity of both the technical and formulated products as well as the application rate and application method, there is minimal concern for inhalation exposure.
Cancer (oral, dermal, inhalation)	Methoxyfenozide has been classified as a ''not likely'' human carcinogen.		The classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.544) for the residues of methoxyfenozide, in or on a variety of raw agricultural commodities including, the pome fruits crop group, apple pomace, cotton seed, cotton gin byproducts, milk, and meat, fat, liver and meat byproducts of cattle, goats, hogs, horses and sheep. Risk assessments were conducted by EPA to assess dietary exposures from methoxyfenozide in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one

day or single exposure. No appropriate endpoint was identified in the oral toxicity studies including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits. Therefore, acute dietary risk assessments were not conducted.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% of all crops were treated and all resulting residues were at tolerance level.

iii. *Cancer*. Methoxyfenozide has been classified as a ''not likely'' human carcinogen. The classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies. Therefore, risk assessments to estimate cancer risk were not conducted.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for methoxyfenozide in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of methoxyfenozide.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to methoxyfenozide they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of methoxyfenozide for chronic exposures are estimated to be 30 parts per billion (ppb) for surface water and 3.5 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Methoxyfenozide is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether methoxyfenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that methoxyfenozide has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies*. In a developmental toxicity study in rats regarding maternal findings, there were no deaths or clinical signs, nor where there any effects on body weights or food consumption. No changes were noted in any of the reproductive parameters. Fetal examinations did not reveal any affects on body weight or gross/visceral/skeletal aspects. The maternal NOAEL is 1,000 mg/kg/day (Highest Dose Tested (HDT), Limit Dose (LD)) and the maternal LOAEL is greater than 1,000 mg/kg/day. The developmental NOAEL is 1,000 mg/kg/ day and the developmental LOAEL is greater than 1,000 mg/kg/day.

In a developmental toxicity study in rabbits regarding maternal findings, there were no deaths or clinical signs, nor where there any effects on body weights, weight gains or food consumption. No changes were noted in any of the reproductive parameters. Fetal examinations did not reveal any affects on body weight or gross/visceral/ skeletal aspects. The maternal NOAEL is 1,000 mg/kg/day (HDT, LD) and the maternal LOAEL is greater than 1,000 mg/kg/day. The developmental NOAEL is greater than 1,000 mg/kg/day and the

developmental LOAEL is greater than 1,000 mg/kg/day.

3. *Reproductive toxicity study*. In a 2–generation reproduction study the LOAEL for systemic toxicity is 20,000 ppm (1,551.9 mg/kg/day), based on increased absolute and relative liver weights in males and females and on hepatocellular hypertrophy in males and females. The NOAEL for systemic toxicity is 2,000 ppm (153.4 mg/kg/day). There were no treatment-related reproductive effects on the P1 and P2 males and females or their F1 and F2 offspring. Therefore, the NOAEL for reproductive toxicity is greater 20,000 ppm (1,551.9–2,036.5 mg/kg/day) (HDT). The LOAEL for reproductive toxicity was not identified.

4. *Neurotoxicity*. In an acute oral neurotoxicity study in rats there were no observable signs of a neurotoxic effect even at the highest concentration in females. Functional observational battery (FOB) assessment on Day 0 revealed a decrease in hindlimb grip strength for males in the 2,000 mg/kg group. Motor activity (MA) assessment remained comparable to controls throughout the study for males and females in all exposure groups. No neuropathological endpoints were observed during the histological examinations of the peripheral or central nervous systems of these animals at any exposure concentration. Based on the absence of any substance-related effects on body weight or body weight gain and any clinical signs of toxicity, the NOAEL for systemic toxicity is a concentration of 2,000 mg/kg for males and females. The NOAEL for neurotoxic effects is 2,000 mg/kg for females. Based on a decrease in hindlimb grip strength on day 0 in the 2,000 mg/kg male group, the NOAEL for males is 1,000 mg/kg and the LOAEL for males is 2,000 mg/kg. No LOAEL was established for systemic effects in males or females or for neurotoxic effects in females.

In a subchronic oral neurotoxicity study in rats there were no observable signs of a neurotoxic effect even at the highest concentration in males or females. FOB and MA remained comparable to controls throughout the study and no neuropathological endpoints were observed during the histological examinations of these animals at any exposure concentration. Based on the absence of any substance-related effects on body weight or body weight gain and any clinical signs of toxicity, the NOAEL for systemic toxicity is 20,000 ppm for males (1,318 mg/kg/day) and females (1,577 mg/kg/day). The NOAEL for neurotoxic effects is also 20,000 ppm for males (1,318 mg/kg/day) and females (1,577 mg/kg/day). No LOAEL was established for systemic or neurotoxic effects.

In none of the other oral toxicity studies on methoxyfenozide were there any signs of neurotoxicity. The studies considered included all the available toxicology studies on methoxyfenozide.

5. *Conclusion*. The toxicology data base for methoxyfenozide is complete and no additional studies are required at this time. The scientific and regulatory quality of the toxicology data base for methoxyfenozide is high and is considered sufficient to clearly define the toxicity of this chemical. There is, therefore, high confidence in the hazard and dose-response assessments conducted for this chemical. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

The toxicology data provided no indication of increased susceptibility in rats or rabbits from *in utero* and/or postnatal exposure to methoxyfenozide. In the prenatal developmental toxicity studies in rats and rabbits, no developmental toxicity was observed at the LD, the HDT. In the 2–generation reproduction study in rats, no effects in the offspring were observed at the HDT. In none of the oral toxicity studies on methoxyfenozide were there any signs of neurotoxicity. The studies considered included all the available toxicology studies on methoxyfenozide.

Therefore, the Agency has determined that the FQPA Safety Factor can be reduced to 1X in assessing the risk posed by this chemical.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to methoxyfenozide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of methoxyfenozide on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No appropriate endpoint was identified in the oral toxicity studies including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits. Therefore, acute dietary risk assessments were not conducted.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to methoxyfenozide from food will utilize 3% of the cPAD for the U.S. population, 13% of the cPAD for all infants (< 1year), the infant subpopulation at greatest exposure and 9% of the cPAD for children (1–6 years old), the children subpopulation at greatest exposure. There are no residential uses registered for methoxyfenozide. In addition, despite the potential for chronic dietary exposure to methoxyfenozide in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of methoxyfenozide in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO METHOXYFENOZIDE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.10	3	30	3.5	3,400
Children (1–6 years old)	0.10	9	30	3.5	900
Infants (< 1 year old)	0.10	13	30	3.5	870

3. *Short-term risk and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Methoxyfenozide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Aggregate cancer risk for U.S. population.* Methoxyfenozide has been classified as a ''not likely'' human carcinogen. The classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies. Therefore, risk assessments to estimate cancer risk were not conducted.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to methoxyfenozide residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no established or proposed Codex, Canadian or Mexican limits for residues of methoxyfenozide in or on plant or animal commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances.

C. Conditions

A 1–year plant back interval is required for crops not having tolerances. Currently, there is a petition under review that may result in rotational crop tolerances being established allowing for shorter plant back intervals. But, in the absence of such tolerances, a 1–year plant back interval is required.

The existing livestock tolerances are adequate for the uses proposed under these emergency exemptions.

VI. Conclusion

Therefore, tolerances are established for residues of methoxyfenozide, benzoic acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide, in or on field corn grain at 0.02 ppm, field corn forage at 10 ppm, field corn stover at 75 ppm, corn oil at 0.1 ppm, aspirated grain fractions at 20 ppm, soybean seed at 0.04 ppm, soybean forage at 10 ppm, soybean hay at 75 ppm and soybean oil at 1.0 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301185 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 2, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or

refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301185, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid 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 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes time limited tolerances under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final

rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 18, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.544 is amended by adding text to paragraph (b) to read as follows.

§ 180.544 Methoxyfenozide; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions*. Time-limited tolerances are established for the residues of the insecticide methoxyfenozide in connection with the use of the pesticide under section 18 emergency exemption granted by EPA. The tolerances will expire on the dates specified in the following tables.

Commodity	Parts per million	Expiration/revocation date
Corn, field, forage	10	12/31/03
Corn, field, grain	0.02	12/31/03
Corn, field, stover	75	12/31/03
Corn, oil	0.1	12/31/03
Soybean, aspirated grain fractions	20	12/31/03
Soybean, forage	10	12/31/03
Soybean, hay	75	12/31/03
Soybean, refined oil	1.0	12/31/03
Soybean, seed	0.04	12/31/03

* * * * *

[FR Doc. 01–27603 Filed 11–1–01; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

41 CFR Parts 101–3 and 102–84

[FPMR Interim Rule A–1]

RIN 3090–AG55

Annual Real Property Inventories

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Interim rule.

SUMMARY: The General Services Administration (GSA) is revising the Federal Property Management Regulations (FPMR) by moving coverage on the annual real property inventories into the Federal Management Regulation (FMR). A cross-reference is added to the FPMR to direct readers to the coverage in the FMR. The FMR coverage is written in plain language to provide agencies with updated regulatory material that is easy to read and understand.

DATES: *Effective Date*: November 2, 2001.

Comment Date: Your comments must reach us by January 2, 2002 to be considered in the formulation of a final rule.

ADDRESSES: Send written comments to Mr. Michael E. Hopkins, Regulatory Secretariat (MVP), Acquisition Policy Division, General Services Administration, 1800 F Street, NW., Washington, DC 20405.

Send e-mail comments to *RIN.3090-AG55@gsa.gov*.

FOR FURTHER INFORMATION CONTACT: Stanley C. Langfeld, Director, Real Property Policy Division, (202) 501–1737.

SUPPLEMENTARY INFORMATION:

A. Background

In furtherance of its leadership role in real property asset management, the Office of Governmentwide Policy, Office of Real Property, conducted a comprehensive review of the policies contained in Federal Property Management Regulations (FPMR) Part 101–3, entitled ''Annual Real Property Inventories.'' This review was based on a collaborative effort with Federal real property holding agencies that utilize the Worldwide Inventory of Federal Real Property.

Representatives from the Department of the Interior, the Department of Energy, and the Army Corps of Engineers participated with GSA in conducting the initial steps of the comprehensive review of the policies in FPMR part 101–3. The review focused on improvements to make the real property inventory program more useful and to enable Federal agencies to more effectively manage their real property inventories. In addition, we have rewritten these regulations in plain language format. These regulations are being transferred from the FPMR to the FMR to enable the Government to better focus on implementing statutory requirements, Executive Orders, and governmentwide policies rather than on detailed operating procedures.

B. Executive Order 12866

GSA has determined that this interim rule is not a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993.

C. Regulatory Flexibility Act

This interim rule is not required to be published in the **Federal Register** for notice and comment; therefore, the Regulatory Flexibility Act does not apply.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this interim rule does not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This interim rule is also exempt from Congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

F. Determination To Issue an Interim Rule

This interim rule is not required to be published for notice and comment under the Administrative Procedures Act because it relates solely to agency management and personnel; therefore, GSA could issue the rule as a final rule. However, GSA would like to receive comments about this action before publishing it as a final rule. An interim rule provides two benefits. First, it gives agencies a chance to comment on aspects of the revised coverage in the FMR. Second, agencies will be able to use the new FMR coverage to respond to the Fiscal Year 2002 data call for real property inventories.

List of Subjects in 41 CFR Parts 101–3 and 102–84

Federal buildings and facilities, Government property management.

For the reasons set forth in the preamble, 41 CFR chapters 101 and 102 are amended as follows:

CHAPTER 101—[AMENDED]

1. Part 101–3 is revised to read as follows:

PART 101–3—ANNUAL REAL PROPERTY INVENTORIES

Authority: 40 U.S.C. 486(c).

§ 101–3.000 Cross-reference to the Federal Management Regulation (FMR) (41 CFR chapter 102, parts 102–1 through 102–220).

For information on annual real property inventories previously contained in this part, see FMR part 84 (41 CFR part 102–84).

CHAPTER 102—[AMENDED]

2. Part 102–84 is added to Subchapter C to read as follows:

PART 102–84—ANNUAL REAL PROPERTY INVENTORIES

Sec.

102–84.5 What is the scope of this part?
102–84.10 What is the purpose of the Annual Real Property Inventory Program?
102–84.15 Why must I provide information for the Annual Real Property Inventory?
102–84.20 Where should I obtain information to be reported for the Annual Real Property Inventory?
102–84.25 Is it necessary for my agency to designate an official to serve as the point of contact for the real property inventories?
102–84.30 Is it necessary for my agency to certify the accuracy of its real property inventory submission?
102–84.35 Which agencies must submit a report for inclusion in the Annual Real Property Inventory?
102–84.40 What types of real property must I report for the Annual Real Property Inventory?
102–84.45 What types of real property must not be reported for the Annual Real Property Inventory?
102–84.50 Can the GSA Form 1166 be used to report information?
102–84.55 When are the Annual Real Property Inventory reports due?

Authority: 40 U.S.C. 486(c).

§ 102–84.5 What is the scope of this part?

GSA's policies contained in this part apply to all Federal agencies. This part prescribes guidance that you must follow in preparing and submitting annual real property inventory information for real property owned by and leased to the United States. The detailed guidance implementing these policies is contained in separate customer guides issued by the GSA Office of Governmentwide Policy.

§ 102–84.10 What is the purpose of the Annual Real Property Inventory Program?

The purpose of the Annual Real Property Inventory program is to:

(a) Maintain a centralized source of information on Federal real property holdings;

(b) Track space utilization of reporting agencies;

(c) Provide support for consolidated Federal financial statements on real property assets; and

(d) Establish a reference for answering inquiries from the Congress, the press, trade associations, educational institutions, Federal, State and local government agencies, and the general public.

§ 102–84.15 Why must I provide information for the Annual Real Property Inventory?

You must provide information for the Annual Real Property Inventory because:

(a) The Senate Committee on Appropriations requests that the Government maintain an Annual Real Property Inventory.

(b) Executive Order 12411, Government Work Space Management Reforms, dated March 29, 1983 (3 CFR, 1983 Comp., p. 155), requires that Executive agencies:

(1) Produce and maintain a total inventory of work space and related furnishings and declare excess to the Administrator of General Services all such holdings that are not necessary to satisfy existing or known and verified planned programs; and

(2) Establish information systems, implement inventory controls and conduct surveys, in accordance with procedures established by the Administrator of General Services, so that a governmentwide reporting system may be developed.

§ 102–84.20 Where should I obtain information to be reported for the Annual Real Property Inventory?

You should obtain data reported for the Annual Real Property Inventory from the most accurate real property and accounting records maintained by your agency, preferably the same accounting records used to support your agency's financial statements.

§ 102–84.25 Is it necessary for my agency to designate an official to serve as the point of contact for the real property inventories?

Yes, you must designate an official to serve as your agency's point of contact for the Annual Real Property Inventories. We recommend that you designate the same point of contact for the Federally-owned and leased real property inventory, although separate points of contact are permitted. You must advise the General Services Administration, Office of Governmentwide Policy, Office of Real Property (MP), 1800 F Street, NW., Washington, DC 20405, in writing, of the name(s) of these representative(s) and any subsequent changes. Each agency's point of contact for the real property inventories can be found at *http://worldwide.gsa.gov.*

§ 102–84.30 Is it necessary for my agency to certify the accuracy of its real property inventory submission?

Yes, your agency's highest ranking real property official must certify the accuracy of the real property information submitted to GSA.

§ 102–84.35 Which agencies must submit a report for inclusion in the Annual Real Property Inventory?

Each agency that carries real property on its financial statement as of September 30 each year has the responsibility for submitting the real property inventory information. Information provided in these reports related to asset values must be consistent with agency records used for financial reporting in accordance with standards issued by the Federal Accounting Standards Advisory Board (FASAB). For purposes of this part, this requirement shall apply regardless of the method used to acquire the property or which agency is currently using or occupying the property.

§ 102–84.40 What types of real property must I report for the Annual Real Property Inventory?

You must report for the Annual Real Property Inventory all land, buildings, and other structures and facilities

owned by the United States (including wholly-owned Federal Government corporations) throughout the world and all real property leased by the United States from private individuals, organizations, and municipal, county, State, and foreign governments. These reports must include all real property that a Federal agency carries on its financial statement and/or in documentation accompanying the financial statement, such as:

(a) Unreserved public domain lands;

(b) Public domain lands reserved for national forests, national parks, military installations, or other purposes;

(c) Real property acquired by purchase, construction, donation, eminent domain proceedings, or any other method;

(d) Real property in which the Government has a long-term interest considered by the reporting agency as being equivalent to ownership. This would include land acquired by treaty or long-term lease (*e.g.,* 99-year lease), and that your agency considers equivalent to Federally-owned land;

(e) Buildings or other structures and facilities owned by or leased to the Government whether or not located on Government-owned land;

(f) Excess and surplus real property;

(g) Real property held in trust by the Federal Government;

(h) Leased real property (including leased land, leased buildings, leased other structures and facilities, or combination thereof); and

(i) Real property leased rent free or for a nominal rental rate if the real property is considered significant by the reporting agency.

§ 102–84.45 What types of real property must not be reported for the Annual Real Property Inventory?

You must not report real property that is not carried on your agency's financial statements, such as:

(a) Properties acquired through foreclosure, confiscation, or seizure to be liquidated in settlement of a claim or debt to the Federal Government;

(b) Rights-of-way or easements granted to the Federal Government; and

(c) Lands administered by the United States under trusteeship by authority of the United Nations.

§ 102–84.50 Can the GSA Form 1166 be used to report information?

No, GSA Form 1166 may not be used to report information. Agencies must submit information in an electronic format. For more information on format requirements, contact GSA's Office of Governmentwide Policy, Office of Real Property (MP), 1800 F Street NW., Washington, DC 20405, by telephone at (202) 501–0856, or e-mail at *assetmanagement@gsa.gov.*

§ 102–84.55 When are the Annual Real Property Inventory reports due?

You must prepare the Annual Real Property Inventory information prescribed in § 102–84.50 as of the last day of each fiscal year. This information is due to the General Services Administration, Office of Governmentwide Policy, Office of Real Property (MP), 1800 F Street, NW., Washington, DC 20405, no later than November 15 of each year.

Dated: October 25, 2001.

Stephen A. Perry,

Administrator of General Services.

[FR Doc. 01–27609 Filed 11–1–01; 8:45 am]

BILLING CODE 6820–23–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 221

[Docket No. MARAD–2001–10256]

RIN 2133–AB44

Denial of Vessel Transfer to Foreign Registry Upon Revocation of Fishery Endorsement

AGENCY: Maritime Administration, Transportation.

ACTION: Final rule.

SUMMARY: The Maritime Administration (MARAD, we, our, or us) is amending regulation to state that approvals will not be granted for the transfer of a Fishing Vessel, Fish Processing Vessel, or Fish Tender Vessel to a foreign registry or operation under authority of a foreign country when the vessel's fishery endorsement has been revoked as a result of the fishing capacity reduction program for crab fisheries established by the Secretary of Commerce. Pub. L. 106–554 requires that the Secretary of Transportation shall refuse to grant the approval required under section 9(c)(2) of the Shipping Act of 1916 for the placement of a Fishing Vessel, Fish Processing Vessel, or Fish Tender Vessel under foreign registry or the operation of such vessel under the authority of a foreign country when the vessel's fishery endorsement has been revoked under the Secretary of Commerce's fishing capacity reduction program. The intended effect of this final rule is to clearly state in the regulation that approvals required under section 9(c)(2) of the 1916 Act will not be granted in the circumstances described.

DATES: The effective date of this rule is December 3, 2001.

FOR FURTHER INFORMATION CONTACT: Edmund T. Sommer, Jr., Chief, Division of General and International Law at (202) 366–5181. You may send mail to Mr. Sommer at Maritime Administration, Office of Chief Counsel, Room 7221, 400 Seventh Street, SW., Washington, DC 20590. An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

Pub. L. 106–554 requires the Secretary of Commerce to implement a fishing reduction program for crab fisheries included in the Fishery Management Plan for Commercial King and Tanner Crab Fisheries in the Bering Sea and Aleutian Islands. The Secretary of Commerce must notify the Secretary of Transportation which vessels are being removed from the fishery and request that the Secretary of Transportation revoke the vessel's fishery endorsement and refuse permission to transfer the vessel to a foreign flag.

Section 9 of the Shipping Act, 1916, as amended, (46 App. U.S.C. 808) governs the transfer of any documented vessel, or any vessel the last documentation of which was under the laws of the United States, to a foreign registry or operation of that vessel under the authority of a foreign country. This rulemaking amends the general approval granted under 46 CFR 221.15. We published a notice of proposed rulemaking (NPRM) on August 3, 2001 at 66 FR 40664). The NPRM proposed amendments to § 221.15 to state that approval to place under foreign registry or to operate under the authority of a foreign country a Fishing Vessel, Fish Processing Vessel, or Fish Tender Vessel that has had its fishery endorsement revoked pursuant to Appendix D of Pub. L. 106–554, 114 Stat 2763 will not be granted. This final rule mirrors the NPRM to which we received no public comments.

Plain Language

Executive Order 12866 requires each agency to write all rules in plain language. The Department of Transportation and MARAD are committed to plain language in government writing; therefore, we have written this final rule in plain language. Our goal is to provide a clear regulation.

Rulemaking Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

We have reviewed this final rule under Executive Order 12866 and have determined that this is not a significant regulatory action. Additionally, this final rule is not likely to result in an annual effect on the economy of $100 million or more. The purpose of this final rule is to ensure that Fishing Vessels, Fish Processing Vessels, or Fish Tender Vessels who lose their fishery endorsement in the Fishery Management Plan for Commercial King and Tanner Crab Fisheries in the Bering Sea and Aleutian Islands will not operate under foreign flag or under the authority of a foreign country.

This final rule is also not significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034, February 26, 1979). The costs and benefits associated with this rulemaking are considered to be so minimal that no further analysis is necessary. Because the economic impact, if any, should be minimal, further regulatory evaluation is not necessary.

Regulatory Flexibility Act

This Final rule will not have a significant economic impact on a substantial number of small entities. This Final rule only implements a statutory mandate to deny approval for a transfer of a vessel to a foreign registry or operation under authority of a foreign country when the vessel's fishery endorsement has been revoked. This rule does not impose a significant economic impact because owners of Fishing Vessels, Fish Processing Vessels, or Fish Tender Vessels who lose their fishery endorsement have been compensated through the crab fisheries buy-out program. Therefore, I certify that this final rule will not have a significant economic impact on a substantial number of small entities.

Federalism

We have analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (''Federalism'') and have determined that it does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. These regulations have no substantial effects on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. Therefore, consultation with State and local officials was not necessary.

Environmental Impact Statement

We have analyzed this final rule for purposes of compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and have concluded that under the categorical exclusions provision in section 4.05 of Maritime Administrative Order (''MAO'') 600–1, Procedures for Considering Environmental Impacts, 50 FR 11606 (March 22, 1985), the preparation of an Environmental Assessment, and an Environmental Impact Statement, or a Finding of No Significant Impact for this final rule is not required.

Executive Order 13175

MARAD does not believe that this final rule will significantly or uniquely affect the communities of Indian tribal governments when analyzed under the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Therefore, the funding and consultation requirements of this Executive Order do not apply.

Unfunded Mandates Reform Act of 1995

This final rule does not impose an unfunded mandate under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $100 million or more, in the aggregate, to any of the following: State, local, or Native American tribal governments, or the private sector. This final rule is the least burdensome alternative that achieves the objective of the rule.

Paperwork Reduction Act

This final rule does not contain information collection requirements.

Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) 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 number is contained in the heading of this document to cross-reference this action with the Unified Agenda.

List of Subjects in 46 CFR Part 221

Administrative practice and procedure, Maritime carriers, Mortgages, Penalties, Reporting and recordkeeping requirements, Trusts and trustees, Uniform system of accounts.

Accordingly, MARAD amends 46 CFR part 221 to read as follows:

PART 221—REGULATED TRANSACTIONS INVOLVING DOCUMENTED VESSELS AND OTHER MARITIME INTERESTS

1. The authority citation for part 221 continues to read as follows:

Authority: 46 App. U.S.C. 802, 803, 808, 835, 839, 841a, 1114(b), 1195; 46 U.S.C. chs. 301 and 313; 49 U.S.C. 336; 49 CFR 1.66. 2.

2. Section 221.15 is amended by adding introductory text to read as follows:

§ 221.15 Approval for transfer of registry or operation under authority of a foreign country or for scrapping in a foreign country.

In no case will approval be granted to place under foreign registry or to operate under the authority of a foreign country a Fishing Vessel, Fish Processing Vessel, or Fish Tender Vessel that has had its fishery endorsement revoked pursuant to Appendix D of Public Law 106–554, 114 Stat 2763. Subject to this exclusion, approval requests will be considered as set forth in this section.

* * * * *

Dated: October 30, 2001.

By order of the Acting Deputy Maritime Administrator.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. 01–27625 Filed 11–1–01; 8:45 am]

BILLING CODE 4910–81–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2316; MM Docket No. 00–18; RM–9790]

Radio Broadcasting Services; Barnwell, SC, Pembroke, Douglas and Willacoochee, GA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: At the request of the Bullie Broadcasting Corporation, this document substitutes Channel 257C1 for Channel 256C3 at Barnwell, South Carolina, reallots Channel 257C1 to Pembroke, Georgia, and modifies the license of Station WBAW to specify operation on Channel 257C1 at Pembroke. To accommodate this reallotment, this document reallots Channel 258C1 from Douglas, Georgia, to Willacooche, Georgia, and modifies the Station WDMG license to specify Willacoochee as its community of

license. This document also allots Channel 256C3 to Barnwell, South Carolina. *See* 65 FR 7815, published February 16, 2000. This document dismisses a Counterproposal filed by Multi-Service Corp. proposing a channel substitution at Statesboro, Georgia, and new allotments at Pulaski and Twin City, Georgia. The reference coordinates for the Channel 257C1 allotment at Pembroke, Georgia, are 32–11–137 and 81–48–04. The reference Coordinates for the Channel 258C1 allotment at Willacoochee, Georgia, are 31–20–27 and 83–24–30. The reference coordinates for the Channel 256C3 allotment at Barnwell, South Carolina, are 33–24–29 and 81–16–43. With this action, the proceeding is terminated.

DATES: Effective November 20, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Hayne, Mass Media Bureau (202) 418–2177.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order* in MM Docket No. 00–18, adopted October 3, 2001, and released October 5, 2001. The full text of this decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW, Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW, Room CY–B402, Washington, D.C. 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com*

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—RADIO BROADCAST SERVICES

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

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

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Georgia, is amended by adding Pembroke, Channel 257C1.

3. Section 73.202(b), the Table of FM Allotments under Georgia, is amended by removing Channel 258C1 at Douglas, and adding Willacoochee, Channel 258C1.

4. Section 73.202(b), the Table of FM Allotments under South Carolina, is amended by removing Channel 256C3 and adding Channel 257C1 at Barnwell.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 01–27614 Filed 11–1–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2257]

Radio Broadcasting Services; Various Locations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

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

DATES: Effective November 2, 2001.

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

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, adopted September 19, 2001, and released September 28, 2001. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

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—RADIO BROADCAST SERVICES

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

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

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Arizona, is amended by removing Channel 236C and adding Channel 236C2 at Yuma.

3. Section 73.202(b), the Table of FM Allotments under Idaho, is amended by removing Channel 298C and adding Channel 298A at Sun Valley.

4. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Channel 280A and adding Channel 281A at Big Lake and by removing Channel 229C3 adding Channel 229C1 at Krum.

5. Section 73.202(b), the Table of FM Allotments under Utah, is amended by removing Channel 225C2 and adding Channel 225C1 at Logan.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 01–27613 Filed 11–1–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2448; MM Docket No. 01–48; RM–10062 and 10117]

Radio Broadcasting Services; Junction City and Marquand, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Bishop Community Radio, Inc. proposed the allotment of Channel 295A at Junction City, Missouri. *See* 16 FCC Rcd 3527 (2001). No comments were received supporting an allotment at Junction City. In response to a counterproposal filed by Dockins Communications, Inc., we shall allot Channel 295A to Marquand, Missouri, as a first local service. The coordinates for Channel 295A at Marquand are 37–30–00 and 90–06–41.

DATES: Effective December 3, 2001.

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

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 01–48, adopted October 10, 2001, and released

October 19, 2001. The full text of this Commission decision is available for public inspection and copying during regular business hours in the FCC's Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's dulicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

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—RADIO BROADCAST SERVICES

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

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

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by adding Marquand, Channel 295A.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 01–27612 Filed 11–1–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2447; MM Docket No. 01–107; RM–10057]

Radio Broadcasting Services; Mount Pleasant and Hemlock, MI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document reallots Channel 233C1 from Mount Pleasant, Michigan to Hemlock, Michigan, and modifies the license for Station WCEN–FM to specify operation on Channel 233C1 at Hemlock, Michigan, in response to a petition filed by Wilks Broadcasting LLC. *See* 66 FR 27058, May 16, 2001. The coordinates for Channel 233C1 at Hemlock are 43–43–36 and 84–36–16.

DATES: Effective December 3, 2001.

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

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 01–107 adopted October 10, 2001, and released October 19, 2001. The full text of this Commission decision is available for inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW, Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12 Street, SW, Room CY–B402, Washington, DC, 20554, (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.*

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—RADIO BROADCAST SERVICES

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

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

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Michigan, is amended by removing Channel 233C1 at Mount Pleasant and adding Hemlock, Channel 233C1.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 01–27611 Filed 11–1–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 1

[Docket No. OST–2001–6189]

Organization and Delegation of Powers and Duties; Redelegation to the Assistant Secretary for Aviation and International Affairs

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Secretary of Transportation (Secretary) redelegates to the Assistant Secretary for Aviation and International Affairs the authority previously delegated by the President to the Secretary to carry out the duties and powers granted under section 101(a)(2) of the Air Transportation Safety and System Stabilization Act.

EFFECTIVE DATE: This rule is effective November 2, 2001.

FOR FURTHER INFORMATION CONTACT: Nilza F. Velazquez, Attorney, Office of the General Counsel (C–10), Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590; 202–366–9164.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded by using a computer, modem, and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Office of the Federal Register homepage at: *http://www.nara.gov/fedreg* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara.* You can also view and download this document by going to the Web page of the Department's Docket Management System (*http://dms.dot.gov/*). On that page, click on ''search.'' On the next page, type in the four digit docket number shown on the first page of this document (6189). Then click on ''search.''

Background

The Air Transportation Safety and System Stabilization Act (Public Law 107–42, September 22, 2001) (the ''Act'') was enacted in response in response to the terrorist attacks on New York and Washington. Section 101(a)(2) of the Act authorizes the President to compensate air carriers for the direct and incremental losses they incurred from terrorist attacks of September 11, 2001, and any resulting ground stop order. The President signed a Memorandum for the Secretary of Transportation, dated September 25, 2001 (66 FR 49507, September 27, 2001), delegating his authority under Section 101(a)(2) to the Secretary of Transportation. Under the authority of section 322 (b) of title 49, United States Code, the Secretary may delegate his authority unless otherwise prohibited. In the present case the delegation is appropriate.

Since this amendment relates to Departmental management, procedures, and practice, notice and comment on it are unnecessary under 5 U.S.C. 553(b)(3)(A), and it may be made effective in less than 30 days after publication in the **Federal Register** under 5 U.S.C. 553(d)(2) as a change in internal policy.

List of Subjects in 49 CFR Part 1

Authority delegations (Government agencies), Organization and functions (Government agencies).

In consideration of the foregoing, part 1 of title 49, Code of Federal Regulations, is amended as follows:

PART 1—[AMENDED]

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

Authority: 49 U.S.C. 322; Public Law 101–522, 104 Stat. 2744; 28 U.S.C. 2672; 31 U.S.C. 3711(a)(2); 46 U.S.C. 2104(a).

2. In § 1.56a the introductory text is republished and paragraph (j) is added to read as follows:

§ 1.56a Delegations to the Assistant Secretary for Aviation and International Affairs.

The Assistant Secretary for Aviation and International Affairs is delegated the authority to:

* * * * *

(j) Carry out section 101(a)(2) of the Air Transportation Safety and System Stabilization Act (Public Law 107–42, 115 Stat. 230), as delegated to the Secretary of Transportation by the President pursuant to a Presidential Memorandum dated September 25, 2001.

Issued in Washington, DC, on October 24, 2001.

Norman Y. Mineta,

Secretary of Transportation.

[FR Doc. 01–27251 Filed 11–1–01; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 600 and 660

[Docket No. 001226367–0367–01; I.D. 092801C]

Fisheries off the West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Trip Limit Adjustments; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Correction to trip limit adjustments in the Pacific Coast groundfish fishery.

SUMMARY: This document corrects a section heading in the trip limit adjustments for the Pacific Coast groundfish fishery published on October 5, 2001.

DATES: Effective November 2, 2001.

FOR FURTHER INFORMATION CONTACT: Carrie Nordeen, Northwest Region, NMFS, 206–526–6140.

SUPPLEMENTARY INFORMATION: Changes to current management measures were recommended by the Pacific Fishery Management Council at its September 10–14, 2001, meeting in Portland, OR. Adjustments to trip limits were made to stay within the optimum yields and allocations announced in the 2001 annual specifications and management measures for the groundfish fishery, published in the **Federal Register** at 66 FR 2338 (January 11, 2001), as amended at 66 FR 10208 (February 14, 2001), at 66 FR 18409 (April 9, 2001), at 66 FR 22467 (May 4, 2001), at 66 FR 28676 (May 24, 2001), at 66 FR 35388 (July 5, 2001), at 66 FR 38162 (July 23, 2001), and at 66 FR 50851 (October 5, 2001).

Need for Correction

Trip limit adjustments published on October 5, 2001, contained an error in the section heading describing limit changes for groundfish taken with open access gear. This document corrects that error.

Correction

Accordingly, the rule, FR Doc. 01–25031, in the issue of Friday, October 5, 2001 (66 FR 50851), is corrected as follows:

1. On page 50858, in the first column, amendatory instruction 2. is corrected to read ''2. In section IV., under C. *Trip Limits in the Open Access Fishery*, paragraphs (3) and (5) are revised to read as follows:''.

Dated: October 26, 2001.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–27634 Filed 11–1–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 001121328–1041–02; I.D. 102901B]

Fisheries of the Northeastern United States; Black Sea Bass Fishery; Commercial Quota Harvested for Quarter 4 Period

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure; Quarter 4 commercial black sea bass fishery.

SUMMARY: NMFS announces that the black sea bass commercial quota available in the quarter 4 period to the coastal states from Maine through North Carolina has been harvested. Commercial vessels may not land black sea bass in these states north of 35°15.3′ N. lat. for the remainder of the 2001 quarter 4 quota period (through December 31, 2001). Regulations governing the black sea bass fishery require publication of this notification to advise the coastal states from Maine through North Carolina that the quota has been harvested and to advise vessel permit holders and dealer permit holders that no commercial quota is available for landing black sea bass in these states north of 35°15.3′ N. lat.

DATES: Effective 0001 hrs local time, November 6, 2001, through 2400 hrs local time, December 31, 2001.

FOR FURTHER INFORMATION CONTACT: Jennifer L. Anderson, Fishery Management Specialist, at (978) 281–9226.

SUPPLEMENTARY INFORMATION: Regulations governing the black sea bass fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is allocated into four quota periods based upon percentages of the annual quota. The quarter 4 (October through December) commercial quota is distributed to the coastal states from Maine through North Carolina. The process to set the annual commercial quota is described in § 648.140.

The initial total commercial quota for black sea bass for the 2001 calendar year was 3,024,742 lb (1,372,000 kg) (66 FR 12902, March 1, 2001). The quarter 4 period quota, which is equal to 19.77 percent of the annual commercial quota, was 597,991 lb (271,244 kg). The quota allocation was adjusted downward to compensate for 2000 quarter 4 landings in excess of the 2000 quarter 4 quota, consistent with the procedures in § 648.140. The final adjusted quarter 4 quota was 516,939 lb (234,480 kg).

The Regional Administrator, Northeast Region, NMFS (Regional Administrator) monitors the commercial black sea bass quota for each quota period on the basis of dealer reports, state data, and other available information to determine when the commercial quota has been harvested. NMFS is required to publish a notification in the **Federal Register** advising and notifying commercial vessels and dealer permit holders that, effective upon a specific date, the black

sea bass commercial quota has been harvested and no commercial quota is available for landing black sea bass for the remainder of the quarter 4 period, north of 35°15.3′ N. lat. The Regional Administrator has determined, based upon dealer reports and other available information, that the black sea bass commercial quota for the 2001 quarter 4 period has been harvested.

The regulations at § 648.4 (b) provide that Federal black sea bass moratorium permit holders agree as a condition of the permit not to land black sea bass in any state after NMFS has published a notification in the **Federal Register** stating that the commercial quota for the period has been harvested and that no commercial quota for the black sea bass is available. The Regional Administrator has determined that the quarter 4 period for black sea bass no longer has commercial quota available. Therefore, effective 0001 hrs local time, November 6, 2001, further landings of black sea bass in coastal states from Maine through North Carolina, north of 35°15.3′ N. lat., by vessels holding commercial Federal fisheries permits are prohibited through December 31, 2001. The 2002 quarter 1 period for commercial black sea bass harvest will open on January 1, 2002. Effective November 6, 2001, federally permitted dealers are also advised that they may not purchase black sea bass from federally permitted black sea bass moratorium permit holders who land in coastal states from Maine through North Carolina, north of 35°15.3′ N. lat., for the remainder of the quarter 4 period (through December 31, 2001).

The regulations at § 648.4(b) also provide that, if the commercial black sea bass quota for a period is harvested and the coast is closed to the possession of black sea bass north of 35°15.3′ N. lat., any vessel owners who hold valid commercial permits for both the black sea bass and the NMFS Southeast Region snapper-grouper fisheries may surrender their black sea bass moratorium permit by certified mail addressed to the Regional Administrator (see table 1 at § 600.502) and fish pursuant to their snapper-grouper permit, as long as fishing is conducted exclusively in waters, and landings are made, south of 35°15.3′ N. lat. A moratorium permit for the black sea bass fishery that is voluntarily relinquished or surrendered will be reissued upon the receipt of the vessel owner's written request after a minimum period of 6 months from the date of cancellation.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 29, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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Proposed Rules

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

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 319

[Docket No. 01–018P]

Definitions and Standards of Identity or Composition: Elimination of the Pizza Standard

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat inspection regulations to remove the standards of identity for ''pizza with meat'' and ''pizza with sausage.'' The Agency has determined that these standards may be inhibiting manufacturers of federally inspected frozen pizzas from producing and marketing the new styles of pizzas that today's consumers demand. This proposed rule responds to a petition submitted to the Agency by the National Frozen Pizza Institute (NFPI).

DATES: Comments must be received on or before January 2, 2002.

ADDRESSES: Send an original and two copies of comments to:

FSIS Docket Clerk, Docket #01–018P, Room 102, Cotton Annex, 300 C Street, SW, Washington, DC 20250–3700. Reference materials cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0279.

SUPPLEMENTARY INFORMATION:

Background

On February 4, 1999, NFPI petitioned FSIS to amend part 319 of the Federal meat inspection regulations to eliminate the standards of identity for ''pizza with meat'' and ''pizza with sausage.'' In support of the petition, NFPI submitted data to demonstrate that the current standards are restricting the development of new products by the frozen pizza industry, and that consumers' expectations of what is meant by the term ''pizza'' are broader that what is prescribed by the current standards. In the petition, NFPI also demonstrated that, because of the prescribed meat content and cheese requirement, the current pizza standards restrict the frozen pizza industry from developing and marketing products with reductions in constituents that may be of health concern to some consumers, such as cholesterol and saturated fat. The petition and supporting data are available for public viewing in the FSIS docket room.

Under the Federal Meat Inspection Act (FMIA), a product is misbranded, in part, ''if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed * * * unless * * * it conforms to such definition and standards * * *'' (21 U.S.C. 601(n)(7)). The current standard for ''Pizza with Meat'' requires that the product consist of a bread base with tomato sauce, cheese, and meat topping. The product must contain cooked meat made from not less than 15 percent raw meat (9 CFR 319.600(a)). The current standard for ''Pizza with Sausage'' requires that the product consist of a bread base with tomato sauce, cheese, and not less than 12 percent cooked sausage or 10 percent dry sausage (9 CFR 319.600(b)). Thus, if a product subject to FSIS jurisdiction fails to contain any of these components, its labeling can not bear the term ''pizza.''

Pizzas prepared by restaurants have not been required to meet these prescribed standards. In fact, in support of the petition, NFPI provided information to show that several national and regional restaurant chains sell pizzas that do not contain the four traditional components required by the Federal standards (i.e., meat, cheese, tomato sauce, and bread-based crust). The information provided by the petitioner also shows that these new styles of pizzas are popular with consumers.

Under section 7 of the FMIA, FSIS is authorized to prescribe definitions and standards of identity or composition to protect the public (21 U.S.C. 607(c)). In general, standards of identity are intended to protect consumers from economic deception, i.e., from purchasing meat food or poultry products in which inferior ingredients have been substituted for more valuable ones. The meat pizza and sausage pizza standards were established several decades ago and reflect the common understanding at that time of what a food identified as ''meat pizza'' or ''sausage pizza'' should contain. Data submitted by the petitioner indicate that today's consumers accept a broader interpretation of what is expected of a product identified as ''pizza,'' and that consumer expectations are largely driven by the restaurant and food service industries. According to information provided by NFPI, product innovation in the food service industry has broadened the traditional concept of pizza to the extent that consumers understand the product to be an open-faced crust that is topped with one or more of a variety of ingredients.

Based on the information submitted by the petitioner, FSIS agrees that the current pizza standards may be inhibiting manufacturers of federally inspected pizzas from producing and marketing new styles of pizzas, including pizzas with less constituents, such as cheese or meat, that would be more consistent with nutritional guidance (e.g., lower fat). Based on the data submitted by NFPI, this is what today's consumers appear to demand. Furthermore, the Agency has determined that, because consumer expectations of what a product identified as ''pizza'' should contain differ from what is prescribed by the current standards, the standards no longer serve their original purpose of protecting the public from economic deception. Therefore, the Agency is proposing to remove these standards of identity from the regulations.

Under this proposed rule, federally inspected pizzas that are identified as a ''meat pizza'' or ''sausage pizza'' (*e.g.,* ''pizza with bacon,'' ''pizza with pepperoni,'' and ''sausage and mushroom pizza'') will be permitted to reduce their minimum meat content from 12% cooked or 15% raw to 2% cooked or 3% raw, the level of meat

required for a product to be considered a meat food product and, thus, under USDA jurisdiction. The Agency believes that if a new product formulated with less meat or sausage, or without the other components that are currently prescribed by the standard (i.e., cheese, sauce, and crust), does not meet consumer expectations, consumers are not likely to purchase the product and it will fail in the marketplace. In the absence of regulatory standards of identity for pizzas, FSIS has tentatively determined that required labeling features, such as the product name, ingredients statement, and nutrition facts panel, will provide adequate information for consumers to make informed choices when purchasing federally inspected pizza products. In particular, the product name would become a descriptive feature to convey to the consumer the components of the product. FSIS requests comment on whether the product name should be required to include the percentage of meat or poultry in the product.

The Agency proposes to amend title 9, part 319, subpart O, by removing and reserving section 319.600, Pizza. Removing the meat pizza and sausage pizza standards of identity, as proposed, does not mean that the names for these products will be completely unregulated. Sections 317.2(c)(1) and 381.117(a) of Title 9 of the Code of Federal Regulations require that the name of a meat or poultry product appear on the principal display panel of the product label. Under §§ 317.2(c)(1) and 381.117(a), the name of the product is (1) a standardized name, if the product purports to be or is represented as a product for which a regulatory standard of identity or composition has been prescribed; (2) the common or usual name of the food; or (3) if the product has no common or usual name, a truthful, descriptive designation.

The information submitted by NFPI evidences that, because of innovations in the restaurant and food services industries, to most consumers, the term ''pizza'' means an open-faced crust that is topped with any number of a variety of ingredients. Thus, if this proposal is issued as a final rule, and the standards of identity for meat pizza and sausage pizza are removed, FSIS has determined that ''pizza'' represents the appropriate common or usual name for the class of products that have been traditionally formulated with the components currently stipulated in the standard, *i.e.,* tomato sauce, cheese, and meat topping, on an open faced crust. If this proposal is finalized, products that comport with the traditional product and contain a bread-based crust, tomato sauce, cheese, and meat or poultry, may be identified as ''pizza'' together with the term that identifies the meat or poultry component, e.g., ''pizza with pepperoni.'' The names for other products purporting to be pizzas would need to be descriptively labeled to enable consumers to distinguish them from the traditional pizza, *e.g.,* ''pizza—garlic sauce, tomatoes, reduced-fat cheese, and seasoned beef strips on a crust.''

If this proposal is issued as a final rule, FSIS will eliminate or revise its informal labeling policies related to pizza products that contain meat or poultry. Although the regulations do not contain a standard of identity for pizza products that contain poultry, FSIS has treated these products as ''like products'' to pizza with meat or sausage, and the Agency's policy has been that these products contain at least 12% cooked poultry meat. If the standards of identity for meat pizza and sausage pizza are removed, as proposed, the policy that pizzas that contain poultry need to have a minimum poultry content will also be revoked.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. It has been determined to be not significant for purposes of E.O. 12866 and therefore, has not been reviewed by the Office of Management and Budget (OMB).

Effect on Small Entities

Removing the standards of identity for pizza will have no effects on small entities. After the standards are eliminated, small companies may still produce these products and identify them by a common or usual name, or a descriptive term. Thus, if this proposal is adopted as a final rule, small companies could continue to produce these products and label them as a ''meat pizza'' (e.g., ''pizza with ham'') or a ''sausage pizza'' (e.g., ''pepperoni pizza''). Small companies that choose to develop and market new styles of pizzas will incur the normal costs of product development, production, labeling, and marketing.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposal: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5 and 590.320 through 590.370 must be exhausted before any judicial challenge of the application of the provisions of this proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA.

Paperwork Requirements

There are no paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Public Notification and Request for Data

FSIS requests information regarding the impact of this proposed rule on minorities, women, and persons with disabilities, including information on the number of minority-owned meat and poultry establishments, the makeup of establishment workforces, and the communities served by official establishments. Public involvement in all segments of rulemaking and policy development are important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this proposed rule and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS Web page located at *http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html &log=linklog&to= http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

List of Subjects in 9 CFR Part 319

Food grades and standards, Meat inspection.

For the reasons set out in the preamble, FSIS is proposing to amend 9 CFR part 319 as follows:

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

1. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 319.600 would be removed and reserved.

Done at Washington, DC, on October 30, 2001.

Margaret O'K. Glavin,

Acting Administrator.

[FR Doc. 01–27542 Filed 11–1–01; 8:45 am]

BILLING CODE 3410–DM–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

[Docket No. PRM–73–11]

Three Mile Island Alert; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by the Three Mile Island Alert. The petition has been docketed by the NRC and has been assigned Docket No. PRM–73–11. The petitioner is requesting that the NRC regulations governing physical protection of plants and materials be amended to require NRC licensees to post at least one armed guard at each entrance to the ''owner controlled areas'' (OCAs) surrounding all U.S. nuclear power plants. The petitioner states that this should be accomplished by adding armed site protection officers (SPOs) to the security forces—not by simply moving SPOs from their protected area (PA) posts to the OCA entrances. The petitioner believes that its proposed amendment would provide an additional layer of security that would complement existing measures against radiological sabotage and would be consistent with the long-standing principle of defense-in-depth.

DATES: Submit comments by January 16, 2002. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Rulemakings and Adjudications staff.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (*http://ruleforum.llnl.gov*). At this site, you may view the petition for rulemaking, this **Federal Register** notice of receipt, and any comments received by the NRC in response to this notice of receipt. Additionally, you may upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905 (e-mail: *CAG@nrc.gov*).

Documents related to this action are available for public inspection at the NRC Public Document Room (PDR) located at 11555 Rockville Pike, Rockville, Maryland.

Documents created or received at the NRC after November 1, 1999 are also available electronically at the NRC's Public electronic Reading Room on the Internet at *http://www.nrc.gov/NRC/ADAMS/indes.html.* From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov.*

For a copy of the petition, write to Michael T. Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301–415–7163 or Toll-Free: 1–800–368–5642 or E-mail: *mtl@nrc.Gov.*

SUPPLEMENTARY INFORMATION:

Background

The Nuclear Regulatory Commission's regulations require that licensees establish protected areas (PAs) surrounding nuclear power plants, with strict access control at the PA boundaries including armed guards, entry barriers, vehicle barriers, intrusion detectors, personnel screening and vehicle screening. However, they do not require posting armed guards farther out, at the boundaries of the owner controlled areas (OCAs). The NRC has now received a petition for rulemaking dated September 12, 2001, submitted by the Three Mile Island Alert (petitioner) requesting that the regulations at 10 CFR 73.55 be amended to require licensees to post at least one armed guard at each entrance to the OCAs surrounding all nuclear power plants in the U.S.

The NRC has determined that the petition meets the threshold sufficiency requirements for a petition for rulemaking under 10 CFR 2.802. The petition has been docketed as PRM–73–11. The NRC is soliciting public comment on the petition for rulemaking. As a result of the attacks on the World Trade Center and the Pentagon on September 11, 2001, the NRC is conducting a comprehensive reexamination of its security requirements including the issues raised in this petition.

Discussion of the Petition

The petitioner believes that armed guards are needed at OCA entrances to serve as a physical and visual deterrent against potential violent actions. However, the petitioner cautions that additional site protection officers (SPOs) are needed and that licensees should not merely move SPOs from PA posts. The petitioner notes that 10 CFR 73.55, ''Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage'' does not require armed guards at OCA entrances in current security plans. The petitioner states that adding an armed guard at each entrance to the OCA at nuclear power plants would be consistent with defense-in-depth safety principles that have been in place for many years.

The petitioner has concluded that the additional layer of security would complement existing measures against radiological sabotage and would be relatively inexpensive. The petitioner contends that the NRC could not inform the public and Congress that every reasonable precaution had been taken after an attack on a nuclear power facility occurs if the NRC fails to implement this proposed amendment.

The petitioner believes that security should be a clear and visible presence at the OCA entrances, especially since, according to the petitioner, the NRC considers nuclear power plants as ''hardened targets.'' The petitioner states

that if terrorists perform reconnaissance missions at a nuclear power plant, the first thing they would see is that the OCA entrance is open and unguarded. The petitioner believes that the deterrent value of armed guards at the OCA entrances must not be downplayed.

The petitioner is concerned by how the NRC has determined what is ''adequate'' security and how the points of the ''Design Basis Threat'' are specified. The petitioner believes the NRC is reluctant to admit that terrorists might consider nuclear power plants as attractive targets. The petitioner states that nearly half of U.S. nuclear power plants have failed to demonstrate that they can defend against a terrorist attack during force-on-force security tests. The petitioner states that terrorists now take actions that are designed to kill large numbers of people instead of attempting to only instill fear or gain attention as in the past. According to the petitioner, revenge for the destruction of nuclear facilities in terrorists' home countries (e.g. Iraq) may be a motive for an attack in the U.S. The petitioner also states that a terrorist attack could destroy land and property that would be useless for many years and become a monument to terrorist activities. For these reasons, the petitioner has concluded that nuclear power plants are attractive targets to terrorists, that requiring guards at OCA entrances will create a visual deterrent against attacks, and that unguarded OCA entrances encourage attackers.

The petitioner believes that the NRC is not protecting against a large ''Design Basis Bomb.'' That is, the petitioner is concerned that a large enough vehicle bomb driven to the PA boundary and detonated might be able to damage vital equipment. The petitioner states that the FBI has determined that a large conventional bomb is still the weapon of choice for terrorists.

The petitioner believes that the ideal solution is for armed guards to control vehicle access at the OCA entrances and not allow access to the Protected Area without proper security checks. The petitioner contends that the presence of armed guards at the OCA entrance would have prevented the 1993 intrusion at Three Mile Island (TMI). The petitioner also contends that the NRC cannot state it has kept current with terrorist activities and capabilities and that unguarded OCA entrances create the impression that these facilities are soft targets. The petitioner cites a 2000 report by the U.S. Commission on National Security that has recommended an immediate reexamination of security practices because America is less secure than perceived.

The petitioner believes there are lessons to be learned from the 1996 Kobar Towers bombings after the U.S. Air Force was repeatedly assured by Saudi security officers that an expansion of the security perimeter was not necessary and determined that the jersey barrier placement provided reasonable protection proportional to any received threat. The petitioner recommends that the NRC read the report on this bombing to avoid security pitfalls and delays the U.S. Air Force experienced.

The petitioner is troubled by threats associated with the 1993 World Trade Center terrorists, citing articles from the New York Times, Universal Press International, and the Harrisburg, Pennsylvania, Patriot News. The petitioner states that many licensees have reduced the size of their guard force during the past few years, reducing the level of protection provided.

The Petitioner's Conclusions

The petitioner has concluded that the NRC requirements in 10 CFR part 73 should be amended to require an armed guard to be posted at all entrances to the OCAs surrounding all U.S. nuclear power plants. The petitioner requests that the regulations at 10 CFR part 73 be amended as detailed in its petition for rulemaking.

Dated at Rockville, Maryland, this 29th day of October, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 01–27576 Filed 11–1–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR 170

[Docket No. PRM–170–5]

National Mining Association; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of receipt.

SUMMARY: The Nuclear Regulatory Commission has received and requests public comment on a petition for rulemaking filed by the National Mining Association (NMA). The petition, docketed on September 11, 2001, has been assigned Docket No. PRM–170–5. The petition requests that the NRC conduct a rulemaking that would enable the NRC to waive the assessment of all annual and periodic inspection and licensing fees imposed on NRC uranium recovery licensees or, as an alternative, establish the basis for waiving fees associated with a contemplated rulemaking that would establish requirements for licensing uranium and thorium recovery facilities. The NMA believes that relieving the fee pressure on the licensees would be in the public interest and serve to maintain a viable domestic uranium recovery industry, including its substantial waste disposal capacity.

DATES: Submit comments by January 16, 2002. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

Deliver comment to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

For a copy of the petition, write to Michael T. Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

You may also provide comments via the NRC's interactive rulemaking Website at *http://ruleforum.llnl.gov.* This site allows you to upload comments as files in any format, if your web browser supports the function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905 (*e-mail:cag@nrc.gov*).

Documents related to this petition, including comments received, may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Library component on the NRC Web site (the Electronic Reading Room), *www.nrc.gov.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Michael T, Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of

Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Telephone: 301–415–7163 or Toll Free: 1–800–368–5642 or e-mail: *MTL@nrc.gov.*

SUPPLEMENTARY INFORMATION:

The Petitioner

The petitioner, NMA, is an organization composed of companies engaged in mining and mineral processing. The companies include producers of most of the U.S. metals, uranium, coal, industrial and agricultural minerals; manufacturers of mining and mineral processing machinery, equipment, and supplies; engineering and consulting firms and financial institutions that serve the mining industry. NMA submits this petition on behalf of its member companies who are NRC uranium recovery licensees, owners and operators of uranium mill and mill tailings sites and in situ leach (ISL) facilities.

The petitioner notes that since 1990, the NRC has been required to recover 100 percent of its budget authority through the imposition of fees on its licensees; however, the FY 2001 Energy and Water Development Appropriations Act (EWDAA) requires the percentage to decrease by two percent per year until 2005. Therefore, for FY 2001, NRC is only required to recover 98 percent of its budget. The petitioner acknowledges the two percent decrease and subsequent annual decreases up to ten percent in recovery requirements; however, the petitioner states that these decreases may be an example of ''too little, too late.'' The petitioner further recognizes that the Commission has the authority to waive fees if it can be established that to do so would be ''in the public interest'' (e.g., non-profit licensees). The petitioner also recognizes that any waiver of fees for Uranium Recovery (UR) licensees means that the burden of those fees would have to be shifted to other categories of licensees. NMA believes that it can establish that such a burden shift is not only, '' in the public interest,'' but also, in the interest of other NRC licensees, particularly nuclear fuel cycle licensees, including commercial nuclear reactors.

I. Background

A. NRC Fees

The petitioner states that the Omnibus Budget Reconciliation Act of 1990 (OBRA) which authorizes NRC to impose annual and periodic inspection and licensing fees on its licensees requires NRC to recover 100 percent of its budget with specified exceptions. The petitioner notes that inspection and licensing fees which reimburse NRC for activities such as review of license applications are administered under 10 CFR part 170 pursuant to the Independent Offices Appropriations Act of 1952, and that annual fees established under 10 CFR part 171 cover reimbursement for all other costs not covered under 10 CFR Part 170. The petitioner notes that OBRA, section 6101(c)(3) states that fees ''shall have a reasonable relationship to the cost of providing regulatory services.'' The petitioner states that the required two percent reduction each year until FY 2005 will result in a 90 percent recovery requirement. The petitioner states that the eventual ten percent reduction, along with a $3.2 million appropriations from the General Fund was implemented to cover certain agency expenses (e.g., regulatory reviews provided to other Federal agencies and States) because no direct benefit from these activities were realized by NRC licensees.

The petitioner cites that on June 14, 2001 (66 FR 32452), NRC issued a final rule on fee recovery FY 2001 based on the mandatory budget recovery figure of 98 percent. The petitioner states the Commission noted that it must recover approximately $453.3 million for FY 2001. The petitioner has included the Commission imposed FY 2001 fee scheme for UR licensees.

ANNUAL FEES FOR URANIUM RECOVERY LICENSEES

Class I Facilities (uranium mill licensees)	$94,300
Class II Facilities (ISL licensees	79,000
11e. (2) Disposal	58,200
11e. (2) Disposal Incident to Existing Tailing Sites	9,200

Class I and II sites will be billed on a quarterly basis.

In addition, the petitioner notes that NRC levies inspection fees on an increased hourly basis of $144 per hour for UR facilities, an increase from FY 2000's rate of $143 per hour. The petitioner recognizes that NRC fees are not levied universally for all types of licensees and notes that NRC waives the annual fee requirements for those licensees who have relinquished their authority to operate and have permanently ceased operations, that small business entities benefit from their status through lower fee rates, and that non-profit educational institutions are fully exempt from fees.

B. Uranium Recovery Industry

The petitioner asserts that in the past several years, the domestic UR industry has suffered the ramifications of a severely depressed uranium market. The petitioner sets out the following reasons in support of its assertion.

1. Low spot-market prices for uranium coupled with the lack of long-term contracts for domestic UR operations have caused the entire industry to experience significant economic downturns.

2. Employment in the uranium recovery sector has decreased by almost 50 percent since 1996.

3. Poor demand for, and an oversupply of, uranium has caused spot-market prices of uranium to dip below eight dollars per pound.

The petitioner states that, as a result of the depressed market, most all domestic UR companies have seen the value of their stock plummet and their financial stability undermined to the point that they feel their existence is threatened. The petitioner is concerned that current uranium spot-market prices cannot sustain domestic UR conventional or non-conventional (*i.e.*, ISL) capacity and, because of the rapid decline in uranium price production levels, some companies have had to lay off one-third of its workforce. The petitioner cites other companies that have experienced similar economic problems and have had difficulty maintaining consistent operating levels. According to the petitioner, because of the market conditions and the few active UR licensees, all active UR licensees have experienced significant NRC fees. The decline in the number of licensees and the resulting increase in fees for those that remain has created a vicious cycle that the petitioner believes threatens to destroy domestic UR capacity, including conventional mill tailing.

In addition, the petitioner asserts that regulatory inefficiencies also have contributed to the domestic UR problems. NMA references its White Paper which listed several events that caused UR licensees to suffer even more adverse cost impacts, e.g., the NRC closing of the Denver Uranium Recovery Field Office (URFO) which was to allegedly achieve cost-cutting benefits. NMA believes the closure benefits were not recognized and UR licensees paid significantly higher fees because of the loss of virtually all institutional knowledge of UR licensed operations and the subsequent need to re-educate new NRC personnel. According to the petitioner, the most dramatic example of increased costs to UR licensees as a

result of loss of experienced personnel is manifested in the Hydro Resources Inc. (HRI) licensing proceeding. The petitioner offers that post-URFO, NRC inexperience with licensing ISL operations led to a long and drawn out licensing process that culminated in a so-called ''informal'' hearing that began several years ago and continues with interveners filing in excess of 15,000 pages.

II. By Restoring the Domestic UR Industry to Viability, NRC Serves the Public Interest

A. NRC Fee Policies Currently Provide for Fee Reductions and Waivers That Are ''in the Public Interest'

According to the petitioner, the current NRC fee scheme allows certain waivers or reductions in fee payment for certain types of licensee, i.e., licensees recognized as small entities under the Regulatory Flexibility Act; licensees that have relinquished their authority to operate and ceased operations permanently, provided proper notifications comply with fee regulations; and non-profit educational institutions because these institutions provide the potential for creating important scientific information and the formulation of new innovative techniques. The petitioner recognizes that every NRC action to benefit certain licensees with reductions or waivers of fee requirements creates burdens on other licensees because the NRC must recover those lost funds from other licensees; therefore NRC has not relied on economic hardship to justify fee waivers because this would shift the burden of increased fees on other licensees. The petitioner states imposing additional fees on other licensees can only be justified if it can be shown to benefit the ''public interest.'' The petitioner asserts that reducing the impact on an economically challenged segment of NRC's licensees is merely collateral benefit to such burden shifting.

B. Altering Fee Requirements for Domestic UR Licensees To Preserve the Benefits

The petitioner asserts that NRC has demonstrated that acting ''in the public interest'' is a valid justification for reducing and/or waiving fee obligations. The petitioner believes that shifting reasonable economic burdens from UR licensees to other licensees can be justified based on several significant public interest factors and that the issue to be explored is whether the burden to be shifted is reasonable in light of the public interest benefit. The petitioner believes it is reasonable.

The petitioner offers a scenario where NRC would have to shift approximately $4 to 5 million in fees from exempt UR licensees. Spread over 100 fuel cycle licensees, each licensee would pay approximately $40,000 in fees per year. The petitioner states that a shift of $40,000 per year, when weighed against the actual and potential benefits that domestic UR licensees can and will provide, is a modest amount. The petitioner notes the fee shifting may only be necessary for a very short time depending on projected increases in the demand for and price of uranium in the near term. The petitioner asserts that fuel cycle licensees would bear a reasonable burden both in terms of the amount and the duration of the increased fees in order that UR licensees may retain their licenses and protect valuable fuel cycle resources.

According to the petitioner, the public's interest in UR begins with the benefit NRC confers with the issuance of a license. The petitioner asserts that by providing a licensee with a license to utilize certain materials, NRC confers a presumptive benefit which is the authority for the licensee to decide when and how best to use the material authorized by the license. Further, the petitioner states that implicit in this benefit is the assumption that the licensee will be able to use the licensed materials in a useful and cost-effective manner. The petitioner states that NRC's current focus on risk-informed, performance-based regulatory oversight is designed to enhance cost-effective regulation by focusing licensee and NRC resources on more serious potential hazards. The petitioner believes that imposing unreasonable regulatory burdens on such licensees runs counter to prevailing Commission policy and threatens the short-term economic viability at a time of national energy crisis which suggests the potential for significantly increasing demand for a variety of UR services in the finite future. The petitioner asserts that dual regulation and unresolved inefficiencies in the NRC's UR regulatory program are providing a significant ''drag'' on UR licensees'' economic well-being; thereby resulting in increased internal operating costs as well as increased fees. The petitioner notes that NMA requested that the NRC forego a potentially more efficient regulatory program through the development of a new Part 41 because the cost of developing such a program would be prohibitive at present in part because of the increased fee impact on already economically burdened UR licensees.

The petitioner emphasizes the impact of increased costs on present and possibly future loss of human resources which could adversely impact the UR sector's ability to rebound economically as the price of uranium rises to levels that can support profitable domestic production.

The petitioner believes the ISL production can become profitable with relatively limited increases in the price of yellowcake (*i.e.*, $13–16/lb range). The petitioner discusses the increased cost in operating conventional mills and charges that the modest price increases will not be sufficient to support the continued production of yellowcake by conventional milling. However, the petitioner asserts that conventional mills hold the promise of providing significant new benefits to the ISL licensees, other fuel cycle licensees, including reactors and other NRC licensees through the processing of the alternate feed. The petitioner believes that alternate feed processing provides a valuable resource to other parties, including NRC licensees, DOE, and others that can divest themselves of materials that are wastes to them. The petitioner states that conventional mills can recycle the wastes and recover valuable energy resources that would be lost by direct disposal, yet ensure that the post-UR wastes will be contained and controlled in accordance with the Environmental Protection Agency/ Nuclear Regulatory Commission Uranium Mill Tailings Radiation Control Act (EPA/NRC UMTRCA) regulations in perpetuity.

The petitioner believes that only by processing alternate feeds and receiving recycling fees can conventional mills produce yellowcake profitably without a huge increase in the price of yellowcake. The petitioner claims that more efficient regulatory oversight through performance based license conditions authorized under the contemplated part 41 rule could support the viability of such operations and the benefits provided to waste generators and national energy interest.

Also, the petitioner offers that conventional mill tailings impoundments with approximately 20 million tons of disposal capacity offer the potential to assist in solving major radioactive waste disposal problems for ''similar'' high volume, low activity wastes. The petitioner states that stringent regulatory controls for both radiological and non-radiological wastes including a long-term governmental custodian with long-term stewardship costs funded by the licensee make such sites extremely valuable potential resources to address waste disposal

options of NRC licensees including fuel cycle licensees. The petitioner indicates the full scope of these facilities' value to the ''general public interest,'' in permanent disposal as opposed to temporary storage, has only just begun to be examined in detail, and that the loss of the significant low-level radioactive waste disposal options that such facilities may offer before those options have been fully explored by NRC, licensees, States, and the general public would be a blow to the national public interest.

The petitioner believes the UMTRCA UR regulatory program has provided, and will continue to provide, an invaluable ''living laboratory'' that addressed both operating and decommissioning impacts of nuclear fuel cycle facilities. The petitioner claims the information and experience gained through constructing and maintaining engineered barriers; groundwater corrective action, including ISL aquifer restoration; and site cleanup verification will help reduce the impact of future operations and future site closures. This, the petitioner asserts, is ''in the public interest.''

The petitioner states that to allow the domestic UR industry to wither to the point of virtual extinction or to disappear completely cannot be in the ''national public interest'' because of its current and potential benefits. The petitioner states that domestic UR operations provide value to the U.S. by producing energy-generating yellowcake and provide additional waste disposal options to radioactive waste generators.

The petitioner references several bills pending before Congress that acknowledge the importance of UR as a part of the domestic energy market. The petitioner believes consideration of these legislative initiatives demonstrates Congressional interest in maintaining a viable domestic UR industry as an important national resource that should be preserved.

Further, the petitioner states that NRC has recently explicitly noted ongoing Congressional concerns about a viable domestic UR industry. The petitioner cites a Federal concern for the impact on the domestic uranium mining industry as one of several factors regarding timeliness in the defueling and decommissioning (D&D) Standard Review Plan (SRP). The petitioner provided other examples of how the public will be served by an extension and included the following excerpt from the SRP:

The standby period will allow economic conditions in the uranium market to improve. Existing statutes oblige the Secretary of Energy to gather information on the uranium mining industry and to have a continuing responsibility for the domestic industry, to encourage the use of domestic uranium. See 42 U.S.C. 2201(b) & 2296(b)(3). Although this responsibility is not NRC's, we recognize that the viability of the industry is a Federal concern, or an alternate schedule involving some of the Federal licensee's other facilities would better take into account the Federal licensee's overall decommissioning needs, thereby reducing public funds needed for the ultimate decommissioning of the facility, etc.

The petitioner cites a July 17, 2001, NRC staff letter to Kennecott Uranium Company regarding the postponement of the Timeliness in D&D requirements' implementation at its Sweetwater Uranium Facility that stated, ''the continued existence of the mill is in the public interest...'' and ''maintaining the domestic capacity to provide the raw material for nuclear power is in the public interest.'' The petitioner concludes that it can be fairly said that NRC staff recognizes that maintaining a viable domestic UR industry is ''in the public interest'' of the United States. NMA emphasizes that it is also specifically in the interest of the NRC licensees, potentially including reactor licensees, within and without the nuclear fuel cycle.

NMA states that shifting reasonable economic burdens to other licensees can serve the public interest'' if the alternative is to lose all or even some of UR's valuable resources including ISL and conventional uranium mill facilities. The petitioner states that D&D activities have become increasingly important at fuel cycle facilities in part because of NRC's timeliness in D&D and final site D&D standards set forth in 10 CFR 20.1401 *et seq.* As a result, many sites, or portions thereof, are addressing reclamations activities to meet regulatory standards. The petitioner states that NRC has estimated that site D&D activities will generate large volumes of new low-level radioactive waste (LLRW) that will need a home for disposal. Also, licensed sites and government facilities will require the disposal of large volumes of LLRW in the form of soils, sludge, and debris. According to the petitioner, economically viable disposal options will be vital to final site closure and license termination at many complex sites. NMA believes conventional UR facilities can provide new alternatives to current disposal options for fuel cycle facilities with large volumes of LLRW. NMA continues that waste disposal for non-fuel cycle facilities generating technologically enhanced naturally occurring radioactive materials (''TENORM'') may also benefit from more numerous and competing options for disposal. The petitioner asserts that it would be ''in the public interest'' to help to ensure that the resources will not be lost while these important waste disposal opportunities are being debated, perhaps in a (contemplated Part 41) rulemaking process.

The petitioner suggests that UR industry licensees can continue to develop information, techniques, and systems that will add to ongoing protection of workers and the environment at ''active'' sites and ensure long-term post-closure protection at UR mill tailing impoundments, particularly if additional alternate feeds are processed and ''other than 11e.(2) materials'' are disposed there. Research in groundwater restorations at ISL sites, which is explicitly recognized in H.R.4, Section 309, could lead to new or refined methods for efficient, low-impact UR. Therefore, the petitioner believes that shifting a reasonable burden of fees to other licensees will allow UR licensees to continue developing such information in anticipation of a better uranium market and the reinstatement of production activities, is in the public interest.

Conclusion

In conclusion, the petitioner states that for several years, the UR industry has suffered through the effects of a severely depressed uranium market. Despite the fact that prices have remained low enough to threaten the loss of domestic UR capability, it is likely that the market for uranium will recover somewhat in the near term. However, until that happens, according to the petitioner, UR licensees must survive without adequate revenues. If, even without such revenues, UR licensees must still find a way to pay NRC fees imposed, or face loss of their licenses, this would truly put the nail in the coffin. The petitioner states that, as NMA has demonstrated and NRC recognizes, it would be ''in the public interest'' to relieve the fee pressure on UR licensees, at least in the near term, by exempting these licensees from all fees until the price of uranium reaches $13–16/lb. In the alternative, NRC could exempt UR licensees from some fees, including fees for development of the (contemplated Part 41) rule which ultimately would lead to more cost-effective regulatory oversight. The petitioner believes that the fee burden to be shifted (i.e. $40,000 per fuel cycle licensee) and the likely time frame (for at least one year) during which burden shifting would be necessary, are not excessive and that the ''public interest'' benefits, existing and potential, are significant. The petitioner, therefore, believes the burden shift is reasonable and prudent.

Commission Vote to Discontinue Part 41

On May 29, 2001, the Commission issued a staff requirements memoranda (SRM) that approved the discontinuance of the current 10 CFR part 41 rulemaking efforts. The SRM recommended that staff focus its resources on updating guidance documents to implement Commission direction set forth in SRM's for SECY's 99–012, 99–013, and 99–277.

Dated at Rockville, Maryland, this 25th date of October, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 01–27536 Filed 11–1–01; 8:45 am]

BILLING CODE 7590–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1, 41 and 190

RIN 3038–AB71 and 3038–AB76

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240 and 242

[Release No. 34–44996; File Nos. S7–16–01 and S7–17–01]

RIN 3235–AI22 and 3235–AI32

Customer Margin Rules Relating to Security Futures; Applicability of CFTC and SEC Customer Protection, Recordkeeping, Reporting, and Bankruptcy Rules and the Securities Investor Protection Act of 1970 to Accounts Holding Security Futures Products

AGENCIES: Commodity Futures Trading Commission and Securities and Exchange Commission.

ACTION: Joint proposed rules; extension of comment periods.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'') and Securities and Exchange Commission (''SEC'') (collectively, the ''Commissions'') are extending the comment periods for the customer margin rules relating to security futures contained in proposed Release No. 34–44853 (September 26, 2001), 66 FR 50719 (October 4, 2001) and the rule relating to the applicability of CFTC and SEC customer protection, recordkeeping, reporting, and bankruptcy rules and the Securities Investor Protection Act of 1970 to accounts holding security futures products proposed in Release No. 34–44854 (September 26, 2001), 66 FR 50785 (October 4, 2001). The original comment periods for these proposals are scheduled to end on November 5, 2001. The new deadline for submitting public comments on both of the above releases is December 5, 2001.

DATES: Public comments are due on or before December 5, 2001.

ADDRESSES: Comments should be sent to both agencies at the addresses listed below.

CFTC: Comments should be sent to the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581, Attention: Office of the Secretariat. Comments may be sent by facsimile transmission to (202) 418–5521, or by e-mail to *secretary@cftc.gov*. Reference should be made to ''Customer Margin for Security Futures'' or ''Proposed Rule 41.42—Treatment of Customer Funds.'' All comment letters will be posted, as submitted, on the CFTC's Internet web site (*http://www.cftc.gov*).

SEC: Persons wishing to submit written comments should send three copies to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Comments also may be submitted electronically at the following e-mail address: *rule-comments@sec.gov*. All comment letters should refer to File No. S7–16–01 (relating to customer margin for security futures) or S7–17–01 (relating to treatment of customer funds); this file number should be included on the subject line if e-mail is used. Comment letters received will be available for public inspection and copying in the SEC's Public Reference Room, 450 Fifth Street, NW, Washington, DC 20549–0102. Electronically submitted comment letters will be posted on the SEC's Internet web site (*http://www.sec.gov*). The SEC does not edit personal identifying information, such as names or e-mail addresses, from electronic submissions. Submit only the information you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: *CFTC:* Regarding Customer Margin Rules Relating to Security Futures, Phyllis P. Dietz, Special Counsel, Division of Trading and Markets, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581. Telephone: (202) 418–5000. E-mail: (*PDietz@cftc.gov*).

Regarding Applicability of CFTC and SEC Customer Protection, Recordkeeping, Reporting, and Bankruptcy Rules and the Securities Investor Protection Act of 1970 to Accounts Holding Security Futures Products, Helene D. Schroeder, Special Counsel, Division of Trading and Markets, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581. Telephone: (202) 418–5430. E-mail: (*hschroeder@cftc.gov*).

SEC: Regarding Customer Margin Rules Relating to Security Futures, Jennifer Colihan, Special Counsel, at (202) 942–0735, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–1001.

Regarding Applicability of CFTC and SEC Customer Protection, Recordkeeping, Reporting, and Bankruptcy Rules and the Securities Investor Protection Act of 1970 to Accounts Holding Security Futures Products Bonnie L. Gauch, Attorney, at (202) 942–0765, Office of Risk Management and Control; and with respect to Exchange Act Rule 10b-10, Catherine McGuire, Chief Counsel, or Theodore R. Lazo, Special Counsel, at (202) 942–0073, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–1001.

SUPPLEMENTARY INFORMATION: On October 4, 2001, the Commissions published for comment proposed rules governing customer margin for security futures. The proposed rules would apply to margin arrangements between brokers, dealers, and members of national securities exchanges and their customers with respect to security futures, subject to certain exclusions. Also on October 4, 2001, the Commissions published for comment proposed rules relating to the applicability of the Commissions' customer protection, recordkeeping, reporting, and bankruptcy rules and the Securities Investor Protection Act of 1970 to accounts holding security futures products. These proposing releases established a deadline of November 5, 2001 for submitting public comment.

The Commissions have received a request from the Securities Industry Association (''SIA'') and Futures Industry Association (''FIA'') to extend the deadline on each release by an additional 30 days so that their members have an adequate opportunity to review these proposals and provide thoughtful comment.[1] The SIA and FIA explained that, in light of the tragic events of September 11, the securities and futures industries need more time to provide meaningful comments. They stated their belief that such extensions would not have any adverse consequences, recognizing that such extensions could delay commencement of trading of security futures on other than a principal-to-principal basis between eligible contract participants beyond December 21, 2001.[2] In letters to the leadership of the Senate Committee on Banking, Housing and Urban Affairs and the House Committees on Financial Services and Agriculture, the SIA and

[1] *See* letter to Jean A. Webb, Secretary, CFTC, and Jonathan G. Katz, Secretary, SEC, from the SIA and FIA, dated October 16, 2001 (''SIA/FIA Extension Request'').

[2] Section 6(g)(5) of the Securities Exchange Act of 1934 (''Exchange Act'') permits security futures products to commence trading on the later of December 21, 2001 or such date that a futures association registered under Section 17 of the Commodity Exchange Act has met the requirements set forth in Section 15A(k)(2) of the Exchange Act. 15 U.S.C. 78f(g)(5).

FIA further pointed out that ''the tragic events of September 11, 2001 have severely strained the systems, personnel and related operational resources of the firms, exchanges and clearing organizations that provide the infrastructure for the U.S. capital markets.'' [3]

The Commissions are extending the comment periods for the proposed rules until December 5, 2001, even if, as noted by Chairmen Oxley and Combest, granting such extension would mean that security futures would not commence trading on other than a principal-to-principal basis between eligible contract participants until after December 21, 2001, because they believe that an additional 30-day comment period is appropriate for the reasons described above and will facilitate more meaningful comments from the public.

By the Commodity Futures Trading Commission.

Dated: October 25, 2001.

Jean A. Webb,

Secretary.

By the Securities and Exchange Commission.

Dated: October 29, 2000.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–27523 Filed 11–1–01; 8:45 am]

BILLING CODE 8010–01–P

[3] *See* letters to The Honorable Paul S. Sarbanes, Chairman, Senate Committee on Banking, Housing and Urban Affairs, The Honorable Michael G. Oxley, Chairman, House Committee on Financial Services, and The Honorable Larry Combest, Chairman, House Committee on Agriculture, from the SIA and FIA, dated October 10, 2001 (attached to the SIA/FIA Extension Request). The Commissions also note that the House Committees on Financial Services and Agriculture support an extension of the public comment period by joint letter to Chairmen Newsome and Pitt. *See* letter to The Honorable James E. Newsome, Chairman, CFTC, and The Honorable Harvey Pitt, Chairman, SEC, from The Honorable Michael G. Oxley, Chairman, House Committee on Financial Services, and The Honorable Larry Combest, Chairman, House Committee on Agriculture, dated October 15, 2001.

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 918

[SPATS No. LA–022–FOR]

Louisiana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of a proposed amendment to the Louisiana regulatory program (Louisiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Louisiana proposes additions of regulations concerning revegetation success standards for post-mining land uses of pastureland and wildlife habitat. Louisiana also proposes to add to its program a policy document that describes the criteria and procedures for determining reclamation phase III ground cover and stocking success for areas developed for wildlife habitat. Louisiana intends to revise its program to be consistent with the corresponding Federal regulations.

This document gives the times and locations that the Louisiana program and the proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments until 4 p.m., c.s.t., December 3, 2001. If requested, we will hold a public hearing on the amendment on November 27, 2001. We will accept requests to speak at the hearing until 4 p.m., c.s.t., on November 19, 2001.

ADDRESSES: You should mail or hand deliver written comments and requests to speak at the hearing to Michael C. Wolfrom, Director, Tulsa Field Office, at the address listed below.

You may review copies of the Louisiana program, the amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Tulsa Field Office.

Michael C. Wolfrom, Director, Tulsa Field Office, Office of Surface Mining, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135–6547, Telephone: (918) 581–6430.

Louisiana Department of Natural Resources, Office of Conservation, Injection and Mining Division, 625 N . 4th Street, P.O. Box 94275, Baton Rouge, LA 70804, Telephone: (225) 342–5540.

FOR FURTHER INFORMATION CONTACT: Michael C. Wolfrom, Director, Tulsa Field Office. Telephone: (918) 581–6430. Internet: *mwolfrom@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Louisiana Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''* * * a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of this criteria, the Secretary of the Interior approved the Louisiana program on October 10, 1980. You can find background information on the Louisiana program, including the Secretary's findings and the disposition of comments in the October 10, 1980, **Federal Register** (45 FR 67340). You can find later actions concerning the Louisiana program at 30 CFR 918.15 and 918.16.

II. Description of the Proposed Amendment

By letter dated October 2, 2001 (Administrative Record No. LA–367), Louisiana sent us an amendment to its program under SMCRA and the Federal regulations at 30 CFR 732.17(b). Louisiana sent the amendment in response to our letters dated March 24, 1999, and August 16, 2000 (Administrative Record Nos. LA–365 and LA–365.01, respectively), that we sent to Louisiana under 30 CFR 732.17(c). Louisiana proposes to amend the Louisiana Surface Mining Regulations. Below is a summary of the changes proposed by Louisiana. The full text of the program amendment is available for your inspection at the locations listed above under **ADDRESSES.**

A. Section 5423. Revegetation: Standards for Success

1. Louisiana proposes to add new paragraph e. to subsection B.1. of its regulations to read as follows:

e. The criteria and procedures for determining ground cover and production success are found at § 5424.

2. Louisiana proposes to add new paragraph a. to subsection B.8. of its regulations to read as follows:

a. The criteria and procedures for determining ground cover and stocking success are found at § 5425.

B. Section 5424. Revegetation: Standards for Success—Post-Mining Land Use of Pastureland

Louisiana proposes to add a new section to its regulations that describes the criteria and procedures for determining ground cover and production success for areas being restored to pastureland.

C. Section 5425. Revegetation: Standards for Success—Post-Mining Land Use of Wildlife Habitat

Louisiana proposes to add a new section to its regulations that describes the criteria and procedures for determining ground cover and stocking success for areas developed for wildlife habitat.

D. Reclamation Phase III Revegetation Success Standards for Post-Mining Land Use of Wildlife Habitat

Louisiana proposes to add a policy document to its program that describes the criteria and procedures for determining reclamation phase III ground cover and stocking success for areas developed for wildlife habitat.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Louisiana program.

Written Comments: If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, should be confined to issues pertinent to the notice, and should explain the reason for your recommendation(s). We may not be able to consider or include in the Administrative Record comments delivered to an address other than the one listed above (see **ADDRESSES**).

Electronic Comments: Please submit Internet comments as an ASCII, WordPerfect, or Word file avoiding the use of special characters and any form of encryption. Please also include ''Attn: SPATS NO. LA–022–FOR'' and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Tulsa Field Office at (918) 581–6430.

Availability of Comments: Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours at OSM's Tulsa Field Office (see **ADDRESSES**). Individual respondents may request that we withhold their home address from the administrative record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Public Hearing: If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., c.s.t. on November 19, 2001. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a public hearing provide us with a written copy of his or her testimony. The public hearing will continue on the specified date until all persons scheduled to speak have been heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

If you are disabled and need a special accommodation to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Public Meeting: If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. If you wish to meet with us to discuss the proposed amendment, you may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES.** We will also make a written summary of each meeting a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulations.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary under SMCRA.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

Executive Order 13211—Regulations That Significantly Affect The Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866 and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse

effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that a decision on a proposed State regulatory program provision does not constitute a major Federal action within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(C)). A determination has been made that such decisions are categorically excluded from the NEPA process (516 DM 8.4.A).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million.

b. Will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions.

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

This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 918

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 16, 2001.

Ervin J. Barchenger,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 01–27544 Filed 11–1–01; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 924

[SPATS No. MS–017–FOR]

Mississippi Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of a proposed amendment to the Mississippi regulatory program (Mississippi program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Mississippi proposes revisions to and additions of regulations concerning valid existing rights; roads; formal review of citations; and revegetation success standards. Mississippi intends to revise its program to be consistent with the corresponding Federal regulations and to improve operational efficiency.

This document gives the times and locations that the Mississippi program and the proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments until 4 p.m., c.s.t., December 3, 2001. If requested, we will hold a public hearing on the amendment on November 27, 2001. We will accept requests to speak at the hearing until 4 p.m., c.s.t. on November 19, 2001.

ADDRESSES: You should mail or hand deliver written comments and requests to speak at the hearing to Arthur W. Abbs, Director, Birmingham Field Office, at the address listed below.

You may review copies of the Mississippi program, the amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Birmingham Field Office.

Arthur W. Abbs, Director, Birmingham Field Office, Office of Surface Mining, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209, Telephone: (205) 290–7282.

Department of Environmental Quality, Office of Geology, 2380 Highway 80 West, P.O. Box 20307, Jackson, Mississippi 39289–1307, Telephone: (601) 961–5500.

FOR FURTHER INFORMATION CONTACT: Arthur W. Abbs, Director, Birmingham Field Office. Telephone: (205) 290–7282. Internet: *aabbs@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Mississippi Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''. . . a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act . . .; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Mississippi program on September 4, 1980. You can find background information on the Mississippi program, including the Secretary's findings and the disposition of comments, in the September 4, 1980, **Federal Register** (45 FR 58520). You can find later actions on the program at 30 CFR 924.10, 924.15, 924.16, and 924.17.

II. Description of the Proposed Amendment

By letter dated September 28, 2001 (Administrative Record No. MS–0388), Mississippi sent us an amendment to its

program under SMCRA and the Federal regulations at 30 CFR 732.17(b). Mississippi sent the amendment in response to our letters dated August 17, 2000, and August 23, 2000 (Administrative Record Nos. MS–0382 and MS–0381, respectively), that we sent to Mississippi in accordance with 30 CFR 732.17(c), and in response to required program amendments at 30 CFR 924.16(i) and (l). The amendment also includes changes made at Mississippi's own initiative. Mississippi proposes to amend the Mississippi Surface Coal Mining Regulations. Below is a summary of the changes proposed by Mississippi. The full text of the program amendment is available for your inspection at the locations listed above under **ADDRESSES**.

A. Section 105, Definitions

Mississippi proposes to add a definition for ''immediate mining area.'' Mississippi also proposes to revise its definition of ''valid existing rights.''

B. Section 1103, Responsibility

Mississippi proposes to add the phrase, ''a valid existing rights determination made by OSM'' after the reference to ''30 U.S.C. 1272(e).'' Mississippi also proposes to replace the phrase, ''this Chapter'' with the phrase, ''these regulations.''

C. Section 1105, Areas Where Mining Is Prohibited or Limited

Mississippi proposes to add the phrase, ''or qualify for the exception for existing operations under paragraph (h) of this section'' at the end of the introductory language to this section. Mississippi also proposes to add new paragraph (h) to provide that the prohibitions and limitations of section 1105 do not apply to surface coal mining operations for which a valid permit exists when the land comes under the protection of section 1105 of the Mississippi regulations, section 522(e) of SMCRA, or 30 CFR 761.11.

D. Section 1106, Submission and Processing of Requests for Valid Existing Rights Determinations

Mississippi proposes to add this new section to describe the authority of the Permit Board to make valid existing rights determinations; what an applicant must submit as part of a request for a valid existing rights determination; what the Department must do when it receives a request for a valid existing rights determination; and how the Permit Board will make decisions concerning valid existing rights claims. This new section also provides that determinations concerning valid existing rights are subject to administrative and judicial review under Mississippi Code Annotated (Miss. Code Ann.) 53–9–77. Finally, this new section requires the Department and Permit Board to make requests for valid existing rights determinations and associated records available to the public.

E. Section 1107, Procedures

At paragraph (a), Mississippi proposes to add the phrase, ''or earlier, if properly requested under § 1106'' after the opening phrase, ''upon receipt of a complete application for a surface coal mining and reclamation operation permit.''

In the first sentence of paragraph (b), Mississippi proposes to delete the specific references to section 1105(a), (f) and (g), and the phrase, ''or if the operation did not exist on August 3, 1977.'' The revised sentence reads as follows:

(b) Where the proposed operation would be located on any lands listed in § 1105, the Permit Board shall deny the permit if the applicant has no valid existing rights for the area.

Mississippi proposes to revise paragraph (f) to provide that the Permit Board will follow the procedures required by section 3114(d) when it determines that a proposed surface coal mining operation will adversely affect any publicly owned park or any place included in the National Register of Historic Places.

Finally, Mississippi proposes to remove paragraph (h), which provides that a valid existing rights determination by the Permit Board is subject to administrative and judicial review under Miss. Code Ann. 53–9–77.

F. Section 2103, Permit Requirements for Exploration Removing More Than 250 Tons of Coal, or Occurring on Lands Designated as Unsuitable for Surface Coal Mining Operations

Mississippi proposes to redesignate several paragraphs in this section. Mississippi proposes to redesignate paragraph (b)(13)(A) in its entirety as paragraph (c). Mississippi also proposes to redesignate paragraph (b)(13)(B), except paragraph (b)(13)(B)(iii), as new paragraph (d). Mississippi proposes to redesignate paragraph (b)(13)(B)(iii) as new paragraph (e). Finally, Mississippi proposes to redesignate paragraph (b)(13)(C) in its entirety as new paragraph (f).

Mississippi also proposes to add new paragraphs in this section. Mississippi proposes to add new paragraph (b)(14) to require applicants for coal exploration permits to submit, as part of their permit application, a demonstration that, for any lands listed at section 1105, the proposed exploration activities have been designed to minimize interference with the values for which those lands were designated as unsuitable for surface coal mining operations. Furthermore, applicants must provide documentation that they have consulted with the owner of the feature causing the land to come under the protection of section 1105, as well as the regulatory authority with primary jurisdiction over the feature, when applicable.

Mississippi also proposes to add a new provision at redesignated paragraph (d)(2)(iv) to require the Permit Board to approve an application for a coal exploration permit if it finds, for lands protected under section 1105, the applicant has demonstrated that the proposed exploration and reclamation activities will minimize interference with the values for which those lands were designated as unsuitable for surface coal mining operations. The new provision also requires the Permit Board to provide reasonable opportunity to the owner of the feature causing the land to come under the protection of section 1105, as well as the agency with primary jurisdiction over the feature when applicable, to comment on whether the finding is appropriate.

G. Section 3114, Valid Existing Rights Review at Time of Permit Application Review

Mississippi proposes to add this new section to describe the procedures the Permit Board or Department will follow when reviewing an administratively complete application for a surface coal mining operation, or an administratively complete application for revision or modification of the boundaries of a surface coal mining operations permit.

H. Section 53103, Revegetation: Standards for Success

Mississippi proposes to revise paragraph (a) to require the success of revegetation to be judged on the effectiveness of the vegetation for the approved post-mining land use, the extent of perennial cover compared to the cover occurring in natural vegetation areas, the general requirements of §§ 5397–53103, and the specific requirements of Appendix A, ''Revegetation Success Standards.''

Mississippi also proposes to redesignate paragraph (a)(1) as paragraph (b)(1); paragraph (b)(1) as paragraph (b)(2); paragraph (b)(2) in its entirety as paragraph (b)(3); and paragraph (b)(3) as new paragraph (4).

I. Section 53111, Roads: General

Mississippi proposes to add new paragraph (a)(4) to describe when a limited use vehicular pathway is not classified as a road. Mississippi also proposes to add new paragraph (a)(5) to read as follows:

(5) A limited use vehicular pathway: (i) May include water bars across the pathway and drainage ways incidental to the area; (ii) shall be reclaimed with vegetation sufficient to prevent erosion prior to phase II bond release; (iii) along with the area it disturbs, is a mining related activity and must be covered by an appropriate reclamation bond; (iv) will be reclassified as a road if upgraded by construction activities such as blading, construction, placement of a compacted surface, cut and fill of the natural grade, construction of drainage ditches or low water crossings, or installation of drainage structures not previously approved by the Department as appropriate to a limited use vehicular pathway. The submittal and approval of plans and drawings required by these regulations must be completed prior to the upgrading of a limited use vehicular pathway.

J. Section 6511, Formal Review of Citations

Mississippi proposes to revise the first sentence of paragraph (c) to allow any party to a proceeding that is the result of the issuance of a notice of violation or cessation order to apply to the Commission for temporary relief from the notice or cessation order. Mississippi also proposes to replace all references throughout this section to ''Chief of the Legal Division'' with ''General Counsel.''

K. Appendix A, Revegetation Success Standards

Mississippi proposes to add Appendix A to describe the standards for revegetation success on commercial forest lands, croplands, industrial or commercial lands, pasture and previously mined areas, prime farmlands, recreation lands, residential lands, and wildlife habitats.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Mississippi program.

Written Comments: If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, should be confined to issues pertinent to the notice, and should explain the reason for your recommendation(s). We may not be able to consider or include in the Administrative Record comments delivered to an address other than the one listed above (see **ADDRESSES**).

Electronic Comments: Please submit Internet comments as an ASCII, WordPerfect, or Word file avoiding the use of special characters and any form of encryption. Please also include ''Attn: SPATS NO. MS–017-FOR'' and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Birmingham Field Office at (205) 290–7282.

Availability of Comments: Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours at OSM's Birmingham Field Office (see **ADDRESSES**). Individual respondents may request that we withhold their home address from the administrative record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Public Hearing: If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., c.s.t. on November 19, 2001. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a public hearing provide us with a written copy of his or her testimony. The public hearing will continue on the specified date until all persons scheduled to speak have been heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

If you are disabled and need a special accommodation to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Public Meeting: If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. If you wish to meet with us to discuss the proposed amendment, you may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES.** We will also make a written summary of each meeting a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulations.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary under SMCRA.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of this section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and

732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13211—Regulations That Significantly Affect The Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866, and because it is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that a decision on a proposed State regulatory program provision does not constitute a major Federal action within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)). A determination has been made that such decisions are categorically excluded from the NEPA process (516 DM 8.4.A).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Therefore, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million.

b. Will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions.

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

This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 924

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 10, 2001.

Ervin J. Barchenger,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 01–27543 Filed 11–1–01; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AI44

Ankylosis and Limitation of Motion of Digits of the Hands

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Department of Veterans Affairs (VA) Schedule for Rating Disabilities by revising the evaluation criteria for ankylosis and limitation of motion of the fingers and thumb. This change is necessary to ensure that veterans diagnosed with these conditions receive consistent evaluations.

DATES: Comments must be received by VA on or before January 2, 2002.

ADDRESSES: Mail or hand deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1154, Washington, DC 20420; or fax comments to (202) 273–9289; or e-mail comments to *OGCRegulations@mail.va.gov.* Comments should indicate that they are in response to ''RIN 2900–AI44.'' All written comments received will be available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Caroll McBrine, M.D., Consultant, Regulations Staff (211A), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420, (202) 273–7230.

SUPPLEMENTARY INFORMATION: This document proposes to amend the Department of Veterans Affairs (VA) Schedule for Rating Disabilities by clarifying the method of evaluation for ankylosis and limitation of motion of the digits of the hands.

Current diagnostic codes (DC's) 5216 through 5227 represent ankylosis of individual digits or combinations of digits, and they are grouped in the following way: DC's 5216 through 5219 represent unfavorable ankylosis of multiple digits; DC's 5220 through 5223 represent favorable ankylosis of multiple digits; and DC's 5224 through 5227 represent ankylosis of individual digits. Explanatory notes preceding DC 5216, following DC 5219, preceding DC 5220, following DC 5223, and following DC 5227 give specific directions on evaluating limitation of motion or ankylosis of single and multiple digits, determining whether ankylosis is favorable or unfavorable, and evaluating combinations of digit amputations at various levels or any combination of digit amputation, ankylosis, or limitation of motion of the digits.

The United States Court of Veterans Appeals (now the Court of Appeals for Veterans Claims), in *Hill* v. *Principi,* 3 Vet. App. 540, 541 (1992), noted that ''[n]either the format of the code pertaining to finger injuries nor its interpretive notes are a model of clarity.'' We therefore propose to clarify the method of evaluation of ankylosis

and limitation of motion of single and multiple digits by revising and reorganizing the diagnostic codes and explanatory notes that address the evaluation of these conditions. The intent of this revision is to assure fair and consistent evaluations of these disabilities by clarifying existing evaluation criteria.

We propose to relocate the interpretive notes regarding evaluations of ankylosis and limitation of motion of the digits of the hands into a single set of instructions preceding DC 5216 and to delete current notes (1), (2), (3), and (4) preceding DC 5216; notes (a), (b), and (c) following DC 5219; notes (1), (2), (3) and (4) preceding DC 5220; notes (a) and (b) following DC 5223; and the note following DC 5227. We propose to incorporate the content of these notes into the proposed instructions preceding DC 5216, with modifications as discussed below.

We propose to change the term used for the third digit from ''middle finger'' to ''long finger,'' the currently preferred terminology. We also propose to add descriptions of the position of function of the hand, and of the normal range of motion of the index, long, ring, and little fingers, in order to assist the rating agency in assessing impairment due to limitation of motion or ankylosis. We also propose to add Roman numeral designations for the digits: The thumb is digit I; the index, long, ring, and little fingers are digits II, III, IV, and V, respectively.

In the current schedule, ankylosis, *i.e.,* immobility of a joint, and limitation of motion, *i.e.,* loss of any portion of the normal range of motion of a joint, are evaluated using the same criteria. We propose to revise the criteria under diagnostic codes 5216 through 5227 so that they address ankylosis only, and to add three new diagnostic codes, 5228, 5229, and 5230, to evaluate limitation of motion of the thumb, the index or long finger, and the ring or little finger, respectively. The proposed criteria are derived from the material contained in note (3) preceding DC 5216 and note (3) preceding DC 5220, which state that with only one joint of a digit ankylosed or limited in its motion, evaluation will be based on whether motion is possible to within 2 inches (5.1 cms.) of the median transverse fold of the palm, and in note (a) following DC 5223, which states that limitation of motion of less than 1 inch (2.5 cms.) in either direction is not considered disabling. We propose to evaluate limitation of motion of the index, long, ring, and little fingers on either the number of degrees by which extension is limited, or on a measurement of the gap between the fingertip and the palm when the finger is flexed to the extent possible. We propose to evaluate the thumb based on its most important function, opposing the fingers, as measured by the gap between the thumb pad and the fingers with the thumb attempting to oppose the fingers. These criteria are consistent with § 4.71, ''Measurement of ankylosis and joint motion,'' which states that motion of the thumb and fingers should be described by appropriate reference to the joints whose movement is limited, with a statement as to how near, in centimeters, the tip of the thumb can approximate the fingers, or how near the tips of the fingers can approximate the median transverse fold of the palm.

Current note (a) under DC 5219 indicates that extremely unfavorable ankylosis, *i.e.,* all joints in extension or in extreme flexion, will be evaluated as amputation; note (1) preceding DC 5216 establishes that ankylosis of both the metacarpophalangeal and proximal interphalangeal joints, with either in extension or extreme flexion, will be evaluated as amputation. We propose to evaluate an ankylosed digit as amputation when both joints are ankylosed, and either is in extension or ''full'' flexion. (Flexion of the fingers is not possible beyond ''full,'' or complete, flexion.)

In DC's 5217 through 5223, we propose to simplify the criteria where feasible by indicating, for example, ''thumb and any three fingers,'' rather than separately listing ''thumb, index, middle, and ring,'' ''thumb, index, middle, and little,'' etc.

The current schedule refers to motion of the fingertips to within certain distances of the ''median transverse fold of the palm.'' Since that fold is mentioned neither in standard anatomy texts nor in ''Dorland's Illustrated Medical Dictionary,'' we propose to change that term to ''proximal transverse crease of the palm,'' an anatomic landmark where the fingertips normally meet the palm when they are in full flexion. The current schedule uses different language in different places to describe limited motion between the fingers and the palm or between the thumb and the fingers, *e.g.,* using ''whether motion is possible to within 2 inches (5.1 cms.) of the median transverse fold of the palm'' in one place and ''limited motion preventing flexion of tips to within 2 inches (5.1 cms.) of median transverse fold of the palm'' in another place. For the sake of clarity, we propose to measure these distances in terms of the gap, expressed in inches or centimeters, between the fingertips and the proximal transverse crease of the palm, with the finger flexed to the extent possible, or between the pad of the thumb and the fingers, with the thumb attempting to oppose the fingers.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Executive Order 12866

This document has been reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance numbers are 64.104 and 64.109.

List of Subjects in 38 CFR Part 4

Disability benefits, Individuals with disabilities, Pensions, Veterans.

Approved: October 2, 2001.

Anthony J. Principi,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 4, subpart B, is proposed to be amended as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

Subpart B—Disability Ratings

2. Section 4.71a is amended by removing the tables ''MULTIPLE FINGERS: UNFAVORABLE ANKYLOSIS''; MULTIPLE FINGERS: FAVORABLE ANKYLOSIS''; and ANKYLOSIS OF INDIVIDUAL FINGERS'' and adding, in their place, the following table to read as follows:

§ 4.71a Schedule of ratings—musculoskeletal system.

* * * * *

EVALUATION OF ANKYLOSIS OR LIMITATION OF MOTION OF SINGLE OR MULTIPLE DIGITS OF THE HAND

	Rating	
	Major	Minor
(1) For the index, long, ring, and little fingers (digits II, III, IV, and V), zero degrees of flexion represents the fingers fully extended, making a straight line with the rest of the hand. The position of function of the hand is with the wrist dorsiflexed 20 to 30 degrees, the metacarpophalangeal and proximal interphalangeal joints flexed to 30 degrees, and the thumb (digit I) abducted and rotated so that the thumb pad faces the finger pads. Only joints in these positions are considered to be in favorable position. For digits II through V, the metacarpophalangeal joint has a range of zero to 90 degrees of flexion, the proximal interphalangeal joint has a range of zero to 100 degrees of flexion, and the distal (terminal) interphalangeal joint has a range of zero to 70 or 80 degrees of flexion.		
(2) When two or more digits of the same hand are affected by any combination of amputation, ankylosis, or limitation of motion that is not otherwise specified in the rating schedule, the evaluation level assigned will be that which best represents the overall disability (*i.e.*, amputation, unfavorable or favorable ankylosis, or limitation of motion), assigning the higher level of evaluation when the level of disability is equally balanced between one level and the next higher level.		
(3) Evaluation of ankylosis of the index, long, ring, and little fingers:		

EVALUATION OF ANKYLOSIS OR LIMITATION OF MOTION OF SINGLE OR MULTIPLE DIGITS OF THE HAND—Continued

	Rating	
	Major	Minor
(i) If both the metacarpophalangeal and proximal interphalangeal joints of a digit are ankylosed, and either is in extension or full flexion, or there is rotation or angulation of a bone, evaluate as amputation without metacarpal resection, at proximal interphalangeal joint or proximal thereto.		
(ii) If both the metacarpophalangeal and proximal interphalangeal joints of a digit are ankylosed, evaluate as unfavorable ankylosis, even if each joint is individually fixed in a favorable position.		
(iii) If only the metacarpophalangeal or proximal interphalangeal joint is ankylosed, and there is a gap of more than two inches (5.1 cm.) between the fingertip(s) and the proximal transverse crease of the palm, with the finger(s) flexed to the extent possible, evaluate as unfavorable ankylosis.		
(iv) If only the metacarpophalangeal or proximal interphalangeal joint is ankylosed, and there is a gap of two inches (5.1 cm.) or less between the fingertip(s) and the proximal transverse crease of the palm, with the finger(s) flexed to the extent possible, evaluate as favorable ankylosis.		
(4) Evaluation of ankylosis of the thumb:		

EVALUATION OF ANKYLOSIS OR LIMITATION OF MOTION OF SINGLE OR MULTIPLE DIGITS OF THE HAND—Continued

	Rating	
	Major	Minor
(i) If both the carpometacarpal and interphalangeal joints are ankylosed, and either is in extension or full flexion, or there is rotation or angulation of a bone, evaluate as amputation at metacarpophalangeal joint or through proximal phalanx.		
(ii) If both the carpometacarpal and interphalangeal joints are ankylosed, evaluate as unfavorable ankylosis, even if each joint is individually fixed in a favorable position.		
(iii) If only the carpometacarpal or interphalangeal joint is ankylosed, and there is a gap of more than two inches (5.1 cm.) between the thumb pad and the fingers, with the thumb attempting to oppose the fingers, evaluate as unfavorable ankylosis.		
(iv) If only the carpometacarpal or interphalangeal joint is ankylosed, and there is a gap of two inches (5.1 cm.) or less between the thumb pad and the fingers, with the thumb attempting to oppose the fingers, evaluate as favorable ankylosis.		
(5) If there is limitation of motion of two or more digits, evaluate each digit separately and combine the evaluations.		
I. Multiple Digits: Unfavorable Ankylosis		
5216 Five digits of one hand, unfavorable ankylosis of	60	50

EVALUATION OF ANKYLOSIS OR LIMITATION OF MOTION OF SINGLE OR MULTIPLE DIGITS OF THE HAND—Continued

	Rating	
	Major	Minor
Note: Also consider whether evaluation as amputation is warranted		
5217 Four digits of one hand, unfavorable ankylosis of:		
Thumb and any three fingers	60	50
Index, long, ring, and little fingers	50	40
Note: Also consider whether evaluation as amputation is warranted.		
5218 Three digits of one hand, unfavorable ankylosis of:		
Thumb and any two fingers	50	40
Index, long, and ring; index, long, and little; or index, ring, and little fingers	40	30
Long, ring, and little fingers	30	20
Note: Also consider whether evaluation as amputation is warranted.		
5219 Two digits of one hand, unfavorable ankylosis of:		
Thumb and any finger	40	30
Index and long; index and ring; or index and little fingers	30	20
Long and ring; long and little; or ring and little fingers	20	20
Note: Also consider whether evaluation as amputation is warranted.		
II. Multiple Digits: Favorable Ankylosis		
5220 Five digits of one hand, favorable ankylosis of	50	40
5221 Four digits of one hand, favorable ankylosis of:		
Thumb and any three fingers	50	40
Index, long, ring, and little fingers	40	30
5222 Three digits of one hand, favorable ankylosis of:		
Thumb and any two fingers	40	30
Index, long, and ring; index, long, and little; or index, ring, and little fingers	30	20
Long, ring and little fingers	20	20
5223 Two digits of one hand, favorable ankylosis of:		
Thumb and any finger	30	20
Index and long; index and ring; or index and little fingers	20	20
Long and ring; long and little; or ring and little fingers	10	10
III. Ankylosis of Individual Digits		
5224 Thumb, ankylosis of:		
Unfavorable	20	20
Favorable	10	10
Note: Also consider whether evaluation as amputation is warranted.		
5225 Index finger, ankylosis of:		
Unfavorable or favorable	10	10
Note: Also consider whether evaluation as amputation is warranted.		
5226 Long finger, ankylosis of:		
Unfavorable or favorable	10	10
Note: Also consider whether evaluation as amputation is warranted.		
5227 Ring or little finger, ankylosis of:		
Unfavorable or favorable	0	0
Note: Also consider whether evaluation as amputation is warranted.		
IV. Limitation of motion of individual digits		
5228 Thumb, limitation of motion:		
With a gap of more than two inches (5.1 cm.) between the thumb pad and the fingers, with the thumb attempting to oppose the fingers	20	20
With a gap of one to two inches (2.5 to 5.1 cm.) between the thumb pad and the fingers, with the thumb attempting to oppose the fingers	10	10
With a gap of less than one inch (2.5 cm.) between the thumb pad and the fingers, with the thumb attempting to oppose the fingers	0	0
5229 Index or long finger, limitation of motion:		
With a gap of one inch (2.5 cm.) or more between the fingertip and the proximal transverse crease of the palm, with the finger flexed to the extent possible, or; with extension limited by more than 30 degrees	10	10
With a gap of less than one inch (2.5 cm.) between the fingertip and the proximal transverse crease of the palm, with the finger flexed to the extent possible, and; extension is limited by no more than 30 degrees	0	0
5230 Ring or little finger, limitation of motion:		
Any limitation of motion	0	0

* * * * *

[FR Doc. 01–27426 Filed 11–1–01; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 89, 90, 91, 94, 1048, 1051, 1065, and 1068

[AMS–FRL–7096–9]

RIN 2060–AI11

Control of Emissions from Nonroad Large Spark Ignition Engines and Recreational Engines (Marine and Land-based); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; correction.

SUMMARY: The Environmental Protection Agency published in the **Federal Register** of October 5, 2001 a document

concerning new emission standards for large spark-ignition engines, recreational vehicles using spark-ignition engines, and recreational marine diesel engines. This document corrects two items in the preamble to that document.

DATES: *Comments:* Send written comments on this proposed rule by December 19, 2001.

Hearings: Hearings were held in the Washington, DC, area on October 24 and in Denver, CO, on October 30.

ADDRESSES: You may send written comments in paper form to Margaret Borushko, U.S. EPA, National Vehicle and Fuels Emission Laboratory, 2000 Traverwood, Ann Arbor, MI 48105. We must receive them by the date indicated under **DATES** above. You may also submit comments via e-mail to ''*nranprm@epa.gov.*'' In you correspondence, refer to Docket A–2000–01.

FOR FURTHER INFORMATION CONTACT: Margaret Borushko, U.S. EPA, National Vehicle and Fuels Emission Laboratory, 2000 Traverwood, Ann Arbor, MI 48105; Telephone (734) 214–4334; FAX: (734) 214–4816; e-mail: *borushko.margaret@epa.gov.* EPA hearings and comments hotline: 734–214–4370.

SUPPLEMENTARY INFORMATION: EPA published a document in the **Federal Register** of October 5, 2001 (66 FR 51098). That document proposed new emission standards for large spark-ignition engines, recreational vehicles using spark-ignition engines, and recreational marine diesel engines. On page 51172, in the first column, the information about the public hearing in Denver, Colorado should state that the hearing will occur on October 30, 2001. This is consistent with the information published in the original document under **DATES**.

Also, on page 51131, column 3, in the second paragraph under b., the CO emission standard that applies to field-testing procedures should be 5.0 g/kW-hr (3.8 g/hp-hr). This is consistent with the proposed regulations at § 1048.101(c).

Readers should also note a new telephone number that will serve as a hotline for updated information related to public hearings and comment period. People should call 734–214–4370 before traveling to ensure that there is no change in plans for the hearings.

Dated: October 24, 2001.

Robert Brenner,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 01–27466 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[CC Docket No. 94–102; FCC 01–293]

Wireless E911 Service, Petition of City of Richardson, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document responds to a petition for clarification and/or declaratory ruling by amending the Commission's rules to clarify what constitutes a valid Public Safety Answering Point (PSAP) request for Enhanced 911 (E911) service so as to trigger a wireless carrier's obligation to implement E911 within the six-month period following the date of the request. If challenged by the wireless carrier, the request will be deemed valid if the PSAP making the request demonstrates E911-readiness as provided in the amended rule. This action is taken to ensure the continuing clarity of E911 obligations and thus avoid the possibility of confusion leading to delays in critically important emergency services. The decision is adopted to respond to the petition for clarification and/or declaratory ruling filed by the City of Richardson, Texas.

DATES: This document contains revised information collection requirements that have not been approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of this amendment. Public comment on the information collections are due January 2, 2002.

ADDRESSES: A copy of any comments on the information collection contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *jboley@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Jane Phillips, 202–418–1310. For further information concerning the information collection contained in this document, contact Judy Boley, Federal Communications Commission, 202–418–0214, or via the Internet at *jboley@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order in CC Docket No. 94–102, FCC No. 01–293, adopted October 2, 2001, and released October 17, 2001. The complete text of this Order is available for inspection and copying during normal business hours in the FCC Reference Information Center, Courtyard Level, 445 12th Street, SW., Washington, DC, and also may be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Copies of the full text of this decision may also be found at the Commission's Internet site at *www.fcc.gov.*

Synopsis of the Order

1. The Commission responds to a petition for clarification and/or declaratory ruling filed by the city of Richardson, Texas. The Commission amends its rules to clarify what constitutes a valid Public Safety Answering Point (PSAP) request so as to trigger a wireless carrier's obligation to provide enhanced 911 (E911) service to that PSAP. Specifically, the Order finds that a wireless carrier must implement E911 within the six-month period following the date of the PSAP's request and that, if challenged by the wireless carrier, the request will be deemed valid if the PSAP making the request demonstrates that: (1) A mechanism is in place by which the PSAP will recover its costs of the facilities and equipment necessary to receive and utilize the E911 data elements; (2) the PSAP has ordered the equipment necessary to receive and utilize the E911 data and the equipment will be installed and capable of receiving and utilizing that data no later than six months following its request; and (3) the PSAP has made a timely request to the appropriate local exchange carrier (LEC) for the necessary trunking and other facilities to enable the E911 data to be transmitted to the PSAP. In the alternative, a PSAP may demonstrate that a funding mechanism is in place, that it is E911-capable using a Non-call Associated Signaling (NCAS) technology, and that it has made a timely request to the appropriate LEC to upgrade the Automatic Location Identification (ALI) database.

2. The Commission established periods for public comment and replies to those comments upon receiving the Richardson petition. (*See* the document at 66 FR 19781, April 17, 2001, and a second document at 66 FR 36989, July 16, 2001.) Both representatives of PSAPs and of wireless carriers have participated in the record established during the comment periods, and these

comments are discussed in paragraphs 11–30 of the full text of the Order. The Commission believes that the criteria adopted in the Order represent a fair balance between the interests of both PSAPs and carriers.

3. The first alternative that PSAPs may choose to demonstrate their E911-capability, if challenged by a carrier, is a three tiered approach discussed in paragraphs 14 through 16 of the full Order. In this approach, the PSAP must demonstrate that a funding mechanism exists for recovering its costs of facilities and equipment necessary to receive and utilize the E911 data elements to be supplied by the carrier. Citation to or a copy of the relevant finding legislation is sufficient to satisfy this demonstration. As part of this approach, a qualified PSAP must also demonstrate that it has ordered the equipment necessary to fulfill its E911 obligations. This substantiation could take the form of a listing of the necessary facilities and equipment and copies of the relevant vendor purchase orders as well as commitments that the vendor perform under the agreement within the six-month period following the date of the PSAP's request for service. The last element of the three-tier approach requires that a PSAP demonstrate that it has made a timely request to the proper LEC for facilities and equipment necessary to receive and utilize the E911 data elements requested. Evidence in this regard could consist of the letter of request, as well an any other pertinent correspondence between the PSAP and the LEC.

4. Alternatively, a PSAP, could satisfy the E911-capability requirement by demonstrating that funding mechanism is in place, that it has made a timely request to the LEC for upgrades to the ALI database, and that it is E911-capable using an NCAS technology, as detailed in paragraph 17 of the full text of the Order.

5. The Commission believes that the criteria adopted in the Order will be sufficient to eliminate reasonable doubts about a PSAP's capability of receiving and utilizing the E911 data elements by the end of the six-month period established for carrier compliance. The Commission declines to adopt more restrictive criteria, such as those proposed by commenters in response to the two documents, because it finds that more restrictive criteria would be unnecessary, would countermand the Commission's determination to leave the specifics of Phase I and Phase II compliance to the parties, and could interfere with the negotiation process, ultimately delaying Phase I and Phase II implementation.

Procedural Matters

Paperwork Reduction Act of 1995 Analysis

6. This contains a revised information collection. The Commission has requested emergency approval from the Office of Management and Budget for the revised information collection. As part of the Commission's continuing effort to reduce paperwork burdens, the Commission invites the general public and the Office of Management and Budget to take this opportunity to comment on the information collections contained in this Order, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due January 2, 2002. Comments should address: (a) Whether the revised 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; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) 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: 3060–0813.

Title: Revision of the Commission's Rules To Ensure Compatibility with Enhanced 911 Emergency Calling Systems.

Form No.: N.A.

Type of Review: Revision of an existing information collection.

Respondents: Business or other for profit; government entities.

Number of Respondents: 42,324.

Estimated Time Per Response: 1 hour.

Total Annual Burden: 198,200 hours.

Cost to Respondents: 0.

Needs and Uses: The demonstration of E911 capability will be required only when a requesting PSAP's E911 capability is challenged by the wireless carrier and will be used by the carrier to verify that the requesting PSAP is in reality capable of receiving and using E911 data and that the carrier must therefore provide E911 service.

Final Regulatory Flexibility Act Analysis

7. This is a summary of the Commission's Final Regulatory Flexibility Analysis. The full text of the Analysis may be found in Appendix C of the Order.

8. As required by the Regulatory Flexibility Act (RFA), an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities was incorporated in the second document in CC Docket No. 94–102 (the second document). The Commission sought written public comment on the proposals in the second document, including comments on the IRFA. The comments received are discussed in this Final Regulatory Flexibility Analysis (FRFA). This present FRFA conforms to the RFA.

A. Need for, and Objectives of, the Order

9. The rule amendment mandated by this Order is meant to clarify the process by which a Public Safety Answering Point (PSAP) whose request for Enhanced 911 (E911) service is challenged by a wireless carrier may demonstrate E911 capability. This information will ensure that PSAPs and carriers are working with the same knowledge, thus avoiding delays in implementing E911 service or unnecessary or premature investments due to confusion over the PSAP's preparedness. Specifically, for purposes of resolving a challenge to a PSAP request for E911 service, a wireless carrier must implement E911 within the six-month period following the date of the PSAP's request if the PSAP making the request demonstrates that: (a) A mechanism is in place by which the PSAP will recover its costs of the facilities and equipment necessary to receive and utilize the E911 data elements; (b) the PSAP has ordered the equipment necessary to receive and utilize the E911 data and the equipment will be installed and capable of receiving and utilizing that data no later than six months following its request; and (c) the PSAP has made a timely request to the appropriate local exchange carrier (LEC) for the necessary trunking and other facilities to enable the E911 data to be transmitted to the PSAP. In the alternative, a challenged PSAP may demonstrate that a funding mechanism is in place, that it is Phase I-capable using a Non-call Associated Signaling (NCAS) technology, and that it has made a timely request to the appropriate LEC for the upgrade to the ALI database necessary to enable the PSAP to receive the Phase II data.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

10. The Commission received two direct responses to the IRFA. First, the Rural Cellular Association (RCA) argues that the IRFA in this proceeding is deficient, in that it ignores the possible impact on small and rural wireless carriers, and instead focuses only on the possible impact of the proposed rules on PSAPs. RCA also contends that the

IRFA failed to assess adequately the impact of imposing readiness criteria, as opposed to an actual readiness requirement. RCA further denies that an amendment to the rule, clarifying when and how a PSAP will be considered E911-capable, would benefit small/rural carriers by making confirmation of a PSAP's readiness less burdensome. RCA asserts that the burden on small carriers can be minimized by maintaining the application of the Commission's existing rule.

11. In its response to the IRFA, the National Telephone Cooperative Association (NTCA) maintains that small carriers may waste limited resources providing a service that a PSAP may not be ready to utilize, unless the Commission requires that a PSAP be actually capable of receiving and utilizing the data elements associated with the service at the time it requests the service. NTCA further argues that the burden placed on a small PSAP by the requirement that PSAPs be able to utilize the information prior to requiring such information from a carrier would be ''nonexistent.''

12. The Commission responds to this criticism in detail in paragraphs 28 and 29 of the Order. Section C of the IRFA describing the number of small entities affected by the proposed rules, emphasized that the IRFA was drafted at early point in the process when the Commission acknowledged it was premature to quantify the specific impact of the suggested action on any of the affected entities, and specifically invited comment on this issue. Section E of the IRFA noted that leaving the rule as it now stands was an option and was considered with the other alternatives mentioned in the IRFA before the second document was issued. The IRFA concentrated on analyzing the effect of a rule amendment on small PSAPs rather than small carriers because the burden of preparing any type of demonstration would fall on PSAPs and the burden on small carriers would not change. The key issue under discussion in the IRFA was how to make it easier for carriers of all sizes to determine when to provide a PSAP with E911 service without running the financial risk of offering service to a PSAP that is unprepared to use the service. Regardless of whether the Commission elected to maintain the existing rule or change it in some way to require a demonstration of E911 capability, the burden of proof of capability would fall on PSAPs, and the effect on carriers would either remain the same or, the Commission believed at the time of the IRFA and still believes, might even reduce the burden on carriers by possibly reducing the time carriers invest in verifying that a PSAP is E911 qualified. No convincing evidence was presented to the Commission to contradict this viewpoint. However, the Commission has determined that a showing would be appropriate only if a carrier decides to challenge a PSAP's request for service.

13. The Commission also received comments not in direct response to the IRFA, but regarding matters of interest to small entities. In its comments, the Rural Companies Group contends that the second document to assess adequately the impact of imposing readiness criteria, as opposed to an actual readiness requirement, on small and rural carriers. Further, the Rural Companies Group argues that allowing a carrier to wait until a PSAP has full technological capability may enable smaller carriers to take advantage of less-costly technological innovations or of cheaper prices, as existing technologies become less costly.

14. In its reply comments, Dobson Communications Corporation argues that the current rule provides the appropriate certainty for carriers and does not hinder the deployment of Phase II E911 services. Dobson therefore urges the Commission to not amend or clarify the existing rule.

15. Because small carriers lack large customer bases to absorb their E911 implementation costs, a primary concern exists that small and mid-sized carriers are more vulnerable to delays in implementation if a PSAP shows an inability to receive and utilize the E911 data supplied by these smaller carriers. Likewise, there is a concern that smaller carriers may be forced to devote time and resources to some PSAPs that prove to be incapable of receiving E911 service, to the detriment of those PSAPs that have current capability.

16. Taking these concerns into account, the Commission finds that the amendments to the rule, as described in the Order, will in fact reduce the vulnerability of the smaller carriers, as they will be working along with the PSAPs to ensure implementation of E911 service on a timely basis, and will better be able to plan their progression and allocation of resources during the implementation process. The Commission also finds that the rule amendments will make confirmation of a PSAP's readiness for E911 service less burdensome for all carriers, as the onus is placed on the PSAPs to demonstrate readiness as described in the Order, and because the showing will only be required to settle a challenge to the PSAP's preparedness.

17. The Commission finds unpersuasive the assertion that smaller carriers may be able to benefit from less-costly technological innovations by waiting to provide service. While it is possible that smaller carriers will pay less the longer they wait to provide service, the Commission finds that without the amendments to the existing rule, the smaller PSAPs will be unduly burdened, and will be more vulnerable, if required to be fully capable of receiving E911 service, without their providers' having to even begin the process of supplying the service.

18. Considering the potential burdens placed on all small entities, the Commission finds that the institution of objective criteria by rule amendment will benefit all PSAPs and carriers, including small entities, by more clearly defining E911 readiness, thus reducing the potential for misunderstanding between parties, and by reducing instances of delay in E911 implementation. In turn, this will reduce the likelihood that any PSAP or carrier, including all small entities, will have to expend its limited capital resources prematurely and/or improvidently.

19. Finally, as discussed in paragraph 29 of the Order, the Commission is sympathetic to the concerns of all small entities, carriers and PSAPs. In reaching its decision in the Order, the Commission attempted to balance these interests with critical interests at stake in this proceeding. The Commission believes that the approach taken in the Order will, ultimately, provide carriers of all sizes, including small carriers, with the tools they need to determine whether a PSAP will, in reality, be E911 capable, while not placing an unnecessarily onerous burden on PSAPs, 96 percent of whom qualify as small entities. Again, the showing will only be necessary when a PSAP's request for E911 service is challenged on the basis of preparedness.

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

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

developed one or more definitions that are appropriate for its activities. Nationwide, there are 4.44 million small business firms, according to SBA reporting data.

21. Under the Small Business Act, a ''small business concern'' is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). A small organization is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of 1992, there were approximately 275,801 small organizations.

22. The definition of ''small governmental jurisdiction'' is one with populations of fewer than 50,000. There are 85,006 governmental jurisdictions in the nation. This number includes such entities as states, counties, cities, utility districts and school districts. There are no figures available on what portion of this number has populations of fewer than 50,000. However, this number includes 38,978 counties, cities and towns, and of those, 37,556, or ninety-six percent, have populations of fewer than 50,000. The Census Bureau estimates that this ratio is approximately accurate for all government entities. Thus, of the 85,006 governmental entities, the Commission estimates that ninety-six percent, or about 81,600, are small entities that may be affected by our rules.

23. Neither the Commission nor the SBA has developed definitions for small providers of the specific industries affected. Therefore, throughout our analysis, the Commission uses the closest applicable definition under the SBA rules, the North American Industry Classification System (NAICS) standards for ''Cellular and Other Wireless Telecommunications'' and ''Wired Telecommunications Carriers.'' According to this standard, a small entity is one with no more than 1,500 employees. To determine which of the affected entities in the affected services fit into the SBA definition of small business, the Commission has consistently referred to Table 5.3 in Trends in Telephone Service (Trends), a report published annually by the Commission's Common Carrier Bureau.

24. The Commission has included small incumbent local exchange carriers in this RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (e.g., a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent local exchange carriers are not dominant in their field of operation because any such dominance is not ''national'' in scope. The Commission has therefore included small incumbent carriers in this RFA analysis, although the Commission emphasizes that this RFA action has no effect on the Commission's analyses and determinations in other, non-RFA contexts.

25. Local Exchange Carriers. According to the most recent Trends data, 1,335 incumbent carriers reported that they were engaged in the provision of local exchange services. The Commission does not have data specifying the number of these carriers that are either dominant in their field of operations, or are not independently owned. However, Trends indicates that 1,037 local exchange carriers report that, in combination with their affiliates, they have 1,500 or fewer employees, and would thus be considered small businesses as defined by NAICS.

26 Also included in the number of local exchange carriers is the rural radio telephone service. A significant subset of the Rural Radiotelephone Service is the Basic Exchange Telephone Radio Systems (BETRS). There are approximately 1,000 licensees in the Rural Radiotelephone Service, and the Commission estimates that almost all of them qualify as small entities under the NAICS definition.

27. Competitive Access Providers and Competitive Local Exchange Carriers (CAPs and CLECs). Trends indicates that 349 CAPs and CLECs, 87 local resellers, and 60 other local exchange carriers reported that they were engaged in the provision of competitive local exchange services. The Commission does not have data specifying the number of these carriers that are not independently owned and operated. However, Trends states that 297 CAPs and CLECs, 86 local resellers, and 56 other local exchange carriers report that, in combination with their affiliates, they have 1,500 or fewer employees, for a total of 439 such entities qualified as small entities.

28. Fixed Local Service Providers and Payphone Providers. Trends reports that there are 1,831 fixed local service providers and 758 payphone providers. Using the NAICS standard for small entity of fewer than 1,500 employees, Trends estimates that 1,476 fixed local service providers, in combination with affiliates, have 1,500 or fewer employees and thus qualify as small entities. In addition, 755 payphone providers report that, in combination with their affiliates, they employ 1,500 or fewer individuals.

29. Wireless Telephone Including Cellular, Personal Communications Service (PCS) and SMR Telephony Carriers. There are 806 entities in this category as estimated in Trends, and 323 such licensees in combination with their affiliates have 1,500 or fewer employees, and thus qualify, using the NAICS guide, as small businesses.

30. Other Mobile Service Providers. Trends estimates that there are 44 providers of other mobile services, and again using the NAICS standard, 43 providers of other mobile services utilize with their affiliates 1,500 or fewer employees, and thus may be considered small entities.

31. Toll Service Providers. Trends calculates that there are 738 toll service providers, including 204 interexchange carriers, 21 operator service providers, 21 pre-paid calling card providers, 21 satellite service carriers, 454 toll resellers, and 17 carriers providing other toll services. Trends further estimates that 656 toll service providers with their affiliates have 1,500 or fewer employees and thus qualify as small entities as defined by NAICS. This figure includes 163 interexchange carriers, 20 operator service providers, 20 pre-paid calling card providers, 16 satellite service carriers, 423 toll resellers, and 15 carriers providing other toll services.

32. Offshore Radiotelephone Service. This service operates on several TV broadcast channels that are not otherwise used for TV broadcasting in the coastal area of the states bordering the Gulf of Mexico. At present, there are approximately 55 licensees in this service. The Commission is unable at this time to estimate the number of licensees that would qualify as small entities under the SBA definition for radiotelephone communications. The Commission assumes, for purposes of this FRFA, that all of the 55 licensees are small entities, as that term is defined by NAICS.

33. Public Safety Answering Points. Neither the Commission nor the SBA has developed a definition of small entities applicable to PSAPs. In order to give a numerical quantification of the number of PSAPs that are small entities affected by the rule modifications, it appears there are approximately 10,000 PSAPs nationwide. For purposes of this FRFA, The Commission assumes that all of the PSAPs are small entities, and may be affected by the rule amendments.

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

34. As indicated in paragraph 1 of the Order, if a PSAP's request for E911 service is challenged by a wireless carrier, the PSAP must make a demonstration to the carrier, as detailed in Section A, in this FRFA. In the alternative, the PSAP may demonstrate that a funding mechanism is in place, that it is Phase I-capable, using a Non-Call Associated Signaling (NCAS) technology, and that it has made a timely request to the appropriate LEC for the upgrade to the ALI database necessary to enable the PSAP to receive the Phase II data. Once the showing is made, the carrier must implement E911 within six months of the date of the PSAP's request.

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

35. The Commission is severely limited in this proceeding as to minimizing the burden on small entities. The proceeding is intended to provide all Americans with the most reliable, responsive emergency services that are technologically possible. The critical nature of this goal demands that all entities involved, regardless of size, bear the same responsibility for complying with requirements adopted to expedite reaching this goal. A delay in response caused by a small entity could result in the same fatal consequences as a delay caused by a large entity.

36. Several commenters have asserted the possibility that small carriers may expend monies prematurely and/or improvidently if the PSAPs request E911 service, but are not fully capable of receiving and utilizing it within six months. The alternative adopted herein is intended to minimize the possibility of this situation's developing by providing criteria that PSAPS and carriers may use to determine if a PSAP, whose E911 capability is challenged, is in reality prepared to use the service within six months of the request. Commenters who maintain that small carriers are at risk, ignore the fact that smaller carriers relying on smaller customer bases will likely be dealing with PSAPs that are themselves small governmental entities facing similar financial constraints. It would therefore be inequitable and short-sighted to require a small governmental entity to fund fully its share of the E911 costs, while allowing a small business entity to wait several months before funding its own share.

37. The Commission considered several alternatives before reaching its final decision in the Order. First, the Commission could have left the existing rule as it stands with regard to small entities. The Commission believes, however, that this would inevitably lead to more delays due to confusion as to when a PSAP has made a valid E911 service request. The Commission could also amend the rule to remove demonstration burdens and criteria on PSAPs. This alternative would seem to have a greater chance of negatively impacting small carriers though, particularly in terms of risking financial losses when a PSAP requesting E911 service claims to be fully E911 capable but isn't. In this case, carriers could provide the service prematurely and diminish the value of their financial investment until the PSAP is ''in actuality'' E911 capable. Finally, the Commission could amend the rule to place a more burdensome demonstration requirement on PSAPs, a course favored by several carrier commenters. As discussed in paragraphs 18 through 20 of the Order, the Commission finds that this alternative would not be beneficial for any of the involved parties. Not only would this place an unnecessarily oppressive burden on PSAPs, most of whom are small entities, but small carriers would need to spend more time and resources reviewing and evaluating the submission.

38. Commenters encouraged the Commission to require small governmental entities to fund fully their share of the E911 costs and establish a fully functional system before requiring small carriers to provide the requisite service. This alternative, while it relieves, for a while, the burden on small carriers, places the burden on small governmental entities. In addition, this alternative places all of the risk and uncertainty on the PSAPs, most of whom are small entities, and could delay the implementation of this vital public safety service for several months. The alternative adopted seeks to balance the burden between small carriers and small governmental entities by providing that the showing is only required when a PSAP's claim of E911 capability is challenged by a carrier. Therefore, no demonstration is required of the PSAP unless a carrier elects to set the newly adopted process in motion by challenging a PSAP's E911 capability. The PSAP would then need to make a demonstration that it is E911 capable. To satisfy this requirement, a PSAP may use the three-tier option by demonstrating that a cost recovery mechanism is in place, that the equipment needed to receive and utilize the E911 data has been ordered and will be installed and capable of receiving and utilizing E911 data no later than six months after its request for E911 service and that the PSAP has made a timely request to the appropriate local exchange carrier for the encessary trunking and other facilities to enable the E911 data to be transmitted to the PSAP. This three-tier option is more fully described in paragraphs 14–16 of the Order. Alternatively, as described in paragraph 17 of the Order, the PSAP may demonstrate that a funding mechanism is in place, that it is Phase I-capable, and that it has made a timely request to the appropriate LEC for the upgrade to the ALI database necessary to enable the PSAP to receive the Phase II data.

39. As noted in paragraph 11 of the Order, as well as in several of the comments, the process of implementing E911 services must be a joint and concerted effort between the carriers and the PSAPs. Neither side can perform the necessary functions required to implement timely and effective E911 service without working with the other. While the Commission has taken into account the concerns of small carriers, it cannot do so to the detriment of small PSAPs. This alternative balances the concerns of all parties, including those that may be small entities, and encourages all parties to work together to minimize delays and financial risk. In light of the critical nature of our E911 rules and the need for ubiquitous, reliable emergency services, all entities involved, regardless of size, must comply with those rules.

40. *Report to Congress:* The Commission will send a copy of this Order, including this FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996. In addition, the Commission will send a copy of this Order, including this FRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

Ordering Clauses

41. The Petition filed by the City of Richardson is granted as provided in the Order.

42. This document contains revised information collection requirements that have not been approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of this rule amendment. Public comment on the information collections are due January 2, 2002.

43. The Commission's Consumer Information Bureau, Reference Information Center, shall send a copy of this Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 20

Communications common carrier, Communications equipment, Radio.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

Rule Changes

For the reasons discussed in the preamble, the Federal Communications amends 47 CFR part 20 as follows:

PART 20—COMMERCIAL MOBILE RADIO SERVICES

1. The authority citation for part 20 continues to read as follows:

Authority: 47 U.S.C. 154, 160, 251–254, 303, and 332 unless otherwise noted.

2. Section 20.18 is amended by revising paragraph (j) to read as follows:

§ 20.18 911 Service.

* * * * *

(j) *Conditions for enhanced 911 services.* The requirements set forth in paragraphs (d) through (h) of this section shall be applicable only if the administrator of the designated Public Safety Answering Point has requested the services required under those paragraphs and is capable of receiving and utilizing the data elements associated with the service, and a mechanism for recovering the Public Safety Answering Point's costs of the enhanced 911 service is in place. A Public Safety Answering Point will be deemed capable of receiving and utilizing the data elements associated with the service requested if it can demonstrate that it has ordered the necessary equipment and has commitments from suppliers to have it installed and operational within the six-month period specified in paragraphs (f) and (g) of this section, and can demonstrate that it has made a timely request to the appropriate LEC for the necessary trunking and other facilities. In the alternative, a Public Safety Answering Point will be deemed capable of receiving and utilizing the data elements associated with Phase II service if it is Phase I-capable using an NCAS methodology, and if it can demonstrate that it has made a timely request to the appropriate LEC for the ALI database upgrade necessary to receive the Phase II information.

* * * * *

[FR Doc. 01–27605 Filed 11–1–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2001–10916]

RIN 2127–AI55

Federal Motor Vehicle Safety Standards; Child Restraint Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: NHTSA has been mandated by Congress to consider whether to prescribe clearer and simpler labels and instructions for child restraints. This notice reviews research NHTSA has conducted on child restraint labels and proposes changes to those labels and to the written instructions that accompany child restraints. NHTSA is proposing changes to the format, location, and content of some of the existing requirements. NHTSA is also proposing a new labeling requirement for harness slots.

DATES: You should submit your comments early enough to ensure that Docket Management receives them not later than January 2, 2002.

ADDRESSES: You should mention the docket number of this document in your comments and submit your comments in writing to: Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC, 20590.

You may call Docket Management at 202–366–9324. You may visit the Docket from 10 a.m. to 5 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For non-legal issues, you may call Mary Versailles of the NHTSA Office of Planning and Consumer Programs, at 202–366–2057.

For legal issues, you may call Deirdre Fujita of the NHTSA Office of Chief Counsel at 202–366–2992.

You may send mail to both of these officials at National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC, 20590.

SUPPLEMENTARY INFORMATION:

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X. Comments

I. Overview

NHTSA has been mandated by Congress to consider whether to prescribe clearer and simpler labels and instructions for child restraints. This notice reviews research NHTSA has conducted on child restraint labels and proposes changes to those labels and to the written instructions that accompany child restraints. NHTSA is proposing changes to the format, location, and content of some of the existing requirements. Specifically, NHTSA is proposing (1) a requirement that some information be molded into or heat embossed to the shell to improve durability, (2) changes to existing location requirements for some labels, (3) a uniform font specified for all labels on all child restraints, (4) a requirement that most labels be white with black text, and (5) color-coding of installation information to distinguish forward-facing from rear-facing information.

With regard to content, NHTSA is proposing (1) a reworded warning statement, (2) a requirement that all mandated statements related to use be arranged below that statement in a bulleted form, and (3) rewording of some of these statements to simplify their language. With regard to written instructions, NHTSA is proposing conforming changes with those proposed for labels and a new requirement for information to assist owners in determining the meaning of the term ''snugly'' used on child restraint labels. Last, NHTSA is proposing a new labeling requirement for harness slots.

II. Tread

The National Highway Traffic Safety Administration (NHTSA) has been mandated by Congress to consider whether to prescribe clearer and simpler labels and instructions for child restraints (Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act, November 1, 2000, Pub.L. 106–414, 114 Stat. 1800). Section 14 of the TREAD Act directed NHTSA to initiate a rulemaking for the purpose of improving the safety of child restraints by November 1, 2001, and to complete it by issuing a final rule or taking other action by November 1, 2002.

III. Current Requirements

A. Labels

Federal Motor Vehicle Safety Standard (FMVSS) No. 213 (49 CFR 571.213) requires that all currently manufactured add-on child restraint systems[1] must be labeled with the following information (S5.5.2): the model name or number, the manufacturer's (or distributor's) name, the statement ''manufactured in (*month, year*),'' the place of manufacture (or location of the distributor's principal office), a certification statement, a statement concerning the manufacturer's recommendations for maximum mass and height of children who should use the child restraint, a warning statement concerning the consequences of failing to follow the instructions, statements about proper use of belts or other restraints as appropriate, an air bag warning label if the child restraint can be used rear-facing, an installation diagram, a registration statement for recalls, and a statement about use in motor vehicles and/or aircraft as appropriate.[2] This information must be in English, lettered not smaller than 10 point type, and on contrasting background, except the air bag warning label has very specific requirements for location and size.[3] The warning statement to follow the instructions, the statements about proper use of belts and other restraints, and the air bag warning must also be visible when the restraint is installed in a vehicle.

B. Written Instructions

Each add-on child restraint system must have printed installation instructions (an owner's manual) that includes a step-by-step procedure, including diagrams, for installing the system in motor vehicles, securing the system in the vehicles, positioning a child in the system, and adjusting the system to fit the child (S5.6). The installation instructions must include information on attaching the child restraint to a tether anchorage or a child restraint anchorage system[4] if appropriate. The owner's manual must also include a statement that children are safer in rear seating positions; information about the types of vehicles, seats and seat belts with which the restraint can or cannot be used; a statement about the consequences of not following the warnings; a statement that the restraint should be secured in the vehicle even when not occupied, an air bag warning statement, and a registration statement for recalls. There are also some specific statements about proper use required for various types of restraints. Finally, the child restraint must have a location on the restraint for storing the owner's manual.

IV. History

A. 1978 NPRM and 1979 Final Rule

On May 18, 1978, NHTSA proposed to upgrade and extend the applicability of then Standard No. 213, Child Seating Systems (43 FR 21470). Included was a proposal for new labeling requirements to encourage proper use of child restraints. So that information would serve as a constant reminder, NHTSA proposed information on the correct use of the restraint be visible on the child restraint when it is installed in a vehicle and include a diagram showing the restraint properly installed, height and weight limits, warnings to use and snugly adjust all belts, and to secure the restraint according to instructions. The proposal also required the label to identify the manufacturer; make of the child restraint; month, year and place of manufacture; and a statement that the child restraint complies with all applicable Federal motor vehicle safety standards. Also included was a proposal that an instruction sheet accompany all child restraints.

On December 13, 1979, NHTSA published a final rule establishing a new Standard No. 213, Child Restraint Systems (44 FR 72131). In response to manufacturer concerns about the limited space available for labels visible when the child restraint is installed, only some of the new labeling requirements had to be visible. Depending on the design, the following information had to be visible when the child restraint was installed: a warning to secure the restraint with the vehicle lap belt, a warning to snugly adjust all belts provided with the restraint, a warning to correctly attach the top tether strap, a warning to only use a restraint adjustment position which is intended for use in a motor vehicle, a warning to not use rear-facing infant restraints in any other position, and a statement about the primary consequences of misusing the restraint. The following information did not have to be visible when the child restraint was installed: manufacturer, model, date and place of manufacture, and the certification statement. Because of the complexity of showing a diagram for all types of belt systems, NHTSA only required two diagrams—a diagram showing the restraint correctly installed with a continuous loop lap/shoulder belt and a diagram showing the restraint correctly installed in the center rear seating position with a lap belt. For restraints with top tethers, the diagram had to show the tether correctly attached. The agency adopted the instruction sheet requirement, but, based on comments also added a requirement that the restraint include a place to store it.

B. 1995 Public Meeting

On April 2, 1995, NHTSA held a public meeting in Indianapolis, Indiana regarding the misuse of child restraint systems. In the notice announcing the meeting, NHTSA asked

* * *child seat labeling requirements have often been criticized as overwhelming the consumer with long and complex warnings

[1] Please note that the requirements for built-in child restraint systems are not summarized here. Factory-installed built-in's are required to have some, but not all, of the information required for add-on's, primarily due to the lack of need for warnings about proper installation. While this section of the preamble will only discuss requirements in terms of add-on's, this NPRM is proposing conforming changes to the built-in labeling requirements. These changes can be found in the proposed regulatory text for paragraphs S5.5.4, S5.5.5, S5.5.5(f), S5.5.5(g), S5.5.5(J), and S5.5.5(m). NHTSA is also proposing conforming changes to written instruction requirements in S5.6.1 and S5.6.2(a).

[2] The use statement must be in red lettering and placed after the certification statement.

[3] These requirements can be found in S5.5.2(k)(4).

[4] See 49 CFR 571.225.

and instructions. How can these labeling requirements be improved? Which aspects of the labeling requirements should be retained, and which should be abolished, and why? (60 FR 12192, 12193; March 6, 1995)

A number of commenters to the public docket for this notice criticized existing labels as difficult for consumers to read. One commenter noted that the cloth cover sometimes conceals seat belt routing slots and labels, resulting in misuse when consumers only use the visible routing slots. Commenters suggested that the labels be written for a lower reading comprehension level, and suggested point-by-point or numbered instructions accompanied by pictures.

C. 1996 Air Bag Warning Label

On November 27, 1996, NHTSA issued a final rule requiring rear-facing child restraints to bear a new, enhanced warning label to replace the existing label (61 FR 60206). The labels were developed using focus groups, with the aim to make the labels clearer and easier to understand. Because the goal of this rulemaking is to make child restraint labels clearer and easier to understand also, and because of the tight deadline set for completing this rulemaking action, the air bag warning label on rear-facing child restraints will not be considered in this rulemaking.

D. 2000 Public Meeting

On February 9, 2000, NHTSA conducted a public meeting in Washington, DC, to discuss the safety performance of child restraint systems and options for providing consumers with information on the safety performance of different child restraints. In the notice announcing the meeting, improved labeling was one of the listed topics (65 FR 1224, January 7, 2000).

While most of the comments submitted to the docket, and most of the presentations at the public meeting focused on child restraint ratings, some labeling issues were also raised. The most common issue discussed was permanency of labels, particularly the labels with identifying information and date of manufacturer. Most notably, Transport Canada gave a presentation about their on-going research on possible performance criteria and tests to ensure that labels will be permanent. SafetyBeltSafe noted that 26% of the child restraints checked by the Family Safety in the Car program from 1992 to 1998 had no readable manufacture date. The Juvenile Products Manufacturers Association noted that some of the language required by NHTSA on child restraint labels requires up to a 12th grade education to read and understand. Other issues raised were the need for an additional warning that a restraint should not be used after even a minor crash, clearer wording, and a requirement that recommended heights and weights be limited to the size of the dummy used for certification.

E. 2000 Plan

1. Labels

On November 27, 2000, NHTSA published a notice requesting comments on a draft Child Restraint Systems Safety Plan (65 FR 70687). With regard to labels, the agency indicated that it would have current labels analyzed to determine whether to propose changes to the existing labels. The agency also indicated that it would consider proposing a requirement for basic identifying information to be permanently molded into the shell of the restraint at a specific location. Finally, the agency indicated that it would monitor ongoing research being conducted by Transport Canada on the durability of child restraint labels.

The agency did not receive extensive comments on aspects of the plan concerning child restraint labels. One commenter stated that the height and weight limits labeled on child restraints should not be allowed to exceed the size of the dummy used for certification. Another commenter requested that NHTSA prohibit additional information on child restraints and that NHTSA consider the space constraints when developing its proposal.

2. Harness Slots

In the draft Child Restraint Systems Safety Plan, NHTSA also indicated that it planned to study alternatives to address misuse of adjustable child restraint systems regarding child size and seat orientation. One of the suggested alternatives was a label requiring height indicator lines for each harness slot. One commenter, the American Academy of Pediatrics, addressed the issue of labeling harness slots. That commenter recommended a performance standard rather than a labeling requirement, as incorrect harness slot usage is believed to be a widespread problem.

V. Research

In anticipation of conducting research, NHTSA contacted child restraint manufacturers to obtain samples of currently used child restraint labels. Of the labels provided to the agency, three sets of labels were chosen by the agency to use in our research. The labels were chosen because they provide three distinctly different styles of child restraint labels. Each had a different amount of text ranging from extensive text to little text. Each uses graphic elements differently and has a differing amount of graphics. Additionally, each label uses color differently.

Our research on the readability of child restraint labels consisted of two phases: consumer focus group testing and a passive evaluation. Passive evaluation refers to an evaluation based on the characteristics of the language, vocabulary and visual presentation of the information using standard readability measures, rather than an evaluation based on consumer feedback. Copies of the full report on each research phase are available in the docket for this notice.

A. Child Restraint Focus Groups

Four focus groups were conducted in the suburbs of Chicago, IL, and Phoenix, AZ during the week of February 12, 2001. The purpose of this research was to explore parent/guardian perceptions about current child restraint labels. While many group participants admitted that they did not read the written instructions or labels that came with the child restraints, at least until they perceived they were having a problem, they also felt that it was important to have such information readily available. Participants also noted, that while they felt the language on the labels or instructions was clear when they read them, it was often difficult to translate the information into action. One of the most common problems noted was knowing for sure that the vehicle safety belt was threaded through the correct location. Of the samples shown, some of the features that participants felt made the instructions easier to understand were: color-coded distinction between forward- and rearward-facing use instructions, clear illustrations showing the vehicle belt path, numbered installation steps, dark copy on white background, positioning of the labels to indicate placement of the vehicle belts[5], strongly worded warnings, use of color to highlight warnings, illustrations which are ''see-through'' so it is clear where the belts path is, and good illustrations of what the restraint should look like when properly installed. Some common criticisms were: vague words such as ''snugly,'' unfamiliar words like ''child restraint'' rather than ''child seat,'' other words with which they

[5] **Note:** While the participants were not shown the labels on child restraints, it was clear that some of the labels would be positioned on the child restraint to mark belt paths. For example, one label states: ''Belt here forward facing 20–40 lbs.''

were not familiar and that were not defined, not enough specifics about the risks of improper use, and lack of illustrations of what the child should look like in the restraint.

B. Passive Evaluation of Child Restraint Labels

The vocabulary and syntax of the sample labels were evaluated using standard readability tests, including: Flesch Reading Ease Score, Flesch-Kincaid Grade Level Score, and the Simple Measure of Gobbledegook (SMOG). The written language was also reviewed for overall tone, overall information organization, presence of subordinate clauses and other potential hindrances, presence of distant or formal language, presence of prescriptive or negative language, and presence of patronizing language. The labels were also evaluated based on visual examination using criteria that screen for: visual tone, visual appearance and justification of written material, typeface selection, arrangement of written and illustrative information, graphic discrimination, presence of subheadings, bullets and other visual aids, and presence of illustrations, photographs and other visual references. A team of reading and language experts performed the readability analysis. Because child restraints are used by a wide variety of persons with a wide variety of literacy, including persons with less than 8 years of formal education and persons whose first language is not English, readability was evaluated against a Grade 5 reading level.

The passive evaluation found that the most clear and ''readable'' samples were characterized by:

- Distinctive color-coding of information and illustrations to indicate importance and to lead the reader
- Simplicity of language
- Clear integration of written and visual information
- High contrast type/background relationships
- Clear, easy-to-follow illustrations
- Heavy use of ''white space''

The least ''readable'' samples were characterized by:

- Dull, monochromatic visual appearance
- Densely packed written information
- Low contrast combinations of type, illustration and background.

While the language on the samples required by FMVSS No. 213 fell within the desirable ranges on many of the standard readability tests, it was found that the information is not written for a suitably low grade level. The Flesch-Kincaid Reading Grade Level analysis found that the mandatory information required between a 10.9 and an 11.1 grade reading level to comprehend.[6] The SMOG test found the 3 sets of sample labels to require 8th, 9th, and 11th grade reading levels. The evaluators noted that information added beyond the mandatory statements tended to use more readable language. The visual considerations varied widely however. Some of the features criticized were: full justification, sans serif typefaces, arrangements which made it difficult to distinguish warnings information from other less critical information, gray backgrounds and densely packed labels.

VI. Proposed Changes to the General Label Requirements

The following sections discuss format requirements for mandatory labels. NHTSA requests comments on whether NHTSA should require additional voluntary labels to comply with the any or all of these requirements.

A. Permanence and Location (S5.5.1, S5.5.3 and S5.5.4)

NHTSA currently requires that mandatory information be ''permanently labeled'' on the child restraint. One of the most common criticisms about child restraint labels is that they are not permanent. Unlike vehicle labels that are often printed directly on the vehicle component, child restraint labels are usually paper glued to the shell. As such, they fade from exposure to sunlight and peel off restraints. Because NHTSA does not have performance criteria for permanence in FMVSS No. 213, enforcing the existing requirement is difficult.

NHTSA also requires the warning statement about failure to follow the instructions, the statements about proper use of belts and other restraints, and the air bag warning to be visible when the restraint is installed in a vehicle. Location is not specified for other mandatory information.

Transport Canada is currently conducting research to develop an objective test for permanence. NHTSA is monitoring that activity, and depending on its outcome, may consider proposing criteria for permanence in the future.

In the interim, NHTSA is proposing to require the model name or number, manufacturer name, manufacturing date, and place of manufacture to be permanently molded into the rear surface of the structure supporting the child's back or on the side of the restraint if the restraint does not have a back. While focus group participants felt this was important information, NHTSA does not believe that it is as critical that this information be visible when the child restraint is installed in the vehicle. However, by standardizing the location, recall notices and announcements can direct owners to the location of this information. A requirement that the information be molded into the shell similar to the way tire information is molded should ensure that the information is always available in case of a recall.

NHTSA requests comments on whether the specification that this information be permanently molded is design restrictive in that it assumes that the child restraint shell is made out of a material such as plastic. Are there shells made out of materials that could not be molded? How else could NHTSA ensure the permanence of this information? Would other technologies better achieve the goals of this proposal? Would molding create problems with readability unless the molded material is color contrasted with the child restraint plastic?

NHTSA is proposing that all other required information be labeled on the child restraint so that it is visible when the restraint is installed in a motor vehicle. This is a change for the requirements for the certification statement, height and weight labeling, the installation diagram, the registration statement, and the statement about use in motor vehicles and/or aircraft, which are not currently required to be visible by FMVSS No. 213. NHTSA believes that this is important information that should be readily available to the user. NHTSA also notes that most, if not all, child restraint labels are currently visible, even when not required by NHTSA. Because most are already visible, and because as discussed in the previous section NHTSA is proposing that some information be located in a new location, it does not believe that this new requirement will cause space problems.

B. English language (S5.5.2, S5.5.5, and S5.5.6)

NHTSA is keeping the English language requirement for child restraints. However, NHTSA notes that many manufacturers also label child restraints in Spanish or other languages. NHTSA applauds these attempts to convey the information to owners who do not speak English, or for whom English is not their first language. NHTSA does not intend to restrict in any way a manufacturer's ability to also label child restraints in one or more

[6] The mandatory language on the three samples scored differently depending on how the manufacturer had organized the information.

additional languages as long as the required information is labeled in English. NHTSA also requests comments on whether Spanish should be required on child restraint labels.

C. Typeface (S5.5.2 and S5.5.5)

NHTSA currently requires information to be in letters and numbers that are not smaller than 10 point type. While we have not had any complaints about font size on existing labels, NHTSA notes that specifying a point size without also specifying a font does not guarantee legibility. In addition, the passive evaluation criticized the labels that were reviewed because all used a sans serif font, and serif fonts are considered easier to understand. NHTSA's graphics department has indicated that the most common serif font in publications and graphics is Times New Roman. Therefore, NHTSA is proposing to require all labels to be in Times New Roman and no less than 10 point.

D. Background (S5.5.2 and S5.5.5)

NHTSA currently requires the information to be labeled ''on a contrasting background.'' Both the passive evaluation and the focus group participants noted the difficulty in reading the sample labels that were on a gray background or conversely, the ease of reading the labels with a white background. For this reason, unless specified otherwise, NHTSA is proposing to require all information to be in black text on a white background.

E. Color (S5.5.2(l), S5.5.5(j), and S5.6.5)

NHTSA currently has minimal color requirements for child restraint labels. Other than the air bag warning, the only color requirement is that the statement about use in motor vehicles and/or aircraft must be in red lettering (S5.5.2(n)). NHTSA is not proposing changes to either of these requirements, however we are proposing a new color requirement.

Focus group participants preferred sample labels which used different colors to indicate different instructions for forward- or rearward-facing use. Distinctive color coding was also mentioned as a desirable attribute in the passive evaluation. European Regulation 44 (4.3) requires that ''the correct routing of the webbing shall be clearly indicated by means of a drawing,'' and the routing diagram must be color coded red for forward-facing and blue for rearward-facing. The same colors are required for labels ''that illustrate the methods of use.''

NHTSA is proposing a new requirement that illustrations and instructions for forward-facing use be enclosed within a red box, and that illustrations and instructions for rearward-facing use be enclosed within a blue box. NHTSA is also proposing to require vehicle belt routing to be indicated in red for forward-facing, and in blue for rearward-facing.

F. All Capital Letters

While the text required by FMVSS No. 213 is shown in all capital letters in the standard, capitalization is not generally required if not expressly required by the standard. However, because ''block letters'' are generally more difficult to read, NHTSA is proposing to delete this requirement. In this proposal the only requirement for all capital letters is the heading for the warnings.

VII. Proposed Changes To Label Contents

In the following subsections, NHTSA discusses possible changes and additions to mandated language for child restraint labels. NHTSA requests comments on whether instead of mandating specific language NHTSA should mandate only that specific information be provided, leaving the wording to each individual manufacturer. For example, S5.5.2(f) of FMVSS No. 213 mandates that child restraints be labeled with one of three statements regarding height and weight limits. As an alternative, NHTSA could require only that manufacturers label child restraints with either the maximum weight and height or a permissible range of weight and height.

A. Statement Regarding Height and Weight (S5.5.2(f) and S5.5.5(f))

NHTSA has made minor changes to simply the language. Currently each option states, ''This child (infant) restraint is designed for use only by children * * *'' NHTSA is proposing to revise the options to read, ''Use only with children * * *'' NHTSA further asks for comments on deleting the height references in these statements to further simplify them.

B. Warning Regarding the Consequences of Not Following Instructions (S5.5.2(g) and S5.5.5(g))

NHTSA currently requires the following statement to be on each child restraint:

WARNING! FAILURE TO FOLLOW EACH OF THE FOLLOWING INSTRUCTIONS CAN RESULT IN YOUR CHILD STRIKING THE VEHICLE'S INTERIOR DURING A SUDDEN STOP OR CRASH. SECURE THIS CHILD RESTRAINT WITH A VEHICLE BELT AS SPECIFIED IN THE MANUFACTURER'S INSTRUCTIONS LOCATED _____.

Both the passive analysis and the focus group participants criticized this statement as difficult to understand and too indirect about the risks. Consumer feedback after the changes to the air bag warning label indicate that the new air bag labels were noticed. Therefore, NHTSA is proposing to require the following similar statement on child restraints:

WARNING! DEATH OR SERIOUS INJURY CAN OCCUR

- Follow all instructions on this child restraint and in the written instructions located _____

This would be followed with additional bullets for any additional mandated statements, including the statement about maximum height and weight, and the statements about use of belts or other restraints. NHTSA is also proposing to require the heading (Warning! Death or Serious Injury Can Occur) to be in black text on a yellow background. NHTSA also requests comments on whether it should require or allow the alert symbol used on the air bag warning label (see Figure 10 in FMVSS No. 213).

C. Belt Use Statement (S5.5.2(h), S5.5.5(h) and S5.6.6)

Focus group participants criticized the term ''snugly'' used on child restraint labels as being too vague. NHTSA has not changed this language, because it would be difficult to have a more accurate description of how tightly belts should be adjusted on a label. However, NHTSA is requiring the following information to be included in the written instructions. This information is used in NHTSA's Standardized Child Passenger Safety Training Curriculum.

—A snug harness should not allow any slack. A snug harness should not, however, be so tight as to press into the child's body.

—A ''snug'' strap lies in a relatively straight line without sagging, but neither does it press on the child's flesh or push the child's body into an unnatural position.

D. Installation Diagram (S5.5.2(l))

NHTSA currently requires an installation diagram showing the child restraint installed in a seating position with a continuous-loop lap/shoulder belt and another diagram showing the child restraint installed in a seating position equipped with a lap belt. NHTSA is proposing to require an additional installation diagram showing the child restraint installed in a seating position with a child restraint anchorage system. By September 1, 2002, all child

restraints are required to have attachments that work with these anchorages. Most new vehicles will have the child restraint anchorage system by the same date. NHTSA requests comments on whether the requirement for a diagram showing the child restraint installed in a seating position equipped with a lap belt can be deleted.

E. Registration Statement and Card (S5.5.2(m), S5.5.5(k) and S5.8)

Some focus group participants indicated that they would like to be able to register their child restraint via the internet. Currently, NHTSA requires a child restraint to be labeled with a statement about how to register the child restraint. NHTSA also requires a registration card to be attached to the child restraint that conforms to a specified format. In order to inform owners about the ability to register a child restraint via the internet, child restraint manufacturers could currently add an additional statement to a label or they could attach a separate card to the child restraint. Child restraint manufacturers could not modify the mandatory registration card. NHTSA requests comments on the availability now or in the future of online registration to determine whether the current requirements related to registration be modified to allow child restraint manufacturers the option of informing purchasers about this method of registration. Given that the current return rate on child restraint registrations is approximately 33%, NHTSA believes that anything which improves the number of registrations should be considered.

F. Harness Slot Labeling (S5.5.2(o) and S5.5.5(m))

NHTSA has decided to propose a requirement that all harness slot positions be labeled with information indicating the maximum height and weight of the children who should be restrained by the harness in the slot position. Child restraints are often misused because parents do not use the correct harness slots for the size child and/or seat orientation. In the event of a crash, the force of an older child loading harness strap slots that were designed only for the weight of an infant can result in structural damage to the child restraint and cause severe injury to the child.

A performance requirement is likely to have much higher costs than a labeling requirement. NHTSA also believes that more obviously available information about which harness slots to use can correct the misuse problem. In looking at labels and written instructions, NHTSA has found that this advice is often buried in the written instructions. As focus group participants stated, consumers often fail to read the written instructions unless they believe that they are having difficulty with the restraint. For these reasons, NHTSA has decided that it would be preferable to propose labeling to see if that can reduce the incidence of misuse. NHTSA will use child restraint fitting stations to determine if labeling has reduced the incidence of harness slot misuse, and if the problem continues will revisit the issue.

G. Reading Level Requirement

In the passive evaluation, sample labels were evaluated using the Flesch Reading Ease Score, the Flesch-Kincaid Grade Level Score, and the Simple Measure of Gobbledegook (SMOG). The Flesch Reading Ease Score, highly validated since its introduction in 1943, rates text on a 100-point scale in which the higher the score the easier it is to understand the material. The State of Indiana mandates that insurance policies sold in the state must have a Flesch Readability Ease score of 40 or better. The Flesch-Kincaid Grade Level Score converts the Reading Ease score to a U.S. grade-school level. The SMOG test is similarly based on a U.S. grade-school level and is intended to predict 90–100% comprehension. It is used extensively in health oriented literature.

NHTSA requests comments on whether it should mandate a minimum score on one or more of these standard tests. NHTSA believes such a requirement may be particularly useful if the final rule were to replace mandatory statements with requirements that certain topics are covered by labeling.

H. Other Information

In their comments on the child plan, Graco asked the agency to prohibit any labeling on child restraints other than that which is required or design specific instructions. NHTSA is not proposing such a prohibition. NHTSA prohibits information from being given to consumers in some limited situations. For example, vehicle manufacturers are prohibited from labeling sun visors with air bag information other than that required by NHTSA regulation because of concern that other information in close proximity to the required warnings would detract from the attention paid to those warnings. However, a broad prohibition such as Graco suggests would prevent manufacturers from providing supplementary information that could enhance the correct use of child restraints, or mitigate a safety problem that present labels do not address. Because supplementary information can benefit consumers, NHTSA is generally not prohibiting additional labeling. However, such supplementary labeling must not obscure or confuse the meaning of the required labeling, or be otherwise misleading to the consumer.

NHTSA has been asked in the past to limit the maximum height and weight recommendations to the size of the dummy used in the certifications tests. NHTSA has declined to make such a change in the past, and is not proposing such a change at this time either. In 1996, NHTSA denied a petition for reconsideration from Consumers Union (61 FR 30824, June 18, 1996). At the time, NHTSA expressed concerns that such a change would actually detract from safety, stating:

> Because 20 pounds is the weight of an average nine-month-old child, CU's approach would continue to limit weight recommendations in such a way as to possibly mislead consumers into thinking that an infant must be switched to face forward when the baby is only nine months old. This is likely to be before the infant's bones and muscular system have developed sufficiently to make seating the child in a forward facing position appropriate. Thus, CU's approach could have the unintended effect of detracting from the real-world safety needs of older infants (ages nine- to 12-months) to make such a change to the labeling requirements. (61 FR 30824, 30827)

NHTSA continues to believe this is true.

VIII. Future Research

Because of the tight deadline set for completion of this rulemaking action, NHTSA did not conduct additional research on the proposed changes to child restraint labels. NHTSA is confident that the proposed formatting and content changes to the mandatory warnings have reduced the grade level needed to read the labels. Figure 1 shows a label that is similar to some seen on child restraints today. Figure 2 shows an example of how the new warnings would look for an infant restraint. In addition, after reviewing the comments NHTSA may want to make further changes to the mandatory language and final version is the version that should be evaluated. NHTSA intends to conduct further passive analysis, at a minimum, prior to issuance of a final rule to verify that the changes have reduced the reading level necessary to comprehend the labels.

BILLING CODE 4910–59–P

Black Text with Gray Background

WARNING! Failure to follow each of the following instructions can result in your child striking the vehicle's interior during a sudden stop or crash. Secure this child restraint with a vehicle belt as specified in the manufacturer's instructions located on the bottom of the child restraint. Snugly adjust the belts provided with this child restraint around your child. Place this infant restraint in a rear-facing position when using it in a vehicle. This infant restraint is designed for use by children who weigh 20 pounds (9 kg) or less and whose height is 26 inches (61 cm) or less.

Figure 1-Sample Current Label

Black Text with Yellow Background

WARNING! DEATH OR SERIOUS INJURY CAN OCCUR

- Follow all instructions on this child restraint and in the written instructions located on the bottom of the restraint.
- Secure this child restraint with the vehicle's child restraint anchorage system if available or with a vehicle belt.
- Place this infant restraint in a rear-facing position when using it in the vehicle.
- Use only with children who weigh 20 pounds (9 kg) or less and height is 26 inches (61 cm) or less.
- Snugly adjust the belts provided with this child restraint around your child.
- Register your child restraint with the manufacturer.

Black Text with White Background

Figure 2-Sample Proposed Label

BILLING CODE 4910–59–C

IX. Rulemaking Analyses and Notices

A. Executive Order 12866 (Federal Regulation) and DOT Regulatory Policies and Procedures

This rulemaking document was not reviewed under E.O. 12866, ''Regulatory Planning and Review.'' The agency has considered the impact of this rulemaking action under the Department of Transportation's regulatory policies and procedures, and has determined that it is not ''significant'' under them. In the ''Final Economic Assessment, FMVSS No. 213, FMVSS No. 225, Child Restraint Systems, Child Restraint Anchorage Systems,'' February 1999, the agency estimated that there were 68 fatalities and 874 injuries caused annually by misuse of child restraints. We are unable to estimate the effectiveness of these proposals on this target population, but by providing clearer instructions we expect to reduce misuse.

NHTSA anticipates that the cost of changing the location and text of the labels to be minor. There is a cost for adding color, estimated to be $.01 to $.03 per label. NHTSA requests comments on the cost of technologies such as molding or other technologies which would be used to meet the requirements of proposed S5.5.1 and S5.5.4.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (Public Law 96–354), as amended, requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations and small governmental jurisdictions. Section 603 of the Act requires agencies to prepare and make available for public comment a preliminary regulatory flexibility analysis (PRFA) describing the impact of proposed rules on small entities. NHTSA has not included a PRFA in the PRE for this proposal. Of the 10 current child restraint manufacturers, 4 are small business. However, we do not believe this proposal adds a significant economic cost to child restraints.

Business entities are generally defined as small businesses by the North American Industry Classification System (NAICS) code, for the purposes of receiving Small Business Administration assistance. One of the criteria for determining size, as stated in 13 CFR 121.201, is the number of employees in the firm. To qualify as a small business in the Motor Vehicle Seating and Interior Trim Category (NAICS 336360) or the All Other Transportation Equipment Manufacturing Category (NAICS 336999), the firm must have fewer than 500 employees. The agency has considered the small business impacts of this proposed rule based on this criterion.

C. Paperwork Reduction Act

The Department of Transportation has not submitted an information collection request to OMB for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). The affected public is 10 child restraint manufacturers. Except for the proposal for harness slot labeling, this rule does not impose any new information collection requirements on manufacturers. NHTSA does not anticipate a significant change to the hour burden or costs associated with child restraint labels and written instructions.

D. Executive Order 13132 (Federalism)

Executive Order 13132 requires NHTSA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with Federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, the agency consults with State and local governments, or the agency consults with State and local officials early in the process of developing the proposed regulation. NHTSA also may not issue a regulation with Federalism implications and that preempts State law unless the agency consults with State and local officials early in the process of developing the proposed regulation.

We have analyzed this proposed rule in accordance with the principles and criteria set forth in Executive Order 13132 and have determined that this proposal does not have sufficient Federal implications to warrant consultation with State and local officials or the preparation of a Federalism summary impact statement. The proposed rule would not have any substantial impact on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials.

E. National Environmental Policy Act

NHTSA has analyzed this rulemaking action for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

F. Executive Order 12778 (Civil Justice Reform)

This proposed rule would not have any retroactive effect. A petition for reconsideration or other administrative proceeding will not be a prerequisite to an action seeking judicial review of this proposed rule. This proposed rule would not preempt the states from adopting laws or regulations on the same subject, except that it would preempt a state regulation that is in actual conflict with the Federal regulation or makes compliance with the Federal regulation impossible or interferes with the implementation of the Federal statute.

X. Comments

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

Please submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

How Can I Be Sure That My Comments Were Received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How Do I Submit Confidential Business Information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR part 512.)

Will the Agency Consider Late Comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

How Can I Read the Comments Submitted By Other People?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location.

You may also see the comments on the Internet. To read the comments on the Internet, take the following steps:

I. Go to the Docket Management System (DMS) Web page of the Department of Transportation (*http://dms.dot.gov/*).
II. On that page, click on ''search.''
III. On the next page type in the four-digit docket number shown at the beginning of this document. Example: If the docket number were ''NHTSA–1999–1234,'' you would type ''1234.'' After typing the docket number, click on ''search.''
IV. On the next page, which contains docket summary information for the docket you selected, click on the desired comments.

You may download the comments. However, since the comments are imaged documents, instead of word processing documents, the downloaded comments are not word searchable.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

List of Subjects in 49 CFR Part 571

Federal Motor Vehicle Safety Standards; Child Restraint Systems.

PART 571—[AMENDED] FEDERAL MOTOR VEHICLE SAFETY STANDARDS

In consideration of the foregoing, NHTSA proposes to amend 49 CFR part 571 as set forth below.

1. The authority citation for part 571 would continue to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, 30166 and 30177; delegation of authority at 49 CFR 1.50.

2. Section 571.213 would be amended by revising S5.5.1, the introductory text of S5.5.2, S5.5.2(f), S5.5.2(g), S5.5.2(k), S5.5.2(l), S5.5.3, S5.5.4, the introductory text of S5.5.5, S5.5.5(f), S5.5.5(g), and S5.5.5(j); and adding new sections S5.5.2(o), S5.5.5(m), S5.6.5, and S5.6.6 to read as follows:

§ 571.213 Standard No. 213; Child restraint systems.

* * * * *

S5.5.1 Each add-on child restraint system shall be permanently labeled with the information specified in S5.5.2(a) through (o). The information specified in (a) through (d) shall be molded or heat embossed on the shell on the rear surface of the structure supporting the child's back, or on the side of the restraint if the restraint does not have a back.

S5.5.2 The information specified in paragraphs (a) through (o) of this section shall be stated in the English language and lettered and numbered using Times New Roman font not smaller than 10 point. Unless otherwise specified, the information shall be labeled on a white background with black text.

* * * * *

S5.5.2(f) One of the following statements, inserting the manufacturer's recommendations for the maximum mass and height of children who can safely occupy the system, except that booster seats shall not be recommended for children whose masses are less than 13.6 kg:

(1) Use only with children who weigh __ pounds (__ kg) or less and whose height is (insert values in English and metric units; use of word ''mass'' in label is optional) or less; or

(2) Use only with children who weigh between __ and __ pounds (insert appropriate English and metric values; use of word ''mass'' is optional) and whose height is (insert appropriate values in English and metric units) or less and who are capable of sitting upright alone; or

(3) Use only with children who weigh between __ and __ pounds (insert appropriate metric values; use of word ''mass'' is optional) and whose height is (insert appropriate values in English and metric units) or less.

S5.5(g) The following statement specified in paragraphs (1) through (3):

(1) The statement WARNING! DEATH OR SERIOUS INJURY CAN OCCUR in all capitalized letters and in yellow with black text. This statement will be followed by the bulleted statements in the following order:

(i) Follow all instructions on this child restraint and in the written instructions located (insert storage location on the restraint for the manufacturer's installation instruction booklet or sheet).

(ii) Secure this child restraint with the vehicle's child restraint anchorage system if available or with a vehicle belt.

(2) As appropriate, the statements required by the following sections will be bulleted and placed after the statements required by 5.5.2(g)(1) in the following order: 5.5.2(k)(1)(i) or 5.5.2(k)(2)(i), 5.5.2(f), 5.5.2(h), 5.5.2(j), and 5.5.2(i).

(3) The statements required by 5.5.2(g)(1) and 5.5.2(g)(2) will be followed by the following statement:

Register your child restraint with the manufacturer.

* * * * *

S5.5(k)(1) In the case of each rear-facing child restraint system that is designed for infants only, the statement: Place this infant restraint in a rear-facing position when using it in the vehicle.

(2) In the case of a child restraint system that is designed to be used rearward-facing for infants and forward-facing for older children, the statement: PLACE THIS CHILD RESTRAINT IN A REAR-FACING POSITION WHEN USING IT WITH AN INFANT WEIGHING LESS THAN (insert a recommended weight that is not less than 20 pounds).

(3) Except as provided in paragraph (k)(4) of this section, each child restraint system that can be used in a rear-facing position shall have a label that conforms in content to Figure 10 of this section and to the requirements of S5.5.2(k)(3)(i) through S5.5.2(k)(3)(iii) of this standard permanently affixed to the outer surface of the cushion or padding in or adjacent to the area where a child's head would

rest, so that the label is plainly visible and easily readable.

(i) The heading area shall be yellow with the word ''warning'' and the alert symbol in black.

(ii) The message area shall be white with black text. The message area shall be no less than 30 square cm.

(iii) The pictogram shall be black with a red circle and slash on a white background. The pictogram shall be no less than 30 mm in diameter.

(4) If a child restraint system is equipped with a device that deactivates the passenger-side air bag in a vehicle when and only when the child restraint is installed in the vehicle and provides a signal, for at least 60 seconds after deactivation, that the air bag is deactivated, the label specified in Figure 10 of this section may include the phrase ''unless air bag is off'' after ''on front seat with air bag.''

S5.5.2(l) Installation diagrams and instructions.

(1) An installation diagram showing the child restraint system installed in:

(i) A seating position equipped with a continuous-loop lap/shoulder belt;

(ii) A seating position equipped with only a lap belt, as specified in the manufacturer's instructions; and

(iii) A seating position equipped with a child restraint anchorage system.

(2) Any installation diagrams and installation instructions labeled on child restraints shall be outlined in red for forward-facing use and blue for rearward-facing use. No other color shall be used for each orientation position.

* * * * *

S5.5.2(o) Except for child restraints with a single position for the harness straps, each child restraint system that has belts designed to restrain children using them shall have one of the following statements, inserting the manufacturer's recommendations for the maximum mass and height of children:

(1) Use only with children who weigh __ pounds (__ kg) or less and whose height is (insert values in English and metric units; use of word ''mass'' in label is optional) or less; or

(2) Use only with children who weigh between __ and __ pounds (insert appropriate English and metric values; use of word ''mass'' is optional) and whose height is (insert appropriate values in English and metric units) or less; or

(3) Use only with children who weigh more than ____ pounds (insert appropriate English and metric values; use of word ''mass'' is optional) and whose height is more than (insert appropriate values in English and metric units).

S5.5.3 The information specified in S5.5.2(e) through (j) and S5.5.2(l) through (n) shall be located on the add-on child restraint system so that it is visible when the system is installed as specified in S5.6.1.

S5.5.4 (a) Each built-in child restraint system other than a factory-installed built-in restraint shall be permanently labeled with the information specified in S5.5.5 (a) through (m). The information specified in (a) through (d) shall be molded or heat embossed on the shell. The information specified in S5.5.5(a) through (l) shall be visible when the system is activated for use. The information specified in S5.5.5(a) through (d) shall be located on the rear surface of the structure supporting the child's back, or on the side of the restraint if the restraint does not have a back.

(b) Each factory-installed built-in child restraint shall be permanently labeled with the information specified in S5.5.5(f) through (m), so that the information is visible when the restraint is activated for use. The information shall also be included in the vehicle owner's manual.

S5.5.5 The information specified in paragraphs (a) through (m) of this section that is required by S5.5.4 shall be in English and lettered in letters and numbers using Times New Roman Font not smaller than 10 point. Unless specified otherwise, the information shall be labeled on a white background with black text.

* * * * *

(f) One of the following statements, inserting the manufacturer's recommendations for the maximum mass and height of children who can safely occupy the system, except that booster seats shall not be recommended for children whose masses are less than 13.6 kg:

(1) Use only with children who weigh ____ pounds (____ kg) or less and whose height is (insert values in English and metric units; use of word ''mass'' in label is optional) or less; or

(2) Use only with children who weigh between ____ and ____ pounds (insert appropriate English and metric values; use of word ''mass'' is optional) and whose height is (insert appropriate values in English and metric units) or less and who are capable of sitting upright alone; or

(3) Use only with children who weigh between ____ and ____ pounds (insert appropriate English and metric values; use of word ''mass'' is optional) and whose height is (insert appropriate values in English and metric units) or less.

(g) The following statement specified in paragraph (1), and if appropriate, the statements in paragraph (2) and (3):

(1) The statement WARNING! DEATH OR SERIOUS INJURY CAN OCCUR in all capitalized letters and in yellow with black text. This statement will be followed by the bulleted statement: Follow all instructions on this child restraint and in the written instructions located (insert location).

(2) In the case of each built-in child restraint system which is not intended for use in motor vehicles in certain adjustment positions or under certain circumstances, an appropriate statement of the manufacturers restrictions regarding those positions or circumstances.

(3) As appropriate, the statements required by the following sections will be bulleted and placed after the statement required by 5.5.5(g)(1) in the following order: 5.5.5(g)(2), 5.5.5(f), S5.5.5(h) and S5.5.5(i).

* * * * *

(j) Installation diagrams and instructions.

(1) A diagram or diagrams showing the fully activated child restraint system in infant and/or child configurations.

(2) Any installation diagrams and installation instructions labeled on child restraints shall be outlined in red for forward-facing use and blue for rearward-facing use. No other color shall be used for each orientation position.

* * * * *

(m) Except for child restraints with a single position for the harness straps, each child restraint system that has belts designed to restrain children using them shall have one of the following statements, inserting the manufacturer's recommendations for the maximum mass and height of children:

(1) Use only with children who weigh ____ pounds (____ kg) or less and whose height is (insert values in English and metric units; use of word ''mass'' in label is optional) or less; or

(2) Use only with children who weigh between ____ and ____ pounds (insert appropriate English and metric values; use of word ''mass'' is optional) and whose height is (insert appropriate values in English and metric units) or less; or

(3) Use only with children who weigh more than ____ pounds (insert appropriate English and metric values; use of word ''mass'' is optional) and whose height is more than (insert

appropriate values in English and metric units).

* * * * *

S5.6.5 Any installation diagrams and installation instructions included in the written instructions shall be outlined in red for forward-facing use and blue for rearward-facing use. No other color shall be used for each orientation position.

S5.6.6 The printed instructions for each child restraint system shall include the following statement:

(a) A snug harness should not allow any slack. A snug harness should not, however, be so tight as to press into the child's body.

(b) A ''snug'' strap lies in a relatively straight line without sagging, but does not press on the child's flesh or push the child's body into an unnatural position.

* * * * *

Issued on October 29, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–27545 Filed 10–30–01; 3:26 pm]

BILLING CODE 4910–59–P

Notices

Federal Register

Vol. 66, No. 213

Friday, November 2, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 01–036N]

National Advisory Committee on Meat and Poultry Inspection

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: The National Advisory Committee on Meat and Poultry Inspection (NACMPI) will hold a public meeting on November 14–15, 2001, to review and discuss two issues: (1) Retail Store Exemption-FSIS Current Thinking, and (2) Modernizing Standards of Identity for Meat and Poultry Products. Two subcommittees of the full Committee will also meet on November 14, 2001, to work on issues discussed during the full Committee session. All interested parties are welcome to attend the meetings and to submit written comments and suggestions concerning issues the Committee will review and discuss.

DATES: The full Committee will hold a public meeting on Wednesday, November 14, and Thursday, November 15, 2001 from 8:30 a.m. to 5 p.m. Subcommittees will hold open meetings on Wednesday, November 14, 2001 from 7 p.m. to 9 p.m.

ADDRESSES: All Committee meetings will take place at the Washington Plaza, 10 Thomas Circle, Washington, DC 20005; telephone (202) 842–1300. The full committee will meet in The National Hall on November 14–15, 2001. A meeting agenda is available on the FSIS Web site at *http://www.fsis.usda.gov/OPPDE/nacmpi*, which is a sub-web page of the FSIS homepage at *http://www.fsis.usda.gov*. A summary of the agenda may also be obtained from the contacts listed below. Submit one original and two copies of written comments to FSIS Docket Room, Docket #01–036N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102 Cotton Annex, 300 12th Street SW., Washington, DC 20250–3700. Comments may also be sent by facsimile (202) 205–0381. The comments and the official transcript of the meeting, when they become available will be kept in the FSIS Docket Room at the address provided above. All comments received in response to this notice will be considered part of the public record and will be available for reviewing in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Charles L. Gioglio for technical information at (202) 205–0256 and Sonya L. West for meeting information at (202) 720–2561, FAX (202) 205–0157, or e-mail *sonya.west@usda.gov*. Persons requiring a sign language interpreter or other special accommodations should notify Ms. West by November 6, 2001, at the above numbers or by e-mail. Information is also available on FSIS Web site at *http://www.fsis.usda.gov/OPPDE/nacmpi.*

SUPPLEMENTARY INFORMATION:

Background

On January 19, 2001, the Secretary of Agriculture renewed the charter for the NACMPI. The Committee provides advice and recommendations to the Secretary of Agriculture pertaining to the Federal and State meat and poultry inspection programs pursuant to sections 7(c), 24, 205, 301(a)(3), and 301(c) of the Federal Meat Inspection Act and sections 5(a)(3), 5(c), 8(b), and 11(e) of the Poultry Products Inspection Act. The Administrator of FSIS is the chairperson of the Committee. Membership of the Committee is drawn from representatives of consumer groups; producers, processors, and marketers from the meat and poultry industry; State government officials; and academia. The current members of the NACMPI are: Dr. Gladys Bayse, Spelman College; Nancy Donley, Safe Tables Our Priority; Sandra Eskin, American Association of Retired Persons; Carol Tucker Foreman, Food Policy Institute, Consumer Federation of America; Michael Govro, Oregon Department of Agriculture; Martin Holmes, North American Meat Processors; Dr. Lee C. Jan, Texas Department of Health; Dr. Alice Johnson, National Food Processors Association; Collette Schutlz Kaster, Premium Standard Farms; Dr. Daniel E. LaFontaine, South Carolina Meat Poultry Inspection Department; Dr. Irene Leech, Virginia Tech; Charles Link, Cargill Turkey Products; Dr. Catherine Logue, North Dakota State University; Michael Mamminga, Iowa Department of Agriculture; Dr. Dale Morse, New York Office of Public Health; and John Neal, Courseys Smoked Meats.

The Committee has two standing subcommittees to deliberate on specific issues and make recommendations to the whole Committee.

Members of the public will be required to register before entering the meeting.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on-line through the FSIS web page located at *http://www.fsis.usda.gov*. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could effect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience.

For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

Done at Washington, DC on: October 30, 2001.

Margaret O'K. Glavin,

Acting Administrator.

[FR Doc. 01–27538 Filed 10–30–01; 9:59 am]

BILLING CODE 3410–DM–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed additions and deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List a commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete a commodity and a service previously furnished by such agencies.

COMMENTS MUST BE RECEIVED ON OR BEFORE: December 3, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice for each commodity or service will be required to procure the commodity and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity and services to the Government.

2. The action will result in authorizing small entities to furnish the commodity and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information. The following commodity and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodity

Stand, Office Machine
7110–00–601–9849
7110–01–136–1563
7110–00–601–9835
NPA: Knox County ARC, Knoxville, Tennessee
Government Agency: GSA/National Furniture Center for Zones 2 and 3

Services

Compact Disc Duplication and Printing, U.S. Department of Agriculture, Beltsville, Maryland
NPA: ServiceSource, Inc., Alexandria, Virginia
Government Agency: U.S. Department of Agriculture

Mailroom Operation, Federal Deposit Insurance Corporation, 1910 Pacific Avenue, Dallas, Texas
NPA: Dallas Lighthouse for the Blind, Inc., Dallas, Texas
Government Agency: Federal Deposit Insurance Corporation

Photocopying, James E. Van Zandt Veterans Affairs Medical Center, Altoona, Pennsylvania
NPA: North Central Sight Services, Inc., Williamsport, Pennsylvania
Government Agency: Department of Veterans Affairs

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will result in authorizing small entities to furnish the commodity and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for deletion from the Procurement List.

The following commodity and service are proposed for deletion from the Procurement List:

Commodity

Hood, Radioactive Contaminant Protective
8415–00–NSH–0027

Service

Janitorial/Custodial
U.S. Air Force Recruiting Station, Wasilla, Alaska

Sheryl D. Kennerly,
Director, Information Management.

[FR Doc. 01–27570 Filed 11–1–01; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List a commodity and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: December 3, 2001.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly (703) 603–7740.

SUPPLEMENTARY INFORMATION: On August 31 and September 18, 2001 the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (66 FR 45959 and 48115) of proposed additions to the Procurement List.

The Following Comments Pertain to Milk, Non-Fat Dry, Instantized

Comments were received from the three current contractors for the dry milk, from workers at one of the designated nonprofit agencies, from five Members of Congress, two State representatives, and a county executive supporting the proposed addition to the Procurement List, and from two Members of Congress and two State legislators opposing the proposed addition. Congressional and State legislative opposition to the proposed addition focuses on one plant operated by one of the three current contractors, a very large business which will be only minimally impacted by the addition of dry milk to the Procurement List. That contractor told the Committee it intends to sell the plant to another of the current contractors for the dry milk, but will close it instead if the proposed addition is approved.

If this plant is closed, the contractor indicated that 22 people will lose their jobs, in an area where comparable employment is not easy to find locally. The proposed addition to the Procurement List, however, is projected to create over 100 jobs for people with severe disabilities, a group whose unemployment rate has recently been estimated to be 70 percent, well above the rate for other groups including those in the locality of the affected plant. Consequently, the Committee has concluded that the benefit to people with severe disabilities created by this Procurement List addition outweighs the harm which may be done to the plant's employees, who could more readily find other jobs.

The current contractor which intended to purchase the other contractor's plant informed the Committee that the proposed addition would have a serious impact on its plant which produces dry milk for the Government. Like the plant mentioned above, this contractor's plant has become increasingly dependent on Government sales in recent years as consumer use of dry milk has declined, to the point where such sales now represent a large minority of the plant's total sales. Loss of these sales, according to the contractor, will mean downsizing of the plant and loss of jobs for an unspecified number of its 61 workers.

As indicated above, the Committee believes that any job loss at this contractor's plant would be outweighed by the creation of a larger number of jobs for people with severe disabilities. In addition, the four nonprofit agencies designated to supply the Government with the dry milk intend to subcontract the instantizing process to an approved supplier. This contractor is one of the approved suppliers with which the nonprofit agencies are negotiating. If this contractor supplies instantized milk to the nonprofit agencies, the job losses at its plant should be less than it currently estimates.

Both these contractors noted that there are health issues involved in the production of instantized dry milk, and that their plants are certified by the U.S. Department of Agriculture (USDA) as meeting the health standards for dry milk production. USDA has informed the Committee that the designated nonprofit agencies either have been certified as meeting these standards or are in the process of being certified.

The third current contractor informed the Committee that it is a small business, and that USDA policy prohibits the transfer of contracts from successful contractors such as itself to the Committee's program. USDA has informed the Committee that it has no such policy.

The contractor claimed that it would be severely impacted by not being able to recoup its investment in equipment and processes needed to produce the dry milk through further Government contracts. The contractor also claimed that the process of having the milk instantized by a subcontractor in bulk and shipped to the nonprofit agencies for packaging at their locations would destroy the effects of the instantizing and make the milk unable to meet Government quality standards, as well as raising the price to the Government. The contractor provided a letter from its instantizing subcontractor which noted that losing this contract could result in job losses for employees with disabilities at the subcontractor's plant.

By its own admission, this contractor is an ''autonomous subsidiary'' of a larger entity, which is not a small business. The Committee looks at the entire corporate structure of an affected contractor when assessing impact of a Procurement List addition. 41 CFR 51–2.4(a)(4)(A). Loss of the dry milk contract would not cause a severe impact on the larger corporate entity. The contractor has only been producing dry milk for USDA for a short time, so it cannot be said to be dependent on this contract. Because of the competitive bidding requirement, the contractor cannot rely on the possibility of retaining the contracts for an item long enough to recoup a substantial investment. Accordingly, the Committee does not consider the frustration of this expectation to constitute severe adverse impact on the contractor.

USDA has informed us that instantized milk can be successfully shipped in bulk without noticeably reducing the quality of the milk, and such shipments are the norm in the dry milk industry. The designated nonprofit agencies are considering using the instantizing subcontractor mentioned in the previous paragraph to do their instantizing, in which case any loss of jobs by that company would be less than the subcontractor has predicted. The price of the dry milk would not be increased beyond the level of a fair market price as a result of this addition to the Procurement List.

For the reasons stated in the above paragraphs, the Committee has concluded that this addition to the Procurement List is not likely to have a severe adverse impact on the three current suppliers of this dry milk. However, in order to provide a more orderly transition from commercial suppliers to the Committee's program, and to mitigate the immediate impact of the addition on those suppliers, the Committee has agreed to a partial waiver of its mandatory source authority over the dry milk, in the amount of 34 percent of USDA's supply requirement, for a period not to exceed one year.

The Following Material Pertains to All of the Items Being Added to the Procurement List

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity and service and impact of the additions on the current or most recent contractors, the Committee has determined that the commodity and service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity and service to the Government.

2. The action will not have a severe economic impact on current contractors for the commodity and service.

3. The action will result in authorizing small entities to furnish the commodity and service to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46—48c) in connection with the commodity and service proposed for addition to the Procurement List.

Accordingly, the following commodity and service are added to the Procurement List:

Commodity

Milk, Non-Fat Dry, Instantized

8910–00–NSH–0002

Service

Office Supply Store

Federal Aviation Administration, Mike Monroney Aeronautical Center, Oklahoma City, Oklahoma

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 01–27571 Filed 11–1–01; 8:45 am]

BILLING CODE 6353–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the New Mexico Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the New Mexico Advisory Committee to the Commission will convene at 1:30 p.m. and adjourn at 4 p.m. on Friday, November 30, 2001, at the Albuquerque Marriott, 2101 Louisiana Boulevard NE, Albuquerque, New Mexico 87110. The purpose of the meeting is to discuss civil rights issues in New Mexico and plan future activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Philip Montez, Director of the Western Regional Office, 213–894–3437 (TDD 213–894–3435). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 29, 2001.

Ivy L. Davis,

Chief, Regional Programs Coordination Unit.

[FR Doc. 01–27556 Filed 11–1–01; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 42–2001]

Foreign-Trade Zone 204—Tri-Cities Area (TN/VA); Application for Expansion

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board), by the Tri-Cities Airport Commission, grantee of Foreign-Trade Zone 204, requesting authority to expand its zone in the Tri-Cities area (TN/VA). The Tri-Cities Regional Airport has been designated a Customs user fee facility by the U.S. Customs Service. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on October 26, 2001.

FTZ 204 was approved on October 21, 1994 (Board Order 706, 59 FR 54432, 10/31/94). The zone project currently consists of the following sites in the Tri-Cities area: *Site 1* (1,040 acres)—Tri-Cities Regional Airport complex, Blountville (Sullivan County), TN; *Site 2* (440 acres)—St. John/Eldred Business Park, Johnson City (Washington County), TN; *Site 3* (330 acres)—Northeast Tennessee Business Park, adjacent to the Tri-Cities Regional Airport, Kingsport (Sullivan County), TN; *Site 4* (129 acres)—Bristol Tennessee Industrial Park, Bristol (Sullivan County), TN; *Site 5* (750 acres)—Tri-County Industrial Park, Piney Flats (Sullivan County), TN; *Site 6* (206 acres)—Regional Med-Tech Center, Johnson City (Washington County), TN; and, *Site 7* (103 acres)—Linden/Hairston Industrial Park, Linden Drive at Bonham Road, Bristol, VA.

The applicant is now requesting authority to expand the general-purpose zone to include two new sites in the Tri-Cities area (Proposed Sites 8 and 9): *Proposed Site 8* (3,000 acres)—Holston Business and Technology Park, 4509 West Stone Drive, Kingsport (Hawkins County), TN; and, *Proposed Site 9* (134 acres)—Washington County Industrial Park, Cherry Hill Road, Johnson City (Washington County), TN. Proposed Site 8 is part of the Holston Army Ammunitions Plant which is owned by the U.S. Department of the Army and being converted to commercial use. BAE Systems has entered into a facilities use contract with the U.S. Department of Army to manage, maintain, operate and develop the facility for commercial use. BAE's plans include the development of the industrial park described above. Proposed Site 9 is owned by Washington County. No specific manufacturing requests are being made at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the following addresses:

1. Submissions via Express/Package Delivery Services: Foreign-Trade Zones Board, U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099—14th St., NW., Washington, DC 20005; or

2. Submissions via the U.S. Postal Service: Foreign-Trade Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Ave., NW., Washington, DC 20230.

The closing period for their receipt is January 2, 2002. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to January 6, 2002).

A copy of the application and accompanying exhibits will be available for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at the first address listed above, and at the Greater Tri-Cities Foreign-Trade Zone, 2525 Highway 75, Air Cargo Terminal Building, Suite 103, Blountville, TN 37617.

Dated: October 29, 2001.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 01–27622 Filed 11–1–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–421–807]

Notice of Amended Final Determination of Sales at Less Than Fair Value; Certain Hot-Rolled Carbon Steel Flat Products From The Netherlands

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of amended final determination of sales at less than fair value.

EFFECTIVE DATE: November 2, 2001.

FOR FURTHER INFORMATION CONTACT: Melissa Blackledge, Mike Heaney, or Robert James, Antidumping and Countervailing Duty Enforcement Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, at (202) 482–3518, (202) 482–4475, or (202) 482–0649, respectively.

Applicable Statute and Regulations

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 Tariff Act) by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce's (the Department's) regulations refer to the regulations codified at 19 CFR part 351 (2000).

Amendment to the Final Determination

On September 21, 2001, the Department determined that certain hot-

rolled carbon steel flat products (hot-rolled) from the Netherlands are being, or are likely to be, sold in the United States at less than fair value (LTFV), as provided in section 735(a) of the Tariff Act. See Notice of Final Determination of Sales at Less Than Fair Value: Certain Hot-Rolled Carbon Steel Flat Products From The Netherlands, 66 FR 50408 (October 3, 2001) (Final Determination). On October 3, 2001, respondent Corus Staal BV (Corus Staal) timely filed an allegation that the Department had made two ministerial errors in its final determination. Petitioners (United States Steel LLC, Bethlehem Steel Corporation, Gallatin Steel Company, IPSCO Steel, Inc., LTV Steel Company, Inc., National Steel Corporation, Nucor Corporation, and Steel Dynamics, Inc.) also timely alleged several ministerial errors on October 3, 2001. Both interested parties requested that we correct the errors and publish a notice of amended final determination in the **Federal Register**. See 19 CFR 351.224(e). In addition, on October 9, 2001, petitioners filed comments in rebuttal of one of Corus Staal's alleged errors.

Corus Staal's submission alleges the following errors:

- The Department inadvertently applied the revised inland freight expense for sales by Rafferty-Brown of North Carolina (RBN) to all U.S. sales; and
- The Department inadvertently treated all U.S. sales as export price (EP) sales when it intended to treat only sales of tolled subject merchandise as EP sales.

See Letter, Steptoe & Johnson LLP, October 3, 2001 passim.

In their rebuttal submission petitioners note that the treatment of all U.S. sales as EP sales by the Department was not a ministerial error, and that the Department intended to treat all U.S. sales as EP sales.

Petitioners' submission alleges the following errors:

- The Department double-counted early payment discounts for both Laura Metaal BV and Namascor BV;
- The Department double-counted a rebate for one customer which was reported incorrectly as a billing adjustment and correctly as a rebate;
- The Department inadvertently applied the revised warranty expense factor for sales made by RBN to all U.S. sales instead of only to RBN sales;
- The Department failed to correctly adjust the billing adjustments for certain U.S. sales on an invoice-specific basis, the Department applied an adjustment rate to all U.S. sales and not only to the sales in question, the Department then failed to recalculate credit for the invoices in question, and the Department applied the incorrect factor to adjust the respondent's billing adjustments;
- The Department attempted but failed to adjust further manufacturing costs for certain sales by Rafferty-Brown of Connecticut; and
- Finally, the Department inadvertently omitted changes in the margin calculation and model match programs which would have revised costs for one model, as intended by the Department and stated in its Memorandum from Heidi Norris to Neal Halper, Director of Office of Accounting, re: Cost of Production and Constructed Value Calculation Adjustments for the Final Determination (Sept. 19, 2001) at 1–2.

See Letter, Skadden, Arps, Slate, Meagher & Flom LLP, October 3, 2001 passim.

The Department's regulations define a ministerial error as one involving ''addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication or the like, and any other similar type of unintentional error which the Secretary considers ministerial.'' 19 CFR 351.224(f).

After reviewing both parties' allegations and petitioners' rebuttal we have determined, in accordance with 19 CFR 351.224, that the Final Determination includes several ministerial errors. As to Corus Staal's allegations, we agree with Corus Staal that each of the points raised by Corus Staal constitutes a ministerial error. See Memorandum For Richard Weible; ''Allegations of Ministerial Errors; Final Determination in the Investigation of Certain Hot-Rolled Carbon Steel Flat Products from the Netherlands' (Ministerial Errors Memorandum), dated October 23, 2001, a public version of which is on file in room B–099 of the main Commerce building, and the Final Determination, 66 FR at 50408.

Finally, we agree that, with the exception of one allegation, the errors alleged by petitioners represent ministerial errors and have been corrected for this amended final determination. The alleged ministerial error with which we do not agree is petitioners' belief that the Department's methodology for adjusting the respondent's billing adjustments constituted a ministerial error. For a detailed description of each of these allegations and, where applicable, our resultant corrections, see the Ministerial Errors Memorandum. Therefore, in accordance with 19 CFR 351.224(e), we are amending the final determination of the antidumping duty investigation of certain hot-rolled carbon steel flat products from the Netherlands. The revised weighted-average dumping margins are in the **Amended Final Determination section, below.**

Scope of the Investigation

For purposes of this investigation, the products covered are certain hot-rolled carbon steel flat products of a rectangular shape, of a width of 0.5 inch or greater, neither clad, plated, nor coated with metal and whether or not painted, varnished, or coated with plastics or other non-metallic substances, in coils (whether or not in successively superimposed layers), regardless of thickness, and in straight lengths, of a thickness of less than 4.75 mm and of a width measuring at least 10 times the thickness. Universal mill plate (i.e., flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm, but not exceeding 1250 mm, and of a thickness of not less than 4.0 mm, not in coils and without patterns in relief) of a thickness not less than 4.0 mm is not included within the scope of this investigation. Specifically included within the scope of this investigation are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, and the substrate for motor lamination steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium or niobium (also commonly referred to as columbium), or both, added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such silicon and aluminum.

Steel products to be included in the scope of this investigation, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTS), are products in which:(i) Iron predominates, by weight, over each of the other contained elements; (ii) the carbon content is 2 percent or less, by weight; and (iii) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

1.80 percent of manganese, or
2.25 percent of silicon, or
1.00 percent of copper, or
0.50 percent of aluminum, or
1.25 percent of chromium, or
0.30 percent of cobalt, or
0.40 percent of lead, or

1.25 percent of nickel, or
0.30 percent of tungsten, or
0.10 percent of molybdenum, or
0.10 percent of niobium, or
0.15 percent of vanadium, or
0.15 percent of zirconium.

All products that meet the physical and chemical description provided above are within the scope of this investigation unless otherwise excluded. The following products, by way of example, are outside or specifically excluded from the scope of this investigation:

- Alloy hot-rolled steel products in which at least one of the chemical elements exceeds those listed above (including, e.g., ASTM specifications A543, A387, A514, A517, A506).
- Society of Automotive Engineers (SAE)/American Iron and Steel Institute (AISI) grades of series 2300 and higher.
- Ball bearings steels, as defined in the HTS.
- Tool steels, as defined in the HTS.
- Silico-manganese (as defined in the HTS) or silicon electrical steel with a silicon level exceeding 2.25 percent.
- ASTM specifications A710 and A736.
- USS Abrasion-resistant steels (USS AR 400, USS AR 500).
- All products (proprietary or otherwise) based on an alloy ASTM specification (sample specifications: ASTM A506, A507).
- Non-rectangular shapes, not in coils, which are the result of having been processed by cutting or stamping and which have assumed the character of articles or products classified outside chapter 72 of the HTS.

The merchandise subject to this investigation is classified in the HTS at subheadings: 7208.10.15.00, 7208.10.30.00, 7208.10.60.00, 7208.25.30.00, 7208.25.60.00, 7208.26.00.30, 7208.26.00.60, 7208.27.00.30, 7208.27.00.60, 7208.36.00.30, 7208.36.00.60, 7208.37.00.30, 7208.37.00.60, 7208.38.00.15, 7208.38.00.30, 7208.38.00.90, 7208.39.00.15, 7208.39.00.30, 7208.39.00.90, 7208.40.60.30, 7208.40.60.60, 7208.53.00.00, 7208.54.00.00, 7208.90.00.00, 7211.14.00.90, 7211.19.15.00, 7211.19.20.00, 7211.19.30.00, 7211.19.45.00, 7211.19.60.00, 7211.19.75.30, 7211.19.75.60, and 7211.19.75.90. Certain hot-rolled flat-rolled carbon steel flat products covered by this investigation, including: vacuum degassed fully stabilized; high strength low alloy; and the substrate for motor lamination steel may also enter under the following tariff numbers: 7225.11.00.00, 7225.19.00.00, 7225.30.30.50, 7225.30.70.00, 7225.40.70.00, 7225.99.00.90, 7226.11.10.00, 7226.11.90.30, 7226.11.90.60, 7226.19.10.00, 7226.19.90.00, 7226.91.50.00, 7226.91.70.00, 7226.91.80.00, and 7226.99.00.00. Subject merchandise may also enter under 7210.70.30.00, 7210.90.90.00, 7211.14.00.30, 7212.40.10.00, 7212.40.50.00, and 7212.50.00.00. Although the HTS subheadings are provided for convenience and U.S. Customs purposes, the written description of the merchandise under investigation is dispositive.

Amended Final Determination

We are amending the final determination of the antidumping duty investigation of Certain Hot-Rolled Carbon Steel Flat Products from the Netherlands to reflect the correction of the above-cited ministerial errors. The revised final weighted-average dumping margins are as follows:

Manufacturer/exporter	Weighted-average margin (percent)
Corus Staal BV (Corus Staal)	2.59
All Others	2.59

Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Tariff Act, we are directing the United States Customs Service (Customs) to continue suspending liquidation on all imports of the subject merchandise from the Netherlands. Customs shall require a cash deposit or the posting of a bond equal to the weighted-average amount by which normal value exceeds the export price as indicated in the chart above. These suspension-of-liquidation instructions will remain in effect until further notice.

ITC Notification

In accordance with section 735(d) of the Tariff Act, we have notified the International Trade Commission of our amended final determination. This determination is issued and published in accordance with section 736(d) and 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: October 24, 2001.

Richard W. Moreland,

Acting Assistant Secretary, for Import Administration.

[FR Doc. 01–27621 Filed 11–1–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–816]

Notice of Extension of Final Results of Antidumping Duty Administrative Review: Certain Stainless Steel Butt-Weld Pipe Fittings from Taiwan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of final results of antidumping duty administrative review.

EFFECTIVE DATE: November 2, 2001.

FOR FURTHER INFORMATION CONTACT: Alex Villanueva or James Doyle, Office IX, DAS Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–6412 and (202) 482–0159, respectively.

Extension of Final Results

The Department of Commerce (''the Department'') is postponing the final results in the antidumping duty administrative review of Certain Stainless Steel Butt-Weld Pipe Fittings (''SSBWPF'') from Taiwan. The deadline for issuing the final results in this administrative review is currently November 9, 2001.

On July 31, 2000, the Department published a notice of initiation of this antidumping duty administrative review for the period of June 1, 2000 through May 31, 2001. *See Notice of Initiation of Antidumping or Countervailing Duty Administrative Reviews and Requests for Revocation in Part* 65 FR 46687 (July 31, 2000). On July 12, 2001, the Department published the preliminary results of this review (66 FR 36555). The date for issuing the final results of the review is currently November 9, 2001.

Section 751(a)(3)(A) of the Act states that if it is not practicable to complete the final results within 120 days from the date of publication of the preliminary results, the administering authority may extend the period within which to issue its final results by an additional 60 days. Completion of the final results within the 120-day period is impracticable for the following reasons: (1) This review involves certain complex United States indirect selling expense issues including, but not limited to, financial statements and interest expenses; (2) this review involves certain complex Constructed Export Price (''CEP'') adjustments including, but not limited to, CEP profit

and CEP offset; (3) this review involves certain complex warehouse expenses in the United States including, but not limited to, inland freight and inventory; (4) there is a concurrent scope analysis underway in this same proceeding.

Because it is not practicable to complete the review within the time specified, we are extending the time limit for the final results of the administrative review of SSBWPF from Taiwan by 30 days, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended.

The date for issuing the final results is extended from November 9, 2001 to December 9, 2001.

Dated: October 25, 2001.

Edward C. Yang,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 01–27620 Filed 11–1–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–814]

Stainless Steel Sheet and Strip in Coils From France: Extension of Time Limit for the Final Results of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for the final results of antidumping duty administrative review.

SUMMARY: The Department of Commerce (''the Department'') is extending the time limit for the final results of the review of stainless steel sheet and strip in coils from France. This review covers the period January 4, 1999 through June 30, 2000.

EFFECTIVE DATE: November 2, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Bolling at (202) 482–3434; Office of AD/CVD Enforcement, Group III, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

Statutory Time Limits

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department of Commerce (''the Department'') to issue the final results of an antidumping duty investigation within 120 days of the date on which the preliminary results are published. However, if the Department concludes that it is not practicable to issue the results by the original deadline, it may extend the 120-day period to 180 days.

Background

On September 6, 2000, the Department published a notice of initiation of the administrative review of stainless steel sheet and strip in coils from France, covering the period January 4, 1999 through June 30, 2000 (65 FR 53980). *See Notice of Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 65 FR 53980 (September 6, 2000). The preliminary results were published in the **Federal Register** on August 8, 2001. *See Stainless Steel Sheet and Strip in Coils from France: Notice of Preliminary Results of Antidumping Duty Administrative Review* (''*Preliminary Results*''), 66 FR 41538 (August 8, 2001). The current due date for the final results is December 6, 2001.

Extension of Time Limits for the Final Results

Due to the complexity of issues, such as home market affiliated downstream sales, U.S. further manufacturing sales of five entities, and complicated cost accounting issues present in this administrative review, it is not practicable to complete this review with the original time limit. *See* Memorandum from Edward C. Yang to Joseph A. Spetrini, *Extension of Time Limit for the Preliminary Results of Administrative Review of Certain Stainless Steel Sheet and Strip in Coils from France,* on file in the Central Records Unit (CRU) of the Main Commerce Building, Room B–099. Therefore, the Department has postponed the deadline for issuing the final results until February 4, 2002, which is 180 days after publication of the *Preliminary Results.*

Dated: October 25, 2001.

Edward C. Yang,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 01–27619 Filed 11–1–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Monterey Bay National Marine Sanctuary Advisory Council

AGENCY: Marine Sanctuaries Division (MSD), Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The Monterey Bay National Marine Sanctuary (MBNMS or Sanctuary) is seeking applicants for the following four seats on its Sanctuary Advisory Council (Council): Conservation, Tourism, Education, and Diving. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the conservation and management of marine resources; and the length of residence in the area affected by the Sanctuary. Applicants who are chosen as members should expect to serve three-year terms, ending on February 1, 2005, pursuant to the Council's Charter.

DATES: Applications are due by December 14, 2001.

ADDRESSES: Application kits may be obtained Karen Grimmer at the Monterey Bay National Marine Sanctuary, 299 Foam Street, Monterey, California 93940. Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Karen Grimmer at (831) 647–4253, or *Karen.Grimmer@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MBNMS Advisory Council was established in March 1994 (the current Council has served since February 2001) to assure continued public participation in the management of the Sanctuary. Since its establishment, the Council has played a vital role in the decisions affecting the Sanctuary along the central California Coast.

The Council's nineteen voting members represent a variety of local user groups, as well as the general public, plus seven local, state and federal governmental jurisdictions. In addition, the respective managers for the four California National Marine Sanctuaries (Channel Islands National

Marine Sanctuary, Cordell Bank National Marine Sanctuary, Gulf of the Farallones National Marine Sanctuary, and the Monterey Bay National Marine Sanctuary) and the Elkhorn Slough National Estuarine Research Reserve sit as non-voting members.

The Council is supported by four working groups: The Research Activity Panel (RAP) chaired by the Research Representative, the Sanctuary Education Panel (SEP) chaired by the Education Representative, the Conservation Working Group (CWG) chaired by the Conservation Representative, and the Business & Tourism Activity Panel (BTAP) chaired by the Business/Industry Representative, each dealing with matters concerning research, education and resource protection. The working groups are composed of experts from the appropriate fields of interest and meet monthly, or bi-monthly, serving as invaluable advisors to the Council and the Sanctuary Superintendent.

The Council represents the coordination link between the Sanctuary and the state and federal management agencies, user groups, researchers, educators, policy makers, and other various groups that help to focus efforts and attention on the central California coastal and marine ecosystems.

The Council functions in an advisory capacity to the Sanctuary Manager and is instrumental in helping develop policies, program goals, and identify education, outreach, research, long-term monitoring, resource protection and revenue enhancement priorities. The Council works in concert with the Sanctuary Manager by keeping him or her informed about issues of concern throughout the Sanctuary, offering recommendations on specific issues, and aiding the Manager in achieving the goals of the Sanctuary program within the context of California's marine programs and policies.

Authority: 16 U.S.C. 1431 *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: October 25, 2001.

Jamison S. Hawkins,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 01–27615 Filed 11–1–01; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for a new collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This is a proposed collection of information not previously approved by the Office of Management and Budget.

DATES: Consideration will be given to all comments received by December 3, 2001.

Title and OMB Number: Air Force Research Laboratory Public Awareness Survey; OMB Number 0701–[To Be Determined].

Type of Request: New Collection.

Number of Respondents: 441.

Responses Per Respondent: 1.

Annual Responses: 441.

Average Burden Per Response: 15 minutes.

Annual Burden Hours: 110.

Needs and Uses: The Air Force Research Laboratory will use this information collection to serve as a basis to educate and communicate to the public contributions the Research Laboratory plays in developing the Air Force of the future. As such, it is imperative the Research Laboratory understands the current level of information the average Air Force member has regarding the laboratory's contributions. With this information, the Air Force Research Laboratory will be better able to develop communication strategies to employ with the public.

Affected Public: Individuals or Households.

Frequency: Biennially.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Edward C. Springer. Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DoD Clearance Officer: Mr. Robert Cushing. Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: October 24, 2001.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–27517 Filed 11–1–01; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Intent To Grant an Exclusive License of a U.S. Government-Owned Patent; Correction

AGENCY: U.S. Army Medical Research and Materiel Command, DOD.

ACTION: Notice; correction.

SUMMARY: The U.S. Army Medical Research and Materiel Command published a document in the **Federal Register** of October 18, 2001, concerning intent to grant an exclusive license of a U.S. Government-owned patent. Inadvertently, the incorrect information was provided under the summary.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664. Both at telefax (301) 619–5034.

Correction

In the **Federal Register** of Oct 18, 2001, in FR Doc. 01–26191, on page 52898, in the second column, correct the **SUMMARY** caption to read:

SUMMARY: In accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(I)(i), announcement is made of the intent to grant an exclusive, royalty-bearing, revocable license to U.S. patent number 5,607,979 issued March 4, 1997 entitled ''Topical Skin Protectants'' to DFB Pharmaceuticals, Inc with its principal place of business at 3909 Hulen Street, Fort Worth, Texas 76107.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–27627 Filed 11–1–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exclusive, Exclusive, or Partially Exclusive Licensing of U.S. Patent Application Concerning Critical Care Platform Litters

AGENCY: U.S. Army Medical Research and Materiel Command, DOD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6, announcement is made of the availability for licensing of U.S. Patent Application No. 09/961,405 entitled ''Critical Care Platform for Litters'' and filed September 25, 2001. Foreign rights are also available (PCT/US01/29848). The United States Government, as represented by the Secretary of the Army, has rights in this invention.

ADDRESSES: Commander, U.S. Army Medical Research and Materiel Command, ATTN: Command Judge Advocate, MCMR–JA, 504 Scott Street, Fort Detrick, Frederick, Maryland 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664. Both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: This invention includes a platform having a support surface, a pair of legs connected to the support surface, and footings and securing mechanism on the legs for attaching the invention to a litter that satisfies NATO requirements. The invention attaches to the poles used to carry a patient on a litter such that the invention provides space for the patient's legs to pass under if necessary. A further embodiment of the invention adds at least one accessory clip, which includes at least one attachment for a piece of medical equipment such as medical monitors, ventilators, and infusion pumps.

Luz D. Ortiz,

Army Federal Register.

[FR Doc. 01–27633 Filed 11–1–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability of U.S. Patent Application for Non-Exclusive, Exclusive, or Partially Exclusive Licensing

AGENCY: U.S. Army Soldier and Biological Chemical Command, DoD.

ACTION: Notice.

SUMMARY: In accordance with 35 U.S.C. 209 and 37 CFR part 404 announcement is made of the availability for licensing of the following U.S. Patent application for non-exclusive, exclusive, or partially exclusive licensing. The patent application listed below has been assigned to the United States Government as represented by the Secretary of the Army, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. John Biffoni, Intellectual Property Attorney, U.S. Army SBCCOM, ATTN: AMSSB–CC (Bldg E4435), APG, MD 21010–5424, Phone: (410) 436–1158; FAX: 410–436–2534 or e-mail: *John.Biffoni@sbccom.apgea.army.mil.*

SUPPLEMENTARY INFORMATION:

Title: ''Immunoassay and Reagents and Kits for Performing the Same.''

Description: The present invention relates to novel immunoassay methods and devices or kits that utilize a sandwich assay for detection of an antigen or hapten in a sample, particularly a biological sample. In a preferred embodiment, the present invention relates to a simple one-step electrochemiluminescent (ECL) assay approach that requires approximately 15 minutes for identification and/or quantification of an antigen or analyte. The present invention also relates to reagents and kits useful for carrying out such immunoassays.

Patent Application Number: 09/433,787.

Filing Date: November 3, 1999.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–27629 Filed 11–1–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability of U.S. Patents for Non-Exclusive, Exclusive, or Partially Exclusive Licensing

AGENCY: U.S. Army Soldier and Biological Chemical Command, DoD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.7(a)(1) and 35 U.S.C. 209 announcement is made of the availability for licensing of the following U.S. Patents for non-exclusive, exclusive or partially exclusive licensing. All of the patents listed below have been assigned to the United States of America as represented by the Secretary of the Army, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Bob Gross, Technology Transfer Office, U.S. Army SBCCOM, ATTN: AMSSB–RAS–C, 5183 Blackhawk Road (Bldg E3330/245), APG, MD 21010–5423, Phone: (410) 436–5387 or e-mail: *rlgross@sbccom.apgea.army.mil.*

SUPPLEMENTARY INFORMATION: The following Patent Numbers, Titles, Issue Dates and a Brief Summary are provided:

''Method and Kit for Rapid Detection of Toxins and Bacteria'', U.S. Patent 5,994, 067 Issued November 30, 1999

The present invention relates to toxin detection methods using bacteria stained with a fluorescent indicator. The invention also relates to methods of detecting bacteria using fluorescent indicators.

''Solid Particle Aerosol Belt and Dissemination Method'', U.S. Patent 6,170,234 Issued January 9, 2001

The present invention relates to a device and method that provide easy handling and dissemination of the solid particle aerosol material. The device and method permit the rapid and efficient dissemination of solid particle aerosol into the atmosphere for military and civilian purposes.

''Analytical Methodology for Qualitative and Quantitative Determination of Chemical Agent Vapor'' U.S. Patent 6,174,732 Issued January 16, 2001

The present invention is a method for determining O-ethyl S (2-diisopropylanimoethyl) methylphosphonothiolate; better known as VX, vapor. This invention permits the generation of a purer non-contaminated VX vapor and the analytical determination of the VX samples collected under various relative humidity conditions.

''Advanced Chemical Biological Mask'' U.S. Patents 6,176,239 Issued January 23, 2001

This invention is directed to an advanced chemical-biological mask for protecting a wearer from chemical and biological environmental contaminants. The mask is especially suitable for military applications, but is of interest in any civil emergency situation where highly toxic substances are in the atmosphere.

''Rapid Identification of Bacteria by Mass Spectrometry'' U.S. Patent 6,177,266 Issued January 23, 2001

This invention relates to a method for the chemotaxonomic classification of bacteria with genus, species and strain specific biomarkers generated by matrix assisted laser desorption ionization time-of-flight mass spectrometry (MALDI–TOF–MS) analysis of either cellular protein extracts or whole cells.

"Alarm System for Hand-Held Chemical Monitor" U.S. Patent 6,191,696 Issued February 20, 2001

The present invention relates to an alarm system, which is capable of being interfaced with portable chemical monitors. The alarm system is for the Chemical Agent Monitor (CAM) and Improved Chemical Agent Monitor (ICAM).

"Environmental Material Ticket Reader and Airborne Hazard Detection System" U.S. Patent 6,228,657 Issued May 8, 2001

The present invention relates to a reader device that automatically reads collection elements for determining the presence of hazardous material, such as biological and chemical agents. The reader device may be used with a modified M256 ticket or other types of collection elements.

"Universal Decontaminating Solution for Chemical Warfare Agents" U.S. Patent 6,245,957 Issued June 23, 2001

The present invention is a composition, and a method that uses the composition, which decontaminate nerve and mustard chemical warfare agents. The composition is generally non-toxic to handling personnel prior to its use as a decontaminate for chemical warfare agents.

"Detector for Nucleic Acid Typing and Methods of Using the Same" U.S. Patent 6,238,866 Issued May 29, 2001

The present invention provides devices and methods for detecting or characterizing a nucleic acid analyte without requiring electrophoresis or the direct sequencing of analyte samples or analyte fragments.

"System and Method for Remote Detection of Hazardous Vapors and Aerosols" U.S. Patent 6,266,428 Issued July 24, 2001

The invention pertains generally to a system and method for remote detection and warning of hazardous vapors and aerosols and in particular to a system and method for imaging hazardous clouds.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–27628 Filed 11–1–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Availability of the Draft Detailed Project Report and Environmental Impact Statement (DPR/EIS), Marlinton Local Protection Project, Marlinton, Pocahontas County, WV

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of availability.

SUMMARY: In accordance with the requirements of the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers (USACE), Huntington District has prepared a Draft Detailed Project Report and Environmental Impact Statement (DEIS) in response to section 579 of the Water Resources Development Act of 1996 (WRDA). This act authorizes the Corps to design and implement flood damage reduction measures for certain named communities in the Greenbrier River Valley. The report focuses on providing protection for the Town of Marlinton, Pocahontas County, West Virginia against flooding such as occurred in November 1985, January 1996 and May 1996.

The purpose of the Corps action would be to implement a local protection measure that would reduce or eliminate the damages associated with flood-stage flows of the Greenbrier River and Knapp Creek near Marlinton to the elevation of the 1985 flood of record.

DATES: The agency must receive comments on or before December 21, 2001. A public hearing on the Marlinton Local Protection Project Draft DPR/EIS will be held at the Marlinton Town Hall auditorium, 709 2nd Avenue, Marlinton, Pocahontas County, West Virginia on Thursday, December 6, 2001, beginning at 7 PM.

ADDRESSES: Send written comments and suggestions concerning this proposed project to S. Michael Worley, PM–PD, U.S. Army Corps of Engineers, Huntington District, 502 Eighth Street, Huntington, West Virginia 25701–2070. Telephone: (304) 529–5636. Requests to be placed on the mailing list should also be sent to this address. Submit electronic comments in ASCII, Microsoft Word, or Word Perfect file format to *Stephen.M.Worley@usace.army.mil.*

FOR FURTHER INFORMATION CONTACT: To obtain additional information about the proposed project, contact Karen Miller, PM–PD–F, U.S. Army Corps of Engineers, Huntington District, 502 Eighth Street, Huntington, West Virginia 25701–2070. Telephone: 304–529–5638. Electronic mail: *Karen.V.Miller@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Detailed project studies have included consideration of a number of basin-wide and local flood damage reduction measures including mainstem dams and reservoirs, tributary impoundments, floodwall/levee combinations, channel modification and various non-structural measures. As part of the Marlinton Local Protection Project study, various alternatives considered were found effective for protecting Marlinton from the 1985 flood of record, including: floodwall/levee, floodwall/levee with diversion of the lower portion of Knapps Creek, and floodproofing and structure relocation options. More detailed evaluations determined that all the alternatives except levee/floodwall combinations and stream diversion were ineffective, very costly and/or too disruptive to the community. The most effective plans are a levee/floodwall combination for Marlinton including Riverside, and a levee/floodwall combination with diversion of Knapps Creek. These two alternatives along with the no action alternative have been evaluated in detail and the results documented in this report and EIS.

A public hearing on the Marlinton Local Protection Project Draft DPR/EIS will be held at the Marlinton Town Hall auditorium on Thursday, December 6, 2001, beginning at 7 PM. The hearing will provide an opportunity for the public to present oral, or written comments.

USACE has distributed copies of the Draft EIS to appropriate Members of Congress, State and local government officials in West Virginia, Federal agencies, and other interested parties. Copies of the document may be obtained by contacting USACE Huntington District Office of the Corps of Engineers (See **ADDRESSES**) and are available for public review at the following locations:

(1) McClintic Library, 500 8th Street, Marlinton, WV 24954.

(2) Hillsboro Library, HC 64, Box 398, Hillsboro, WV 24954.

(3) Durbin Library, P.O. Box 333, Durbin, WV 26264.

(4) Green Bank Library, P.O. Box 1, Green Bank, WV 24944.

(5) U.S. Army Corps of Engineers, Room 3100, 502 Eighth Street PD–R, Huntington, WV 25701.

(6) Internet—*http://www.lrh.usace.army.mil/pd/MarlintonLPP/.*

After the public comment period ends on December 21, 2001, USACE will consider all comments received, revise the Draft EIS as appropriate, and issue a Final EIS.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–27631 Filed 11–1–01; 8:45 am]

BILLING CODE 3710–GM–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent To Prepare a Draft Supplemental Environmental Impact Statement (DSEIS) for the Missouri River Fish and Wildlife Mitigation Project Located on the Missouri River From Sioux City, IA to the Mouth Near St. Louis, MO in the States of Iowa, Nebraska, Kansas and Missouri

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The purpose of the DSEIS is to identify and evaluate the potential environmental impacts associated with the reauthorized Missouri River Fish and Wildlife Mitigation Project and to provide this information in the form of a Draft Supplemental Environmental Impact Statement. The reauthorized project includes the development, restoration, or enhancement of an additional 118,650 acres on individual sites purchased from willing sellers. The project study area is located along 735 miles of the Missouri River from Sioux City, Iowa to the mouth near St. Louis, Missouri. The reauthorized project is a continuation of the Missouri River Mitigation Project authorized in 1986 for 48,100 acres currently being developed on over 20 individual sites. The purpose of the mitigation project is to restore fish and wildlife habitat losses resulting from the construction and development of the Missouri River Bank Stabilization and Navigation project.

FOR FURTHER INFORMATION CONTACT: Mr. Kelly Ryan, Civil Works Branch, ATTN: CENWK–PM–CJ, U.S. Army Engineer District, Kansas City, 601 East 12th Street, Kansas City, Missouri, 64106–2896, Phone: 816–983–3324.

SUPPLEMENTARY INFORMATION:

1. The Kansas City District, Corps of Engineers, is the lead District in undertaking a DSEIS to supplement the EIS prepared for the Missouri River Fish and Wildlife Mitigation Project authorized by section 601(a) of the 1986 Water Resources Development Act (WRDA86). WRDA86 authorized 48,100 acres for mitigation. Section 334(a) of WRDA99 modifies the authority of the Mitigation Project for an additional 118,650 acres.

2. The DSEIS will evaluate the no action alternative and other reasonable alternatives that may be identified during the public scoping process. The proposed action will include the acquisition of sites from willing sellers and the construction of mitigation sites designed to develop, restore or enhance aquatic and terrestrial habitat.

3. Scoping Process

a. The DSEIS public involvement program will include nine pubic scoping meetings that will use an open house format to obtain input from Native American tribes, government agencies, non-government organizations, and the general public. Tribes, individuals, organizations, and government agencies may participate in the scoping process by written comment and/or by attending a scoping meeting. The scoping meetings will be held at the following locations.

November 13, 2001: Sidney, Iowa—Sidney Elem. School, Cafeteria, 1004 Illinois Street.

November 14, 2001: Onawa, Iowa—West Monona Community High School, Commons Area, 1314 15th Street.

November 15, 2001: St. Joseph, Missouri—St. Joseph Civic Center, Meeting Room, 100 N. 4th Street.

November 19, 2001: Blair, Nebraska—Arbor Park Elementary School, Cafeteria, 1717 Adams Street.

November 26, 2001: Leavenworth, Kansas—Riverfront Community & Convention Center, Riverview Rm, 123 S. Esplanade.

November 27, 2001: Columbia, Missouri—Columbia College, Delaney Hall Banquet Room, 600 N. 8th Street.

November 28, 2001: Lexington, Missouri—Lexington High School, Cafeteria, 2309 Aull Lane.

November 29, 2001: Plattsmouth, Nebraska—Plattsmouth High School, Commons Area, 1916 E. Hwy 34.

December 5, 2001: Washington, Missouri—Washington West Elementary, 1570 W. 5th Street.

All meetings will be held from 5 p.m. to 8:30 p.m. CST.

b. The times and locations of the meetings will also be announced in a primary paper serving each county along the river and by notice sent to parties on the mailing list maintained for this project. The Corps of Engineers encourages participation of affected Native American tribes, affected Federal, State, and local agencies, and other individuals and organizations.

c. Agency scoping and preparation of the DSEIS will be conducted with appropriate Federal and state environmental and natural resource management agencies.

4. The anticipated date of availability of the DSEIS for public review is in the spring of 2002.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–27632 Filed 11–1–01; 8:45 am]

BILLING CODE 3710–KN–M

DEPARTMENT OF DEFENSE

Department of Army; Corps of Engineers

Intent To Prepare a Draft Environmental Impact Statement for Va Shly'ay Akimel Salt River Restoration Project, Maricopa County, AZ

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The Los Angeles District intends to prepare an Environmental Impact Statement (EIS) to support the proposed study for the Salt River Pima-Maricopa Indian Community and the City of Mesa. The Va Shly'ay Akimel study area is located in the upper Sonoran Desert in the Salt River watershed. It includes portions of the Salt River Pima-Maricopa Indian Community and the City of Mesa, and includes upland ares around the vicinity of the Salt River between the Pima Freeway (US 101) and Granite Reef Dam. The study area will be refined during the course of the study to include appropriate areas of consideration in accordance with the general study objectives.

The proposed project involves restoration of riparian habitat along the Salt River in Maricopa County, also increased recreational opportunities consistent with ecosystem restoration.

ADDRESSES: Commander, U.S. Army Corps of Engineers, Attn: Stephen Dibble, CESPL–PD–RN, Los Angeles District, Ecosystem Planning Section, P.O. Box 532711, Los Angeles, CA 90053–2325.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Dibble, Environmental Manager, at (213) 452–3849. He can also be reached by e-mail at *ddibble@spl.usace.army.mil.*

SUPPLEMENTARY INFORMATION:

1. *Study Authority:* This study would be conducted under two separate authorities provided by Congress. The first and most recent authority is provided by House Resolution 2425 (HR 2425), dated May 17, 1994. The second

authority is given in Public Law 761, Seventy-fifth Congress, known as Section 6 of the Flood Control Act of 1938.

2. *Proposed Action:* Provide for restoration of riparian habitat, increase recreation facilities, and flood protection. The U.S. Army Corps of Engineers (USACE) intends to prepare a Draft EIS to assess the environmental effects associated with the proposed VA Shly'ay Akimel project. The Environmental Impact Statement will evaluate impacts of viable alternatives along with a No Action Alternative. Resources categories that will be analyzed in the EIS are: land use, physical environment, geology, biological, agricultural, air quality, water quality, groundwater, recreational usage, aesthetics, cultural resources, transportation/communications, hazardous waste, socioeconomic and safety. The public will have the opportunity to comment on this analysis before any action is taken to implement the proposed action.

3. *Scoping Process:* The Corps will conduct a scoping meeting prior to preparing the Environmental Impact Statement to aid in determining the significant environmental issues associated with the proposed action. The public, as well as Federal, State, and local agencies are encouraged to participate in the scoping process by submitting data, information, and comments identifying relevant environmental and socioeconomic issues to be addressed in the environmental analysis. Useful information includes other environmental studies, published and unpublished data, alternatives that should be addressed in the analysis, and potential mitigation measures associated with the proposed action.

A public scoping meeting will be held in conjunction with the local sponsor to discuss the project scope and invite public participation in developing alternatives for the project. Individuals and agencies may offer information or data relevant to the environmental or socioeconomic impacts by attending the public scoping meeting, or by mailing the information to the above address.

4. *Public Scoping Meeting:* A public scoping meeting will be held in November 2001. The location, date, and time of the public scoping meeting will be announced by means of letter, public announcements and news releases.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–27630 Filed 11–1–01; 8:45 am]

BILLING CODE 3710–KF–M

DEPARTMENT OF DEFENSE

Department of the Navy

Record of Decision for Transfer and Reuse of the Naval Weapons Industrial Reserve Plant, Bethpage, NY

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy announces its decision to transfer the Naval Weapons Industrial Reserve Plant, at Bethpage, New York, to Nassau County, New York.

SUPPLEMENTARY INFORMATION: Pursuant to the Defense Authorization Act for Fiscal Year 1998, section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, and the Council on Environmental Quality Regulations for implementing NEPA procedures (40 CFR parts 1500–1508), the Department of the Navy (Navy) announces its decision to transfer the Naval Weapons Industrial Reserve Plant Bethpage (NWIRP) to Nassau County, New York. The conveyance and subsequent reuse of this property will be in accordance with the preferred alternative as described in the Final Environmental Impact Statement (FEIS).

Background

NWIRP Bethpage is located in the hamlet of Bethpage, town of Oyster Bay, and consists of two land parcels encompassing about 109.5 acres. The larger parcel (105 acres) contains Plant 3; Plant 10; Buildings 4–9 (north warehouses); Buildings 11–20 (south warehouses); and 30 Navy-owned ancillary buildings. The smaller parcel (4.5 acres) contains Plant 20 and one out-building. In addition to these land holdings, the transfer of NWIRP Bethpage includes Plant 5, a Navy-owned research and development building, and six other Navy-owned buildings located on land owned by the Northrop Grumman Corporation.

The Defense Authorization Act for fiscal year 1998 authorized the Secretary of the Navy to convey the property to Nassau County, NY, provided the property is used for economic redevelopment or other public uses.

Alternatives Considered—The Federal action is the conveyance of the NWIRP property outside of federal control. The EIS considered reuse of the NWIRP property an indirect effect of conveyance. The EIS analyzed the indirect effects of Nassau County's Preferred Reuse Plan, as well as the indirect effects of two other reuse plans, one that proposed a lesser intensity use and the other a greater intensity use of the site.

Nassau County's Preferred Reuse Plan proposes a mix of light industrial, warehousing, and office uses for the 105-acre parcel, and commercial uses on the 4.5-acre parcel. A total of about 1.97 million square feet of new and existing buildings would provide employment opportunities for about 5,400 workers. Full build-out of the NWIRP Bethpage property under the Preferred Reuse Plan was estimated to occur in 2010.

The EIS evaluated the development of NWIRP Bethpage under a second mixed reuse plan that proposed a less intense use than that in the Preferred Reuse Plan. Under the less intense reuse plan, about 1.7 million square feet in existing buildings and new construction would provide employment opportunities for 2,200 workers.

The EIS evaluated a third use plan that proposed a more intense use than the Preferred Reuse Plan. Under the more intense reuse plan, the NWIRP property would be redeveloped entirely for administrative use. This alternative would result in about 2.2 million square feet of office space and create job opportunities for approximately 9,900 employees.

Under the No Action Alternative, the NWIRP property would not be conveyed and would remain in U.S. Government ownership. The property would be placed in federal caretaker status with Navy maintaining the physical condition of the property, providing a security force, and making repairs essential to safety.

Environmental Impact of the Preferred Alternative—The EIS analyzes direct, indirect and cumulative environmental impacts. There are no direct environmental impacts associated with Navy conveyance of the property to Nassau County because conveyance simply results in a change in ownership. There are indirect and cumulative impacts that would result from Nassau County implementing its Preferred Reuse Plan after conveyance of the property.

Redevelopment of the property will generate an estimated 5,400 new jobs, resulting in beneficial socioeconomic impacts. Annual estimated earnings of these new jobs would be about $220 million. Other employment occurring in the region as a result of the new development on the NWIRP property is estimated at 7,250 new jobs providing an additional $203 million in earnings. As the property is transitioned from county ownership to private ownership, and thereby subject to local real estate taxes, the estimated tax generated would be about $13 million.

The Reuse Plan does not provide for any new housing units on the NWIRP

site. The new workers at the NWIRP site are expected to commute from elsewhere in the region and therefore the local school system will not be significantly impacted. Even if there is worker migration into the area, local school systems have sufficient capacity to accommodate any corresponding increase in student enrollment. There will be additional demands on community support services such as police, fire, and emergency care. It is expected that this need would increase gradually over several years. The Reuse Plan provides for additional property tax revenue to support increased service costs.

Traffic generated by implementation of the Reuse Plan is expected to cause degraded levels of service at several intersections in the vicinity of the NWIRP site. State and Local governments will need to make intersection and roadway improvements to mitigate the impacts of increased traffic. With such improvements, there will be no significant traffic-related impacts.

The Clean Air Act General Conformity rule is not applicable to the transfer of the NWIRP Bethpage property, as stated in 40 CFR part 153(c), exemptions (XIV) and (XIX). While there will be an increase in carbon monoxide emissions due to the increase in traffic, the increase in CO will not be significant since the levels will remain below the National Ambient Air Quality Standards.

Noise levels will increase approximately three decibels due to additional traffic. These higher noise levels will exceed Federal Highway Administration and U.S. Department of Housing and Urban Development standards for residential property located in the surrounding area. However, existing noise levels in the area already exceed established residential noise standards, and the three-decibel increase will be barely perceptible to the general population.

Implementation of the Reuse Plan will result in the demolition of 18 of the 19 historic buildings comprising the Bethpage Naval Aircraft Production Historic District. Demolition of the historic buildings will alter the historic setting, feeling, and character of the historic district and will result in an adverse effect. The Final EIS discussed the possible use of protective covenants as mitigation for adverse impacts on the historic district in the event Nassau County and the New York State Historic Preservation Officer (SHPO) could not agree on how to mitigate those impacts. After the Final EIS was published, Nassau County and the SHPO agreed that recordation of the historic buildings as mitigation. Nassau County completed the recordation process and the SHPO accepted this recordation process as adequate mitigation for demolition of the historic structures.

There will be no significant impacts to biological resources. Nearly all of the NWIRP Bethpage property is fully developed. There is insufficient habitat at the site to support most wildlife species and there are no federally listed threatened or endangered species at NWIRP Bethpage.

There will be no significant impacts associated with existing hazardous waste sites. Transfer of Navy property must include a determination of the environmental suitability of the land for transfer to a nonfederal agency or to the public. Most areas on NWIRP Bethpage meet the requirements for transfer set out in the Comprehensive Environmental Response, Compensation and Liability Act without further environmental action. The Navy is working with Nassau County and the Grumman Master Planning Council to coordinate transfer of the parcels scheduled for reuse. The Navy intends to clean up the NWIRP site to levels approved by U.S. Environmental Protection Agency (EPA), the New York State Department of Environmental Conservation, and the Nassau County Department of Health Bureau of Environmental Exposure Investigations.

In accordance with Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Populations* and *Low-Income Populations*, Navy analyzed the direct and indirect effects of the proposed conveyance and reuse on low income and minority populations. The conveyance and reuse will not cause adverse and disproportionately high environmental or economic impacts to minority or low-income populations residing in the region.

Mitigation—No mitigation is required for direct impacts associated with conveyance of the property. Reuse will result in indirect impacts that can be mitigated through measures taken directly by state and local governments or imposed on private developers through state and local permitting processes. For example, Nassau County could change traffic signal timing, realign roadways, and institute traffic regulatory measures, thereby reducing intersection delays and overall congestion. Nassau County could impose limitations on air emissions or water discharges as conditions in building permits.

Comments Received on the FEIS—The Navy received one comment letter on the FEIS. EPA requested that the Navy incorporate measures to reduce reliance on automobile travel into the deed or other conveyance documents. The Navy has no authority to impose such restrictions in a deed or other conveyance document. Measures relating to limitations on parking or traffic control measures are a function of local zoning and permitting authorities that are purely functions of state and local government police powers.

EPA also requested that Navy determine whether airborne volatile organic compounds emanating from contaminated groundwater affected indoor air. Navy gathered and analyzed indoor air samples and provided the results of the analysis to EPA and the New York Department of Environmental Conservation. The results of this indoor air analysis will be incorporated into the Navy's Finding of Suitability to Transfer (FOST).

Conclusion—Nassau County identified the Preferred Reuse Plan as the plan that best responds to local and regional economic conditions and promotes economic recovery from the closure of the NWIRP Bethpage. The Preferred Reuse Plan complies with the conditions imposed by Congress on the conveyance of the NWIRP property. Potentially significant environmental impacts associated with implementation of the Preferred Reuse Plan can be mitigated either directly by the State and Nassau County or indirectly through the regulatory authorities exercised by the State and Nassau County over private landowners and developers.

Although the ''no action'' alternative has less potential for adverse environmental impacts and is the environmentally preferred alternative, it would not promote local economic redevelopment and create jobs. Keeping the property in caretaker status would not be the highest and best use of the property because it would not take advantage of the property's physical characteristics and infrastructure.

Based on the analysis contained in the FEIS and associated administrative record, I have decided to convey the Naval Weapons Industrial Reserve Plant Bethpage, New York, to the County of Nassau as provided for in the Defense Authorization Act for fiscal year 1998.

Dated: October 23, 2001.

Duncan Holaday,

Deputy Assistant Secretary of the Navy (Installations and Facilities).

[FR Doc. 01–27617 Filed 11–1–01; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 2, 2002.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: October 29, 2001.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Bilingual Education and Minority Languages Affairs

Type of Review: New.

Title: Descriptive Study of the Emergency Immigrant Education (EIEA) Program.

Frequency: Semi-annually.

Affected Public: Individuals or households; State, local, or tribal gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 20.

Burden Hours: 344.

Abstract: Congress passed the Emergency Immigrant Education Act in 1984. In FY 2001, the appropriation for the EIEA program was $150,000,000. The goals of the Descriptive Study of the Emergency Immigrant Education are to provide information about: (1) The quality of instruction to immigrant children and youth; (2) the ease with which immigrant children and youth are transitioning into American society; and (3) the degree to which they are able to meet state performance standards. This study will include case studies of 15 districts that represent diverse circumstances and populations, and a range of approaches to serving recent immigrant children and youth.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, DC 20202–4651. Requests may also be electronically mailed to the Internet address *OCIO.RIMG@ed.gov* or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Sheila Carey at 708–6287 or via her Internet address *Sheila.Carey@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 01–27527 Filed 11–1–01; 8:45 am]

BILLING CODE 4000–1–P

DEPARTMENT OF ENERGY

Notice of Stakeholder Involvement Opportunity: Stakeholder Forum on Alternative Technologies to Incineration

AGENCY: Department of Energy.

ACTION: Notice of opportunity for involvement in early planning of forum.

SUMMARY: The Department of Energy (DOE) seeks to improve stakeholder involvement in its efforts to develop and evaluate alternative technologies to incineration for treatment of mixed transuranic and mixed low level waste. To encourage broad, diverse stakeholder participation, the Department is planning an Alternative Technologies to Incineration Stakeholder Forum in 2002.

DATES: Comments, suggestions and recommendations are requested by Spring 2002.

ADDRESSES: Comments, suggestions, and recommendations on the Stakeholder Forum should be directed to Noeleen Tillman of the Global Environment and Technology Foundation (GETF), a non-profit organization providing support for the Forum, at 7010 Little River Turnpike, Suite #460, Annandale, VA 22003; e-mail *ntillman@getf.org;* Telephone (703) 750–6401. Commenters are requested to provide Ms. Tillman with their name and e-mail and mailing addresses so she can follow-up as necessary.

FOR FURTHER INFORMATION CONTACT: Ms. Noeleen Tillman, Global Environment and Technology Foundation, 7010 Little River Turnpike, Suite #460, Annandale, VA 22003; e-mail *ntillman@getf.org;* Telephone (703) 750–6401.

SUPPLEMENTARY INFORMATION: The objectives of the Forum include: (1) To facilitate an exchange of information between technical experts, regulators, and interested stakeholders, and (2) to identify stakeholder values and concerns that the Department should consider in its technology development and evaluation process.

Topics for discussion at the Stakeholder Forum include:

- The Department of Energy's plans for developing alternative technologies to incineration. (A DOE ''Action Plan'' is available online at *http://www.em.doe.gov/ftplink/integrat/actionplan.pdf*).
- The current state of alternative technology development.
- Factors to be considered in determining the acceptability of new technologies.

• Stakeholder views regarding the benefits and drawbacks of various alternative technologies.

• Opportunities for stakeholder involvement in new technology development and evaluation.

• Federal and State regulatory processes, including permitting.

The Department invites interested stakeholders to participate early in the planning of this Stakeholder Forum. The Department requests suggestions and recommendations on the Forum's agenda, format and venue. The expected date and location will be announced later in a subsequent **Federal Register** notice.

Issued in Washington, D.C., on October 29, 2001.

Gerald G. Boyd,

Deputy Assistant Secretary for Science and Technology.

[FR Doc. 01–27554 Filed 11–1–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2416]

Aquenergy Systems, Inc.; Notice of Authorization for Continued Project Operation

October 29, 2001.

On October 5, 1999, Aquenergy Systems, Inc., licensee for the Ware Shoals Project No. 2416, filed an application for a new or subsequent license pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 2416 is located on the Saluda River in Laurens, Greenwood, and Abbeville Counties, South Carolina.

The license for Project No. 2416 was issued for a period ending September 30, 2001. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2416 is issued to Aquenergy Systems, Inc. for a period effective October 1, 2001, through September 30, 2002, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before October 1, 2002, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that Aquenergy Systems, Inc. is authorized to continue operation of the Ware Shoals Project No. 2416 until such time as the Commission acts on its application for subsequent license.

David P. Boergers,

Secretary.

[FR Doc. 01–27563 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP02–8–000]

Copper Eagle Gas Storage, L. L. C.; Notice of Petition

October 26, 2001.

Take notice that on October 17, 2001, Copper Eagle Gas Storage, L. L. C. (Copper Eagle), Phoenix, Arizona, filed a Petition for Exemption of Temporary Acts and Operations from Certificate Requirements, pursuant to rule 207(a)(5) of the Commission's Rules of Practice and Procedure (18 CFR 387.207(a)(5)), and section 7(c)(1)(B) of the Natural Gas Act (15 U.S.C. 717(c)(1)(B)), seeking approval of an exemption from certificate requirements to perform temporary activities related to drill site preparation and the drilling of a stratigraphic test well. The petition is on file with the Commission and open to public inspection. This filing may also be viewed on the Web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (please call (202) 208–2222 for assistance).

Copper Eagle seeks authorization to engage in certain temporary activities for the sole purpose of drilling a 7,000 foot stratigraphic test well, through the Luke salt deposit and into the sub-salt strata. This well will be located in Section 24, Township 2 North, Range 2 West, Maricopa County, Arizona. The temporary activities for which approval is requested is the drilling of a stratigraphic well, the identification of the characteristics of the strata, and the plugging and abandonment of the well according to the requirements of the Arizona Oil and Gas Conservation Commission. Copper Eagle states the proposed stratigraphic test well is critical in determining the feasibility of utilizing deep injection as the method of brine disposal during the possible development of a natural gas salt cavern storage facility. Copper Eagle also requests the Commission include pre-granted abandonment authority under section 7(b) of the Natural Gas Act to the extent it is necessary or required.

Any questions regarding this petition are to be directed to J. Gordon Pennington, Senior Counsel, El Paso Corporation, 555 11th St. NW., Suite 750, Washington, DC 20004, Phone (202) 637–3544 or facsimile (202) 637–3501.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before November 7, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the

Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

David P. Boergers,

Secretary.

[FR Doc. 01–27532 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP02–009–000]

Dominion Transmission, Inc.; Notice of Application

October 29, 2001.

Take notice that on October 19, 2001, Dominion Transmission, Inc. (DTI), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP02–009–000, an application, pursuant to sections 7(b) and (c) of the Natural Gas Act (NGA) and Part 157 of the Commission's Regulations for abandonment authorization and a certificate of public convenience and necessity authorizing the construction and operation of certain compression facilities in Pennsylvania, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

DTI proposes to install 2 compressor units, each with a capacity of 1,775 horsepower (hp) (for a total of 3,550 hp) at DTI's Ardell Compressor Station in Elk County, Pennsylvania. DTI states that it requires the additional compressors to replace capacity formerly provided by a deteriorating portion of Line LN–280 located in Elk, Cameron, Clinton, Potter, and Tioga Counties in Pennsylvania. DTI requests permission and approval to abandon in place 71 miles of this line, consisting of 8 miles of 20-inch line, 53 miles of 16-inch line, and 10 miles of 18-inch line. In addition, DTI proposes to abandon 5 miles of 14-inch line known as Line LN–4, located in Potter and Tioga Counties, Pennsylvania. It is stated that only above-ground facilities would be removed. It is asserted that DTI has determined that this proposal is the most cost-effective means of providing service to its customers with minimal environmental impact. DTI estimates the total cost of the proposed facilities at $6,500,000, and requests rolled-in rate treatment for the project. DTI requests that the Commission issue a preliminary determination by January 1, 2002 and a final certificate by April 1, 2002.

Any questions regarding this application should be directed to Sean R. Sleigh, Certificates Manager, at (304) 627–3305, Dominion Transmission, Inc., Post Office Box 2450, Clarksburg, West Virginia 26302–2450.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before November 19, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding. Comments and protests may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the Commission's Web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents, and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, Commenters will not receive copies of all documents filed by other parties or issued by the Commission, and will not have the right to seek rehearing or appeal the Commission's final order to a Federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and ion landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a

person has comments on community and landowner impacts from this proposal, it is important to file comments or to intervene as early in the process as possible.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

David P. Boergers,

Secretary.

[FR Doc. 01–27560 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2694]

Duke Power, a Division of Duke Energy Corporation, Nantahala Area; Notice of Authorization for Continued Project Operation

October 29, 2001.

On September 27, 1999, Duke Power, a division of Duke Energy Corporation, Nantahala Area (on August 10, 2001, the Commission approved the transfer of the license from Nantahala Power and Light Company to Duke Power, a division of Duke Energy Corporation, Nantahala Area and redesignated the applicant of the relicense application as Duke Power, a division of Duke Energy Corporation, Nantahala Area), licensee for the Queens Creek Project No. 2694, filed an application for a new or subsequent license pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 2694 is located on Queens Creek in Macon County, North Carolina.

The license for Project No. 2694 was issued for a period ending October 1, 2001. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2694 is issued to Duke Power, a division of Duke Energy Corporation, Nantahala Area for a period effective October 2, 2001, through October 1, 2002, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before October 2, 2002, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that Duke Power, a division of Duke Energy Corporation, Nantahala Area is authorized to continue operation of the Queens Creek Project No. 2694 until such time as the Commission acts on its application for subsequent license.

David P. Boergers,

Secretary.

[FR Doc. 01–27566 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2935]

Enterprise Mill, LLC; Notice of Authorization for Continued Project Operation

October 29, 2001.

On September 24, 2001, Enterprise Mill, LLC, licensee for the Enterprise Mill Project No. 2935, filed an application for a new or subsequent license pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 2935 is located on the Augusta Canal in Richmond County, Georgia.

The license for Project No. 2935 was issued for a period ending September 30, 2001. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2935 is issued to Enterprise Mill, LLC for a period effective October 1, 2001, through September 30, 2002, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before October 1, 2002, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that Enterprise Mill, LLC is authorized to continue operation of the Enterprise Mill Project No. 2935 until such time as the Commission acts on its application for subsequent license.

David P. Boergers,

Secretary.

[FR Doc. 01–27568 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2724]

City of Hamilton, OH; Notice of Authorization for Continued Project Operation

October 29, 2001.

On September 30, 1999, the City of Hamilton, Ohio, licensee for the City of Hamilton Project No. 2724, filed an application for a new or subsequent license pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 2724 is located on Ford Canal and the Great Miami River in Butler County, Ohio.

The license for Project No. 2724 was issued for a period ending September 30, 2001. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2724 is issued to the city of Hamilton, Ohio for a period effective October 1, 2001, through September 30, 2002, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before October 1, 2002, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that the City of Hamilton, Ohio is authorized to continue operation of the City of Hamilton Project No. 2724 until such time as the Commission acts on its application for subsequent license.

David P. Boergers,

Secretary.

[FR Doc. 01–27567 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2576]

Northeast Generation Company; Notice of Authorization for Continued Project Operation

October 29, 2001.

On August 31, 1999, Northeast Generation Company, licensee for the Housatonic Project No. 2576, filed an application for a new or subsequent license (in its relicense application, Northeast Generation Company proposes to combine this project with the licensed Falls Village Project, FERC No. 2597) pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 2576 is located on the Housatonic, Rocky, and Shepaug Rivers in Fairfield, New Haven, and Litchfield Counties, Connecticut.

The license for Project No. 2576 was issued for a period ending October 1, 2001. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in Section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2576 is issued to Northeast Generation Company for a period effective October 2, 2001, through October 1, 2002, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before October 2, 2002, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that Northeast Generation Company is authorized to continue operation of the Housatonic Project No. 2576 until such time as the Commission acts on its application for subsequent license.

David P. Boergers,

Secretary.

[FR Doc. 01–27564 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 472]

PacifiCorp; Notice of Authorization for Continued Project Operation

October 29, 2001.

On September 27, 1999, PacifiCorp, licensee for the Oneida Project No. 472, filed an application for a new or subsequent license pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 472 is located on the Bear River in Franklin County, Idaho.

The license for Project No. 472 was issued for a period ending October 1, 2001. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA,

then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 472 is issued to PacifiCorp for a period effective October 2, 2001, through October 1, 2002, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before October 2, 2002, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that PacifiCorp is authorized to continue operation of the Oneida Project No. 472 until such time as the Commission acts on its application for subsequent license.

David P. Boergers,

Secretary.

[FR Doc. 01–27561 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2401]

PacifiCorp; Notice of Authorization for Continued Project Operation

October 29, 2001.

On September 27, 1999, PacifiCorp, licensee for the Grace/Cove Project No. 2401, filed an application for a new or subsequent license pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 2401 is located on the Bear River in Caribou County, Idaho.

The license for Project No. 2401 was issued for a period ending October 1, 2001. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2401 is issued to PacifiCorp for a period effective October 2, 2001, through October 1, 2002, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before October 2, 2002, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that PacifiCorp is authorized to continue operation of the Grace/Cove Project No. 2401 until such time as the Commission acts on its application for subsequent license.

David P. Boergers,

Secretary.

[FR Doc. 01–27562 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No.CP95–168–006]

Sea Robin Pipeline Company; Notice of Informal Settlement Conference

October 29, 2001.

Take notice that an informal settlement conference in this proceeding will be convened on Thursday, November 8, 2001 at 10:00 a.m. The settlement conference will be held at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, for the purpose of exploring the possible settlement of the above referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined in 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact Thomas J. Burgess at 208–2058.

David P. Boergers,

Secretary.

[FR Doc. 01–27558 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–8–001]

Texas Eastern Transmission, LP; Notice of Amendment

October 29, 2001.

Take notice that on October 19, 2001, Texas Eastern Transmission, LP (Texas Eastern), 5400 Westheimer Court, P.O. Box 1642, Houston, Texas 77251–1642, filed an amendment to its pending application in Docket No. CP01–8–000, requesting authority for a firm hourly swing service (Firm Hourly Service) all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the Web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Specifically, Texas Eastern seeks authorization to offer a Firm Hourly Service that will provide hourly flexibility of up to 110 percent of 1/24th of daily scheduled quantities for up to six hours on any day for customers who receive service under Rate Schedules CDS, FT–1, SCT, and SS–1 at primary

firm delivery points. The service will be offered on a seasonal basis: November to March (winter service) or April to October (summer service). The rate for Firm Hourly Service will be an incremental rate based on the cost of the lease proposed in Docket No. CP01–8–000 plus the cost of purchasing gas at Beverly, Massachusetts, the primary receipt point under the lease. This incremental rate is in lieu of Texas Eastern's original proposal to rely on a reduction in storage cost credits to cover the lease costs. Texas Eastern has included Pro Forma Tariff Sheet Nos. 651–653. These sheets replace Pro Forma Tariff Sheet No. 685 which was filed in the original application. Texas Eastern states that these tariff sheets set out the proposed incremental rates and the terms and conditions of the Firm Hourly Service. As proposed in the original filing in Docket No. CP01–8–000, Texas Eastern states that its customers will have the right to transport gas on an interruptible basis using the leased capacity to the extent the lease is not being utilized for Firm Hourly Service.

Any questions regarding the application should be directed to Steven E. Tillman, Director of Regulatory Affairs, Texas Eastern Transmission Corporation, P.O. Box 1642, Houston, Texas 77251–1642 at 713–627–5113.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 2001, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the regulations under the NGA (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 in any proceeding must file a motion to intervene in accordance with the Commission's rules.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents issued by the Commission, filed by the applicant, or filed by all other intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must serve copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as filing an original and 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of such comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents, and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission, and will not have the right to seek rehearing or appeal the Commission's final order to a Federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Commission by sections 7 and 15 of the NGA and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that the proposal is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure provide for, unless otherwise advised, it will be unnecessary for Texas Eastern to appear or to be represented at the hearing.

David P. Boergers,

Secretary.

[FR Doc. 01–27559 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2631]

Woronoco Hydro LLC; Notice of Authorization for Continued Project Operation

October 29, 2001.

On August 1, 1999, Woronoco Hydro LLC, licensee for the Woronoco Project No. 2631 (in a May 22, 2001 Order, the Commission approved the transfer of the project from International Paper Company to Woronoco Hydro LLC and substitution of Woronoco Hydro LLC as the relicense applicant), filed an application for a new or subsequent license pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 2631 is located on the Westfield River in Hampden County, Massachusetts.

The license for Project No. 2631 was issued for a period ending September 1, 2001. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2631 is issued to Woronoco Hydro LLC for a period effective September 2, 2001, through September 1, 2002, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before September 2, 2002, notice is hereby given that,

pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that Woronoco Hydro LLC is authorized to continue operation of the Woronoco Project No. 2631 until such time as the Commission acts on its application for subsequent license.

David P. Boergers,

Secretary.

[FR Doc. 01–27565 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–2566–003, et al.]

Public Service Company of New Mexico, et al., Electric Rate and Corporate Regulation Filings

October 26, 2001.

Take notice that the following filings have been made with the Commission:

1. Public Service Company of New Mexico

[Docket No. ER01–2566–003]

Take notice that on October 23, 2001, Public Service Company of New Mexico (PNM) submitted for filing an amendment to its October 22, 2001 filing in this proceeding. The amendment consists of an executed signature page for the amended version of the Wholesale Requirements Power Sale and Services Agreement (Agreement) between PNM and Texas-New Mexico Power Company (TNMP) filed by PNM in this proceeding, designated as Substitute Service Agreement No. 28 under PNM's FERC Electric Tariff, First Revised Volume No. 3.

Copies of this filing have been served upon TNMP, Southwestern Public Service Company, and the New Mexico Public Regulation Commission.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. Combined Locks Energy Center, LLC

[Docket No. ER01–2659–002]

Take notice that on October 23, 2001, Combined Locks Energy Center, L.L.C. (CLEC), filed an amendment to its application for market-based rate authority pursuant to the Commission's deficiency letter issued on October 5, 2001.

CLEC respectfully requests that the Commission grant an effective date of October 17, 2001, the date CLEC began producing and selling test power.

Copies of the filing were served upon the public utility's jurisdictional customers, Public Service Commission of Wisconsin.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

3. Florida Power Corporation

[Docket No. ER01–2918–001]

Take notice that on October 23, 2001, Florida Power Corporation (FPC) tendered for filing a revised Market-Based Wholesale Power Sales Tariff, FERC Electric Tariff, Second Revised Volume No. 8 (Revised Tariff) to comply with an unpublished letter order issued by the Commission on September 25, 2001 in the above-captioned proceeding (Letter Order). The Revised Tariff has been revised to specifically comport with designation requirements set forth in Order No. 614.

The Letter Order allows the Revised Tariff to become effective as of August 24, 2001.

Copies of the filing were served upon FPC's customers receiving service under the Revised Tariff and the Florida Public Service Commission.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. South Carolina Electric & Gas Company

[Docket No. ER01–3087–000]

Take notice that on October 23, 2001 South Carolina Electric & Gas Company (SCE&G) submitted a correction to the service agreement with North Carolina Electric Membership Corporation that SCE&G filed on September 19, 2001 in the above referenced docket.

SCE&G states that the only change made in this filing is to correct the name of the issuing officer that appears on the cover page to this agreement. Accordingly, SCE&G continues to request an effective date of August 8, 2001.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. Virginia Electric and Power Company

[Docket No. ER02–150–000]

Take notice that on October 23, 2001, Virginia Electric and Power Company (Dominion Virginia Power) tendered for filing with the Federal Energy Regulatory Commission (Commission), a Notice of Termination of Service Agreement with Enron Power Marketing, Inc. designated as First Revised Service Agreement No. 1 under FERC Electric Tariff, Third Revised Volume 4.

Dominion Virginia Power respectfully requests an effective date of November 6, 2001.

Copies of the filing were served upon Enron Power Marketing, Inc., the Virginia State Corporation Commission and the North Carolina Utilities Commission.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. Virginia Electric and Power Company

[Docket No. ER02–151–000]

Take notice that on October 23, 2001, Virginia Electric and Power Company (Dominion Virginia Power) tendered for filing Notice of Termination of Service Agreement with Aquila Energy Marketing Corporation (formerly Aquila Power Corporation) designated as First Revised Service Agreement No. 51 under FERC Electric Tariff, Third Revised Volume 4.

Dominion Virginia Power respectfully requests an effective date of November 5, 2001.

Copies of the filing were served upon Aquila Energy Marketing Corporation (formerly Aquila Power Corporation), the Virginia State Corporation Commission and the North Carolina Utilities Commission.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Virginia Electric and Power Company

[Docket No. ER02–153–000]

Take notice that on October 23, 2001, Virginia Electric and Power Company (Dominion Virginia Power) tendered for filing Notice of Termination of Service Agreement with CMS Marketing, Services and Trading Company designated as First Revised Service Agreement No. 104 under FERC Electric Tariff, Third Revised Volume 4.

Dominion Virginia Power also respectfully requests an effective date of November 5, 2001.

Copies of the filing were served upon CMS Marketing, Services and Trading Company, the Virginia State Corporation Commission and the North Carolina Utilities Commission.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Virginia Electric and Power Company

[Docket No. ER02–154–000]

Take notice that on October 23, 2001, Virginia Electric and Power Company (Dominion Virginia Power) tendered for filing Notice of Termination of Service Agreement with Constellation Power Source, Inc. designated as First Revised Service Agreement No. 114 under FERC Electric Tariff, Third Revised Volume 4.

Dominion Virginia Power respectfully requests an effective date of November 5, 2001.

Copies of the filing were served upon Constellation Power Source, Inc., the Virginia State Corporation Commission and the North Carolina Utilities Commission.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. Virginia Electric and Power Company

[Docket No. ER02–155–000]

Take notice that on October 23, 2001, Virginia Electric and Power Company (Dominion Virginia Power) tendered for filing Notice of Termination of Service Agreement with Duke Energy Trading and Marketing, L.L.C. (formerly Pan Energy Power Services, Inc.) designated as First Revised Service Agreement No. 67 under FERC Electric Tariff, Third Revised Volume 4.

Dominion Virginia Power respectfully requests an effective date of November 5, 2001.

Copies of the filing were served upon Duke Energy Trading and Marketing, L.L.C. (formerly Pan Energy Power Services, Inc.), the Virginia State Corporation Commission and the North Carolina Utilities Commission.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Wisconsin Public Service Corporation

[Docket No. ER02–157–000]

Take notice that on October 23, 2001, Wisconsin Public Service Corporation (WPSC) tendered for filing its proposed Rate Schedule No. 63, consisting of a six-year renewal lease of a feeder bay in WPSC's Cranberry Substation and related feeder facilities to Eagle River Light & Water Utility (Eagle River). The lease was approved under section 203 of the Federal Power Act by an order issued on September 21, 2001 in Docket No. EC01–135–000.

WPSC requests that the proposed rate schedule become effective on October 24, 2001, the date of the commencement of the six-year renewal of the lease.

WPSC states that it has sent copies of the proposed rate schedule to Eagle River, the Public Service Commission of Wisconsin, the Michigan Public Service Commission, and Wisconsin Public Power, Inc.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Mountain View Power Partners II, LLC

[Docket No. ER02–158–000]

Take notice that on October 23, 2001, Mountain View Power Partners II, LLC (Mountain View) tendered for filing with the Federal Energy Regulatory Commission (Commission) a service agreement for power sales (Service Agreement) with its affiliate, PG&E Energy Trading-Power, L.P. (PGET) as required by the Commission in its letter Order of April 16, 2001. See Mountain View Power Partners II, LLC, Docket No. ER01–1336–000 (delegated letter order issued April 16, 2001) (Section 205 Letter Order). See also Prior Notice and Filing Requirements Under Part II of the Federal Power Act, 64 FERC ¶ 61,139 clarified, 65 FERC ¶ 61,081 (1993) (permitting non-marketer public utilities with umbrella form of service agreements on file with the Commission to file individual, executed service agreements with the Commission within thirty days of commencing service). The Service Agreement commits Mountain View to sell capacity, energy and ancillary services to PGET at market-based rates according to its FERC Electric Tariff No. 1.

Comment date: November 13, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Florida Power & Light Company

[Docket No. OA96–39–007]

Take notice that on October 24, 2001, Florida Power & Light Company (FPL) filed with the Federal Energy Regulatory Commission (Commission) a refund compliance report in connection with the December 10, 1998 settlement agreement between FPL, Florida Municipal Power Agency and Seminole Electric Cooperative, Inc., which the Commission approved by a letter order issued September 13, 2001, in the above-captioned docket.

FPL states that a copy of this filing has been served on the official service list in the above-captioned docket as well as the other dockets listed in the letter order.

Comment date: November 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

David P. Boergers,

Secretary.

[FR Doc. 01–27531 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

October 26, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type*: Transfer of License.

b. *Project No*: 9988–012.

c. *Date Filed*: July 9, 2001, supplemented July 30, 2001, and October 1, 2001.

d. *Applicants*: Spartan Mills, Mr. Peter L. Tourtellot, Receiver, and the Augusta Canal Authority.

e. *Name of Project*: John P. King Mill.

f. *Location*: The project is located on the Augusta Canal and the Savannah River in Richmond County, Georgia. The project does not occupy Federal or Tribal land.

g. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact*: Ms. Beth E. Harris, CHI Energy, Inc., P.O. Box 8597, Greenville, SC 29604, (864) 281–9630 ext. 105.

i. *FERC Contact*: Mr. James Hunter, (202) 219–2839.

j. *Deadline for filing comments and or motions*: December 5, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Please include the project number (P–9988–012) on any comments or motions filed.

k. *Description of Proposal*: The applicants propose a transfer of the license for Project No. 9988 from Spartan International, Inc., also known as Spartan Mills (Spartan), the current licensee, by and through Mr. Peter L. Tourtellot, Receiver, to the Augusta Canal Authority. The transfer is being sought in connection with a judicial foreclosure proceeding initiated by General Electric Capital Corporation against Spartan. On October 1, 2001, the Governor of Georgia signed legislation giving the Augusta Canal Authority the authority to operate hydropower projects.

l. *Locations of the Application*: A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–27533 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

October 26, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application*: Preliminary Permit.

b. *Project No*: 12116–000.

c. *Date Filed*: September 5, 2001.

d. *Applicant*: Public Utility District No. 1 of Franklin County.

e. *Name of Project*: Esquatzel Hydroelectric Project.

f. *Location*: The proposed project would be located approximately 9 miles northwest of Pasco at the termination of the Esquatzel Wasteway into the Columbia River in Franklin County, Washington. The project will require the use of an existing irrigation wasteway administered by the U.S. Bureau of Reclamation (BOR) and would be contained entirely on federal lands.

g. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact*: Mr. Kenneth A. Sugden, Manager, Public Utility District No. 1 of Franklin County, 1411 W. Clark, Pasco, WA 99302–2407, Telephone: (509) 547–5591.

i. *FERC Contact*: Mr. Lynn R. Miles, Sr. (202) 219–2671.

j. Deadline for filing motions to intervene, protests and comments: 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Please include the Project Number (12116–000) on any comments, protest, or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project*: The proposed project would utilize the BOR's existing Esquatzel Wasteway and would not require a new or existing dam. The project would consist of: (1) a 54-inch diameter 1,800-foot long steel penstock, (2) a powerhouse with an installed capacity of 2,000 kW, (3) a 13.8 kv transmission line approximately 1,000 feet long, and (4) appurtenant facilities. The project would have an annual generation of 7.2 GWh.

l. Copies of this filing are on file with the Commission and are available for public inspection. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular

application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–27534 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Regulations Governing Off-the-Record Communications; Public Notice

October 26, 2001.

This constitutes notice, in accordance with 18 CFR 385.2201(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication should serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of exempt and prohibited off-the-record communications received in the Office of the Secretary within the preceding 14 days. Copies of this filing are on file with the Commission and are available for public inspection. The documents may be viewed on the Web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance).

Exempt

Project or Docket, Date, and Name

1. Project Nos. 1975, 2061 and 2777
   10–15–01, Susan P. Neitzel
2. Project No. 2778–000
   10–15–01, Susan P. Neitzel
3. Project No. 2114–000
   10–16–01, Adeline Fredin
4. Project No. 2114–000
   10–16–01, William J. Judge
5. Project No. 2661–000
   10–16–01, Edward C. Cole
6. Docket No. ER97–1523–065, *et al.*
   10–17–01, Theodore Glick
7. Project No. 2342–000
   10–17–01, Frank Winchell
8. Project No. 2030–000
   10–18–01, Nan Allen
9. Project No. 2030–000
   10–18–01, Fred Winchell
10. Docket No. RP00–241–000
    10–18–01, Brian R. Hellebuyck
11. Project No. 2042–000
    10–23–01, Tim Bachelder

12. Docket No. CP01–415–000 10–25–01, Medha Kochhar

David P. Boergers,

Secretary.

[FR Doc. 01–27535 Filed 11–1–01; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7097–6]

Agency Information Collection Activities: Proposed Collection; Comment Request; Protection of Stratospheric Ozone—Recordkeeping and Periodic Reporting of the Production Import, Export, Recycling, Destruction, Transhipment and Feedstock Use of Ozone-Depleting Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following proposed and/or continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB):

Recordkeeping and Periodic Reporting of the Production Import, Export, Recycling, Destruction, Transhipment and Feedstock Use of Ozone-Depleting Substances ICR #1432.20, OMB Control No. 2060–0170, Expiration Date 9/28/01. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before January 2, 2002.

ADDRESSES: Copies of the material supporting this ICR renewal notice are available free of charge from The Stratospheric Ozone Protection Hotline at 1–800–269–1996 between the hours of 10 am and 4 pm Eastern Standard Time.

FOR FURTHER INFORMATION CONTACT: Suzanne Bratis, Telephone: (202) 564–3515, Fax: (202) 564–2155, E-mail: *Bratis.Suzanne@epa.gov.*

SUPPLEMENTARY INFORMATION:

Affected entities: Entities potentially affected by this action are those which produce, use feedstocks, import, export, and/or destroy the ozone-depleting substance, methyl bromide.

Title: Recordkeeping and Periodic Reporting of the Production Import, Export, Recycling, Destruction, Transhipment and Feedstock Use of Ozone-Depleting Substances (OMB Control No. 2060–0170; ICR #1432.20).

Abstract: This action revises reporting requirements so companies may produce and import for special exempted uses of methyl bromide for quarantine and preshipment applications during the interim period when production and consumption is capped at 50% of the 1991 baseline level. In order to monitor each company's production, import, export, destruction, and transformation, the reporting system continues to require information to check industry compliance with the stratospheric ozone protection regulations. Compliance during the reduction steps for methyl bromide mean that companies can produce and import 50% of 1991 baseline levels, except for the specific exemption created by this action. The information required satisfies statutory mandates for reporting and monitoring under section 603 of Title VI of CAAA and will be used to generate reports to Congress as mandated under section 603(d) of Title VI.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. Give enough background information so someone could comment on points (i)-(iv) below.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Burden Statement: The burden hours shown below represent the hours for the information collection request (ICR). The ICR provides a detailed explanation of this estimate, which is only briefly summarized in this notice. The annual public burden for collection of information associated with the reporting is estimated to average 865 hours. This estimate accounts for all responses provided by all effected entities per year.

The following is a summary of the estimates taken from the ICR:

Estimated total number of potential respondents: 536.

Frequency of response: Quarterly.

Estimated total/average number of responses for each respondent: 1–10.

Estimated total annual burden hours: 865.

Estimated O&M costs: $141.87.

Estimated total annual burden costs: $52,275.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: October 29, 2001.

Paul Stolpman,

Director, Office of Atmospheric Programs.

[FR Doc. 01–27590 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6622–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or www.epa.gov/oeca/ofa.

Weekly receipt of Environmental Impact Statements

Filed October 22, 2001 Through October 26, 2001

Pursuant to 40 CFR 1506.9.

EIS No. 010401, DRAFT SUPPLEMENT, FEW, MI, US–31 Petoskey Area Improvement Study, To Reduce Congestion on US–31 in the City of Petoskey and Resort and Bear Creek Townships, COE Section 404 Permit, Emmet County, MI, Due: December

17, 2001, Contact: James A. Kirschensteiner (517) 702–1835.

EIS No. 010402, FINAL EIS, DOE, TN, Programmatic EIS—Oak Ridge Y–12 Plant Mission, Processing and Storage Highly Enriched Uranium, U.S. Nuclear Weapons Stockpile, Anderson County, TN, Due: December 10, 2001, Contact: Gary Hartman (865) 576–0273.

EIS No. 010403, DRAFT EIS, COE, WV, Marlington Local Protection Project, To Evaluate Flood Damage Reduction Measures for the Town of Marlington, Three Alternatives: Two Levee/Floodwall for Managing Flooding from Knapp Creek, Greenbrier River, Pocahontas County, WV, Due: December 21, 2001, Contact: S. Michael Worley (304) 529–5636.

EIS No. 010404, FINAL EIS, AFS, AK, Emerald Bay Timber Sale, Implementation, Ketchikan-Misty Fiords Ranger District, Tongass National Forest, U.S. Cost Guard Bridge Permit, NPDES Permit, and COE Section 10 and 404 Permits, Cleveland Peninsula, AK, Due: December 10, 2001, Contact: Colleen Grundy (907) 228–4114.

EIS No. 010405, DRAFT EIS, BLM, OR, Lakeview Resource Management Plan, To Unified Land Use Plan that will Replace all or Portion of three nearly Twenty year old Existing Land Use Plans, Implementation, Lake and Bend Counties, OR, Due: January 31, 2002, Contact: Dwayne Sykes (541) 947–2177.

This document is available on the Internet at: *http://(www.or.blm.gov/Lakeview/Planning/planninglist.htm).*

EIS No. 010406, DRAFT EIS, USA, PA, Fort Indiantown Gap National Guard Training Center, To Enhance Training and Operations, Pennsylvania National Guard (PANG), Annville, Dauphin and Lebanon Counties, PA, Due: December 10, 2001, Contact: Richard H. Shertzer (717) 861–2548.

EIS No. 010407, DRAFT SUPPLEMENTAL, COE, MO, St. Johns Bayou and New Madrid Floodway Project, Channel Enlargement and Improvement, Revised Information to Formulate and Analyze Additional Alternatives, Flood Control, National Economic Development (NED) New Madrid, Mississippi and Scott Counties, MO, Due: December 17, 2001, Contact: Mr. Shawn Phillips (901) 544–3321.

Dated: October 30, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–27604 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00748; FRL–6809–9]

Association of American Pesticide Control Officials/State FIFRA Issues Research and Evaluation Group

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Association of American Pesticide Control Officials (AAPCO)/State FIFRA Issues Research and Evaluation Group (SFIREG) will hold a 2–day meeting, beginning on December 3, 2001, and ending December 4, 2001. This notice announces the location and times for the meeting and sets forth the tentative agenda topics.

DATES: The meeting will be held on Monday, December 3, 2001, from 8:30 a.m. to 5 p.m. and Tuesday, December 4, 2001, from 8:30 a.m. to noon.

ADDRESSES: This meeting will be held at the Double Tree Hotel, 300 Army Navy Drive, Arlington, Crystal City, VA.

FOR FURTHER INFORMATION CONTACT: Philip H. Gray, SFIREG Executive Secretary, P.O. Box 1249, Hardwick, VT 05843–1249; telephone number: (802) 472–6956; fax (802) 472–6957; e-mail address: aapco@plainfield.bypass.com.

Georgia A. McDuffie, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605–0195; fax number: (703) 308–1850; e-mail address: mcduffie.georgia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to all parties interested in SFIREG's information exchange relationship with EPA regarding important issues related to human health, environmental exposure to pesticides, and insight into EPA's decision-making process are invited and encouraged to attend the meetings and participate as appropriate. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–00748. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Tentative Agenda

The tentative agenda items identified by the AAPCO and SFIREG follows:

1. E-labels.
2. State and Federal pesticides Agency's activities - post September 11th terrorists attacks.
3. Status of the water quality registration review team.
4. Other OPP water quality activities.
5. Issues from water quality PREP course.
6. Committee reports and introduction of issue papers.
7. Update on current OPP activities.
8. SFIREG issue paper status reports.
9. Update on current OECA activities.
10. Regional reports.
11. Other topics, as appropriate.

List of Subjects

Environmental protection.

Dated: October 25, 2001.

Jay S. Ellenberger,

Acting Director, Field and External Affairs Division, Office of Pesticide Programs.

[FR Doc. 01–27597 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1047; FRL–6806–1]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1047, must be received on or before December 3, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1047 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7610; e-mail address: jackson.sidney@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1047. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1047 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1047. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI,

please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 24, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4

6E4703

EPA has received a pesticide petition 6E4703 from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for combined residues of the herbicide, bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on the raw agricultural commodities clover forage at 1.0 part per million (ppm) and clover hay at 2.0 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition. Bentazon is manufactured by the BASF Corporation, Agricultural Products Division.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residue in plants is adequately understood. Bentazon is rapidly metabolized, conjugated and incorporated into natural plant constituents. Metabolism involves the hydroxylation of bentazon at the 6- and 8-position. The terminal residues of regulatory concern are bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon (as specified in 40 CFR 180.355(a)).

2. *Analytical method.* Adequate enforcement methods are available for the determination of residues of bentazon and its 6- and 8-hydroxy metabolites in/on plant commodities. The Pesticide Analytical Manual (PAM) Vol. II lists Method II, a GLC method with flame photometric detection for the determination of bentazon and its hydroxy metabolites in/on corn, rice, and soybeans; the limit of detection for each compound is 0.05 ppm. Method III, modified from Method II, is available for the determination of bentazon and its hydroxy metabolites in/on peanuts and seed and pod vegetables with a limit of detection of 0.05 ppm for each compound.

3. *Magnitude of residues.* A total of 2 field residue trials were conducted on red clover in 1993 in Oregon. A single application of Basagran herbicide was made to clover at a rate of either 1.0 lb. active ingredient per acre (a.i./acre) (0.5X) or 2.0 lb/a.i./acre (1X). The spray volume was 20 gal/acre. An adjuvant (R-11) was included in all treatments at 2 oz./acre. Samples of forage and hay were harvested from each treated plot 36 days after treatment. Samples were analyzed for the combined residues of bentazon and its 6- and 8-hydroxy metabolites. Analysis of the treated samples showed that the maximum total residue was 0.77 ppm in forage and 1.19 ppm in hay.

B. Toxicological Profile

1. *Acute toxicity.* Acute toxicity data for bentazon show that this chemical is not acutely toxic by the oral, inhalation, or dermal routes of exposure (Toxicity Categories III and IV). It is moderately irritating to the eye (Toxicity Category II) and slightly irritating to the skin (Toxicity Category IV). Bentazon is also a dermal sensitizer.

2. *Genotoxicty.* Bentazon was not mutagenic in the tests for gene mutations, which were reverse mutation assays in *S. typhimurium* and in *E. coli* WP2 uvrA as well as forward mutation assays with *in vitro* Chinese hamster ovary cell (HGPRT) cultures. Bentazon was also negative in the mouse micronucleus test for assessing structural chromosomal aberrations and the unscheduled DNA synthesis assay with primary mouse hepatocytes for detecting DNA damage.

3. *Reproductive and developmental toxicity.* A developmental study in rats was conducted at doses of 0, 40, 100, or 250 milligrams per kilogram per day (mg/kg/day). The maternal NOAEL (no observed adverse effect level) is 250 mg/kg/day, HDT (highest dose tested). The maternal LOAEL (lowest observed adverse effect level) is greater than 250 mg/kg/day. The developmental NOAEL is 100 mg/kg/day. The developmental LOAEL is 250 mg/kg/day, based on increased postimplantation loss, skeletal variations (incomplete or absent ossification in the phalangeal nucleii of the extremities, the sternebrae and cervical vertebrae), and reduced body weights or fetuses surviving to day 21.

A developmental study in rabbits was conducted at doses of 0, 75, 150, or 375 mg/kg/day. The maternal/developmental NOAEL is 150 mg/kg/day. The maternal/developmental LOAEL is 375 mg/kg/day (HDT), based

on doe with partial abortion, embryonic resorptions, and no living fetuses. A 2–generation reproduction toxicity study in rats was conducted at doses of 0, 200, 800, or 3,200 ppm; equivalent to 0, 15, 62, or 249 mg/kg/day. The parental systemic NOAEL is 62 mg/kg/day. The parental systemic LOAEL is 249 mg/kg/day, based on increased incidences of kidney mineralization and liver microgranuloma. The reproductive NOAEL is 15 mg/kg/day. The reproductive LOAEL is 62 mg/kg/day, based on reduced pup growth (body weight gain) during lactation.

4. *Subchronic toxicity.* A 21–day dermal toxicity study in rabbits was conducted at doses of 0, 250, 500, or 1,000 mg/kg/day. The NOAEL is 1,000 mg/kg/day (HDT). The LOAEL is greater than 1,000 mg/kg/day. A 13–week feeding study in rats was conducted at doses of 0, 400, 1,200, or 3,600 ppm; equivalent to 0, 25.3, 77.8, or 243.3 mg/kg/day for males and 0, 28.9, 86.1, or 258.3 mg/kg/day for females. The NOAEL is 77.8 mg/kg/day. The LOAEL is 243.3 mg/kg/day for males and 258.3 mg/kg/day for females based on depressed mean body weights in females, a slight increase in food consumption in males, increased thromboplastin and prothrombin times (males only), and increased kidney and liver weights.

5. *Chronic toxicity.* A chronic feeding study in dogs was conducted at doses of 0, 100, 400, or 1,600 ppm; equivalent to 0, 3.2, 13.1, or 52.3 mg/kg/day. The NOAEL is 3.2 mg/kg/day. The LOAEL is 13.1 mg/kg/day based on a dose-dependent presence of feces with red areas in dogs at 13.1 mg/kg/day (400 ppm) and 52.3 mg/kg/day (1,600 ppm) and slight to severe anemia at the high dose. A chronic feeding/carcinogenicity study in rats was conducted at doses of 0, 200, 800, or 4,000 ppm; equivalent to 0, 9, 35, or 180 mg/kg/day in males and 0, 11, 45, or 244 mg/kg/day in females. The NOAEL is 9/11 mg/kg/day, in males/females. The LOAEL is 35/45 mg/kg/day, in males/females, based on increased water consumption, changes in urinalysis and hematology/coagulation parameters, and decreased absolute and relative thyroid weight. No evidence of carcinogenicity was observed. An oncogenicity study in mice was conducted at doses of 0, 100, 400, or 2,000 ppm; equivalent to 0, 12, 47, or 242 mg/kg/day in males and 0, 12, 48, or 275 mg/kg/day in females. The NOAEL is 12 mg/kg/day. The LOAEL is 47/48 mg/kg/day in males/females, based on increased prothrombin time, increased liver and kidney weights, calcification of the tunica albuginea, and islet cell hyperplasia of the pancreas. No evidence of carcinogenicity was observed.

6. *Animal metabolism.* A rat metabolism study with oral dosing showed that parent bentazon was the major metabolite found in urine, amounting to 77.37–91.02% of the dose. Another metabolism study demonstrated that the absorption and excretion of bentazon or its sodium salt in male rats after oral administration is rapid and essentially equivalent. No sex differences in the absorption, metabolism or excretion of sodium bentazon are apparent based on equivalent excretion half-lives (4 hours), pattern of excretion greater than 90% in urine or urinary metabolite identification greater than 80% as free acid. A dermal penetration study in rats was conducted at doses of 0.12, 1.2, 12, or 120 mg/kg. Single topical application of radioactive sodium bentazon did not appear to significantly penetrate the skin since a maximum of only 1-2% of the radioactivity was recovered primarily in the urine at 72 hours. Negligible amounts of dermally applied radioactivity were retained in the liver, kidneys, G.I. tract and carcass. For risk assessment purposes, dermal penetration is estimated to be 1-2%.

7. *Metabolite toxicology.* There are no metabolites of toxicological significance to mammals.

8. *Endocrine disruption.* No special studies investigating potential estrogenic or endocrine effects of bentazon have been conducted. However, the standard battery of required studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology exposure. These studies are generally considered to be sufficient to detect any endocrine effects but no such effects of the endocrine organs following repeated or long-term were noted in any of the studies.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* In 1999, EPA evaluated the hazard and exposure data for bentazon and recommended that the FQPA safety factor be retained at 10X in assessing the risk posed by this chemical because there was evidence of increased susceptibility in the developmental toxicity study in rats and in the 2-generation reproduction toxicity study in rats. The 10X FQPA Safety Factor is applicable to females 13–50 years old for acute dietary and residential exposure assessments and to all population subgroups for chronic dietary and residential exposure assessments. The acute and chronic Population Adjusted Doses (aPAD and cPAD, respectively) are modification of the acute and chronic Reference Doses (RfDs) to include the FQPA safety factor. The acute or chronic PAD is equal to the acute or chronic RfD divided by the FQPA safety factor.

Acute and chronic dietary exposure analyses for bentazon were performed using the Dietary Exposure Evaluation Model (DEEM) which incorporates data generated in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII). For the acute analysis, tolerance level residues were used and 100% crop treated (CT) was assumed for all commodities (Tier I) for the females 13–50 years old subgroup (the subpopulation of concern). For all the females 13–50 years old subgroup, 5% or less of the aPAD is occupied by dietary exposure from food. Results of the acute analysis indicate that the acute dietary risk residues in food associated with existing and proposed uses of bentazon do not exceed EPA's level of concern.

A refined chronic dietary exposure analysis (Tier 3) was performed using anticipated and tolerance level residues for commodities for the general U.S. population and all population subgroups. For the chronic analysis, percent crop treated information was used for several commodities. The percent chronic population adjusted dose (%cPADs) for all subgroups were less than 100%, with the highest being 28% for the children 1–6 years subgroup. Results of the chronic analysis indicate that the chronic dietary risk from residues in food associated with the existing and proposed uses of bentazon do not exceed EPA's level of concern.

ii. *Drinking water.* SCI-GROW (Screening Concentration in Ground Water) modeling indicates that bentazon residue (bentazon + its metabolite, 2-amino-N-isopropyl benzamide (AIBA) concentrations in ground water used as drinking water are not likely to exceed 4.25 parts per billion (ppb). The other regulated bentazon metabolites (6-hydroxy and 8-hydroxy bentazon) have not been found in environmental fate studies. Limited monitoring data indicated a range of bentazon concentrations (excluding degradation products) in ground water of 20 to 120 ppb. Because monitoring data indicate a higher concentration than the SCI-GROW screening model, EPA used the 20 ppb as the environmental exposure concentration (EEC) for both acute and chronic scenarios. The EEC for surface water (from EPA's Pesticide Root Zone Model-EXAMS modeling) is 41 ppb for the peak (acute) and 8 ppb for the 36-year annual mean (chronic). The surface

and ground water estimates were used to compare against back-calculated drinking water levels of comparison (DWLOCs) for aggregate risk assessments. For the acute exposure scenario, the DWLOC is 2800 ppb for females (13+/nursing). For the chronic exposure scenario, the DWLOCs are 95, 82, 22, 94, and 95 ppb for the U.S. population, females (13+/nursing), children (1–6 years), Hispanics and males (13–19 years), respectively.

2. *Non-dietary exposure*. Because bentazon is registered for consumer use on turf and ornamentals, there is potential for residential exposure to adult applicators and adults and children entering recreational and residential areas treated with bentazon.

The handler exposure is expected to be short-term while the post-application exposure is expected for both the short- and intermediate-term. However, since there is no short-term dermal endpoint, the residential post-application exposure cannot be aggregated with the handler exposure. Short-term, non-dietary ingestion exposure for toddlers is not a concern because it was determined that there is no acute dietary or oral endpoint applicable to infants and children. However, intermediate-term, non-dietary ingestion exposure to toddlers playing on treated turf is possible and was assessed using the intermediate-term endpoint identified from the 1 year dog feeding study. Intermediate-term exposure is not expected for the ornamental use. The level of concern for residential exposures to bentazon is for MOE's less than 1,000.

There are no chemical-specific or site-specific data available to determine the potential risks associated with residential exposures from handling bentazon. Therefore, the exposure estimates are based on assumptions and generic data as specified by the December 18, 1997 Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Because bentazon is applied no more than twice per year, only short-term exposure is expected for the residential handler. Because a dermal endpoint of concern for the short-term duration was not identified, only inhalation exposure estimates are relevant. Assuming that a homeowner treats his lawn and ornamental plants on the same day, the aggregate inhalation short-term MOE is 500,000 for the residential handler. This estimate indicates that the potential handler risks from residential uses of bentazon do not exceed EPA's level of concern.

Environmental fate data indicate that bentazon is moderately resistant to degradation (t1/2 = 24–65 days). Due to the length of time bentazon is expected to remain in the environment, both short- and intermediate-term residential post-application exposures are expected. For toddlers playing on treated turf, the oral intermediate-term endpoint was used to assess toddler incidental ingestion exposures. Based on the residential use pattern, no long-term post-application residential exposure is expected. Short-term, non-dietary oral exposures to the toddler were not assessed because the subgroup of concern was identified as females 13–50 years old. This endpoint is not applicable to the infant and children population subgroups. Intermediate-term, post-application exposure is not expected from the ornamental use of bentazon.

Changes to the residential SOPs have been proposed that alter the residential post-application scenario assumptions. The proposed assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. Therefore, the proposed assumptions are used to calculate exposure estimates.

The dermal post-application exposure from the turfgrass use for the adult results in an MOE of 9,100. The MOEs for post-application exposures for the toddler are calculated as 6,400 and 3,500 for dermal and hand-to-mouth exposures, respectively. The aggregate intermediate MOE for post-application residential exposure to toddlers is 2,200. Therefore, all residential post-application exposure estimates are well below EPA's level of concern. Because these estimates were calculated using screening-level assumptions, it is believed that the actual risks will be lower. For the intermediate-term, typical lawn maintenance practices such as mowing and watering are expected to expedite the dissipation of bentazon on turfgrass. Therefore, with less residue available, potential incidental hand-to-mouth exposures are expected to be substantially lower.

D. Cumulative Effects

There is no available data to determine whether bentazon has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, bentazon does not appear to produce a toxic metabolite produced by other substances. For the purposes of this notice of filing, therefore, it is assumed that bentazon does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Acute risk estimates from aggregate exposure to bentazon in food and water are below EPA's level of concern. For Tier 1 acute dietary exposure analysis, it was assumed that 100% of the crops treated with bentazon and that residues equaled the tolerance level. For all females 13–50 years old subgroups, less than or equal to 5% of the aPAD is occupied by dietary exposure from food. The acute dietary risk from food associated with the existing and proposed uses of bentazon is below EPA's level of concern. The estimated average concentrations of bentazon in surface and ground water are less than EPA's levels of comparison for bentazon in drinking water as a contribution to acute aggregate exposure.

Chronic (non-cancer) aggregate risk estimates are below EPA's level of concern. The chronic dietary exposure analysis for residues in food incorporated anticipated and tolerance level residues for commodities. Percent crop treated information was used for several commodities. The %cPADs for all subgroups were less than 100%, with the highest being 28% for the children 1–6 years old subgroup. Thus, the chronic dietary risk estimates from food associated with existing and proposed uses of bentazon do not exceed EPA's level of concern. For ground and surface water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to chronic aggregate exposure.

Aggregate short-term risk estimates are below EPA's level of concern. In aggregating short-term risk, the background chronic dietary exposure (food + drinking water) and short-term inhalation exposures from residential uses are considered. Because a dermal endpoint of concern for the short-term duration was not identified, only inhalation exposure estimates are relevant for the adult handler. Short-term inhalation exposure may occur for a homeowner treating turf and ornamentals on the same day. The total short-term food and residential aggregate MOE value is 220,000. As this MOE is greater than 1,000, the short-term food and residential aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water contribution to short-term aggregate exposure.

Aggregate intermediate-term risk estimates are below EPA's level of concern for adults. In aggregating intermediate-term risk, the background chronic dietary exposure (food + drinking water) and intermediate-term dermal exposures from residential uses are considered. For adults, dermal post-application exposures may result from dermal contact with treated turf. For adults, the total food and residential intermediate-term aggregate MOE is 7,600. As this value is greater than 1,000, the intermediate-term aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to intermediate-term aggregate exposure.

A cancer risk assessment was not done. Bentazon is classified as a Group E chemical (evidence of non-carcinogenicity for humans) based upon lack of evidence of carcinogenicity in rats and mice. Based on these risk assessments, it is concluded that there is a reasonable certainty that no harm will result from aggregate exposure to bentazon residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of bentazon, data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children.

Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

The toxicological data base for evaluating prenatal and postnatal toxicity of bentazon is complete with respect to current data requirements. There was evidence of increased susceptibility following *in utero* exposure to bentazon in the prenatal developmental toxicity study in rats and there was quantitative evidence of increased susceptibility following prenatal/postnatal exposure to bentazon in the 2-generation reproduction study in rats.

There is a complete toxicity data base for bentazon and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor for protection of infants and children will be retained at 10x for bentazon due to the increased prenatal/postnatal susceptibility. The FQPA Safety Factor for bentazon is applicable to females 13–50 years old only for acute dietary and residential exposure assessments because increased susceptibility was demonstrated in the developmental study in rats which is designed to evaluate chemical effects on the mother and fetus from the time of implantation of the fertilized egg in the uterus through the end of gestation. The safety factor is also applicable to all population subgroups for chronic dietary and residential exposure assessments because increased susceptibility was demonstrated in the 2-generation reproduction study (which is designed to assess the effects of the pesticide on male and female reproductive processes, from egg and sperm production and mating through pregnancy, birth, nursing, growth and development, and maturation). An acute endpoint was not identified and this risk assessment was not required.

Using the exposure assumptions described in this unit, it was concluded that aggregate exposure to bentazon from food will utilize 28% of the chronic PAD for children 1–6 years old. EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to bentazon in drinking water and from non-dietary, non-occupational exposure, the aggregate exposure is not expected to exceed 100% of the chronic PAD.

Although bentazon is a registered herbicide for use on turf and ornamentals, short-term non-dietary ingestion exposure for toddlers is not assessed because EPA determined that there is no acute dietary or oral endpoint applicable to infants and children. Aggregate intermediate-term risk estimates are below EPA's level of concern for infants and children. In aggregating intermediate-term risk, background chronic dietary exposure (food + drinking water) and intermediate-term, non-dietary oral and dermal exposures from residential uses are considered. For toddlers, dermal and non-dietary oral postapplication exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. For infants and children, the total food and residential intermediate-term aggregate MOE is 2,000. As this value is greater than 1,000, the intermediate-term aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to intermediate-term aggregate exposure.

Based on these risk assessments, BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to bentazon residues.

F. International Tolerances

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of bentazon in clover. Therefore, a compatibility issue is not relevant to the proposed tolerance.

[FR Doc. 01–27600 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7097–9]

Proposed CERCLA Administrative Cost Recovery Settlement; Cliff/Dow Dump, Marquette, MI

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past response costs

concerning the Cliff/Dow Dump site in Marquette, Michigan with the following setting parties: The Cleveland-Cliffs Iron Company, The Dow Chemical Company, Georgia-Pacific Corporation and the City of Marquette, Michigan. The settlement requires the setting parties to pay $412,600 to the EPA Hazardous Substances Superfund. The settlement includes a covenant not to sue the settling parties pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a). For thirty (30) days following the date of publication of this notice, the Agency will receive all written comments relating to the settlement. The Agency will consider all comments and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at U.S. EPA, Region 5, Administrative Records, 77 W. Jackson Boulevard, Chicago, IL 60604 (312) 886–0900; the Peter White Public Library, 217 N. Front St. Marquette, MI 49855; and the Michigan Department of Environmental Quality, Knapps Center, Lansing, Michigan 48909.

DATES: Comments must be submitted on or before December 3, 2001.

ADDRESSES: The proposed settlement is available for public inspection at U.S. EPA, Region 5, 77 W. Jackson Boulevard, Chicago, IL 60640. A copy of the proposed settlement may be obtained from Christine M. Liszewski, at U.S. EPA, Region 5, 77 W. Jackson Boulevard (C–14J), Chicago, IL 60640, phone (312) 886–4670. Comments should reference the Cliff/Dow Dump located in Marquette, Michigan, and Docket No. V–W–01–C–655 and should be addressed to Christine M. Liszewski, U.S. EPA, Region 5, 77 W. Jackson Boulevard (C–14J), Chicago, IL 60640.

FOR FURTHER INFORMATION CONTACT: Christine M. Liszewski, at U.S. EPA, Region 5, 77 W. Jackson Boulevard (C–14J), Chicago, IL 60640, phone (312) 886–4670.

Dated: October 10, 2001.

William E. Muno,

Director, Superfund Division, Region 5.

[FR Doc. 01–27592 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) being Reviewed by the Federal Communications Commission, Comments Requested

October 26, 2001.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (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 estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before January 2, 2002. 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 as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commissions, 445 12th Street, SW., Room 1-A804, Washington, DC 20554 or via the Internet to *lesmith@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via the Internet at *lesmith@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0496.

Title: ARMIS Operating Data Report.

Form No.: FCC 43–08.

Type of Review: Extension.

Respondents: Business or other for profit.

Number of Respondents: 50.

Estimated Time Per Response: 160 hours per response (avg).

Total Annual Burden: 8000 hours.

Estimated Annual Reporting and Recordkeeping Cost Burden: $0.

Frequency of Response: Annually.

Needs and Uses: Section 220 of the Communications Act of 1934, as amended, 47 U.S.C. 220, allows the Commission, at its discretion, to prescribe the forms of any and all accounts, records and memoranda to be kept by carriers subject to this Act, including the accounts, records and memoranda of the movement of traffic, as well as the receipts and expenditures of moneys. Section 219(b) of the Communications Act of 1934, as amended, 47 U.S.C. 219(b), authorizes the Commission by a general or special orders to require any carriers subject to this Act to file annual reports concerning any matters with respect to which the Commission is authorized or required by law to act. Section 43.21 of the Commission's rules detail that requirement. ARMIS was implemented to facilitate the timely and efficient analysis of revenue requirements, rates of return and price caps; to provide an improved basis for audits and other oversight functions; and to enhance the Commission's ability to quantify the effects of alternative policy. The ARMIS 43–08 Report collects network operating data in a consistent format. The ARMIS 43–08 Report monitors network growth, usage, and reliability. The information contained in the ARMIS 43–08 Report provides the necessary detail to enable this Commission to fulfill its regulatory responsibilities.

OMB Control No.: 3060–0763.

Title: The ARMIS Customer Satisfaction Report.

Form No.: FCC Report 43–06.

Type of Review: Extension.

Respondents: Business or other for Profit.

Number of Respondents: 8.

Estimated Time Per Response: 720 hours per response (avg).

Total Annual Burden: 5760 hours.

Estimated Annual Reporting and Recordkeeping Cost Burden: $0.

Frequency of Response: Annually.

Needs and Uses: Section 220 of the Communications Act of 1934, as amended, 47 U.S.C. 220, allows the Commission, at its discretion, to prescribe the forms of any and all accounts, records and memoranda to be kept by carriers subject to this Act, including the accounts, records and memoranda of the movement of traffic, as well as the receipts and expenditures of moneys. Section 219(b) of the Communications Act of 1934, as amended, 47 U.S.C. 219(b), authorizes the Commission by a general or special orders to require any carriers subject to

this Act to file annual reports concerning any matters with respect to which the Commission is authorized or required by law to act. Section 43.21 of the Commission's rules detail that requirement. ARMIS was implemented to facilitate the timely and efficient analysis of revenue requirements, rates of return and price caps; to provide an improved basis for audits and other oversight functions; and to enhance the Commission's ability to quantify the effects of alternative policy. The Customer Satisfaction Report reflects the results of customer satisfaction based on surveys conducted by individual carriers from their customers. The information contained in the ARMIS 43–06 Report provides the necessary detail to enable this Commission to fulfill its regulatory responsibilities.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–27487 Filed 11–1–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2511]

Petition for Reconsideration of Action in Rulemaking Proceeding

October 29, 2001.

Petition for Reconsideration has been filed in the Commission's rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR Section 1.429(e). The full text of this document is available for viewing and copying in Room CY–A257, 445 12th Street, SW., Washington, DC or may be purchased from the Commission's copy contractor, Qualex International (202) 863–2893. Oppositions to this petition must be filed by November 19, 2001. See section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

SUBJECT: Amendment of section 2.106 of the Commission's Rules to Allocate Spectrum at 2 GHz for Use By the Mobile-Satellite Service (ET Docket No. 95–18)

In the Matter of establishment of Policies and Service Rules for the Mobile Satellite Service in the 2 GHz Band (IB Docket No 99–81)

In the Matter of New Advanced Mobile and Fixed Terrestrial Services; Use of Frequencies Below 3 GHz (ET Docket No. 00–258)

Number of petitions filed: 1.

Magalie Roman Sales,

Secretary.

[FR Doc. 01–27488 Filed 11–1–01; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 27, 2001.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Tri-County Bancorp, Inc., West Union, West Virginia; to become a bank holding company by acquiring 100 percent of the voting shares of West Union Bank, West Union, West Virginia.

B. Federal Reserve Bank of Atlanta (Cynthia C. Goodwin, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309–4470:

1. FNC S-Corp, Inc., Douglas, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of FNC Bancorp, Inc., Douglas, Georgia, and First National Bank of Coffee County, Douglas, Georgia.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Northwest Delaware, Inc., Wilmington, Delaware; and Northwest Bancshares, Inc., Roanoke, Texas; to become bank holding companies by acquiring 100 percent of the voting shares of Northwest Delaware, Inc., Wilmington, Delaware, and thereby indirectly acquire Northwest Bank, Roanoke, Texas.

Board of Governors of the Federal Reserve System, October 29, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–27492 Filed 11–1–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Budget, Technology and Finance, Office of Assistant Secretary for Administration and Management; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended as follows: Chapter AM, ''HHS Management and Budget Office'' as last amended at 60 FR 52403–05 (10/6/95); 63 FR 38836–7 (7/20/98); 61 FR 43363–65 (8/22/96); 63 FR 9555–6 (2/25/98); and 60 FR 52403–5 (10/6/95). This reorganization will do the following: Abolish the HHS Management and Budget Office (MB), retitle it as the Office of Budget, Technology and Finance (OBTF), headed by an Assistant Secretary, and transfer its functions between OBTF and a newly established Chapter AJ to be titled, the ''Office of the Assistant Secretary for Administration and Management (OASAM),'' which will be headed by an Assistant Secretary. The Assistant Secretary for Administration and Management (ASAM) will share responsibility with the Assistant Secretary for Budget, Technology and Finance (ASBTF) for ensuring that HHS meets the goals set forth in the President's Management Agenda, and the OASAM Assistant Secretary will serve as the OPDIV Head for the Secretary. The OBTF will focus on the

financial and budgetary concerns for the Department, as well as the investments the Department is making in 3-government and technology. The OBTF Assistant Secretary will serve as the Department's Chief Financial Officer and manage the HHS Chief Information Officer functions. The changes are as follows:

1. Under Part A, ''Office of the Secretary,'' make the following changes to Chapter AM:

A. Delete all references to the ''HHS Management and Budget Office,'' and the Assistant Secretary for Management and Budget (ASMB) in their entireties; and retitle the ''HHS Management and Budget Office,'' as the Office of Budget, Technology and Finance (OBTF) and the ASMB as the Assistant Secretary for Budget, Technology and Finance (ASBTF).

B. Delete Chapter AM, in its entirety and replace with the following:

Office of Budget, Technology and Finance (AM)

Section AM.00 Mission: The mission of the Office of Budget, Technology and Finance (OBTF) is to provide advice and guidance to the Secretary on budget, financial management, and information technology, and to provide for the direction and coordination of these activities throughout the Department.

Section AM.10 Organization: The Office of Budget, Technology, and Finance is headed by the Assistant Secretary for Budget, Technology and Finance (ASBTF). The Assistant Secretary for Budget, Technology, and Finance is the Departmental Chief Financial Officer (CFO), and reports to the Secretary. The office consists of the following components:

- Immediate Office of the ASBTF (AM)
- Office of Budget (AML)
- Office of Information Resources Management (AMM)
- Office of Finance (AMS)

Section AM.20. Functions: 1. Immediate Office of the Assistant Secretary for Budget, Technology, and Finance/Chief Financial Officer (AM). Provides executive direction to OBTF components. The ASBTF is the principal adviser to the Secretary on all aspects of budgetary and financial management and information technology. By delegation from the Secretary, the ASBTF/CFO exercises full Department-wide authority of the Secretary in the assigned areas of responsibility to include all responsibilities provided by the Chief Financial Officers Act of 1990. This includes the approval of the job descriptions and skill requirements, and the selection of OPDIV CFOs as well as participation with the OPDIV Head in the annual performance plan/evaluation of the OPDIV CFO. In addition, the ASBTF/CFO provides Department-wide policy guidance on the qualifications, recruitment, performance, training, and retention of all financial management personnel. The ASBTF manages the Chief Information Officer (CIO) and all functional responsibilities included in the Clinger-Cohen Act.

2. Office of Budget (AML): The Office of Budget: (1) Advises and supports the Secretary and the Assistant Secretary for Budget, Technology and Finance/CFO and oversees the preparation of the Departmental budget estimates and forecasts resources required to support programs and activities of the Department; (2) analyzes budgetary and financial management implications of new or proposed legislation, programs or activities; (3) appraises program activities and operations in terms of policies, goals and objectives of the Department; (4) operates HHS' integrated funding system; (5) recommends and administers policies and procedures for allocation and control of employment ceilings; (6) establishes and monitors audit management policy for the Department and prepares reports to Congress on audit resolution management; (7) develops and executes Department-wide procedures relating to implementation and management of Government Performance and Results Act (GPRA); (8) responsible for the Office of the Secretary activities under the Paperwork Reduction Act; (9); serves as the focal point for OS budget operations, providing assistance for the development of budget policy and management of positions and financial resources for the OS; (10) manages audit follow-up and resolves issues relating to audit resolution management in the OS; (11) with particular reference to the Office of the Secretary (OS), is responsible for the overall formulation and execution of the OS budget; (12) serves as the focal point for OS budget operations, providing assistance for the development of budget policy and management of positions and financial resources for the OS; and review proposed recommendation on draft regulations, proposed legislation, reorganization, and delegations of authority proposal.

3. Office of Information and Resources Management (OIRM): The Deputy Assistant Secretary for Information Resources Management (DASIRM), who is also the Deputy CIO, heads the Office of Information Resources Management (OIRM). OIRM provides the Secretary and the Assistant Secretary for Budget, Technology, and Finance (ASBTF) and the Chief Information Officer (CIO) with strategic planning, information resources management and technology policy, architecture, investment review, and Office of the Secretary (OS) computer operations management support. More specifically, OIRM, in collaboration with the HHS agencies and Staff Divisions, (1) develops and updates the Information Technology Five Year Strategic Plan; (2) develops and coordinates information resources management policies applicable across the Department and the Office of the Secretary, including the creation, handling, storage, dissemination, and disposition of information; (3) leads the development and implementation of an enterprise information infrastructure across the Department (including a Departmental information technology architecture and information technology-based services for the Office of the Secretary's clients and employees); (4) manages risks associated with major information systems and information technology; (5) evaluates major investments in information technology based on return on investment and is responsible for their subsequent periodic review; (6) guides and oversees the development of information systems and communications networks; (7) leads e-government activities to achieve strategic improvements in service in the following areas: Government to citizen, Government to business, Government to Government, and internal efficiency and effectiveness; and (8) provides data processing and communications equipment for the Office of the Secretary and implements and maintains standards office automation applications running on the OS network.

4. Office of Finance (AMS): The Office of Finance is headed by the Deputy Assistant Secretary for Finance and is also the Deputy Chief Financial Officer: (1) Advises and supports the Secretary and the Assistant Secretary for Budget, Technology, and Finance/CFO on all aspects of financial activities across the Department; (2) oversees, monitors and evaluates the design, development, operation, and enhancement of Department-wide and component accounting systems; (3) coordinates CFO activities and reports throughout HHS including the preparation of audited financial statements and the preparation of the annual CFO report for submission to the ASBTF/CFO; (4) in coordination with other ASBTF components, participates in the clearance/approval

process for program information systems that provide financial and/or program performance data which are used in financial statements; (5) provides advice to the ASBTF/CFO on approval of the job descriptions and skills requirements for OPDIV CFOs and on the approval of the selection of OPDIV CFOs; (6) provides advice to the ASBTF/CFO who participates with the OPDIV Head in the annual performance plan/evaluation of the OPDIV CFO; (7) provides advice to the ASBTF/CFO on the qualifications, recruitment, performance, training and retention of all financial management personnel; (8) serves as the Departmental liaison with GAO, OMB, Treasury, and other Federal agencies on financial matters; (9) maintains Departmental finance and accounting standards; (10) resolve monetary findings involving management systems; (11) directs regional review and negotiation of cost allocation plans and indirect cost rates; (12) in coordination with the Office of Budget, recommends and implements Departmental Budget execution policies and procedures, and serves as the focal point dealing with OMB on these matters; (13) manages the day-to-day finance and accounting activities of the Office of the Secretary and other Departmental components as determined by the ASBTF/CFO.

C. Delete Chapter AML, ''Office of Budget,'' in its entirety and replace with the following:

Section AML.00 Mission: The Office of Budget provides advice and support to the Secretary and the Assistant Secretary for Budget, Technology, and Finance on matters pertaining to: formulation of the HHS and President's budgets, presentation of budgets and reconciliation legislation to OMB and the Congress, and resolution of issues arising from the execution of final appropriations.

Section AML.10 Organization: The Office of Budget is headed by the Deputy Assistant Secretary for Budget who reports to the Assistant Secretary Budget, Technology and Finance/Chief Financial Officer and includes the following:

- Division of Discretionary Programs (AML1)
- Division of Health Benefits and Income Support (AML3)
- Division of Budget Policy and Management (AML4)
- Division of Program Integrity and Accountability (AML2)

Section AML.20 Functions: 1. Division of Discretionary Programs: The Division—a. Provides analytical services and assistance to the Secretary, the Assistant Secretary for Budget, Technology, and Finance, and Department OPDIV heads in their budgetary management of the Department's principal discretionary programs including science and health services programs administered by the Public Health Service components; and social service programs of the Administration for Children and Families and the Administration on Aging.

b. Reviews, budgets, and related requests, for resources, and analyzes plans and proposals for new or alternative legislation.

c. Analyzes proposed regulations, reorganizations, or program initiatives to determine their policy, resource and management implications.

d. Proposes recommendations on draft regulations, proposed legislation and reorganization proposals.

e. Proposes budget options and policy initiatives as necessary to achieve program objectives established by the Secretary.

f. Assists in the development of strategies for the presentation of the budget to the Office of Management and Budget and the Congress and develops materials for key Departmental officials who testify at hearings before these bodies.

g. Provides guidances to OPDIVs and STAFFDIVs in the formulation of their budgets.

h. Conducts special reviews and analyses to examine assigned OPDIV and STAFFDIV program operations and management effectiveness.

2. Division of Health Benefits and Income Support: The Division—a. Provides analytical services and assistance to the Secretary, the Assistant Secretary for Budget, Technology, and Finance, and the Department OPDIV heads in the budgetary management of the Department's principal entitlement programs including Medicare, Medicaid, Family Support Payments and other entitlements in support of children and families.

b. Reviews budget and related requests for resources; analyzes plans and proposals for new legislation, regulations, or program initiatives to determine their resource, policy, and management implications; proposes recommendations for the Office of Budget on budget requests, draft regulations, proposed legislation, and reorganization proposals.

c. Assists the Secretary, the Assistant Secretary of Budget, Technology, and Finance and the OPDIV heads in evaluating programs and budgetary proposals by developing reliable cost projections for legislative and planning proposals, and ensuring that proposals are consistent with approved plans and policies.

d. Coordinates the preparation of budget estimates and forecasts of resources required to support the programs and operations of the Department.

e. Reviews reprogramming requests and recommends appropriate action to the Office of Budget.

f. Provides guidance in budget formulation for the appropriate OPDIV.

g. Conducts special management reviews and analyses, and develops management options to ensure efficient and effective program operations and to encourage management improvements.

h. Proposes budget options and policy initiatives as necessary to achieve program objectives established by the Secretary.

i. Assists in the development of strategies for presentation of the budget to the Office of Management and Budget and the Congress and develops materials for key Department officials who testify at hearings before these bodies.

3. Division of Budget Policy, Execution and Management: The Division—a. Directs the formulation and presentation of the HHS budget by developing and promulgating to the OPDIVs and others the policies, procedures, guidance, and schedules for preparing budget submissions.

b. Coordinates the presentation of the Department's budget to Congress including preparation and submission of justifications, reports, significant items, and crosscutting materials; preparation of the Secretary's testimony before the Appropriations Committees; and coordination of transcripts, questions for the record, and other hearing materials.

c. Provides advice and analysis to support Department-wide budget decision-making.

d. Maintains active communication with Department budget officers with regard to external budget events.

e. Manages a computerized budget information system reflecting data on HHS-wide basis and coordinates OPDIV input into this system.

f. Provides direct staff support to the Secretary in preparation for appropriation hearings and other budget related presentations and briefings.

g. Actively communicates with the Budget and Appropriations Committees in the Congress and provides intelligence and analyses of budget decisions to senior HHS staff and the Operating Divisions.

h. Prepares guidelines for determining funding levels under continuing resolutions.

i. Coordinates preparation of guidelines governing reprogrammings, transfers between accounts, and other crosscutting funding methods; provides recommendations and staff support in processing crosscutting funding proposals.

j. Analyzes and prepares reports on HHS performance in achieving streamlining and FTE reduction goals; provides expert advice on Departmentwide staffing policy.

k. Provides leadership and direction in the Department-wide review, analysis and appraisal of financial elements of program execution and the development and execution of policies related to efficient allocation, expenditure and control of funds.

l. Coordinates and tracks outlay projections: (1) To assist OMB in the continuing effort to monitor spending and to thereby improve the management of the Government's overall cash and debt operations; and (2) in support of formulation of the budget, including the maintenance of HHS ceiling controls and the development of outlay estimates shown in the President's Budget for controllable programs.

m. Promulgates Departmental spending policies, especially in the event of Continuing Resolutions and possible suspension of operations due to the failure of the Congress to enact appropriations on time and works with agency budget officers and the Office of Budget in formulating agency funding plans.

n. Maintains a system of Department-wide budget execution, including the management and control of the apportionment of funds in accordance with the requirements of the Anti-Deficiency Act and OMB regulations; and requests and monitors the receipt of Treasury warrants.

o. Serves as principal staff advisor to the OBTF on all matters involving budget execution.

p. Acts as liaison with the Office of Management and Budget, the Treasury Department, the Congressional Budget Office, and other agencies on matters involving budget execution.

q. Responsible for the development and maintenance of a system of financial information which involves the collection, organization, and maintenance of financial data in electronic form as well as the development of reporting mechanisms for making the financial information useful and available for decision making.

4. Division of Program Integrity and Accountability: The Division—a. Reviews and analyzes the budgets of the Office of Inspector General (OIG) and Office for Civil Rights (OCR). Prepares special analyses of OIG and OCR budgets for the purpose of evaluating capacity and determining if alternative approaches are feasible. These analyses would usually be for the use of the Deputy Assistant for Secretary Budget, the Assistant Secretary for Budget, Technology and Finance, and the Secretary. Monitors Congressional appropriations hearings in which the OIG and OCR are participants.

b. Establishes Department policy in the management of Inspector General Reports and audits.

c. Manages, in accordance with the Paperwork Reduction Act of 1980, as amended, the OS activities related to the review and approval of all public use reports and record-keeping requirements which impose a paperwork burden on the public. Develops policies for and manages the OS Information Collection Budget and the Information Collection Budget process. Develops policies and procedures for the OS and carries out analytical and oversight activities related to the Department's paperwork burden reduction efforts.

d. Provides staff assistance to the Assistant Secretary for Budget, Technology and Finance and the HHS Operating Divisions in the implementation, management and analysis for: (1) Strategic planning and for the development and implementation of performance measures under the Government Performance and Results Act (GPRA); and (2) budget related performance planning and annual performance plans required under the Government Performance and Results Act (GPRA).

e. Represents the Department in government-wide activities to implement the development and implementation of performance measures under GPRA and budget-related GPRA performance planning policies, requirements and processes.

f. Provides special management review services for selected activities.

g. Provides staff assistance to the Secretary, the Assistant Secretary for Budget, Technology and Finance, the Service and Supply Funds (SSF) Board of Directors, OPDIV Budget Officers and STAFFDIV Heads in the budgetary and financial management of the Service and Supply Fund.

h. Provides for budget policy management and financial integrity of the SSF in the provision of Departmental common use administrative services.

i. Assists in the planning and preparation of the SSF budget for presentation to the SSF Board, the Office of Management and Budget, and Congress.

j. Prepares apportionment requests for the Services and Supply fund.

D. Make the following changes to Chapter AMM, ''Office of Information and Resources Management,'' delete Section AMM.00 Mission in its entirety and replace with the following:

Section AMM.00 Mission: Office of Information and Resources Management. The Office of Information Resources Management (OIRM) provides the Department and the Office of the Secretary with information resources management and technology policy, strategic planning, architecture, investment review, e-government guidance, and Office of the Secretary (OS) computer operations management support. The Office of Information Resources Management (OIRM) advises the Secretary and the Assistant Secretary for Budget, Technology, and Finance (ASBTF) and the Chief Information Officer (CIO) on information resources and information technologies to accomplish Department goals and program objectives. The Office represents the Department to central management agencies (e.g., the Office of Management and Budget, General Accounting Office); exercises delegated authorities and ensures adherence to any other applicable laws, Executive Orders, and oversight agency mandates; and promotes improved management of Departmental information resources and technology. Delegated authorities and applicable laws include the Information Technology Management Reform Act of 1996, the Paperwork Reduction Act of 1995, the Computer Matching and Privacy Act of 1988, the Computer Security Act of 1987, the National Archives and Records Administration Act of 1984, the Competition in Contracting Act of 1984, the Federal Records Act of 1950, OMB Circular A–130: Management of Federal Information Resources, the Government Information Security Reform Act, and the Government Printing and Binding Regulations issued by the Joint Committee on Printing.

E. Delete Chapter AMS. ''Office of Finance,'' in its entirety and replace with the following:

Section AMS.10 Mission: The Office of Finance is headed by the Deputy Assistant Secretary, Finance, who is also the Deputy Chief financial Officer and reports to the Assistant Secretary for Budget, Technology and Finance/

Chief Financial Officer. The Office of Finance provides financial management advice and leadership to the Secretary and the Assistant Secretary for Budget, Technology and Finance, and the Operating Divisions CFOs.

Section AMS.20 Organization: The Office of Finance is headed by the Deputy Assistant Secretary for Finance who is also the Deputy Chief Financial Officer and reports to the Assistant Secretary for Budget, Technology and Finance. The Office includes the following:

- Immediate Office (AMS)
- Office of Financial Policy (AMS1)
- Program Management and Systems Policy Office (AMS4)
- Office of Audit Resolution and Cost Policy (AMS5)

Section AMS.20 Functions: Immediate Office (AMS) The Immediate Office is responsible for: (1) Standards for financial systems and financial reporting including audited financial statements in conformance with government wide accounting concepts and standards; (2) cash and credit management, debt management, payment management including disbursement activities and functions, (3) the design and development of Department-wide and component financial systems; (4) the preparation of the HHS Financial Management Status Report and Five Year Plan and the HHS Annual Report including financial statement and discussion and analysis and performance measures; (5) the development of outcome-based performance measures and performance plans through facilitation and training forums and best practices; (6) in coordination with other ASBTF components, participates in the clearance/approval process for program information systems that provide financial and/or program performance data which are used in financial statements; (7) approves the job descriptions and skill requirements for OPDIV CFOs, on the selection of OPDIV CFOs, and provides advice to the ASBTF/CFO who participates with the OPDIV Head in the annual performance plan/evaluation of the OPDIV CFO; and on the qualifications, recruitment, training and retention of all financial management personnel. In addition, improve financial performance by implementing a unified financial management system across HHS and ensure the preparation of financial statements that accurately represent HHS' financial condition.

2. Office of Financial Policy (AMS1): The Office of Financial Policy comprises the Division of Financial Management Policy (DFMP). (1) Division of Financial Management Policy (AMS11). The Division (a) Develops Department-wide policies, procedures, and standards for financial management areas including cash management, credit management, debt management, payment and disbursement activities and functions, and promulgates these and related government-wide financial management requirements through the Departmental Staff Manual system;

(b) Establishes a financial management planning process for the development of strategic and tactical plans and prepares the Department's Annual Financial Management Status Report and 5 Year Plan under the CFO Act;

(c) Provides support to the Operating Division Chief Financial Officers for financial planning and improvement initiatives;

(d) Serves as principal staff advisors on fiscal and accounting policy matters to the Office of Finance;

(e) Maintains liaison with the Office of Management and Budget (OMB), the Treasury Department, the General Accounting Office (GAO), the General Services Administration and other agencies on all financial management policy matters;

(f) Recommends policy and maintains a system for tracking and improving cash and credit management and debt collection performance throughout the Department;

(g) Establishes a financial management planning process for providing guidance and financial management indicators that enable the ASBTF/CFO to evaluate the financial management programs and activities of the Department;

(h) Prepares the annual HHS report on CFO activities as guided by the DASF/Deputy CFO.

3. Program Management and Systems Policy Office (AMS4): The Program Management and Systems Policy Office will be responsible for overseeing implementation of a unified financial management system consistent with the Secretary's directive. These responsibilities include:

a. Serve as a focal point for (1) overseeing the design, development, and implementation of the unified financial management system; and the development of life-cycle and budgetary plans; (2) monitoring the milestones and schedules as well as budget expenditures; and (3) the mediation and coordination of activities throughout all levels of HHS.

b. Ensure that all Federal accounting concepts and standards, as well as all HHS accounting policies and procedures are implemented throughout the unified financial management system.

c. Ensure that business requirements are met, the future direction of the initiative is consistent with HHS planning, and the status of the project is communicated to internal and external organizations.

d. Oversee a comprehensive program of change management that includes departmental communication, training plans and human resource issues.

e. Coordinate with workgroups to maximize the input from the cross-functional areas of HHS into the implementation process.

f. Oversee all risk management plans to ensure that risks are identified and mitigation strategies are developed.

(1) Division of Accounting and Fiscal Policy (AMS41). The Division: (a) Develops uniform business rules, data standards and accounting policy and procedures in support of new financial systems implementations. Ensures the development of ongoing accounting policy that further supports the consistent development and implementation of these systems;

(b) In collaboration with the Office of Financial Policy, provides advice and assistance to OPDIVs and STAFFDIVs on financial accounting and related fiscal matters and serves as principal advisor to the DASF on these matters as they relate to financial systems implementations;

(c) Maintains liaison with the Office of Management and Budget (OMB), the Treasury Department, the General Accounting Office (GAO), and other agencies on matters involving accounting and fiscal related matters as it relates to financial systems implementations;

(2) Division of Financial Systems Policy (AMS42). The Division: (a) Develops department-wide policies and standards for financial and mixed financial systems;

(b) Provides advice and serves as the focal point with the Federal control agencies on financial systems compliance matters;

(c) Provides for the establishment of Department-wide financial definitions and data structures;

(d) Provides for the administration of a data integrity and quality control program to ensure compliance with applicable Federal directives, Departmental financial systems policy and automated financial data exchange requirements;

(e) Oversees, monitors, evaluates, and recommends approval for the design, implementation, operation, and

enhancement of Department-wide and component accounting and financial management systems;

(f) In collaboration with the Office of Financial Policy, serves as principal staff adviser to the Office of Finance on all financial systems related matters;

(g) Maintains liaison with the Office of Management and Budget, the Treasury Department, the General Accounting Office, and other agencies on matters involving financial systems.

4. Office of Audit Resolution and cost Policy (AMS5): The Office of Audit Resolution and Cost Policy provides leadership in the areas of resolving audits and managing cost policy. The Office has functional responsibility for cost principles and Department-wide cost policies and procedures affecting grants and contracts. In addition, the Office is responsible for resolving crosscutting audit findings and the following:

a. Serves as the Departmental liaison and maintains working relationships with OMB and other Federal agencies in the development of government-wide cost principles and Department-wide audit resolution policies; maintains similar relationships with associations of States, universities and other grantee and contractor organizations.

b. Reviews and resolves audit reports containing monetary and/or systemic findings of grantee and contractor organizations affecting the programs of more than one Operating or Staff Division of Federal agency. Conducts or arranges for additional reviews as needed.

c. Coordinates where necessary with other affected Federal agencies to establish a uniform Federal position on the actions needed to be taken and negotiates resolution on behalf of all Federal Departments and agencies.

d. When deemed necessary to protect the interests of the Department, makes recommendations to the Secretary, the ASBTF and other officials on safeguards or other actions against a grantee or contractor, where the organization is unwilling or unable to correct serious deficiencies in a timely manner.

e. Provides and arranges for technical assistance and/or training programs to grantees, contractors, and other Operating and Staff divisions on audit resolution, cost reimbursement and financial management of grants and contracts.

f. Upon request, reviews and approves accounting or other systems developed by grantees and contractors to meet Federal cost principle requirements.

F. Delete the following Chapters: Chapter AMG, ''Office of Grants and Acquisition Management,'' Chapter AMP, ''Office of Human Resources Management,'' and Chapter AMR, ''Office of Facilities Services''; and under Chapter AML, ''Office of Budget'' delete the Office of Equal Employment Opportunity (AML–1), and transfer these components to the newly established Chapter, ''Office of the Assistant Secretary for Administration and Management (AJ).''

II. Under Part A, establish a new Chapter AJ, to read as follows:

Office of Assistant Secretary for Administration and Management (AJ)

AJ.00 Mission
AJ.10 Organization
AJ.20 Functions

Section AJ.00 Mission: The Office of the Assistant Secretary for Administration and Management (OASAM) performs for the Secretary the administrative management functions (exclusive of financial and information resources management) of the Department. Manages the human resources, equal employment opportunity, acquisition, grants, and general management activities of the Department. Provides leadership and oversight direction to the activities of the Program Support Center. Provides resource management and equal opportunity services to the Office of the Secretary (OS) and is the head of the OS as an Operating Division.

Section AJ.10 Organization: The Office of the Assistant Secretary for Administration and Management is under the direction of the Assistant Secretary for Administration and Management, who reports to the Secretary and consists of the following components.

- Immediate Office of the Assistant Secretary for Administration and Management (AJ)
- Office of Human Resources (AJA)
- Office of Grants and Acquisition Management (AJB)
- Office of Management and Operations (AJC)

Section AJ.20 Functions:

A. Immediate Office of the Assistant Secretary for Administration and Management (AJ). Provides leadership, policy, guidance and supervision, as well as coordinating long and short range planning for the Office of the Assistant Secretary for Administration and Management.

B. Office of Human Resources (AJA):

Section AJA.00 Mission: The Office of Human Resources (OHR) provides leadership in the planning and development of personnel policies and human resource programs that support and enhance the Department's mission. Provides technical assistance to the Operating Divisions (OPDIVs) in building the capacity to evaluate the effectiveness of their human resource programs and policies. Serves as the Departmental liaison to central management agencies on topics relating to EEO and human resources matters.

Section AJA.10 Organization: The Office of Human Resources (OHR), headed by a Deputy Assistant Secretary for Human Resources who reports to the Assistant Secretary for Management and Administration, and consists of the following components:

- Immediate Office (AJA)
- Personnel Programs Group (AJA1)
- Equal Employment Opportunity Programs Group (AJA2)

Section AJA.20 Functions: 1. The Immediate Office of Human Resources (AJA): Provides leadership to the development and assessment of the Department's human resources programs and policies. In coordination with the Operating Divisions, designs human resource programs that support and enhance the HHS missions. Provides technical assistance to the OPDIVs in building the capacity to evaluate the effectiveness of their human resource programs and policies, including the development of performance standards. On behalf of the Department's Director of Equal Employment Opportunity, adjudicate complaints of discrimination. Serves as Departmental liaison to central management agencies exercising jurisdiction over human resources and EEO matters.

2. Personnel Programs Group (AJA1): Provides leadership to the planning and development of personnel policies and programs that support and enhance the Department's mission. In coordination with the OPDIVs, formulates HHS policies pertaining to employment, compensation, position classification, employee benefits, performance management, employee development, and employee and labor relations. Provides technical assistance to the OPDIVs in the proper application of Federal personnel laws, regulations, and policies. Provides strategic advice to the Deputy Assistant Secretary for Human Resources, the Assistant Secretary for Administration and Management, and the Secretary on those initiatives having major workforce implications. Analyzes workforce data and trends to support strategic workforce planning and restructuring efforts, at both the Departmental and OPDIV levels. Promotes and supports OPDIV capacity building efforts, including innovative approaches to personnel program

management. Serves as the Department's focal point for liaison on personnel and labor relations issues with the Office of Personnel Management, the General Accounting Office, the Merit Systems Protection Board, and the Federal Labor Relations Authority.

3. Equal Employment Opportunity Programs Group (AJA2): Provides leadership to the planning and development of affirmative employment policies and programs that recognize and value the diversity of the Department workforce and promote a work place free of discrimination. Provides technical assistance and enabling tools to the OPDIVs in the design of innovative, effective affirmative employment programs. Keeps top HHS officials appraised of workforce demographics and recommends positive interventions as needed. Prepares, for the Director of Equal Employment Opportunity, final Departmental decisions on the merits of complaints of discrimination, and prepares proposed dispositions of complaints presenting conflicts of interest for OPDIV and STAFFDIV officials. Serves as the Department's focal point for liaison with the Office of Personnel Management, the Equal Employment Opportunity Commission, and the General Accounting Office on issues pertaining to affirmative employment and discrimination complaints.

C. Office of Grants and Acquisition Management (AJB):

Section AJB.00 Mission: The Office of Grants and Acquisition Management (OGAM) provides functional management direction in the areas of grants management, acquisition and logistics. Provides Department-wide leadership in these areas through policy development, oversight and training. Awards and administers contracts in support of the program needs of the Office of the Secretary. Represents the Department in dealings with OMB, GSA and other Federal agencies and Congress in the areas of mandatory and discretionary grants, procurement and logistics. Fosters creativity and innovation in the administration of these functions throughout the Department.

Section AJB.10 Organization: The Office of Grants and Acquisition Management (OGAM), headed by a Deputy Assistant Secretary for Grants and Acquisition Management who reports to the Assistant Secretary for Administration and Management, consists of the following components:

- Immediate Office (AJB)
- Logistics Policy Staff (AJB1)
- Office of Acquisition Management (AJB2)
- Office of Grants Management (AJB3)
- Office of Small and Disadvantaged Business Utilization (AJB4)

Section AJB.20 Functions: 1. Office of the Deputy Assistant Secretary for Grants and Acquisition Management (AJB): The Office of the Deputy Assistant Secretary for Grants and Acquisition Management provides leadership, policy, guidance and supervision, as well as coordinating long and short-range planning to constituent organizations.

2. Logistics Policy Staff (AJB1): Serves as the Department's focal point and liaison with the Operating and Staff Divisions for policy development, technical assistance, oversight and training in the area of logistics. The Staff is responsible for the following:

a. Formulates Department-wide logistics policies governing the management of personal property throughout the Department.

b. Provides advice and technical assistance on logistics activities and policy matters to the Department's Operating Divisions.

c. Monitors the adoption of logistics policies by the Department's Operating Divisions to ensure consistent policy interpretation and application.

d. Oversees the implementation of logistics functions throughout the Department.

e. Develops, participates in and evaluates logistics training programs for Department staff.

f. Researches, analyzes and tests innovative ideas, techniques and policies in the area of-logistics.

g. Serves as the Department's liaison in the area of logistics and maintains working relationships with OMB, GSA and other Federal agencies to coordinate and assist in the development of policy.

3. Office of Acquisition Management (AJB2): The Office of Acquisition Management provides leadership in the area of acquisition through policy development, oversight and training. The Office awards and administers contracts in support of the program needs of the office of the Secretary. The office is responsible for the following:

a. Formulates Department-wide acquisition policies governing procurement activities. Publishes these in regulations and manuals. Recommends and participates in development of government-wide acquisition policy.

b. Provides advice and technical assistance on procurement activities and policy matters to the Department's Operating and Staff Divisions.

c. Develops, participates in and evaluates the procurement training and certification program for Department's procurement staff; develops and participates in training activities for the Department's program staff who act as project officers on the Department's contracts.

d. Monitors the adoption of acquisition policies by the Department's Operating and Staff Divisions to ensure consistent policy interpretation and application.

e. Conducts Performance Measurement of the Department's procurement system to ensure compliance with procurement laws and policies and efficient acquisition of the Department's program needs.

f. Makes studies of problems requiring creation of new policies or revision of current policies, including the application of Departmental management controls and reports related to the Department's procurement activities; resolves issues arising from implementation of those policies; maintains similar relationships and associations with public and private contractor organizations.

g. Researches, analyzes and tests innovative ideas, techniques and policies in the area of acquisitions. Establishes and directs ad hoc teams to work on special projects to develop creative approaches to problems in the area of acquisition.

h. Serves as the Department's liaison in the area of acquisitions and maintains working relationships with OMB, GSA, GAO, and other Federal agencies to coordinate and assist in the development of policy and to participate in government-wide tests of procurement innovations.

i. Conducts special projects to develop improved mechanisms for Department-wide management of procurement.

j. Plans, directs, and carries out the centralized contracting program for the Office of the Secretary and the Administration on Aging. In the case of certain consolidated and centralized commodities and services (including information technology) also provides contract support for the Administration on Children and Families as well as other components of the Department.

k. Administers and manages performance of the contracts of the Office of the Secretary to ensure that it receives the timely and quality performance and the products for which it has contracted.

l. Is responsible for award and administration of contracts. Is authorized to enter into contracts at the micro-purchase, simplified acquisition,

and major purchase (purchases in excess of $100,000.00) levels.

m. Tests innovative ideas and techniques to develop improved procurement methodologies.

4. Office of Grants Management (AJB3). The Office of Grants management provides leadership in the area of mandatory and discretionary grants through policy development, oversight and training. The Office has functional responsibility for Department-wide grants policies and grant regulations. In addition, the Office is responsible for oversight of the HHS grants management operations and the following:

a. Manages oversight of the award and administration of mandatory and discretionary grants and other forms of Federal financial assistance throughout the Department.

b. Formulates Department-wide grant policies governing the award and administration of grant activities. Publishes these in regulations and other directives.

c. Monitors the adoption of grant policies and procedures by the Department's Operating and Staff Divisions to ensure consistent policy interpretation and applications.

d. Provides advice and technical assistance to the Department's Operating and Staff Divisions and to the general public on matters relating to the administration of grants and other forms of Federal financial assistance.

e. Develops, participates in and evaluates grants management training programs for Department staff.

f. Serves as the Department's liaison in grants and maintains working relationships with OMB and other Federal agencies to coordinate and assist in the development of government-wide grant policies.

g. Conducts special studies of grants management issues to identify and implements improvements in the way the Department awards and administers grants and other forms of Federal financial assistance; and designs and assists in execution of demonstrations, experimentation and tests of innovative approaches to grants management.

h. Develops, analyzes and tests innovative ideas, techniques and policies in grants management. Fosters creativity in the administration of grants.

i. Establishes and manages improved grants management information and monitoring systems.

j. Establishes and manages training and certification programs for grants management professionals throughout the Department.

5. Offices of Small and Disadvantaged Business Utilization (AJB4): a. Has responsibility within the Department for policy, plans, and oversight of execution of the functions under section 8 and 15 of the Small Business Act as amended and Executive Orders 12073 and 12138, relating to preference programs for small business, disadvantaged businesses, labor surplus area concerns, and women-owned businesses. Under provision of Public Law 95–507, the Director reports directly to the Deputy Secretary. Pursuant to Deputy Secretarial direction, the day-to-day operational review will be provided by the Deputy Assistant Secretary for Grants and Acquisition Management to ensure effective departmental coordination and execution of these programs.

b. Acts as the advocate for the Secretary and Deputy Secretary within the Department for matters relating to sections 8 and 15 of Small Business Act and Executive Orders 12073 and 12138 and represents the Department in dealing with other Federal agencies on those matters.

c. Acts as focal point and advocate for the small business, disadvantaged business, labor surplus area and women-owned business firms in their dealings with the Department.

d. Formulates, recommends and monitors implementation of policies for the Department's small business, Small Business Innovation Research, disadvantaged business, labor surplus area, and women-owned business programs.

e. Coordinates and prepares the Department's goals for assigned programs, recommends Secretarial approval of such goals and subsequent to Secretarial approval, negotiates, establishes and reports on goals for the assigned programs with the cognizant Federal agencies.

f. Encourages the awarding of contracts and subcontracts to small business, disadvantaged business, labor surplus area, and women-owned business firms by providing information and assistance to all of the Department's organizational units.

g. Prepares documentation and reports to the Executive Office of the President, the Congress, Office of Management and Budget, the Small Business Administration, and other agencies, as required.

h. Ensures effective implementation by the Department of mandatory plans and/or contract clauses as required by Public Law 95–507 for small business and disadvantaged business firms and monitors the activities relating to such plans.

i. Provides input for coordinated Departmental positions on proposed legislation and Government regulations on matters affecting cognizant socioeconomic programs and maintain liaison with Congress through established Departmental channels.

j. Manages the Department's Small Business Innovation Research Program (SBIR) established under Public Law 97–219 and provides liaison between the Department and the Small Business Administration on SBIR matters.

k. Oversees and monitors the Departmental review and screening of planned procurement by programs and procurement offices to ensure that preference programs are given thorough consideration throughout the decision-making process.

D. Office of Management and Operations (AJC):

Section AJC.00 Mission: The Office of the Management and Operations (OMO) provides advice on matters having to do with the provision of administrative services, resource and financial management services, facilities services, and equal employment opportunity services for the Office of the Secretary. Provides leadership and direction for the Program Support Center and its Director. Provides Department-wide leadership for reorganizations and delegation of authority, travel policy, and other management programs.

Section AJC.10 Organization: The Office of Management and Operations is headed by a Deputy Assistant Secretary for Management and Operations (DASOMO) who reports to the Assistant Secretary for Administration and Management, provides day-to-day, supervisory review of the Program Support Center and its Director, consists of the following components:

- Office of Departmental Management (AJC1)
- Office of the Secretary Executive Office (AJC2)
  - —Office of the Secretary Equal Employment Opportunity (AJC21)
- Office of Facilities Services (AJC3)

Section AJC.20 Functions: 1. Office of Departmental Management (AJC1): (1) Serves as the principal source of advice on all aspects of Department-wide organizational analysis includes: planning for new organizational elements; evaluating current organizational structures for effectiveness; and conducting the review process for reorganization proposals. (2) Manages the reorganization process for the Office of the Secretary (OS) requiring the Secretary's signature and the Assistant

Secretary for Administration and Management. (3) Administers the Department's system for review, approval and documentation of delegations of authority. Develops Department-wide policies and provides technical assistance on the use and application of delegations of authority. Advises senior officials within the Department on delegations of authority, coordinates review of proposed delegations requiring the Secretary's or other senior officials approval. Analyzes and makes recommendations related to legislative proposals with potential impact upon the Department's organizational structure or managerial procedures; (4) Manages the Departmental Standards Administrative Code (SAC) system, providing oversight, advice, and assistance to ensure codes are in accord with the current approved organization, (5) Develops Departmental policies pertaining to travel and provides oversight to the travel function in the Operating Divisions.

2. Office of the Secretary Executive Office (AJC2): The Office of the Secretary Executive Office (OSEO) will: (1) Provides budget and other financial services to Office of the Secretary Staff Divisions; (2) oversees all aspects of budget formulation and execution for the Office of the Assistant Secretary for Administration and Management; (3) maintains funds controls and coordination of billing and accounts related to the Secretary's dining room and the Immediate Office of the Secretary; (4) plans and directs the provision of centralized purchasing and contracting services for administrative supplies, technical, and research requirements for the OS; (5) provides staff assistance and guidance to OS staff on purchasing and contracting related to purchase order, credit card (MACC), etc.; (6) administer contracts sponsored by the OS; (7) provide advisory services in the areas of classification, staffing, disability hiring, and reasonable accommodation assistance, as well as other human resources services to OS Staff Divisions; (8) provides advice and guidance to officials and employees on employee benefits and services, awards, and related matters; (9) designs and develop programs related to workforce recruitment; (10) determines OS training needs and develops annual training plans to service those needs; (11) coordinates with the Program Support Center on requests for personnel actions, departure closeout processing, and payroll liaison;, as well as other human resources special projects; and (12) as required, conduct special human resources projects.

a. Office of the Secretary Equal Employment Opportunity (AJC21): The OS Officer of Equal Employment Opportunity assists the DAS/OMO in carrying out the delegated authority to establish and maintain equal employment opportunity programs within the Office of the Secretary. The Office is responsible for ensuring that all OS employment policies and actions are based on merit, without regard to race, color, religion, national origin, sex, age, or physical/mental disability. Major functions include: Pre-complaint counseling; formal complaint processing; affirmative employment planning and implementation; technical guidance and policy development. The functions of the office also include program efforts which focus on the Federal Women's Program, the Hispanic Employment Program, and the Program for People with Disabilities.

3. Office of Facilities Services (AJC3):

Section AJC3.00 Mission: The Office of Facilities Services (OFS) provides leadership and direction for real property management operations and provides Department-wide policy support for real property, space management, occupational safety and health, environmental and historic preservation responsibilities. Provides facilities management services to all HHS components in the Southwest Washington, DC complex. Advises senior Departmental officials on management issues related to the effective and efficient operations of the applicable programs and components. Acts as the Department's focal point with other Federal agencies and HHS Operating Divisions (OPDIVs) on policy and regulatory issues involving real property, space management, occupational safety and health, environmental and historic preservation activities for the Office of the Secretary (OS). Directs, plans, obtains, and coordinates building management, space management and design, systems furniture procurement and installation, safety and health and support services in the Southwest Washington, DC complex.

AJC3.10 Organization: The Office of Facilities Services is headed by a Director who reports to the Director, Office of Management and Operations, and consists of the following entitites:

Immediate Office (AJC3)
Division of Policy Coordination (AJC3A)
Division of Buildings Management (AJC3B)
Division of Security and Special Services (AJC3C)

AJC3.20 Functions: The Office of Facilities Services is responsible for the following functions:

1. The Office of the Director (AJC3) provides leadership, policy guidance and supervision as well as coordinating long and short range planning to constituent organizations.

2. Division of Policy Coordination (AJC3A): a. Establishes, maintains and promulgates HHS and OS policy for the HHS real property program. Establishes guidelines and procedures to monitor effectively the real property owned or leased by HHS.

b. Establishes guidelines to monitor the utilization of all space assigned to the Department by GSA.

c. Develops guidance to the OPDIVs on technical and facilities aspects of the HHS annual RENT budget. Provides oversight of OPDIV performance for this function and provides technical assistance on a Department-wide basis as required. Coordinates preparation among OPDIVs on facilities and space aspects, and collaborates with the office of Budget on final Department-wide RENT budgets, consistent with OMB and GSA guidance.

d. Establishes, maintains and promulgates HHS and OS policy for the occupational safety and health, and environmental programs. Provides oversight of OPDIV performance of these functions and provides technical assistance on a Department-wide basis as required.

e. Establishes, maintains and promulgates HHS and OS policy for the physical security program and provides technical assistance on a Department-wide basis as required.

f. Establishes, maintains, and promulgates HHS and OS policy for the historic preservation program. Provides oversight or OPDIV performance for this function and provides technical assistance on a Department-wide basis as required.

g. Establishes, maintains, and promulgates HHS and OS policy for the Health and Wellness, and Day Care Centers. Provides technical assistance on a Department-wide basis as required. Provides oversight of the HHS Health and Wellness Center at Headquarters.

h. Interprets Department of Energy policy on energy management issues and oversees implementation of energy related legislation within HHS.

i. Establishes information and reporting standards for all above listed programs. Collects, assembles, and analyzes required information for mandated reports to Congress, OMB, GSA and other Federal agencies.

3. Division of Buildings Management (AJC3B): a. Under delegation from GSA, is responsible for the physical plan operations and maintenance of the Hubert H. Humphrey Building

including procurement and administration of related contracts.

b. Coordinates with GSA on building operation and maintenance matters for HHS-occupied space in GSA controlled facilities in the Southwest Washington, DC complex.

c. Is responsible for the acquisition, disposition, allocation and monitoring of space for the OS in Washington, DC and for the OPDIVs in the Southwest Washington, DC complex.

d. Enforces compliance with Federal space utilization principles in the Southwest Washington, DC complex by the preparation of high quality space management plans and drawings, and the arrangement of quality and timely renovation work. Provides engineering and architectural services as well as oversight in support of Southwest Washington, DC complex facilities both through in-house staff and manages major renovation and system furniture installation projects, moves and space consolidations. Oversees the restoration and renovation of joint use areas in the HHH Building. Procures systems furniture including related design, installation and maintenance services for the Southwest Washington, DC complex.

4. Division of Security and Special Services (AJC3C): a. Oversees the OS and Southwest complex occupational safety and health programs, including procurement and administration of related contracts. b. Provides physical security for employees and facility protection in the HHH Building through the procurement and administration of guard services and equipment. Serves as liaison with GSA for physical security issues affecting HHS employers in GSA controlled space in the Southwest Washington, DC complex. c. Provides a variety of facility support services to the OS and OPDIVs in the Southwest Washington, DC complex, including the management of conference and parking facilities, the issuance and control of employee identification badges, and special events support; and d. serves as the focal point within OFS for the receipt and referral of customer requests for services and complaints related to building operations and facilities management matters and is responsible for monitoring the timely and efficient corrective action.

III. Continuation of Policy: Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to the Office of the Secretary, the HHS Management and Budget Office and the Program Support Center heretofore issued and in effect prior to the date of this reorganization are continued to full force and effect.

IV. Delegations of Authority: All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

V. Funds, Personnel and Equipment: Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies and other resources.

Dated: October 11, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–27006 Filed 11–1–01; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–02–05]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Tailoring Occupational Safety and Health Messages to Individual Health Construals—NEW—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The mission of the National Institute for Occupational Safety and Health is to promote safety and health at work for all people through research and prevention.

The overall goal of the current project is to examine the effectiveness of tailoring NIOSH web-based communications to the psychological characteristics of the individuals who receive the communications. Typically, NIOSH publications informing at-risk workers about health hazards and safety recommendations are distributed by mail using a printed format. However, the growing use of computers opens the door to a new format for distributing health and safety information to workers: Communication of health information via the Web. Importantly, web-based communication makes it possible to tailor health information to particular users. Past research has demonstrated that health-related behavior may be construed positively by an individual, in terms of wellness, or negatively, in terms in illness. The current project tests the effectiveness of message tailoring on this dimension.

This project will examine the effectiveness of tailoring a web communication based on the NIOSH document ''Stress* * *At Work'' (and additional occupational stress research) to users' personal construals of this issue in terms of wellness or illness. Health care workers, specifically nurses, have been selected as the target audience to receive these tailored messages on occupational stress as they frequently experience multiple, chronic, occupationally related stressors. One important source of occupational stress among nurses has been the move from the traditional inpatient, fee-for-service model to the outpatient, managed care model. The sweeping nature of this organizational change has dramatically altered the working conditions for an estimated 10 million healthcare workers in the United States and has left many healthcare workers, including nurses, without a sense of connection between their professional expectations and the goals of their organizations. Chronic occupational stress of this sort can lead to increased levels of depression among affected workers. Consequently, it is estimated that healthcare workers suffer from rates of depression 2–3 times higher than the general population. The corrosive effects of chronic stress can also leave workers more vulnerable to

incidents of acute stress. This is particularly important among healthcare workers, as research indicates that they are increasingly being exposed to incidents of violence and trauma on the job. As a result, healthcare workers have a significantly increased risk of developing posttraumatic stress disorder. Given the many occupationally related stress risk factors experienced by healthcare workers, the development of effective occupational stress interventions for health care workers is of the utmost importance. Therefore, this study will investigate ways to increase the effectiveness of occupational stress interventions targeted at nurses, the single largest healthcare worker group.

Through the use of message tailoring, the proposed project aims to increase health care workers' adherence to recommendations suggested by NIOSH to prevent and reduce the effects of occupational stress. In study 1, attitudinal predictors of occupational stress prevention/reduction behaviors will be assessed for registered nurses who view this issue as a wellness (health maintenance) issue versus an illness prevention issue. This data will be obtained from a sample of 500 registered nurses who will be asked to complete a mail survey assessing their attitudes and behaviors with regard to preventing and reducing workplace stress. In a second study, a web-based ''occupational stress'' document will be adapted from the NIOSH document ''Stress* * * at Work '' Two formats of this web-based document will be created that are tailored to nurses who construe the issue of workplace stress as a wellness issue, or as an illness issue. The impact of tailoring the message format to the nurse's construal of the issue of occupational stress will be examined in a laboratory setting where 300 participants will indicate whether they construe this issue in terms of maintaining wellness (positively) or in terms of illness prevention (negatively), and will then be randomly assigned to gain or loss frame web communications. The impact of the tailored messages on participants' attitudes and behavioral intentions with regard to occupational stress prevention and reduction will be assessed.

The results of this project should provide NIOSH with information about how to develop effective Web-based communication strategies using message tailoring. This should have the consequence of enhancing occupational safety and health attitudes and behaviors among at-risk workers.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden per response (in hours)	Total burden (in hours)
Nurses (Data collection #1)	500	1	20/60	167
Nurses (Data Collection #2):.				
Survey 1	300	1	30/60	150
Follow-up	300	1	5/60	25
Total				342

Dated: October 25, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–27528 Filed 11–1–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–02–06]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Annual Submission of the Quantity of Nicotine Contained in Smokeless Tobacco Products Manufactured, Imported, or Packaged in the United States—Renewal—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC). Oral use of smokeless tobacco represents a significant health risk, which can cause cancer and a number of noncancerous oral conditions, and can lead to nicotine addiction and dependence. The Office on Smoking and Health (OSH) within the National Center for Chronic Disease Prevention and Health Promotion, CDC has been delegated the authority for implementing major components of the Department of Health and Human Services' (HHS) tobacco and health program, including collection of tobacco ingredients information. HHS overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 *et seq.*, Pub. L. 99–252) requires that each person who manufactures, packages, or imports smokeless tobacco provide the Secretary of HHS annually with a report on the quantity of nicotine contained in smokeless tobacco products. This notice implements this nicotine reporting requirement. CDC is requesting OMB clearance to collect this information for three years. All companies are required to submit this information for all brands. A standard methodology for measurement of quantity of nicotine in smokeless tobacco has been developed.

The methodology (''Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products'') is intended to provide standardized measurement of nicotine, total moisture, and pH in smokeless tobacco products. This information should be submitted in the prescribed format. In addition, we ask that companies provide an electronic copy of this information on a floppy disk or CD–ROM.

Background

In 1989, the smokeless industry submitted a business review letter to the Department of Justice (DOJ), in accordance with 28 CFR 50.6. This letter requested approval of a collaborative industry effort to determine standard nicotine reporting. In January 1993, DOJ extended permission to the smokeless industry to begin the development of uniform methods for analyzing smokeless tobacco products for nicotine or moisture content. The first meeting of the work group, which represented the ten major domestic manufacturers of smokeless tobacco, was convened on July 7, 1993. After a series of meetings of the joint industry work group, a standard methodology was approved by the work group and submitted to OSH for approval. The protocol was revised by OSH based on individual comments received from peer reviewers and the Division of Environmental Health Laboratory Sciences, National Center for Environmental Health, CDC. There are no costs to respondents.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Tobacco Manufacturers	11	1	1,706	18,766
Total				18,766

Dated: October 25, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–27529 Filed 11–1–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9012–NC]

Medicare and Medicaid Programs; Plan to Create an Open and Responsive Federal Agency

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces our efforts to enhance our openness and responsiveness to all of our constituencies including Medicare and Medicaid beneficiaries and other individuals involved in their care, physicians, nurses, other health care providers, advocacy associations, and industry trade associations. We are making structural changes in the way we do business to build in processes that will enhance our ability to be responsive. This notice invites comments on our efforts to create an open and responsive agency.

We are proposing to issue quarterly provider updates that list provider-oriented regulatory documents and program instructions. We plan to release the quarterly provider update to provider associations first as a pilot and, at a later time, publish subsequent provider updates on our Web site on the first business day of each calendar quarter.

We are accepting comments about concerns or suggestions for improving our agency. We are particularly interested in specific suggestions on how we can improve our efforts to create an open responsiveness to better address the needs and concerns of all of our constituencies. We are not placing any time constraints for receipt of public comments.

ADDRESSES: In commenting, please refer to file code CMS–9012–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9012–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Anthony Mazzarella, (410) 786–7501.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. In order to review public comments, you *must* schedule an appointment by calling (410) 786–7197. To obtain entry to our facility, you *must* have a photo identification (preferably a driver's license).

I. Background

Our mission is to serve Medicare and Medicaid beneficiaries by assuring quality health care security for beneficiaries. In keeping with our mission, we are committed to reforming and strengthening our agency by creating an open responsiveness to the needs and concerns of all of our constituencies including Medicare and Medicaid beneficiaries and individuals involved in their care, physicians, nurses, other health care providers, advocacy associations, and industry trade associations.

II. Plan To Create an Open, Responsive Agency

We want to be a reliable Federal agency; one that is open and responsive to the needs of all of our constituencies. In our effort to enhance our responsiveness to Medicare and Medicaid beneficiaries and their health care providers, we are making structural changes in the way we do business to build in processes that enhance our ability to create an open and responsive Agency. We plan to focus on working openly with our stakeholders, soliciting their individual input and feedback, responding to requests for information in a more timely manner, and issuing a

quarterly provider update of all changes to Medicare regulations and instructions that affect providers.

Because our agency focus is to be open and responsive, we are creating mechanisms that will give our employees a greater opportunity to receive and act on feedback from our constituencies. First, we are establishing a series of open listening forums across the country to be chaired by our senior staff, so that we can hear directly from our constituencies about the impact that our regulations, policies, and programs have on them. We want to hear the concerns and individual suggestions for improvement from physicians and other health care providers, from the people who deal with us in communities and facilities from day to day, and from seniors who rely upon Medicare and Medicaid for their health care needs.

Second, we are creating open door listening forums chaired by our senior staff, and made up of our employees, to serve as principal points of contact for beneficiary and provider groups. Our goal in working with these groups is to build stronger relationships, improve their understanding of CMS, and generate ideas for program improvements and reform, as well as ideas about how we can better serve our beneficiaries. Individual senior staff members will serve as the primary contacts for the following stakeholders to bring issues and ideas about our programs and policies:

- Physicians.
- Hospitals.
- Rural providers.
- Nursing homes.
- Medicare+Choice organizations and other health plans.
- Nurses and allied healthcare professionals.
- Home health agencies and hospices.
- End-stage renal disease facilities and dialysis centers.

Third, we will work with each State at both the regional and central office level. A Medicaid/State Children's Health Insurance Program contact person for each State will troubleshoot and resolve disputes for Governors, State Medicaid Directors, and other high-ranking State officials. The contact person will be directly accountable to the Administrator and the Director of the Center for Medicaid and State Operations as they respond to State issues.

Fourth, we will form in-house expert teams across program areas to develop new ways of conducting business that will reduce administrative burdens and simplify our policies and regulations. These teams will look to reduce administrative burden on providers, eliminate complexity when possible, augment some of the individual suggestions we hear in our listening forums, and make Medicare more ''user-friendly.'' These expert teams will be coordinated with the Secretary's Regulatory Reform Initiative and the Secretary's Advisory Committee on Regulatory Reform.

Fifth, providers have advised us that it has become increasingly more difficult for them to stay abreast of the many new and changing instructions concerning our programs. We wish to make it easier for them to understand and comply with our regulatory documents and program instructions and to provide more predictability to program changes. Therefore, we are proposing to issue quarterly provider updates that list provider-oriented regulations we plan to publish in the coming quarter, as well as the **Federal Register** publication date and page reference for all regulations published in the previous quarter. The full text of our regulations is available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is *http://www.access.gpo.gov/nara/index.html.*

The first update serves as a pilot. In the pilot phase of this project, we have established several business objectives that we are testing with this release of the provider update. First, this update will be sent to provider groups and associations for their assessment as to its usefulness of content and format. Second, because of the complexity of the policy decisions associated with much of our regulatory work, we are taking an intermediate step towards enhancing the consistency of our regulatory publications. Specifically, we intend, to the extent practical, to publish regulations on a predictable cycle once a month. We plan to publish CMS business in the **Federal Register** on the fourth Friday of each month. In fact, each issue of the provider update will identify the specific days. We will work in good faith to follow the substance and timing of the provider update in the majority of cases. However, because some of our regulatory work has statutory publication dates that fall outside the fourth Friday of the month, we will continue to comply with the statutory requirements. For example, the public comment period for one of our major payment proposed rules closed the beginning of October. To effectively address the number of comments we anticipate and the complexity of the issues, the final rule titled, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2002 (CMS–1169–FC),'' will be published on November 1, 2001.

In addition, there may be other instances when it is not possible to follow the schedule. We will work hard to minimize these situations to the greatest extent possible.

Also, the provider update will include all instructions (program memoranda, manual transmittals, and Operational Policy Letters) that affect health care providers. These provider-oriented Medicare instructions will be implemented at the beginning of the quarter following the quarter in which the provider update is published. We are proposing to published future provider updates on our Web site, *http://www.cms.gov,* the first business day of each calendar quarter to ensure wider access to this information. We also welcome comments relative to this approach.

In many instances, the publication of the quarterly provider update will lengthen the advance notification period we presently give providers; we will generally create a uniform 90-day period of notice before implementation of coverage and payment changes. We believe the predictability and uniformity offered by set publication and implementation timeframes would significantly reduce the burden on the provider community that our current ''flow basis'' publication processes impose. Further, we believe the benefits gained from predictable publication and implementation timeframes would significantly outweigh the disadvantages of the delays in coverage and payment changes that may occur.

Sixth, we are planning to enhance our system of provider training on new requirements and the resolution of problems through formal training, satellite broadcasts, and web-based information.

Finally, we are revamping the process for developing, reviewing, and clearing all correspondence and, in particular, congressional correspondence. Our goal is to substantially reduce our response time to congressional inquiries by December 1, 2001; thus, greatly improving our responsiveness to our constituency.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact Statement

This notice does not require an impact analysis because it does not have an economic impact on small entities, small rural hospitals, or State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 7, 2001.

Thomas A Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–27700 Filed 11–1–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF–PA–HS–02–01A]

Discretionary Announcement of the Availability of Funds and Request for Applications for Select Service Areas of Early Head Start; Correction

AGENCY: Administration for Children, Youth and Families, ACF, DHHS.

ACTION: Correction.

SUMMARY: This document contains a correction to the Notice that was published in the **Federal Register** on September 20, 2001.

On page 48475, Appendix A, Part II, in the State of Missouri, in the County of St. Charles, in the FY 2002 funding level column, delete ''1,470,549'' and add ''1,497,549''.

On page 48476, Appendix A, Part II, in the State of New York, in the County of Bronx, in the FY 2002 funding level column, delete ''1,334,471'' and add ''1,322,291''. In the State of New York, in the County of Cattaraugus, in the FY 2002 funding level column, delete ''468,962'' and add ''511,079''. In the State of New York, in the County of Cattaraugus, in the FY 2002 funding level column, delete ''450,808'' and add ''568,205''. In the State of New York, in the County of Chenango, in the FY 2002 funding level column, delete ''468,962'' and add ''511,079''. In the State of New York, in the County of Monroe, in the FY 2002 funding level column, delete ''1,995,614'' and add ''2,173,928''. In the State of New York, in the County of Rensselaer, in the FY 2002 funding level column, delete ''670,221'' and add ''732,234''. In the State of New York, in the County of Steuben, in the FY 2002 funding level column, delete ''329,700'' and add ''349,700''. In the State of New York, in the County of Westchester, in the FY 2002 funding level column, delete ''941,224'' and add ''1,033,799''. In the State of New York, in the County of Erie, in the FY 2002 funding level column, delete ''1,277,058'' and add ''1,381,901''. In the State of New York, in the County of Schenectady, in the FY 2002 funding level column, delete ''1,057,663'' and add ''743,672''.

FOR FURTHER INFORMATION CONTACT: The ACYF Operations Center at 1–800–351–2293 or send an e-mail to *ehs@lcgnet.com*. You can also contact Sherri Ash, Early Head Start, Head Start Bureau at (202) 205–8562.

Dated: October 29, 2001.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 01–27610 Filed 11–1–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0336]

Schering Corp. et al.; Withdrawal of Approval of 51 New Drug Applications and 25 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 16, 2001 (66 FR 43017). The document announced the withdrawal of approval of 51 new drug applications (NDAs) and 25 abbreviated new drug applications (ANDAs). The document inadvertently withdrew approval of NDA 17–255 for DTPA (chelate) Multidose (kit for the preparation of Tc-99m pentetate injection) held by Nycomed Amersham Imaging, 101 Carnegie Center, Princeton, NJ 08540. FDA confirms that approval of NDA 17–255 is still in effect.

EFFECTIVE DATE: August 16, 2001.

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

In FR Doc. 01–20605 appearing on page 43017 in the **Federal Register** of Thursday, August 16, 2001, the following correction is made: On page 43018, in the table, the entry for NDA 17–255 is removed.

Dated: October 11, 2001.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 01–27520 Filed 11–01–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0494]

Prescription Drug Products; Doxycycline and Penicillin G Procaine Administration for Inhalational Anthrax (Post-Exposure)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is clarifying that the currently approved indications for doxycycline and penicillin G procaine drug products include use in cases of inhalational exposure to *Bacillus anthracis* (the bacterium that causes anthrax). We also are providing dosing regimens that we have determined are appropriate for these products for this use. We encourage the submission of supplemental new drug applications (labeling supplements) to add the dosage information to the labeling of currently marketed drug products.

ADDRESSES: Submit labeling supplements to the Center for Drug Evaluation and Research, Food and Drug Administration, Central Document Room, 12229 Wilkins Ave., Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dianne Murphy, Center for Drug Evaluation and Research (HFD–950),

Food and DrugAdministration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2350.

SUPPLEMENTARY INFORMATION:

I. Anthrax

Anthrax is caused by the spore-forming bacterium *Bacillus anthracis*. There are three types of anthrax infection in humans: Cutaneous, gastrointestinal, and inhalational.

Until recently, most human experience with anthrax was associated with exposure to infected animals or animal products. Anthrax is reported annually among livestock. In areas where these animal cases occur, most human cases are the cutaneous form. Such cases occur among workers who have handled infected hoofed animals or products from these animals. Gastrointestinal anthrax has been reported following the ingestion of undercooked or raw meat from infected animals. Inhalational anthrax, resulting from inhalation of aerosolized spores, was associated with industrial processing of infected wool, hair, or hides in the United States in the past. Before October 2001, no case of inhalational anthrax had been reported in the United States since 1978. In 1979, at least 64 people died in Sverdlovsk (currently Ekaterinburg), Russia, of inhalational anthrax after *Bacillus anthracis* spores were accidentally released from a Soviet military laboratory.

Administration of certain anti-microbial agents may prevent or reduce the incidence of disease following inhalational exposure to *Bacillus anthracis*.

II. Approved Drug Products

Drug products containing doxycycline, doxycycline calcium, doxycycline hyclate,[1] and penicillin G procaine are currently approved with indications foranthrax.[2] The approved labeling for the doxycycline products states that the drugs are indicated in infections caused by *Bacillus anthracis*. The approved labeling for penicillin G procaine drug products states that the drugs are indicated for anthrax. Presently, the labeling for these drug products does not specify a dosing regimen for inhalational exposure to *Bacillus anthracis*. The indication sections of approved labeling for these drug products does not specify cutaneous, gastrointestinal, or inhalational anthrax. We have determined that the language in the labeling of drug products containing doxycycline, doxycycline calcium, doxycycline hyclate, and penicillin G procaine is intended to, and does, cover all forms of anthrax, including inhalational anthrax (post-exposure): To reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*.

On August 30, 2000, we approved supplements to provide an indication for inhalational anthrax (post-exposure) for ciprofloxacin hydrochloride tablets and ciprofloxacin intravenous (IV) solution, IV in 5 percent dextrose, IV in 0.9 percent saline, and oral suspension. The approved labeling for these ciprofloxacin products provides for a 60-day dosing regimen. Because ciprofloxacin drug products are already specifically indicated for inhalational anthrax (post-exposure) and their approved labeling provides a regimen for inhalational anthrax (post-exposure), we do not discuss ciprofloxacin any further in this notice. It is relevant, however, that the rhesus monkey study supporting the approval of ciprofloxacin for inhalational anthrax also included separate doxycycline and penicillin G procaine treatment arms. Each of these arms showed a survival advantage over placebo.[3] No other antimicrobial drugs were tested in this study.

III. Doxycycline Drug Products

We have determined that 100 mg of doxycycline, taken orally twice daily for 60 days, is an appropriate dosing regimen for administration to adults who have inhalational exposure to*Bacillus anthracis*. The corresponding oral dosing regimen for children under 100 pounds (lb) is 1 mg per (/) lb of body weight (2.2 mg/kilogram (kg)), given twice daily for 60 days.

We have determined that IV doxycycline can be administered to adults in a 100 mg dose twice daily for inhalational anthrax (post-exposure). The corresponding IV dosing regimen for children under 100 lb is 1 mg /lb of body weight (2.2 mg/kg), twice daily. Intravenous therapy is indicated only when oral therapy is not indicated. Intravenous therapy should not be given over a prolonged period of time. Patients should be switched to oral doxycycline, or another antimicrobial drug product, as soon as possible, to complete a 60-day course of therapy.

A. Safety

Doxycycline drug products have been used for over 30 years, and the literature on the products is voluminous. We have reviewed the literature dealing with the long-term administration of doxycycline for treatment of diseases other than anthrax. Several articles report the results of studies involving the administration of doxycycline in amounts comparable to the doses recommended in this notice. They also involve administration of doxycycline for 60 days and periods approaching and exceeding 60 days. We have also reviewed data from our Adverse Event Reporting System (AERS). Analysis of these articles and data indicates no pattern of unlabeled adverse events has been associated with the long-term use of doxycycline.

Doxycycline and other members of the tetracycline class of antibiotics are not generally indicated for the treatment of any patients under the age of 8 years. Tetracyclines are known to be associated with teeth discoloration and enamel hypoplasia in children and delays in bone development in premature infants after prolonged use. We have balanced the nature of the effect on teeth and the fact that this delay in bone development is apparently reversible against the lethality of inhalational anthrax, and concluded that doxycycline drug products can be labeled with a pediatric dosing regimen for inhalational anthrax (post-exposure).

We are not recommending that IV doxycycline be administered for prolonged periods because of the possibility of thrombophlebitis and other complications of IV therapy. Thrombophlebitis as a possible adverse reaction is already described in the approved labeling for IV doxycycline drug products. Patients administered IV doxycycline for inhalational anthrax (post-exposure) should be switched to oral doxycycline or another antimicrobial drug product as soon as possible to complete a 60-day course of therapy.

B. Effectiveness

We have reviewed minimal inhibitory concentration (MIC) data for the tetracycline class and *Bacillus anthracis*, pharmacokinetic data, data from the Sverdlovsk incident, and the outcome data from a study of

[1] Doxycycline hyclate tablets, equivalent to 20 milligrams (mg) base, and doxycycline hyclate 10 percent for controlled release in subgingival application are not subjects of this notice because they have periodontal indications and do not have indications for anthrax or infections caused by *Bacillus anthracis*.

[2] Other drug products are currently approved with indications for anthrax or infections caused by *Bacillus anthracis*, i.e., minocycline, tetracycline, oxytetracycline, demeclocycline, and penicillin G potassium. We have not completed a review on these other drugs. We will not discuss these other drugs further in this notice.

[3] Friedlander, A. M. et al., ''Postexposure Prophylaxis Against Experimental Inhalation Anthrax,'' Journal of Infectious Diseases, 167:1239–1243, 1993.

inhalational exposure to *Bacillus anthracis* in rhesus monkeys.[4] We have concluded that 100 mg of doxycycline, administered twice a day for 60 days, is an effective dosing regimen for adults who have inhalational exposure to *Bacillus anthracis*. The corresponding dosing regimen for children under 100 lb of 1mg/lb of body weight (2.2 mg/kg), given twice daily for 60 days, is also effective.

C. Labeling for Oral Doxycyline

We encourage the submission of labeling supplements for orally administered doxycycline, doxycycline calcium, and doxycycline hyclate drug products. The revised labeling should contain a specific indication for inhalational anthrax (post-exposure), the recommended dosing regimen, safety information relevant to use in children, and other information described below. The following specific changes to the current approved labeling are recommended:

- *Indications and Usage*. The indication for anthrax should be revised from ''Anthrax due to *Bacillus anthracis*'' to ''Anthrax due to *Bacillus anthracis*, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*.'' This indication should be removed from the paragraph of the ''Indications and Usage'' section that begins ''When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of the following infections:'' and inserted at the end of the preceding paragraph that begins ''Doxycycline is indicated for the treatment of infections caused by the following gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug:.''
- *Warnings*. The last sentence in the first paragraph of the ''Warnings'' section should be revised to read as follows: ''TETRACYCLINE DRUGS, THEREFORE, SHOULD NOT BE USED IN THIS AGE GROUP, EXCEPT FOR ANTHRAX, INCLUDING INHALATIONAL ANTHRAX (POST-EXPOSURE), UNLESS OTHER DRUGS ARE NOT LIKELY TO BE EFFECTIVE OR ARE CONTRAINDICATED.''
- *Dosage and Administration*. The following text should be inserted as the last item of the ''Dosage and Administration'' section:

''Inhalational anthrax (post-exposure):

ADULTS: 100 mg of doxycycline, by mouth, twice a day for 60 days.

CHILDREN: weighing less than 100 lb (45 kg); 1 mg/lb (2.2 mg/kg) of body weight, by mouth, twice a day for 60 days. Children weighing 100 lb or more should receive the adult dose.''

D. Labeling for IV Doxycycline

We encourage the submission of labeling supplements for doxycycline hyclate injectable drug products. The revised labeling should contain a specific indication for inhalational anthrax (post-exposure), the recommended dosing regimen, safety information relevant to use in children and prolonged use, and other information described below. We recommend that labeling supplements for doxycycline hyclate injectable drug products include the following specific changes:

- *Indications*. The indication for anthrax should be revised from''*Bacillus anthracis*'' to ''Anthrax due to *Bacillus anthracis*, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*.'' This indication should be removed from the paragraph of the ''Indications'' section that begins ''When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of infections due to:'' and inserted at the end of the preceding paragraph that begins ''Doxycycline is indicated for the treatment of infections caused by the following gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug:.''
- *Warnings*. The last sentence in the first paragraph of the ''Warnings'' section should be revised to read as follows: ''TETRACYCLINE DRUGS, THEREFORE, SHOULD NOT BE USED IN THIS AGE GROUP, EXCEPT FOR ANTHRAX, INCLUDING INHALATIONAL ANTHRAX (POST-EXPOSURE), UNLESS OTHER DRUGS ARE NOT LIKELY TO BE EFFECTIVE OR ARE CONTRAINDICATED.''
- *Dosage and Administration*. The following paragraph should be inserted in the ''Dosage and Administration'' section after the paragraph describing the treatment for syphilis:

''In the treatment of inhalational anthrax (post-exposure) the recommended dose is 100 mg of doxycycline, twice a day. Parenteral therapy is only indicated when oral therapy is not indicated and should not be continued over a prolonged period of time. Oral therapy should be instituted as soon as possible. Therapy must continue for a total of 60 days.''

The following paragraph should be inserted in the ''Dosage and Administration'' section after the paragraph describing the dosages for children above 8 years of age:

''In the treatment of inhalational anthrax (post-exposure) the recommended dose is 1 mg/lb (2.2 mg/kg) of body weight, twice a day in children weighing less than 100 lb (45 kg). Parenteral therapy is only indicated when oral therapy is not indicated and should not be continued over a prolonged period of time. Oral therapy should be instituted as soon as possible. Therapy must continue for a total of 60 days.''

IV. Penicillin G Procaine Drug Products

We have determined that 1,200,000 units of penicillin G procaine, administered every 12 hours, is an appropriate dosing regimen for adults who have inhalational exposure to *Bacillus anthracis*. The corresponding dosing regimen for children is 25,000 units/kg of body weight (maximum 1,200,000 units) every 12 hours.

A. Safety

Penicillin drug products have been used for over 50 years. The amount of literature on penicillin is correspondingly large. We have reviewed published literature on the safety of penicillin G procaine. We have also reviewed data from AERS. Analysis of these articles and data indicates that no pattern of unexpected adverse events is associated with the use of penicillin G procaine as described in the recommended dosing regimen. All adverse events that we have identified are described in the approved labeling. We note that there may be an increased risk of neutropenia and an increased incidence of serum sickness-like reactions associated with use of penicillin for more than 2 weeks. Because prescribing health care professionals should take those factors into consideration when continuing administration of penicillin G procaine for longer than 2 weeks for inhalational anthrax (post-exposure), we are suggesting that the labeling for the drug products reflect these concerns about neutropenia and serum sickness-like reactions.

B. Effectiveness

We have reviewed MIC data for penicillin G and *Bacillus anthracis*, pharmacokinetic data, data from the Sverdlovsk incident, clinical data regarding the use of penicillins in treatment of primarily cutaneous anthrax, and the outcome data from a study of inhalational exposure to *Bacillus anthracis* in rhesus monkeys.[5] We have concluded that the recommended dosing regimens are effective for adults and children who

[4] Friedlander.

[5] Friedlander.

have inhalational exposure to *Bacillus anthracis*.

C. Labeling

We encourage the submission of labeling supplements for penicillin G procaine injectable drug products. The revised labeling should contain a specific indication for inhalational anthrax (post-exposure), the recommended dosing regimen, safety information relevant to prolonged use and use in children, and other information described below. The following specific changes to the current approved labeling are recommended:

- *Indications*. In the ''Indications'' section, the indication for anthrax should be revised from ''Anthrax'' to ''Anthrax due to *Bacillus anthracis*, including inhalational anthrax (post-exposure): to reduce the incidence or progression of the disease following exposure to aerosolized *Bacillus anthracis*.''
- *Precautions*. In the ''Precautions'' section, at the end of the paragraph that begins ''In prolonged therapy with penicillin, and particularly with high-dosage schedules, periodic evaluation of the renal and hematopoietic systems is recommended,'' the following text should be added: ''In such situations, use of penicillin for more than 2 weeks may be associated with an increased risk of neutropenia and an increased incidence of serum sickness-like reactions.''
- *Dosage and Administration*. In the ''Dosage and Administration'' section, immediately following ''Anthrax—cutaneous: 600,000 to 1,000,000 units/day.'' the following text should be inserted:

''Anthrax—inhalational (post-exposure): 1,200,000 units every 12 hours in adults, 25,000 units per kilogram of body weight (maximum 1,200,000 unit) every 12 hours in children. The available safety data for penicillin G procaine at this dose would best support a duration of therapy of 2 weeks or less. Treatment for inhalational anthrax (post-exposure) must be continued for a total of 60 days. Physicians must consider the risks and benefits of continuing administration of penicillin G procaine for more than 2 weeks or switching to an effective alternative treatment.''

V. Conclusions

Drug products containing the following active ingredients are currently approved for administration in cases of inhalational anthrax:

- Doxycycline
- Doxycycline calcium
- Doxycycline hyclate
- Penicillin G procaine

We encourage the submission of labeling supplements for these drug products. The revised labeling should specifically mention inhalational anthrax (post-exposure), the recommended dosing regimen, safety information relevant to prolonged exposure (60 days or longer), and other information described in this notice. The requirement for data to support these labeling changes may be met by citing the published literature we relied on in publishing this notice. A list of the published literature and reprints of the reports will be available forpublic inspection in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is unnecessary to submit copies and reprints of the reports from the listed published literature. We invite applicants to submit any other pertinent studies and literature of which they are aware.

VI. Published Literature

The published literature we have relied on in making our recommendations will be 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. A list of this published literature will be on display in the Dockets Management Branch and on the Internet at www.fda.gov/cder/drug/infopage/penG_doxy/bibliolist.htm.

Dated: October 26, 2001.

Bernard A. Schwetz,

Acting Principal Deputy Commissioner.

[FR Doc. 01–27493 Filed 10–29–01; 4:35 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Cancer Institute.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Cancer Institute.

Date: November 20, 2001.

Time: 11 am to 1 pm.

Agenda: The purpose of the meeting will be to discuss the Gynecologic Cancers Progress Review, Group Report.

Place: National Cancer Institute, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 11A03, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Chitra Mohla, Executive Secretary, Office of Scientific Opportunities, National Cancer Institute, National Institutes of Health, Bldg. 31, Rm. 11A03, Bethesda, MD 20892, (301) 496–1458.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's homepage: *deainfo.nci.nih.gov/advisory/joint/htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27505 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.

Date: November 8, 2001.

Time: 2 pm to 4 pm.

Agenda: To follow up on the Survivorship Forum and to get reports from the Working Groups.

Place: 6116 Executive Boulevard, Suite 300C, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Elaine Lee, Acting Executive Secretary, Office of Liaison Activities, National Institutes of Health, National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Bethesda, MD 20892, 301/594–3194.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's homepage: *deainfo.nci.nih.gov/advisory/dclg/delg.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS).

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27506 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Comparative Medicine.

Date: November 5, 2001.

Time: 10 am to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Office of Review, National Center for Research Resources, 6705 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Camille M. King, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, One Rockledge Centre, MSC 7965, 6705 Rockledge Drive, Suite 6018, Bethesda, MD 20892–7965, (301) 435–0810, *kingc@ncrr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: October 24, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27500 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: November 5, 2001.

Time: 8:30 AM to 5 PM.

Agenda: Discussion of Program policies and issues.

Place: National Institutes of Health, Two Rockledge Center, Conference Room 9112, 9116, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Charles M Peterson, MD, Director, Blood Diseases Program, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, NIH, Two Rockledge Center, Room 10158, MSC 7950, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435–0050.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Information is also available on the Institute's/Center's homepage: *www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 24, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27497 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 a meeting of the Board of Scientific Counselors, NHLBI.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Heart, Lung, and Blood Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NHLBI.

Date: December 13–14, 2001.

Time: 8 AM to 5 PM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 9000 Rockville, Pike, Building 10, Room 7S235, Bethesda, MD 20892.

Contact Person: Elizabeth G. Nabel, MD, Scientific Director for Clinical Research, National Heart, Lung, and Blood Institute, Division of Intramural Research, Building 10, Room 8C103, MSC 1754, Bethesda, MD 20892, 301/496–1518.

Information is also available on the Institute's/Center's homepage: *www.nhlbi.nih.gov/meetings/index.htm,*

where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 24, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27498 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Environmental Health Sciences Review Committee, Review of National Research Service Award Institutional Training Grants.

Date: November 15–16, 2001.

Time: 8:30 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Radisson Governors Inn, I–40 & Davis Dr., Exit 280, Research Triangle Park, NC 27709.

Contact Person: Linda K. Bass, PHD, Scientific Review Administrator, Nat'l Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–24 Research Triangle Park, NC 27709 (919) 541–1307.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences, National Institutes of Health, HHS)

Dated: October 24, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27496 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel.

Date: November 7–8, 2001.

Time: 8:30 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Nasrin Nabavi, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2156, 6700B Rockledge Drive, MSC 7610, Bethesda, MD 20892–7610, 301–496–2550, *nn30t@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 24, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27499 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel.

Date: November 20, 2001.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Joel Sherrill, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9606, Bethesda, MD 20892–9606, 301–443–6102. *jsherrill@mail.nih.gov*

Name of Committee: National Institute of Mental Health Special Emphasis Panel.

Date: November 27, 2001.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Henry J. Haigler, PhD, Associate Director of Staff Developoment, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6150, MSC 9608, Bethesda, MD 20892–9608, 301–443–7216. *hhaigler@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel.

Date: December 3, 2001.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Holiday Inn, 8120 Wisconsin Avevnue, Bethesda, MD 20814.

Contact Person: Henry J. Haigler, PhD, Associate Director for Staff Development, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6150, MSC 9608, Bethesda, MD 20892–9608, 301–443–7216. *hhaigler@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: October 24, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27501 Filed 11–01–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel Review of PO1 Grant Applications.

Date: December 3–5, 2001.

Time: 7 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Pasadena, 150 South Robles Avenue, Pasadena, CA 91101.

Contact Person: Brenda K. Weis, Phd, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institutes of Environmental Health Sciences, P.O. Box 12233, MD/EC–30, Research Triangle Park, NC 27709, 919/541–4964.

(Catalogue of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences, National Institutes of Health, HHS)

Dated: October 24, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27502 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 19(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: November 5, 2001.

Time: 11 AM to 4 PM.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, Chevy Chase Pavillion, 4300 Military Rd., Wisconsin at Western Ave., Washington, DC 20015.

Contact Person: Anne Krey, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Rm. 5E03, Bethesda, MD 20892, 301–435–6908.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27503 Filed 11–01–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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:

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of persons privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel.

Date: December 5, 2001.

Time: 8 am to 4 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Laura K. Moen, PhD, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1AS–13H, Bethesda, MD 20892, 301–594–3998, *moenl@nigms.nih,gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27504 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–1(J2)P.

Date: December 6–7, 2001.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Blvd., Bethesda, MD 20817.

Contact Person: John Connaughton, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 757, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892, (301) 594–7797, *connaughton@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–6(J1).

Date: December 7, 2001.

Time: 8 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Baltimore Washington International Sheraton Hotel, 7032 Elm Road, Baltimore, MD 21240.

Contact Person: Dan E. Matsumoto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 749, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27507 Filed 11–01–01; 8:45 am]

BILLING CODE 4140–1–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institutes of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–4(J1).

Date: November 19–21, 2001.

Time: 7:30 p.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: Houston Marriott Medical Center, 6580 Fannin St., Houston, TX 77030.

Contact Person: John Connaughton, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 757, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892, (301) 594–7797, *connaughtonj@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne J. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27508 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–1–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel.

Date: November 19, 2001.

Time: 8 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: The Hyatt Regency Hotel, 100 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Craig A. Jordan, PhD, Chief, Scientific Review Branch, NIH/NIDCD/DER, Executive Plaza South, Room 400C, Bethesda, MD 20892–7180, 301–496–8683.

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel.

Date: November 19, 2001.

Time: 8 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: The Hyatt Regency Hotel, 100 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Ali A. Azadegan, DVM, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NIDCD, NIH DHHS, Bethesda, MD 20892–7180, 301–496–8683.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27509 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and other Communication Disorders; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel.

Date: November 20, 2001.

Time: 1 pm to 3 pm.

Agenda: To review and evaluate grant applications.

Place: 6120 Executive Blvd., Suite 400C, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Stanley C. Oaks, Jr., PhD, Scientific Review Branch, Division of Extramural Research, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892–7180, 301–496–8683.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27510 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Minority Institutions Drug Abuse Research Development Program (MIDARP).

Date: November 16, 2001.

Time: 2 pm to 4pm.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone conference Call).

Contact Person: Marina L. Volkov, PhD, Health Scientist Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, (301) 435–1433.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27513 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: December 6, 2001.

Time: 11 AM to 1 PM.

Agenda: To review and evaluate grant applications.

Place: 6000 Executive Blvd., Rm 409, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: L. TONY BECK, PhD, Scientific Review Administrator, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Blvd., MSC 7003, Bethesda, MD 20892–7003, 301–443–0913, *lbeck@mail.nih.gov*.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: December 14, 2001.

Time: 8 am to 6 pm.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Ronald Suddendorf, PhD, Scientific Review Administrator, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Boulevard, Bethesda, MD 20892–7003, 301–443–2926.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne, Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27516 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel, SEP Telephone Conference (ZLM1 MMR C J2).

Date: November 28, 2001.

Time: 3 pm to 4 pm.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Division of Extramural Programs, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Merlyn M. Rodrigues, Medical Officer/SRA, National Library of Medicine, Extramural Programs, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27512 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications; the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: November 2, 2001.

Time: 1:45 pm to 2:30 pm.

Agenda: To review and evaluate grant applications.

Place: Westin Grand Hotel 2350 M Street, NW., Washington, DC 20037–1417.

Contact Person: Cheryl M. Corsaro, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, 301/435–1045, *corsaroc&csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, National Institutes of Health, HHS)

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27511 Filed 11–01–01; 8:45 am]

BILLING CODE 4140–1–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Genome Study Section, November 1, 2001, 8:30 AM to November 2, 2001, 2:30 PM, Embassy Square, 2000 N Street, NW., Washington, DC, 20036 which was published in the **Federal Register** on October 19, 2001, 66 FR 53229–53231.

This meeting will be held at the Westin Grand Hotel, 2350 M Street, NW., Washington, DC 20037. The ending time has been changed to 1:45 PM. The meeting is closed to the public.

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27514 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 31, 2001, 1:30 PM to November 1, 2001, 5 PM, Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on October 15, 2001, 66 FR 52441–52444.

The meeting will be one day only October 31, 2001, from 1:30 PM to 5 PM. The location remains the same. The meeting is closed to the public.

Dated: October 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–27515 Filed 11–1–01; 8:45 am]

BILLING CODE 4140–1–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at the following Web sites: *http://workplace.samhsa.gov; http://www.drugfreeworkplace.gov;* and *http://www.health.org/workplace.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014, Fax: (301) 443–3031.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.

To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016 (Formerly: Bayshore Clinical Laboratory)

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 716–429–2264

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513–585–9000 (Formerly: Jewish Hospital of Cincinnati, Inc.)

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866/800–433–2750

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Laboratory Partners, LLC, 129 East Cedar St., Newington, CT 06111, 860–696–8115 (Formerly: Hartford Hospital Toxicology Laboratory)

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–269–3093 (Formerly: Cox Medical Centers)

Diagnostic Services Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 941–561–8200/800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31602, 912–244–4468

DrugProof, Divison of Dynacare, 543 South Hull St., Montgomery, AL 36103, 888–777–9497/334–241–0522 (Formerly: Alabama Reference Laboratories, Inc.)

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206–386–2672/800–898–0180 (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310

Dynacare Kasper Medical Laboratories*, 14940–123 Ave., Edmonton, Alberta, Canada T5V 1B4, 780–451–3702/800–661–9876

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662–236–2609

Express Analytical Labs, 1301 18th Ave., NW., Suite 110, Austin, MN 55912, 507–437–7322

Gamma-Dynacare Medical Laboratories *, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, Canada N6A 1P4, 519–679–1630

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Laboratory Specialists, Inc.)

LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–728–4064 (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 10788 Roselle Street, San Diego, CA 92121, 800–882–7272 (Formerly: Poisonlab, Inc.)

Laboratory Corporation of America Holdings, 1120 Stateline Road West, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc., MedExpress/National Laboratory Center)

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–331–3734

MAXXAM Analytics Inc.*, 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905–890–2555 (Formerly: NOVAMANN (Ontario) Inc.)

Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43699, 419–383–5213

MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 651–636–7466/800–832–3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612–725–2088

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

Northwest Drug Testing, a division of NWT Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 801–293–2300/800–322–3361 (Formerly: NWT Drug Testing, NorthWest Toxicology, Inc.)

One Source Toxicology Laboratory, Inc., 1705 Center Street, Deer Park, TX 77536, 713–920–2559 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134

Pacific Toxicology Laboratories, 6160 Variel Ave., Woodland Hills, CA 91367, 818–598–3110/800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 11604 E. Indiana Ave., Spokane, WA 99206, 509–926–2400/800–541–7891

PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817–215–8800 (Formerly: Harris Medical Laboratory)

Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–339–0372/800–821–3627

Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800–842–6152 (Moved from the Dallas location on 03/31/01; Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Rd., Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 506 E. State Pkwy., Schaumburg, IL 60173, 800–669–6995/847–885–2010 (Formerly: SmithKline Beecham Clinical Laboratories, International Toxicology Laboratories)

Quest Diagnostics Incorporated, 7470 Mission Valley Rd., San Diego, CA 92108–4406, 619–686–3200 / 800–446–4728 (Formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT), CORNING Nichols Institute, CORNING Clinical Laboratories)

Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 818–989–2520 / 800–877–2520 (Formerly: SmithKline Beecham Clinical Laboratories)

Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804–378–9130

S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300 / 800–999–5227

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219–234–4176

Southwest Laboratories, 2727 W. Baseline Rd., Tempe, AZ 85283, 602–438–8507 / 800–279–0027

Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517–377–0520 (Formerly: St. Lawrence Hospital & Healthcare System)

St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics,

2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573–882–1273
Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260
Universal Toxicology Laboratories (Florida), LLC, 5361 NW 33rd Avenue, Fort Lauderdale, FL 33309, 954–717–0300, 800–522–0232x419 (Formerly: Integrated Regional Laboratories, Cedars Medical Center, Department of Pathology)
Universal Toxicology Laboratories, LLC, 9930 W. Highway 80, Midland, TX 79706, 915–561–8851 / 888–953–8851
US Army Forensic Toxicology Drug Testing Laboratory, Fort Meade, Building 2490, Wilson Street, Fort George G. Meade, MD 20755–5235, 301–677–7085

The following laboratories are voluntarily withdrawing from the NLCP:

Withdrawal effective November 1, 2001: Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, Building 38–H, P. O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045 / 847–688–4171
Withdrawal effective October 1, 2001: Quest Diagnostics Incorporated, 801 East Dixie Ave., Suite 105A, Leesburg, FL 34748, 352–787–9006x4343 (Formerly: SmithKline Beecham Clinical Laboratories, Doctors & Physicians Laboratory)
Withdrawal effective October 1, 2001: Quest Diagnostics Incorporated, 4444 Giddings Road, Auburn Hills, MI 48326, 248–373–9120 / 800–444–0106 (Formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath, CORNING Clinical Laboratories)
Withdrawal effective October 1, 2001: Quest Diagnostics Incorporated, One Malcolm Ave., Teterboro, NJ 07608, 201–393–5590 (Formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories, CORNING Clinical Laboratory)

*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. DHHS, with the DHHS' National Laboratory Certification Program (NLCP) contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, the DHHS will recommend that DOT certify the laboratory (**Federal Register**, 16 July 1996) as meeting the minimum standards of the ''Mandatory Guidelines for Workplace Drug Testing'' (59 **Federal Register**, 9 June 1994, Pages 29908–29931). After receiving the DOT certification, the laboratory will be included in the monthly list of DHHS certified laboratories and participate in the NLCP certification maintenance program.

Richard Kopanda,
Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 01–27530 Filed 11–1–01; 8:45 am]

BILLING CODE 4160–20–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Intent To Issue a Notice of Funding Availability for Cooperative Agreements for Addiction Technology Transfer Center (ATTC) Sites and an ATTC National Office

AGENCY: Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), DHHS.

ACTION: Notification of SAMHSA/CSAT's intent to announce the availability of FY 2002 funds for cooperative agreements for seven ATTC sites and an ATTC National Office.

SUMMARY: This notice is to inform the public of SAMHSA/CSAT's intention to issue a Notice of Funding Availability in late October or early November, to announce the availability of FY 2002 funds for cooperative agreements to support 7 ATTC sites to cover 7 ATTC Regions and an ATTC National Office. CSAT's ATTC program is comprised of 14 ATTC Regions and an ATTC National Office that together form a network which, individually and collaboratively, provides academic, continuing education, professional development and practicum training to professionals/providers in the substance abuse treatment field. The ATTC National Office coordinates all cross-site and multi-site activities of the 14 ATTC regions.

In FY 2001, awards were made to sites to cover 7 of the 14 ATTC Regions. In FY 2002, it is SAMHSA/CSAT's intent to solicit applications for an ATTC National Office and for coverage of the following currently uncovered 7 ATTC Regions:

Region 5: Georgia and South Carolina;
Region 7: Puerto Rico and U.S. Virgin Islands;
Region 8: Missouri, Kansas, Oklahoma, and Arkansas;
Region 9: Iowa, Nebraska, North Dakota, South Dakota, and Minnesota;
Region 10: Illinois, Indiana, Ohio, Wisconsin, and Michigan;
Region 13: California, New Mexico, Arizona, and Colorado (criminal justice); and
Region 14: Florida and Alabama.

Questions related to CSAT's ATTC program should be directed to Susanne Rohrer, RN, Office of Evaluation, Scientific Analysis, and Synthesis, CSAT, Rockwall II, Suite 840, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–8521; e-mail *srohrer@samhsa.gov.*

Dated: October 28, 2001.

Richard Kopanda,
Executive Officer, SAMHSA.

[FR Doc. 01–27521 Filed 11–1–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–81]

Notice of Submission of Proposed Information Collection to OMB; Revision of Cost Limits for Native American Housing

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date*: December 3, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Office, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail: *Wayne_Eddins@HUD.gov*; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 350). The Notice

lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Revision to Cost Limits for Native American Housing.

OMB Approval Number: 2577–XXXX.

Form Numbers: None.

Description of the need for the information and its Proposed Use: HUD provides grants to Native American tribes and Alaskan villages for development, construction and operation of low income housing in Indian Areas. Information collected and maintained will be used to ensure that housing is of moderate design.

Respondents: State, local or tribal government.

Frequency of Submission: Reporting.

	Number of respondents	X	Frequency of response	X	Hours per response	=	Burden hours
Reporting burden	365		1		2.2		820

Total Estimated Burden Hours: 820.

Status: New Collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: October 26, 2001.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–27491 Filed 11–1–01; 8:45 am]

BILLING CODE 4210–72–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4579–FA–11]

Announcement of Funding Awards—Fiscal Year 2001, Office of Troubled Agency Recovery Cooperative Agreements

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department from funds distributed to the Office of Troubled Agency Recovery during Fiscal Year 2001. This announcement contains the name and address of all awardees and the amount of each award.

FOR FURTHER INFORMATION CONTACT: Karen A. Newton, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–1141. Hearing- or speech-impaired individuals may call HUD's TDD number (202) 708–4594. (These numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Cooperative Agreement with each of the following recipients was issued pursuant to section 6(j) of the United States Housing Act of 1937. The awards will be used to provide technical assistance to support troubled agency recovery efforts and funding assistance as necessary to remedy the substantial deterioration of living conditions in public housing or other related emergencies that endanger the health, safety, and welfare of the residents.

The Catalog of Federal Domestic Assistance number for this program is 14.859.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the name, address, and amount of each award as follows:

(COOPERATIVE AGREEMENT AWARDS FOR FISCAL YEAR 2001

Awardee	Amount
San Francisco Housing Authority, 440 Turk Street, San Francisco, CA 94102	$147,679
Whitney Housing Authority, PO Box 594, Whitney, TX 76692	5,625
Housing Authority of New London, 78 Walden Avenue, New London, CT 06320	155,000
Bernalillo Housing Authority, PO Box 70 Bernalillo, NM 87004	28,985
Housing Authority of New Orleans, 4100 Touro Street, New Orleans, LA 70122	150,000
Muskegon Housing Commission, 1823 Commerce Street, Muskegon, MI 49440	125,000
Housing Authority of Kansas City, 299 Paseo, Kansas City, MO 64106	200,000
Tulane-Xavier University, Center for the Urban Community, Campus Affiliates Program, 102 Central Building, Tulane University, New Orleans, LA 70118	2,000,000
National Association of Housing and Redevelopment Officials (NAHRO), 1320 18th St. NW, Washington, DC 20035	540,000
Consensus Building Institute, 131 Mt. Auburn Street, Cambridge, MA 02138	183,650
Housing Authority of Havre de Grace, 101 Stansbury Court, Havre de Grace, MD 21078	15,000
Housing Authority of Texarkana, 1611 North Robison Rd., Texarkana, TX 75501	82,102
Housing Authority of the City of Sanford, 94 Castle Brewer Ct., Sanford, FL	1,150,000
Housing Authority of St. James Parish, PO Box 280, Lutcher, LA 70071	88,827
Muskegon Housing Commission, 1823 Commerce St., Muskegon, MI 49441	125,000

Dated: October 29, 2001.

Michael Liu,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 01–27490 Filed 11–1–01; 8:45 am]

BILLING CODE 4210–33–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4644–N–44]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: November 2, 2001.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing– and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: October 24, 2001.

Mark R. Johnston,

Deputy Director, Office of Special Needs Assistance Programs.

[FR Doc. 01–27314 Filed 11–1–01; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Draft Comprehensive Conservation Plan and Environmental Assessment for Antioch Dunes National Wildlife Refuge, Contra Costa County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service announces that a Draft Comprehensive Conservation Plan and Environmental Assessment (CCP/EA) for Antioch Dunes National Wildlife Refuge (Refuge) is available for review and comment. This CCP/EA, prepared pursuant to the National Wildlife Refuge System Improvement Act of 1997 and the National Environmental Policy Act of 1969, describes how the U.S. Fish and Wildlife Service intends to manage the Refuge for the next 15 years. Also available for review with the CCP/EA are draft compatibility determinations for environmental education, interpretation, wildlife observation, and photography, and research.

DATES: Please submit comments on the Draft CCP/EA on or before December 3, 2001.

ADDRESSES: Comments of the Draft CCP/EA should be addressed to: Mark Pelz, Planning Team Leader, U.S. Fish and Wildlife Service, California/Nevada Refuge Planning Office, 2800 Cottage Way, Room W–1916, Sacramento, CA 95825. Comments may also be submitted via electronic mail to *FW1PlanningComments@fws.gov.* Please type ''Antioch Dunes NWR'' in the subject line.

FOR FURTHER INFORMATION CONTACT: Mark Pelz, U.S. Fish and Wildlife Service, California/Nevada Refuge Planning Office, Room W–1916, 2800 Cottage Way, Sacramento, California, 95825; 916–414–6500; fax 916–414–6512.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Copies of the Draft CCP/EA may be obtained by writing to U.S. Fish and Wildlife Service, Attn: Mark Pelz, California/Nevada Refuge Planning Office, Room W–1916, 2800 Cottage Way, Sacramento, California, 95825. Copies of the plan may be viewed at this address or at the San Francisco Bay NWR Complex Headquarters, #1 Marshlands Road, Fremont, California. The Draft CCP/EA will also be available online for viewing and download at *http://pacific.fws.gov/planning.*

Background

The Antioch Dunes Refuge was the first National Wildlife Refuge in the country established to protect endangered plants and insects. Created in 1980 by the U.S. Fish and Wildlife Service (Service), this riverside Refuge provides protection and critical habitat for three endangered species: Lange's metalmark butterfly (*Apodemia mormo langei*) (Lange's), Contra Costa wallflower (*Erysimum capitatum* ssp. *angustatum*) (wallflower), and Antioch Dunes evening primrose (*Oenothera deltoides* ssp. *howellii*) (primrose). The Refuge, 55-acres of former dunes, in addition to the adjacent 12 acres of Pacific Gas and Electric Company (PG&E) land, is an isolated patch of what was once a larger dune system that hosted a unique assemblage of plants, insects, and reptiles. A major effort is currently underway to restore and improve dune habitat on the Refuge. The Refuge staff is based in the San Francisco Bay National Wildlife Refuge Complex office in Fremont, California.

This Draft CCP/EA identifies and evaluates four alternatives for managing the Refuge for the next 15 years. Alternative D is the Service's preferred alternative.

Under Alternative A (No Action), current management and public use would continue unchanged. The Refuge would continue its current weed control program. Various control methods would be used, including hand weeding, treating with herbicide, and prescribed fire. As opportunities arise, the Refuge would recontour existing sand dunes at the Refuge by using heavy equipment to reshape existing sand substrate into steep dunes and by importing sand from offsite. The Service would continue to outplant primrose, wallflower, and buckwheat on an as-needed basis. Annual surveys of the three endangered species would continue. The Refuge boundary would remain the same. The Service would continue to work to finalize a Cooperative Agreement with PG&E to manage its adjacent lands. The Refuge would continue to be closed to public use except for occasional staff guided tours for schools and other groups.

Under Alternative B, the Refuge would be restored and managed to pre-industrial natural conditions (oak woodland on sandy soils) with limited and controlled public access. Most of the Refuge would be managed as upland habitat and blowout areas along the shore would be allowed and encouraged to erode and to be colonized by endangered species. Nonnative weeds would continue to be controlled using

the same measures described in Alternative A. Weed control research would be expanded. As in Alternative A, the Service would continue to recontour existing dunes to make them steeper, as opportunities arise. Under this alternative, the Service would plant oak seedlings and native grasses in addition to the primrose, wallflower, and buckwheat. The Service would continue monitoring the primrose, wallflower, and Lange's populations and encouraging research on the Refuge. The Refuge boundary would remain the same as under Alternative A. Regularly scheduled tours of the Refuge would be conducted by Refuge staff. An outreach program would be developed to help expand the Refuge's presence and support in the community. Interpretive programs and facilities would be developed, including an automobile pull-out with an interpretive kiosk and a parking area for school and other groups. The Service would also promote the Refuge with teachers and develop an educator-led curriculum for Refuge resources.

Under Alternative C, the Refuge would be managed as a mosaic of dune habitat at varying successional stages with unrestricted public access. Nonnative weeds would continue to be controlled using the same measures as described in Alternative A. The Service would create a cycle of disturbance by scraping the soil in a mosaic pattern. In addition, the Service would construct additional dunes using imported sand in the areas that currently do not provide good habitat for endangered species. The Refuge's outplanting program would be expanded to include other native plant species, especially plants that are either locally significant and/or were historically present. The Service would continue monitoring the primrose, wallflower, and Lange's populations and encouraging research on the Refuge. Additional studies would be undertaken to assess the effects of management actions on other plants and animals, including reptiles and invertebrates, at the Refuge. Under this alternative, the Refuge would remove nonnative species such as Ailanthus and oleander from the river shore to the extent possible. Native species would be planted in their place. Parts of the river bank would be allowed to experience erosion and blowouts so that the endangered plants could colonize them. Under this alternative, the Refuge would initiate the Service's land acquisition planning process to investigate riparian easement and dune habitat acquisition from adjacent land owners. The Refuge would be opened to unrestricted access by the public. Environmental education, interpretation, wildlife observation, photography, and fishing would be allowed on the Refuge. Public use facilities and programs would be developed and staffed as described under Alternative B except that there would be fewer guided tours. In addition, the Refuge would construct a nature trail with interpretive signs, a fishing pier, and a restroom.

Under Alternative D, the Service's preferred alternative, the Refuge would be managed as a mosaic of dune habitat at habitat at varying successional stages with limited and controlled public access. Nonnative weeds would be controlled using the same measures as described in Alternative C. Also, nonnative weeds would be removed in some places after spraying by mechanical means to reduce biomass and woody nonnative plants would also be removed. Under this alternative, restoration and dune construction would be implemented as in Alternative C. However, Alternative D, would require more soil scraping to create disturbance than Alternative C. Outplanting, riparian restoration, monitoring, and land protection planning under this alternative would be the same as under Alternative C. Public use services and facilities would be similar to those under Alternative B.

Dated: October 26, 2001.

Steve Thompson,

Acting Manager, California/Nevada Operations Office, Fish and Wildlife Service, Sacramento, California.

[FR Doc. 01–27519 Filed 11–1–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Marine Mammals; Finding on Petition To List the Alaska Stock of Sea Otters as Depleted

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Finding on petition.

SUMMARY: On August 21, 2001, the U.S. Fish and Wildlife Service (FWS) received a petition under section 115 of the Marine Mammal Protection Act (MMPA) from the Center for Biological Diversity. The petition requests that FWS list the Alaska stock of sea otters as depleted. The FWS finds that the petition does not present substantial information that the petitioned action is warranted. The FWS has determined that the statewide population of sea otters in Alaska is larger than presented in the petition. Furthermore, the best available scientific information indicates that multiple stocks of sea otters exist in Alaska.

FOR FURTHER INFORMATION CONTACT: Douglas Burn, Wildlife Biologist, Marine Mammals Management Office, 1011 East Tudor Road, Anchorage, Alaska 99503, or telephone 907/786–3800 or facsimile 907/786–3816.

SUPPLEMENTARY INFORMATION:

Background

The sea otter, *Enhydra lutris,* is the smallest species of marine mammal. Sea otters occur primarily in shallow, nearshore marine habitats (Rotterman and Simon-Jackson 1988). They eat a wide variety of benthic (i.e., bottom dwelling) invertebrates, including bivalves, molluscs, gastropods, crustaceans, echinoderms, and occasionally octopus and fish. This dependence on nearshore benthic invertebrates greatly influences sea otter distribution, and as a result, they are seldom found in deep water. Sea otters seem to prefer areas with kelp beds, but this is not an essential habitat requirement (Riedman and Estes 1990). Although predominantly marine, they will occasionally haul our on shore to rest.

Taxonomically, three subspecies of sea otter have been identified (Wilson *et al.* 1991). The northern sea otter contains two subspecies: *Enhydra lutris kenyoni,* which occurs from the Aleutian Islands to Oregon, and *Enhydra lutris lutris,* which occurs in the Kuril Islands, Kamchatka Peninsula, and Commander Islands in Russia. The third subspecies, *Enhydra lutris nereis,* occurs in California and is known as the southern sea otter.

Historically, sea otters occurred around the North Pacific rim from Hokkaido, Japan, through the Kuril Islands, Kamchatka Peninsula, the Commander Islands, the Aleutian Islands, peninsular and south coastal Alaska, and southward to Baja California (Kenyon 1969). Extensive commercial hunting of sea otters began following the arrival in Alaska of Russian explores in 1741 and continued during the 18th and 19th centuries. By the time sea otters were afforded protection from commercial harvests by international treaty in 1911, the species was nearly extinct throughout its range, and may have numbered only 1,000–2,000 individuals (Kenyon 1969).

The remaining sea otters were distributed as 13 isolated remnant populations scattered throughout the historic range. Once commercial harvests ceased, 11 of the 13 remaining

populations began to grow and recolonize their former range. By the early 1960s, sea otters had not yet returned to southeast Alaska. In the mid-1960s, the Alaska Department of Fish and Game translocated sea otters from Amchitka Island in the Aleutians and Prince William Sound to several sites throughout southeast Alaska. Similar to the remnant populations, these translocated populations began to grow and expand their geographic range. By the mid-1980s, sea otters had recolonized much of their pre-exploitation range.

In April 1992, FWS conducted an aerial survey of sea otters throughout the entire Aleutian archipelago (Evans *et al.* 1997). The most striking results of this survey were that sea otter density and abundance in the Rat, Delarof, and western Andreanof Islands had unexpectedly declined by more than 50% since 1965. Boat-based surveys of sea otters at several islands in the Near, Rat, and Andreanof Islands further documented an ongoing decline of sea otters during the 1990s (Estes *et al.* 1998).

In April 2000, the FWS Marine Mammals Management Office replicated the 1992 aerial survey in the Aleutians. Overall, sea otters in the Aleutian Islands have declined by 70% during the 8-year period from 1992 to 2000 (U.S. Fish and Wildlife Service, unpublished data). The largest declines occurred in the Rat Islands (87%) and the central Aleutians (71%).

Based on the results of this survey, on August 22, 2000, FWS designated sea otters in the Aleutians (from Unimak Pass to Attu) as a candidate species under the Endangered Species Act (ESA) (65 FR 67343). On October 25, 2000, FWS received a petition from the Center for Biological Diversity (CBD) to list sea otters in the Aleutians as threatened or endangered under the ESA. Due to a backlog of court-ordered listing and critical habitat designations, funds were not available to prepare a proposed rule in Fiscal Year (FY) 2001.

Immediately following the completion of the Aleutian sea otter survey, in May 2000 the FWS conducted an aerial survey of sea otters on the north side of the Alaska Peninsula from False Pass to Cape Seniavin. The FWS also conducted aerial surveys along the south side of the Alaska Peninsula in April 2001. The results of these surveys, which replicated a baseline study conducted in 1986 (Brueggeman *et al.* 1988), indicate that the sea otter population has also declined in these areas. In June 2001, the FWS conducted an aerial survey of the Kodiak Archipelago for comparison with data collected in 1994. A comparison of the two surveys, which used the same aircraft, pilot, and observer, indicate the sea otter population has declined in the Kodiak area as well. Based on the results of surveys conducted in the past year, the Alaska Region of the FWS has requested funding in FY2002 to prepare a proposed rule to list sea otters in southwest Alaska under the ESA.

On August 21, 2001, FWS received a petition from CBD to list sea otters throughout their range in Alaska as depleted under the MMPA (September 6, 2001, 66 FR 46651). Section 115(a)(3)(B) of the MMPA requires the FWS to publish a finding in the **Federal Register** as to whether the petition presents substantial information indicating that the petitioned action may be warranted.

Identification of Sea Otter Stocks in Alaska

Findings of depleted status must be made on the species or population stock level. Amendments to the MMPA in 1994 included section 117 (16 U.S.C. 1386), which mandated preparation of stock assessments for each marine mammal stock that occurs in waters under the jurisdiction of the United States. In 1995, FWS published a final stock assessment for the northern sea otter in Alaska as a single stock (60 FR 52008). Section 117(c) requires that stock assessments be reviewed: (A) At least annually for stocks which are specified as strategic stocks; (B) at least annually for stocks for which significant new information is available; and (C) at least once every 3 years for all other stocks. If the review indicates that the status of the stock has changed or can be more accurately determined, the stock assessment shall be revised according to the process outlined in section 117(b). The first revision to the stock assessment occurred in 1998.

In February 1998, FWS published a draft revision of the northern sea otter stock assessment that identified three stocks of sea otters in Alaska (63 FR 10936). The revision identified a southeast Alaska stock (Cape Yakataga to Dixon Entrance), a southcentral Alaska stock (Cook Inlet to Cape Yakataga), and a southwest Alaska stock (Cook Inlet to Attu Island, including the Kodiak archipelago).

In August 1998 the Alaska Sea Otter Commission (ASOC) requested a proceeding on the record as outlined in section 117(b)(2) of the MMPA to contest the identification of multiple stocks of sea otters in Alaska. After considerable discussion, FWS and ASOC signed a Memorandum of Agreement (MOA) in July 1999 to further investigate the issue of stock structure of sea otters in Alaska. On August 12, 1999, the ASOC (now the Alaska Sea Otter and Steller Sea Lion Commission) withdrew the request for a formal proceeding on the record. A revised stock assessment for the northern sea otter in Alaska has not been finalized.

The identification of multiple stocks of sea otters in Alaska in our 1998 draft revision was based on an analysis of existing data on distribution, population response, phenotypic data, and genotypic data according to Dizon *et al.* (1992). One element of the MOA concerned scientific peer review of the analysis that identified multiple stocks of sea otters in Alaska. That element has been satisfied by the publication of Gorbics and Bodkin (2001), who applied the criteria of Dizon *et al.* (1992) and identified three stocks of sea otters in Alaska: Southwest, southcentral, and southeast. Another element of the MOA involved the completion of additional genetics analysis using both mitochondrial and nuclear DNA, as well as a larger sample size. This study is complete and a manuscript is in preparation for scientific peer review and publication (Cronin *et al.* in prep.). The results of this study also support the identification of multiple stocks of sea otters in Alaska.

The FWS is currently in the process of revising our original 1995 stock assessment for northern sea otters in Alaska. Based on the best available scientific evidence, FWS anticipates publishing draft stock assessments identifying multiple stocks of sea otters in Alaska. The drafts soon will be available for public review and comment.

Current Population Size

The Petition presents an estimated statewide sea otter population of fewer than 38,000 individuals. This figure was calculated using population estimates from the 1998 draft stock assessments, along with the estimated abundance for the Aleutians presented in the Candidate Species announcements (65 FR 67343). The statewide population estimate presented in the petition is inaccurate for several reasons. First, available population estimates are omitted from substantial portions of the State, including the Alaska Peninsula and Kodiak archipelago. Second, the estimate used for the Aleutian Islands is incorrect. Further analysis of the Aleutian aerial survey data has resulted in a revised population estimate of 8,742 rather than the previously reported value of 5,812 (Doroff *et al.* in prep.). Finally, most population

estimates presented by the petitioners are not corrected for detection probability. Sea otters may either be at the surface and missed by observers, or below the surface and unavailable for counting. In order to calculate the best estimate of current population size for determination of depleted status, these data must be corrected for detection probability.

Detection probability is often specific to survey design, personnel, and weather conditions. The survey technique used in Prince William Sound, Kodiak, and Yakutat generates a detectability correction factor for each survey (Bodkin and Udevitz 1999). Detection probabilities for this technique ranged from 52–72%. Similarly, the Aleutian Islands survey in 2000 used sea otter counts made from skiffs at six islands to estimate a detection probability of 28% (Doroff *et al.* in prep).

For aerial and ship-based surveys for which no correction factor exists, the results of similar studies can be used as approximate values. For fixed-wing aerial surveys with one observer on each side of the aircraft, Evans *et al.* (1997) calculated that observers saw 42% of the sea otters within a known area. This equates to a detectability correction factor of 2.38 (CV=0.087). For surveys conducted from small boats, Udevitz *et al.* (1995) estimated that observers saw 70% of the sea otters present, for a correction factor of 1.43 (CV=0.071). Detection of sea otters during boat surveys is higher than aerial surveys because the survey platform is moving slower, which gives observers more time to visually search for otters. The additional search time also reduces the likelihood that otters below the surface may be missed. Using the most applicable correction factors for detection probability available, the best estimate for the Aleutians Islands, and including all areas of the State, the current best estimate of the Alaska sea otter population size is 74,143 with a 95% confidence interval of ±15,739 (Table 1).

TABLE 1.—CURRENT STATEWIDE POPULATION ESTIMATES OF SEA OTTERS IN ALASKA. ORIGINAL ESTIMATES FOR LOCATIONS IN ITALICS DID NOT INCLUDE A SURVEY-SPECIFIC DETECTION PROBABILITY CORRECTION FACTOR. ADJUSTED ESTIMATES FOR THESE LOCATIONS USE A CORRECTION FACTOR OF 2.38 FOR FIXED-WING AIRCRAFT AND 1.43 FOR SMALL BOAT SURVEYS

Location	Survey year	Survey type	Original estimate	Coefficient of variation	Adjusted estimate	Reference
Southeast Alaska	1994	Small boat	8,180	0.392	11,697	Agler *et al.* 1995.
Yakutat Bay	1995	Fixed-wing aircraft	404	0.339	404	Doroff and Gorbics 1998.
North Gulf of Alaska (Cape Yakataga to Cape Spencer).	1996	Fixed-wing aircraft	223		531	Doroff and Gorbics 1998.
Lower Cook Inlet	1993	Small boat	5,914	0.267	8,457	Agler *et al.* 1995.
Kenai Peninsula	1989	Helicopter	2,330	0.120	2,330	DeGange *et al.* 1995.
Prince William Sound	1999	Fixed-wing aircraft	13,234	0.198	13,234	USGS unpublished data.
N. Gulf of Alaska (Cape Hinchinbrook to Cape Yakataga).	1996	Fixed-wing aircraft	271		645	Doroff and Gorbics 1998.
Aleutian Islands	2000	Fixed-wing aircraft	8,742	0.215	8,742	Doroff *et al.* in prep.
Unimak Island	2001	Fixed-wing aircraft	42		100	FWS unpublished data.
North Alaska Peninsula (False Pass to Port Heiden).	2000	Fixed-wing aircraft	5,756	0.327	13,699	FWS unpublished data.
South Alaska Peninsula (False Pass to Pavlof Bay).	2001	Fixed-wing aircraft	939	0.809	2,235	FWS unpublished data.
South Alaska Peninsula (Seal Cape to Cape Douglas).	2001	Fixed-wing aircraft	2,190		5,212	FWS unpublished data.
South Alaska Peninsula Islands	2001	Fixed-wing aircraft	405		964	FWS unpublished data.
Kodiak Archipelago	2001	Fixed-wing aircraft	5,893	0.228	5,893	FWS unpublished data.
Total					74,143	

Population Status Relative to OSP

The worldwide population of sea otters in the early 1700s has been estimated at 150,000 (Kenyon 1969) to 300,000 (Johnson 1982). The size of the Alaska sea otter population prior to commercial depletion is unknown. Calkins and Schneider (1985) estimated the statewide sea otter population at 100,000 to 150,000 in 1976. Sea otter populations have potentially high reproductive rates (Riedman and Estes 1990). As a result, recovering otter populations may temporarily exceed carrying capacity (K) on a local level, before stabilizing at a lower equilibrium value (Estes 1990). These uncertainties make a current determination of K for sea otters in Alaska problematic. In the face of these uncertainties, the petitioners propose a conservative estimate of K for sea otters in Alaska of 100,000 individuals. Lacking specific information about habitat and K throughout much of Alaska, we believe this is a reasonable estimate of K at this time.

Determination of the Maximum Net Productivity Level (MNPL), which defines the lower bound of Optimum Sustainable Population (OSP) for any marine mammal stock is difficult. Initial studies on marine mammal populations using a generalized logistic population model resulted in a MNPL of half of K. Later studies based on the life history characteristics of marine mammals suggested that MNPL lies somewhat closer to K (Eberhardt and Siniff 1977, Gerrodette and DeMaster 1990). For most species of marine mammals, there is insufficient data available to estimate MNPL accurately (Taylor and DeMaster 1993). Where a Species-specific estimate of MNPL is unavailable, the best available information calls for applying 60% of K as an approximation (Barlow *et al.* 1995). Using this approximation of MNPL (60%) for the purpose of responding to this petition and in the absence of specific productivity levels for Alaska sea otters and an estimated K of 100,000, the petitioners present a lower threshold of OSP for sea otters in

Alaska of 60,000. The best available population estimate for sea otters in Alaska (74,143) is above this threshold.

Finding on the Petitioned Action

Based on the best available estimate of current population size, the statewide sea otter population is above the conservative estimate of OSP. In addition, although the last finalized stock assessment in 1995 classified sea otters in Alaska as a single stock, the best scientific information currently available indicates that multiple stocks exist. This information suggests that three stocks occur in Alaska: Southwest, southcentral, and southeast. The best available scientific information shows that the population in southeast Alaska is growing (Bodkin *et al.* 1999), and the population in southcentral Alaska is either stable or growing. While these two populations are either stable or growing, the FWS acknowledge that sea otters in southwest Alaska have undergone widespread, dramatic declines in the past 10–15 years.

The FWS is in the process of revising the stock assessment of sea otters in Alaska under the MMPA, and as part of this process will make a final determination on the number and geographic range of Alaska sea otter stocks. Stock identification is a defined process under the MMPA and while the currently available biological data indicates that three stocks are appropriate, the Service needs to complete the stock assessment process properly and in close cooperation with our partners. The genetics study conducted by the FWS was just recently completed and we expect the new stock assessments to be completed soon. Once these stock assessments are finalized, the status of each stock will be evaluated and designation of a southwest stock as depleted may be warranted at that time.

The FWS acknowledged the decline of sea otters of the Aleutians by designating them a Candidate Species under the ESA in August 2000. In the candidate species designation, the FWS treated the sea otters in southwest Alaska as a distinct population segment under the ESA and its implementing regulations. Once funding is available the FWS will proceed to propose the southwest Alaska sea otters for Federal listing under the ESA. This action would be more applicable to the sea otter than a depleted designation. The primary benefits that accrue to a depleted species is the requirement for a conservationn plan which is already in place for the sea otter, and the ability to publish regulations to regulate harvest if harvest is negatively affecting the population; we do not believe harvest is affecting the population. Also, under section 3(1)(C) of the MMPA (16 U.S.C. 1362), a species or population stock that is listed as an endangered species or a threatened species under the ESA is automatically classified as depleted under the MMPA. While continuing to evaluate the sea otter under both statutes, the FWS will also continue to monitor population status and further assess causes of the decline, to the extent possible within available resources.

The FWS finds that the petition did not present substantial information that the petitioned action is warranted. The FWS has determined that the statewide population of sea otters in Alaska is considerably larger than the conservative estimate of OSP presented in the petition. Furthermore, the best available scientific information indicates that multiple stocks of sea otter exist in Alaska.

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Authority: The authority for this action is the Marine Mammal Protection Act of 1972, as amended, 16 U.S.C. 1361 *et seq.*

Dated: October 26, 2001.

Marshall P. Jones, Jr.,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 01–27495 Filed 11–1–01; 8:45 am]

BILLING CODE 4310–55–M

UNITED STATES INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–739 (Review)]

Clad Steel Plate From Japan

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission determines, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), that revocation of the antidumping duty order on clad steel plate from Japan would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on June 1, 2001 (66 FR 29829, June 1, 2001) and determined on September 4, 2001 that it would conduct an expedited review (66 FR 49040, September 25, 2001).

The Commission transmitted its determination in this review to the Secretary of Commerce on October 29, 2001. The views of the Commission are contained in USITC Publication 3459 (October 2001), entitled Clad Steel Plate from Japan: Investigation No. 731–TA–739 (Review).

Issued: October 29, 2001.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–27540 Filed 11–1–01; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR § 207.2(f)).

UNITED STATES INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701–TA–365–366 (Review) and 731–TA–734–735 (Review)]

Certain Pasta From Italy and Turkey

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission determines, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), that revocation of the countervailing and antidumping duty orders on certain pasta from Italy and Turkey would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on June 1, 2001 (66 FR 29831, June 1, 2001) and determined on September 4, 2001 that it would conduct expedited reviews (66 FR 50453, October 3, 2001).

The Commission transmitted its determinations in these reviews to the Secretary of Commerce on October 29, 2001. The views of the Commission are contained in USITC Publication 3462 (October 2001), entitled Certain Pasta from Italy and Turkey: Investigations Nos. 701–TA–365–366 (Review) and 731–TA–734–735 (Review).

Issued: October 29, 2001.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–27539 Filed 11–1–01; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE

Notice of Lodging of Settlement Agreement and Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

Under 28 CFR 50.7 and pursuant to section 122(d)(2) of the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C.. 9622(d)(2), notice is hereby given that on October 10, 2001, a proposed Settlement Agreement and Consent Decree (''Decree'') in United States and State of Colorado v. Robert Friedland, Civil No. 96–N–1213, was lodged with the United States District Court for the District of Colorado. The United States and State of Colorado filed this action pursuant to the Comprehensive Environmental Response, Compensation and Liability Act for recovery of costs incurred by the United States and State of Colorado in responding to releases of hazardous substances at the Summitville Mine Superfund Site near Del Norte, Colorado.

Pursuant to the proposed Decree, the United States and State of Colorado will have an allowed general unsecured claim jointly against defendant Industrial Constructors Corp. and also against Washington Group International, Inc., and Washington Contractors Group, Inc. in the amount of $20,288,080 in the Bankruptcy Case captioned *In re: Washington Group International, Inc.* Case No. BK–N–01–31627 (GWZ) (Bankr. D. Nev.). This general unsecured claim will resolve the claims of the United States and the State of Colorado against defendant Industrial Constructors Corp. in *United States and State of Colorado* v. *Robert Friedland*, Civil No. 96–N–1213 (D. Colo.) and also will resolve the claims of the State of Colorado against defendants Washington Group International, Inc., Washington Contractors Group, Inc., and Dennis Washington in *United States* v. *Sunoco, Inc., et al.*, Civil No. 01–N–1 (D. Colo.).

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to, *United States and State of Colorado* v. *Robert Friedland*, Civil No. 96–N–1213, and D.J. Ref. #90–11–3–1133B.

The Decree may be examined at the office of the U.S. Department of Justice, Environmental Enforcement Section, 999 18th Street, Suite 945, North Tower, Denver, Colorado; at U.S. EPA Region 8, Office of Regional Counsel, 999 18th Street, Suite 300, South Tower, Denver Colorado. A copy of the Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. In requesting a copy, please enclose a check in the amount of $5.75 (25 cents per page reproduction

cost) payable to the Consent Decree Library.

Robert D. Brook,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 01–27608 Filed 11–1–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request.

ACTION: Notice of information collection under review: request for premium processing service.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in an interim rule INS No. 2108–01; RIN 1115–AG03 in the **Federal Register** on June 1, 2001 at 66 FR 29682, allowing for emergency OMB review and approval, as well as a 60-day public comment period. No comments were received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 3, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, 725–17th Street, NW., Room 10235, Washington, DC 20530; Attention: Department of Justice Desk Officer.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of response.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Request for Premium Processing Service.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–907, Immigration Services Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. The data collected on this form is used by the Service to process requests for premium processing of certain employment-based petitions or applications in accordance with section 286(u) of the District of Columbia Appropriations Act of 2002.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 80,000 responses at 30 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 40,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan, 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

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, 601 D Street, NW., Patrick Henry Building, Suite 1600, Washington, DC 20530.

Dated: October 25, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–27548 Filed 11–1–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice of information collection under review: application for removal.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 27, 2001 at 66 FR 39207, allowing for a 60-day public comment period. No public comment was received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 3, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Application for Removal.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–243, Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. The information provided on this form allows the Service to determine eligibility for the alien's request for removal from the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 41 responses at 10 minutes (.166 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 7 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

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, Patrick Henry Building, 601 D Street, NW., Ste. 1600, Washington, DC 20530.

Dated: October 25, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–27549 Filed 11–1–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Canadian border boat landing permit.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on August 1, 2001 at 66 FR 39794, allowing for a 60-day public comment period. No public comment was received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 3, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725—17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the From/Collection:* Canadian Border Boat Landing Permit.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–68, Inspections Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. Section 235 of the Immigration and Nationality Act provides for the inspection of persons entering the United States from Canada by small craft to be inspected only once during the navigational season, rather than each time they enter. Persons issued this form are permitted to visit the immediate shore area for the duration of the boating season without having to travel to the nearest INS office for inspection.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 68,000 responses at 10 minutes (.316 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 11,288 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Solan.

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, Patrick Henry Building, 601 D

Street, NW., Ste. 1600, Washington, DC 20530.

Dated: October 25, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–27550 Filed 11–1–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF LABOR

Employment Standards Administration; Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein. Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department.

Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, N.W., Room S–3014, Washington, DC 20210.

New General Wage Determination Decision

The number of the decisions added to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' are listed by Volume and States:

Volume VII

California
CA010042 (Nov. 2, 2001)

Modification to General Wage Determination Decisions

The number of decisions listed to the Government Printing Office document entitled ''General Wage determinations Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Massachusetts
MA010001 (Mar. 2, 2001)
MA010002 (Mar. 2, 2001)
MA010003 (Mar. 2, 2001)
MA010005 (Mar. 2, 2001)
MA010007 (Mar. 2, 2001)
MA010008 (Mar. 2, 2001)
MA010009 (Mar. 2, 2001)
MA010010 (Mar. 2 2001)
MA010012 (Mar. 2 2001)
MA010013 (Mar. 2 2001)
MA010014 (Mar. 2 2001)
MA010015 (Mar. 2 2001)
MA010016 (Mar. 2 2001)
MA010017 (Mar. 2 2001)
MA010018 (Mar. 2 2001)
MA010019 (Mar. 2 2001)
MA010020 (Mar. 2 2001)
MA010021 (Mar. 2 2001)

Maine
ME010001 (Mar. 2 2001)
ME010002 (Mar. 2 2001)
ME010005 (Mar. 2 2001)
ME010008 (Mar. 2 2001)
ME010012 (Mar. 2 2001)

New Hampshire
NH010011 (Mar. 2 2001)

New Jersey
NJ010001 (Mar. 2 2001)
NJ010002 (Mar. 2 2001)
NJ010003 (Mar. 2 2001)
NJ010006 (Mar. 2 2001)

New York
NY010001 (Mar. 2 2001)
NY010002 (Mar. 2 2001)
NY010003 (Mar. 2 2001)
NY010004 (Mar. 2 2001)
NY010005 (Mar. 2 2001)
NY010007 (Mar. 2 2001)
NY010010 (Mar. 2 2001)
NY010012 (Mar. 2 2001)
NY010013 (Mar. 2 2001)
NY010014 (Mar. 2 2001)
NY010015 (Mar. 2 2001)
NY010016 (Mar. 2 2001)
NY010017 (Mar. 2 2001)
NY010018 (Mar. 2 2001)
NY010020 (Mar. 2 2001)
NY010021 (Mar. 2 2001)
NY010026 (Mar. 2 2001)
NY010033 (Mar. 2 2001)
NY010037 (Mar. 2 2001)
NY010039 (Mar. 2 2001)
NY010041 (Mar. 2 2001)
NY010043 (Mar. 2 2001)
NY010045 (Mar. 2 2001)
NY010048 (Mar. 2 2001)
NY010071 (Mar. 2 2001)
NY010072 (Mar. 2 2001)

Volume II

West Virginia
WV010001 (Mar. 2, 2001)
WV010003 (Mar. 2, 2001)
WV010006 (Mar. 2, 2001)
WV010010 (Mar. 2, 2001)

Volume IIII

Alabama
AL010018 (Mar. 2, 2001)

North Carolina
NC010055 (Mar. 2, 2001)

Volume IV

Illinois

IL010001 (Mar. 2, 2001)
IL010002 (Mar. 2, 2001)
IL010007 (Mar. 2, 2001)
IL010013 (Mar. 2, 2001)
IL010016 (Mar. 2, 2001)
IL010017 (Mar. 2, 2001)
IL010035 (Mar. 2, 2001)
IL010042 (Mar. 2, 2001)
IL010049 (Mar. 2, 2001)
IL010052 (Mar. 2, 2001)
IL010054 (Mar. 2, 2001)

Indiana
IN010001 (Mar. 2, 2001)
IN010002 (Mar. 2, 2001)
IN010003 (Mar. 2, 2001)
IN010004 (Mar. 2, 2001)
IN010005 (Mar. 2, 2001)
IN010006 (Mar. 2, 2001)
IN010008 (Mar. 2, 2001)
IN010016 (Mar. 2, 2001)
IN010047 (Mar. 2, 2001)

Volume V

Iowa
IA010003 (Mar. 2, 2001)
IA010004 (Mar. 2, 2001)
IA010005 (Mar. 2, 2001)
IA010006 (Mar. 2, 2001)
IA010007 (Mar. 2, 2001)
IA010009 (Mar. 2, 2001)
IA010029 (Mar. 2, 2001)
IA010032 (Mar. 2, 2001)
IA010038 (Mar. 2, 2001)
IA010056 (Mar. 2, 2001)
IA010059 (Mar. 2, 2001)
IA010060 (Mar. 2, 2001)
IA010067 (Mar. 2, 2001)
IA010070 (Mar. 2, 2001)

Missouri
MO010006 (Mar. 2, 2001)

Nebraska
NE010001 (Mar. 2, 2001)
NE010003 (Mar. 2, 2001)
NE010019 (Mar. 2, 2001)

Volume VI

North Dakota
ND010001 (Mar. 2, 2001)
ND010002 (Mar. 2, 2001)
ND010004 (Mar. 2, 2001)
ND010008 (Mar. 2, 2001)
ND010015 (Mar. 2, 2001)

Oregon
OR010001 (Mar. 2, 2001)
OR010017 (Mar. 2, 2001)

Washington
WA010001 (Mar. 2, 2001)
WA010002 (Mar. 2, 2001)
WA010008 (Mar. 2, 2001)

Volume VII

California
CA010001 (Mar. 2, 2001)
CA010002 (Mar. 2, 2001)
CA010009 (Mar. 2, 2001)
CA010029 (Mar. 2, 2001)
CA010030 (Mar. 2, 2001)
CA010031 (Mar. 2, 2001)
CA010033 (Mar. 2, 2001)
CA010035 (Mar. 2, 2001)
CA010036 (Mar. 2, 2001)
CA010037 (Mar. 2, 2001)
CA010038 (Mar. 2, 2001)
CA010039 (Mar. 2, 2001)
CA010040 (Mar. 2, 2001)
CA010041 (Mar. 2, 2001)

Nevada
NV010001 (Mar. 2, 2001)
NV010003 (Mar. 2, 2001)
NV010004 (Mar. 2, 2001)
NV010005 (Mar. 2, 2001)
NV010006 (Mar. 2, 2001)
NV010007 (Mar. 2, 2001)
NV010008 (Mar. 2, 2001)
NV010009 (Mar. 2, 2001)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon And Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the Davis-Bacon Online Service (*http://davisbacon.fedworld.gov*) of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, D.C. this 25th day of October 2001.

Terry Sullivan,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 01–27339 Filed 11–1–01; 8:45 am]

BILLING CODE 4510–27–M

MEDICARE PAYMENT ADVISORY COMMISSION

Commission Meeting

AGENCY: Medicare Payment Advisory Commission.

ACTION: Notice of meeting.

SUMMARY: The Commission will hold its next public meeting on Thursday, November 15, 2001, and Friday, November 16, 2001, at the Ronald Reagan Building, International Trade Center, 1300 Pennsylvania Avenue, NW., Washington, DC. The meeting is tentatively scheduled to begin at 10 a.m. on November 15, and at 9 a.m. on November 16.

Topics for discussion include: Quality improvement for health plans and providers; Medicare program complexity and regulatory burden; payment for outpatient pain management procedures; blood safety requirements: impact on hospital costs and payment options; measuring payment adequacy and; updating payments in traditional Medicare; the Medigap insurance market; Medicare's hospice benefit; and Medicare+Choice.

Agendas will be mailed on November 6, 2001. The final agenda will be available on the Commission's Web site (*www.MedPAC.gov*).

ADDRESSES: MedPAC's address is: 1730 K Street, NW., Suite 800, Washington, DC 20006. The telephone number is (202) 653–7220.

FOR FURTHER INFORMATION CONTACT: Diane Ellison, Office Manager, (202) 653–7220.

Murray N. Ross,

Executive Director.

[FR Doc. 01–27553 Filed 11–1–01; 8:45 am]

BILLING CODE 6820–BW–M

NATIONAL COMMUNICATIONS SYSTEM

Request for Information on Telecommunications Emergency Alerting Capabilities

AGENCY: National Communications System (NCS).

ACTION: Request for information.

SUMMARY: The National Communications System (NCS) is seeking information on potential emergency notification capabilities; before, during, and after an emergency; via: (1) The Public Telephone System. Notified telephone numbers might be all lines in a geographic area or a pre-loaded list of telephone numbers; (2) Paging Systems. These might be digital text and/or voice messaging systems. Notified pagers might be all pagers in a geographic area or a pre-loaded list of pager numbers; (3) Cellular Telephones. These might be notified by digital text messaging and/or voice. Notified cellular telephones might be all cellular telephones in a geographic area or a pre-loaded list of cellular telephone numbers.

DATES: Submissions should be made within 21 days of the date of this notice.

ADDRESSES: National Communications System, Attn: N2, 701 South Court House Road, Arlington, VA 22204–2198, *barrd@ncs.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Dale Barr, Jr., National Communications System, Attn: N2, 701 South Court House Road, Arlington, VA 22204–2198, telephone (703) 607–6157, fax (703) 607–4830, e-mail address, *barrd@ncs.gov*.

SUPPLEMENTARY INFORMATION: The requested information is for planning purposes and does not constitute a commitment, implied or otherwise, that a procurement action will be isued. No entitlement to payment of direct or indirect costs or charges by the Government will arise as a result of the submission of information. The Government shall not be liable for or suffer any consequential damages for any improperly identified proprietary information. Proprietary information will be safeguarded in accordance with the applicable Government regulations. If there is a GSA or other contract vehicle already available for the technology being proposed, please include this information in the response.

Peter M. Fonash,

Federal Register Certifying Officer, National Communications System.

[FR Doc. 01–27555 Filed 11–1–01; 8:45 am]

BILLING CODE 5001–08–M

NATIONAL SCIENCE INFORMATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request clearance of this collection. In accordance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting OMB clearance of this collection for no longer than 3 years.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) The accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) Ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; 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.

DATES: Written comments should be received by January 2, 2002, to be assured of consideration. Comments received after that date would be considered to the extent practicable.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 295, Arlington, VA 22230, or by e-mail to *splimpto@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Suzanne Plimpton on (703) 292–7556 or send e-mail to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Title of Collection: The Evaluation of NSF's Graduate Teaching Fellows in K–12 Education (GK–12) Program.

OMB Control No.: 3145–New.

Expiration Date of Approval: Not applicable.

1. *Abstract:* This document has been prepared to support the clearance of data collection instruments to be used in the evaluation of the Graduate Teaching Fellows in K–12 Education (GK–12). GK–12 is a fellowship that offers graduate students and advanced undergraduates the opportunity to serve as resources for K–12 teachers of science and mathematics. The study design focuses on GK–12 projects funded during the period 1999–2002 and involves two types of studies. One consists of **Case Studies** of three cohorts of GK–12 projects. The second is a **SURVEY** of all GK–12 projects funded in this time period. This OMB submission seeks clearance for data collection instruments for both studies.

2. *Expected Respondents:* The expected respondents are GK–12 Fellows, Cooperating Teachers in the school districts where the Fellows are placed, Principal Investigators, and other educators associated directly with the GK–12 Program.

3. *Burden on the Public:* The total elements for this collection is 1,823 burden hours for a maximum of 3,645 participants assuming an 80–100% response rate. The average annual reporting burden is 2 hours per respondent. The burden on the public is negligible; the study is limited to project participants that have received funding from the NSF GK–12 program.

Dated: October 29, 2001.

Suzanne H. Plimpton,

NSF Reports Clearance Officer.

[FR Doc. 01–27489 Filed 11–1–01; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Cyberinfrastructure; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Advisory Committee for Cyberinfrastructure (#10719).

Date/Time: Wednesday, Nov. 21, 2001, 2 pm–5 pm EDT.

Place: Rm. 130, National Science Foundation, 4201 Wilson Blvd., Arlington, VA.

Type of Meeting: Open Teleconference Meeting. Persons wishing to attend the meeting at NSF should contact Richard Hilderbrandt to arrange for a visitor's pass.

Contact Person: Dr. Richard Hilderbrandt, Program Director, Division of Advanced Computational Infrastructure and Research, Suite 1122, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Tel: (703) 292–7093, e-mail: *rhilderb@nsf.gov.*

Purpose of Meeting: To develop a plan for the preparation of a report to the National Science Foundation concerning he broad topic of advanced cyberinfrastructure and the evaluation of the existing Partnerships for Advanced Computational Infrastructure.

Agenda:

Announcements and news sharing.
Sub-committee status reports.
Comments by invited visitors.
Review of draft of outline of report.
Next Steps.
Matters Arising.

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Susanne Bolton,

Committee Management Officer.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 50–331]

Nuclear Management Company, LLC; Duane Arnold Energy Center Environmental Assessment and Finding of No Significant Impact Related to a Proposed License Amendment To Increase the Maximum Rated Thermal Power Level

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License No. DPR–49, issued to Nuclear Management Company, LLC (NMC), for operation of the Duane Arnold Energy Center, located in Linn County, Iowa. Therefore, pursuant to 10 CFR 51.21 and 10 CFR 51.35, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action

The proposed action would allow NMC, the operator of DAEC, to incrementally increase its electrical generating capacity by raising the maximum reactor core power level from 1658 MWt to 1912 MWt, 15.3 percent above the current maximum licensed power level. The change is considered an EPU for a BWR because it would raise the reactor core power level more than approximately 7 percent above the original maximum licensed power level. A previous 4.1-percent power uprate, implemented in 1985, raised the original maximum power level from 1593 MWt to 1658 MWt. A power uprate increases the heat output of the reactor to support increased turbine inlet steam flow requirements and increases the heat dissipated by the condenser to support increased turbine exhaust steam flow requirements.

The proposed action is in accordance with NMC's application for amendment dated November 16, 2000, as supplemented April 16 (two letters) and 17; May 8 (two letters), 10, 11 (two letters), 22, and 29; June 5, 11, 18, 21, and 28; July 11, 19, and 25; and August 1, 10, 16, and 21; and October 17, 2001, and NMC's ''Supplement to DAEC Environmental Report,'' submitted on September 22, 2000, in advance of the application.

The NRC previously published a draft environmental assessment of the proposed action in the **Federal Register** (66 FR 48482, September 20, 2001) and offered an opportunity for public comment. No comments were received.

Need for the Proposed Action

Alliant Energy—IES Utilities (Alliant), the principal owner of DAEC,[1] has compared the projected load growth to its electrical generating capacity and has determined a need for additional capacity in its territory. Alliant's obligated capacity is expected to increase by 2 percent per year. The proposed EPU would add 80 megawatts of electrical generating capacity to the grid. The estimated cost of adding this generating capacity is approximately half the cost of purchasing power and one-third the cost of providing the power by constructing a new combined-cycle, natural-gas-fueled facility. Therefore, Alliant concluded that increasing DAEC's capacity would be the most economical option for increasing power supply. Furthermore, unlike fossil fuel plants, DAEC does not routinely emit sulfur dioxide, nitrogen oxide, carbon dioxide, or other atmospheric pollutants.

Environmental Impacts of the Proposed Action

At the time of the issuance of the operating license for DAEC, the NRC staff noted that any activity authorized by the license would be encompassed by the overall action evaluated in the Final Environmental Statement (FES) for the operation of DAEC, which was issued in March 1973. The original operating license for DAEC allowed a maximum reactor power level of 1593 MWt. On September 22, 2000, NMC submitted a supplement to its Environmental Report supporting the proposed EPU action and provided a summary of its conclusions concerning the environmental impacts of the proposed action. Based on the NRC staff's independent analyses of the nonradiological and radiological impacts and the evaluation performed by the licensee, the staff has concluded that the environmental impacts of the EPU are bounded by the environmental impacts previously evaluated in the FES because the EPU does not involve extensive changes to plant systems that directly or indirectly interface with the environment. Additionally, the licensee states that no changes to the National Pollutant Discharge Elimination System permit issued by the State would be necessary.

[1] On January 10, 2001, the NRC published in the **Federal Register** (66 FR 2009) an Environmental Assessment and Finding of No Significant Impact regarding a requested change to the DAEC operating license to reflect the proposed change in the owner's name from IES Utilities, Inc., to Interstate Power and Light Company. The NRC's final action regarding the requested name change is pending.

Nonradiological Impacts

The following is the NRC staff's evaluation of the nonradiological environmental impacts of the EPU on land use, water use, waste discharges, terrestrial and aquatic biota, transmission facilities, and social and economic conditions at DAEC.

Land Use Impacts

The proposed EPU would not modify the land use at the site, nor have any impacts on lands with historic or archaeological significance. The licensee states that it has no plans to construct any new facilities or alter the land around existing facilities, including buildings, access roads, parking facilities, laydown areas, onsite transmission and distribution equipment, or power line rights-of-way, in conjunction with the EPU. The EPU would not significantly affect the storage of materials, including chemicals, fuels, and other materials stored above or under the ground. The EPU would not alter the aesthetics of the site. Therefore, the FES conclusions for impacts on land use would remain valid under EPU conditions.

Water Use Impacts

The staff evaluated surface water use and groundwater use as environmental impacts of water usage at DAEC.

Surface Water Use

An EPU is accomplished by increasing the heat output of the reactor, thereby increasing the steam flow to the turbine, for which increased feedwater flow is needed. The increased heat load on the cooling tower would cause evaporative losses to increase; therefore, cooling tower makeup to the circulating water system increases to compensate for the increase in evaporative losses. Cooling tower makeup at DAEC is supplied by the Cedar River and well water systems. The EPU would not change the amount of water withdrawn from the well water system. The EPU would require an increase in river water use; however, the licensee stated that DAEC would not use more river water than permitted. In accordance with the water appropriation limits of the Iowa Department of Natural Resources (IDNR), DAEC may withdraw a maximum of 12,575 million gallons per year (MGY) from the Cedar River at a rate of 27,000 gallons per minute (gpm) minus the total well water withdrawal rate (3000 gpm). Special operating restrictions apply at lower-than-average river flows if the withdrawal would reduce the river flow to less than 500 cubic feet per second (cfs). A maximum flow rate of 11,000 gpm and an annual

withdrawal rate of 5782 MGY were analyzed in the FES. During the years 1996 through 1999, the flow at DAEC averaged 5680 gpm. The licensee predicts the flow will be 6700 gpm under EPU conditions. The predicted flow average under EPU conditions is approximately 40 percent less than that analyzed in the FES and is below the IDNR-permitted limits. In the period 1996–1999, the annual withdrawal rate at DAEC averaged 3000 MGY; the licensee projects it will be 3540 MGY under EPU conditions. The 3540 MGY projected average flow withdrawal rate is also below the value evaluated in the FES and the IDNR-permitted limit of 12,575 MGY. The EPU would have no impact on the number of cooling tower concentration cycles or on the cooling tower flow rate. Therefore, current water appropriation limits would be maintained and the conclusions in the FES would remain valid under the proposed EPU conditions.

Groundwater Use

The staff evaluated the consumption of groundwater as an environmental impact of the proposed EPU. Groundwater use at DAEC is governed by a permit issued by the IDNR. The permit limits DAEC to 1575 MGY with the flow from all pumps not to exceed 3000 gpm. A maximum flow rate of 1500 gpm and a withdrawal rate of 788 MGY were evaluated in the FES. The average annual groundwater withdrawal rate for DAEC is 762 MGY, with a normal system flow averaging 1420 gpm.

The licensee stated that the proposed EPU would not increase the consumption of groundwater, would not impact the well water system flow path, and does not require any additional cooling capacity from the groundwater in order to shed heat loads. Therefore, the staff's conclusions in the FES on groundwater use are valid for the proposed EPU.

Discharge Impacts

The staff evaluated environmental impacts such as cooling tower fogging, icing, drift, noise, chemical discharges to surface water, sanitary waste discharges, blowdown, thermal plume spread, temperature of the river water, cold shock to aquatic biota, hazardous waste effluents, and air emissions.

Cooling Tower Fogging, Icing, Drift, and Noise

Environmental impacts such as fogging, icing, cooling tower drift, and noise could result from the increased heat load on the cooling tower under EPU conditions. In the FES, the staff concluded that the operation of the DAEC cooling towers may slightly increase fogging and icing in nearby areas. The staff stated that cooling tower drift was estimated to be a maximum of 0.1 percent of cooling water flow, or 0.65 cubic feet per second (290 gpm). The estimates were based on anticipated evaporation and drift rates of 2.25 percent and 0.5 percent of tower flow, respectively. The licensee stated that the total hours of fogging would increase by approximately 1.1 hour per year above the nominal 240 hours per year, and that icing would be insignificant. The proposed EPU would not change the cooling tower flow or drift rate; however, the evaporation rate was calculated to increase to approximately 3 percent.

Since the original analysis in the FES, the cooling towers at DAEC have been upgraded by replacing the wooden drift eliminators with polyvinyl chloride (PVC) drift eliminators. The PVC drift eliminators allow water droplets to return to the cooling tower air stream and channel water to the cooling tower's cold water basin, which reduces evaporation and drift losses. Consequently, the licensee's analysis of the effect of the EPU on fogging is conservative.

After considering the increase in heat load on the cooling towers, the staff concluded that the incremental effects of fog attributable to the proposed EPU would be negligible and would continue to be bounded by the FES. Other cooling tower impacts, such as drift and icing, would not be expected to change as a result of the EPU. Therefore, the staff finds that the conclusions in the FES for fogging, icing, and cooling tower drift would be valid under the proposed EPU conditions.

The FES also stated that the operation of the cooling towers would result in a noticeable, but acceptable, increase in the noise level at the nearest dwelling. The proposed EPU would not significantly change the character, sources, or energy of noise generated at DAEC. The new equipment necessary to implement the EPU would be installed within existing plant buildings and no significant increase in ambient noise levels within the plant would be expected. Therefore, the FES conclusions for noise levels would remain valid under EPU conditions.

Chemical and Sanitary Discharges

Surface water and wastewater discharges are regulated by the State of Iowa. The National Pollutant Discharge Elimination System (NPDES) permit is periodically reviewed and reissued by the IDNR. The present NPDES permit for DAEC authorizes discharges from two outfalls, only one of which would be affected by the EPU.

The use of chemicals and their subsequent discharge to the environment would not be expected to change significantly as a result of the proposed EPU. The cooling tower concentration cycle would remain within the current range of 3.5 to 4.0. Therefore, the concentration of pollutants in the effluent stream would remain the same. No changes to the sanitary waste systems or to the parameters regulated by the NPDES permit would be needed to accomplish the EPU. Sanitary waste from DAEC is discharged directly to the DAEC sewage treatment plant in accordance with a permit from the State of Iowa.

Blowdown

Total discharge would increase linearly with blowdown flow. It is anticipated that the blowdown flow would increase 18 percent as a result of the EPU. Blowdown for the circulating water system is discharged into the Cedar River. The FES conservatively assumed a blowdown flow rate of 4000 gpm. The actual blowdown flow rate is 1570 gpm and the blowdown flow rate calculated for EPU conditions would be 1850 gpm. During winter, the season which DAEC discharges would have the greatest impact on river water temperature, the actual average blowdown temperature is 30 degrees Fahrenheit (°F) less than that assumed in the FES. The EPU would increase the blowdown discharge temperature by approximately 1.6 °F. Typical discharge temperatures and flow rates are below the current limits so it would not be necessary to modify the NPDES permit to implement the proposed EPU.

Thermal Plume Spread and Temperature of River Water

The actual average blowdown flow rate is 1,570 gpm. The FES assumed a value of 4,000 gpm. The increased values for uprated power blowdown temperature and flow are still bounded by the calculation of the FES. Consequently, the FES conclusions remain valid. The FES concluded that the thermal plume would be less than 1 acre in area and would reach less than a quarter of the reach across the river. The EPU would increase the discharge temperature by 1.6 °F and the flow rate by 18 percent. However, the EPU would not noticeably increase the plume size.

Under worst-case winter conditions, the 2 °F isotherm was predicted to extend about 250 feet downstream with a width of about 70 feet. A discharge temperature of 72 °F for the month of

January was analyzed in the FES. Historically, in winter, when discharges would have the greatest impact on river water temperature, the actual average blowdown temperature is 30 °F less than that assumed in the FES. The average discharge temperature (from 1961 to 1990) for the month of January was 36 °F, and, as stated above, the EPU would increase the discharge temperature by only 1.6 °F. Consequently, the actual size of the thermal plume is smaller than predicted in the FES.

Under worst-case summer conditions, with the same assumptions and data used to calculate the circulating water discharge temperature, the 2 °F isotherm was predicted to extend about 75 feet downstream of the discharge point with a width of about 35 feet. Thermal mapping conducted in August 1989, demonstrated the conservative nature of the assumptions in the FES. The mapping was performed at 100-percent reactor power. The 2 °F isotherm extended to between 100 and 150 feet downstream, and was restricted to within 10 feet of the bank (i.e. 10 feet wide). At 150 feet downstream, there was no detectible plume. The total plume area was less, therefore, than that predicted for the 2 °F isotherm in the FES, and, as stated above, the EPU would not noticeably increase the plume size. The staff concludes the plumes for both summer and winter cases are bounded by the FES. The conditions analyzed in the FES would be expected to remain valid under the proposed EPU conditions.

Cold Shock

Cold shock to an aquatic biota occurs when the warm water discharge from a plant abruptly stops because of an unplanned shutdown, resulting in a temperature drop of the river water and the possible adverse impact on aquatic biota. The probability of an unplanned shutdown is independent of a power uprate. As discussed previously, the discharge canal temperature at EPU conditions would be at least 10 °F less than the value evaluated in the FES. Additionally, the plume size would not increase appreciably under power uprate conditions and would be smaller than analyzed in the FES. Therefore, the risk of aquatic biota mortality by cold shock would continue to be bounded by the conclusions in the FES.

Hazardous Waste Generation and Air Emissions

Hazardous waste generated from routine plant operations and air emissions from the plant heating boiler and diesel generators are controlled by county permits. A power uprate would not have a significant impact on the quality or quantity of effluents from these sources, and operation under EPU conditions would not reduce the margin to the limits established by the applicable permits. Therefore, the conclusions in the FES would remain valid.

Terrestrial Biota Impacts

The proposed EPU would not result in a land disturbance that could adversely impact the habitat of any terrestrial plant or animal species. The licensee stated that according to a recent review by the IDNR, there were no known rare or endangered terrestrial species within the area of the site boundary. Additionally, the licensee stated that land use would remain the same as evaluated in the FES. Therefore, the staff's conclusions in the FES about the impact on terrestrial ecology, including endangered and threatened plant and animal species, would remain valid for the proposed EPU.

Aquatic Biota Impacts

The impacts of operation of the river water intake include impingement of fish on the traveling screens at the intake structure and the entrainment of benthic organisms. The losses associated with the impingement and entrainment of organisms were assessed in the FES and were judged to be insignificant. The effect of the EPU on the impingement and entrainment of organisms also would be insignificant. Fish impingement totals are typically less than 500 fish per year and are considered to be very low, considering the size and composition of the fish population in the Cedar River. Additionally, the licensee stated that there were no known rare or endangered aquatic species in the plant site vicinity. Therefore, the staff's conclusions in the FES as to impingement, entrainment, and endangered and threatened aquatic species would remain valid for the proposed EPU.

Transmission Facility Impacts

Environmental impacts, such as exposure to electromagnetic fields (EMFs) and shock could result from a major modification to transmission line facilities. However, the licensee stated that no change would be made to the existing transmission line design or operation as a result of the proposed EPU. Higher main transformer capacity would be necessary to deliver the additional power to the offsite grid and certain modifications to offsite substations are being planned to enhance stability at various grid locations. These modifications are consistent with Alliant's program of systematic improvements in grid stability and its commitments to the Mid-Continent Area Power Pool and the Mid-America Interconnected Network; modifications would be performed within existing substations. Therefore, no significant environmental impacts from any changes in transmission facilities design and equipment are expected, and the conclusions in the FES would remain valid.

The rise in generator output associated with EPU would slightly increase the current and the EMFs in the onsite transmission line between the main generator and the plant substation. The line is located entirely within the fenced, licensee-controlled boundary of the plant, and neither members of the public nor wildlife are expected to be affected. Exposure to EMFs from the offsite transmission system is not expected to increase significantly and any such increase is not expected to change the staff's conclusion in the FES that no significant biological effects are attributable to EMFs from high voltage transmission lines.

DAEC transmission lines are designed and constructed in accordance with the applicable shock prevention provisions of the National Electric Safety Code and the EPU would not cause the transmission line design to deviate from the NESC provisions. Therefore, the slight expected increase in current attributable to the proposed EPU does not change the staff's conclusion in the FES that adequate protection is provided against hazards from electrical shock.

Social and Economic Impacts

The staff has reviewed information provided by the licensee regarding socioeconomic impacts, including possible impacts on the DAEC workforce and the local economy. DAEC employs more than 500 people and is a major contributor to the local tax base. DAEC personnel also contribute to the tax base by paying sales and property taxes. The proposed EPU would not significantly affect the size of the DAEC workforce and would have no material effect on the labor force required for future outages. Because the plant modifications needed to implement the EPU would be minor, any increase in sales taxes and local and national business revenues would be negligible relative to the large taxes paid by DAEC. It is expected that improving the economic performance of DAEC through cost reductions and lower total bus bar costs per kilowatt hour would enhance the value of DAEC as a generating asset

and lower the probability of early plant retirement. Early plant retirement might have a negative impact upon the local economy and the community as a whole by reducing public services, employment, income, business revenues, and property values, although these reductions might be mitigated by decommissioning activities in the short term. The staff expects that conclusions in the FES regarding social and economic impacts would remain valid under EPU conditions.

The staff also considered the potential for direct physical impacts of the proposed EPU, such as vibration and dust from construction activities. The proposed EPU would be accomplished primarily by changes in station operation and a few physical modifications to the facility. These limited modifications would be accomplished without physical changes to transmission corridors, access roads, other offsite facilities, or additional project-related transportation of goods or materials. Therefore, no significant additional construction disturbances causing noise, odors, vehicle exhaust, dust, vibration, or shock from blasting are anticipated, and the conclusions in the FES would remain valid.

Summary

In summary, the proposed EPU would not result in a significant change in nonradiological impacts on land use, water use, waste discharges, terrestrial and aquatic biota, transmission facilities, or social and economic factors, and would have no nonradiological environmental impacts other than those evaluated in the FES.

TABLE 1.—SUMMARY OF NONRADIOLOGICAL ENVIRONMENTAL IMPACTS OF AN EPU AT DAEC

Land Use Impacts	No change in land use or aesthetics; would not impact lands with historic or archeological significance.
Water Use Impacts:	
Surface Water Use	Increase in river water withdrawal rate to 3540 MGY; withdrawal rate would remain within permitted levels, and within levels evaluated in the FES.
Groundwater Use	No change in groundwater use.
Discharge Impacts:	
Fogging	Increase in total hours of fogging per year by 1.1 hour.
Icing	No significant change in icing.
Cooling Tower Drift	No significant change in cooling tower drift.
Noise	No significant change in noise.
Chemical and Sanitary Discharge	No expected change to chemical use and subsequent discharge, or sanitary waste systems; cooling towers would operate in the current cycle range. No changes to sanitary waste discharges.
Blowdown	Increase in blowdown by 18°; blowdown would remain within the permitted limits.
Thermal Plume and Temperature of the River Water.	No noticeable increase in thermal plume size. Discharge temperature increase by 1.6 EF; river temperature would remain within National Pollution Discharge Elimination System limit of 9 °F.
Hazardous Waste and Air Emissions	No changes to hazardous waste sources or air emissions.
Terrestrial Biota Impacts	No change in terrestrial biota impacts; no known threatened or endangered species within the site boundary.
Aquatic Biota Impacts	No change in aquatic biota impacts; no known threatened or endangered species in the area of surface water intake or discharge.
Transmission Line Facility Impacts	No change to transmission line design or operation; higher main transformer capacity would be needed to deliver additional power and these changes would be made within existing substations; no change in exposure to EMFs.
Social and Economic Impacts	No significant change in size of DAEC workforce. Few modifications to physical station facility. No significant disturbances from noise, odor, vehicle exhaust, dust, vibration, or shock would be expected from construction.

Radiological Impacts

The staff evaluated radiological environmental impacts on waste streams, in-plant and offsite doses, accident analyses, and fuel cycle and transportation factors. The following is a general description of the waste treatment streams at DAEC and an evaluation of the environmental impacts.

Radioactive Waste Stream Impacts

DAEC uses waste treatment systems designed to collect, process, and dispose of radioactive gaseous, liquid, and solid waste in accordance with the requirements of 10 CFR part 20 and Appendix I to 10 CFR part 50. These radioactive waste treatment systems are discussed in the FES. The proposed EPU would not affect the environmental monitoring of these waste streams or the radiological monitoring requirements contained in licensing basis documents. The proposed EPU would not result in any changes in operation or design of equipment in the gaseous, liquid, or solid waste systems. The proposed EPU would not introduce new or different radiological release pathways and would not increase the probability of an operator error or equipment malfunction that would result in an uncontrolled radioactive release. The staff evaluated any changes in the gaseous, liquid, and solid waste streams for radiological environmental impact of the proposed EPU, as set forth below.

Gaseous Radioactive Waste Impacts

During normal operation, the gaseous effluent systems control the release of gaseous radioactive effluents to the site environs, including small quantities of noble gases, halogens, particulates, and tritium, so that routine offsite releases from station operation remain below the limits of 10 CFR part 20 and appendix I to 10 CFR part 50 (10 CFR part 20 includes the requirements of 40 CFR part 190). The gaseous waste management systems include the offgas system and various building ventilation systems. The proposed EPU assumes an increase in the release rate that is linearly proportional to power increase, and an increase in gaseous effluents would, therefore, occur. The resultant effluent increases in noble gas and iodine-131 activity are 0.3 and 4E–07 microcuries per second, respectively. The staff has evaluated information provided by the licensee and concludes that the estimated dose values would be below Appendix I requirements after the EPU. These dose levels are very small,

and have no significant impact on human helath. The effluents for noble gases and effluents are well below those evaluated in the FES. Therefore, the conclusions in the FES would remain valid under EPU conditions.

Liquid Radioactive Waste Impacts

The liquid radwaste system is designed to process and recycle (to the extent practicable) the liquid waste collected so that annual radiation doses to individuals are maintained below the guidelines in 10 CFR Part 20 and 10 CFR Part 50, Appendix I. DAEC operates as a zero radioactive liquid release plant. The staff expects no change in the zero release policy as a result of the proposed EPU.

Filter backwashing provides decanted sludge water into the liquid radwaste system. Increasing the reactor thermal power by 15 percent would increase the frequency of backwashing necessary to decant backwash water from the reactor water cleanup condensate demineralizer filters by approximately 8 to 10 percent. However, since Alliant maintains a zero radioactive liquid release to the environment, the slight increase in flow to the liquid radwaste system would be recycled instead of discharged.

The EPU conditions would not result in significant increases in the volume of fluid from other sources flowing into the liquid radwaste system. The reactor would continue to be operated within its present pressure control band. Valve packing leakage volume into the liquid radwaste system is not expected to increase. There would be no changes in reactor recirculation pump seal flow or the flow of any other normal equipment drain path. In addition, there would be no impact on the dirty radwaste or chemical waste subsystems of the liquid radwaste system as a result of the EPU since the operation and the inputs to these subsystems are independent of power uprate. Based on information submitted by the licensee, the staff concludes that no significant dose increase in the liquid pathway would result from the proposed EPU. Therefore, the conclusions in the FES would remain valid under EPU conditions.

Solid Radioactive Waste Impacts

The solid radioactive radwaste system collects, monitors, processes, packages, and provides temporary storage facilities for radioactive solid wastes prior to offsite shipment and permanent disposal. DAEC has implemented procedures to assure that the processing and packaging of wet and dry solid radioactive waste and irradiated reactor components are accomplished in compliance with the regulations.

Wet Waste: The largest volume contributors to radioactive solid wet waste are the spent resin and filter sludges from the process wastes. Equipment waste from operation and maintenance activities, chemical wastes, and reactor system wastes also contribute to solid waste generation. The staff expects that the process wastes generated from the operation of the reactor water cleanup filter demineralizers and the condensate demineralizers will increase by no more than 10 percent. More frequent reactor water cleanup backwashes are anticipated under EPU conditions due to water chemistry limits. The licensee estimates that the backwashes would increase by approximately 8 to 10 percent, resulting in an additional 3 cubic meters of resin waste per year. The resultant total generation rate of approximately 36 cubic meters per year (CMY), is about half the current industry median value of 85 CMY and well below the FES assumed value of 697 CMY. The EPU would not involve changes in either reactor water cleanup flow rates or filter performance. The staff concludes that implementation of the proposed EPU would not have a significant impact on the volume or activity of wet radioactive solid waste at DAEC.

Dry Waste: Dry waste consists of air filters, miscellaneous paper and rags from contaminated areas, contaminated clothing, tools and equipment parts that cannot be effectively decontaminated, and solid laboratory wastes. The activity of much of this waste is low enough to permit manual handling. Dry waste is collected in containers located throughout the plant, compacted as practicable, and then sealed and removed to a controlled-access enclosed area for temporary storage. Because of its low activity, dry waste can be stored until enough is accumulated to permit economical transportation to an offsite processing facility or a burial ground for final disposal. DAEC has indicated that there will be no significant change in the amounts, level of controls, or methodology used for the processing dry radioactive waste at DAEC. The staff concludes that implementation of the proposed EPU should not have a significant impact on the volume or activity of the dry solid radioactive waste at DAEC.

Irradiated Reactor Components: Irradiated reactor components, such as spent control blades, in-core ion chambers, and fuel assemblies, must be disposed of after the life of the component. The volume and activity of waste generated from spent control blades and in-core ion chambers might increase slightly under the higher flux conditions associated with power uprate conditions. This increase would be mitigated by improved longer-lived local power range monitor strings, improved lower-cobalt-content control rod blades, and longer fuel cycles. Additionally, reactor equipment waste is stored in the spent fuel storage pool before removal to in-plant or offsite storage and final disposal in shielded containers or casks. Because of the mitigating effects of extended burnup and increased U–235 enrichment compared to the burnups and enrichment evaluated in the original FES, implementing the EPU would not be likely to have a significant impact on the amount of irradiated reactor components discharged from the reactor.

DAEC plans to load 152 fresh fuel bundles in the initial refueling to commence operation under the EPU. This is approximately 30 bundles more than for the current refueling cycle. Because of the mitigating effects of extended burnup and increased U–235 enrichment on fuel throughput under power uprate operating conditions, the number of irradiated fuel assemblies discharged from the reactor would not increase during subsequent reloads. Additionally, the 24-month operating cycle would result in one less fuel reload before the license expiration. These wastes are currently stored in the spent fuel pool and are not shipped off site. The staff concludes that implementation of the proposed EPU should not have a significant impact on the volume or activity of the irradiated reactor components at DAEC.

The staff has generically evaluated the annual environmental impact of low- and high-level solid wastes for a 1000 MWe reference reactor. The estimated activity of these wastes is given in Table S–3 in 10 CFR 51.51 and would be bounding under the proposed EPU conditions.

Dose Impacts

The staff evaluated in-plant and offsite radiation as part of its review of environmental impacts of the proposed EPU.

In-Plant Radiation

Increasing the rated power at DAEC might increase the radiation levels in the reactor coolant system; however, these potential increases would be compensated for by physical plant improvements and administrative controls, such as shielding, feedwater chemistry, and the plant radiation

protection program. Over the past 7 years, DAEC has decreased the occupational dose to DAEC workers by 15 percent per year (based on a rolling 3-year average). The licensee stated that it expects to continue its downward trend while operating under the proposed EPU conditions. The staff evaluated shielding, dose reduction programs, and corrosion as part of its evaluation.

Shielding: DAEC was conservatively designed with respect to shielding and radiation sources. In the shielding analysis, the assumed concentrations for reactor water fission and corrosion products were 4 microcuries per cubic centimeter and 0.06 microcuries per cubic centimeter, respectively. The normal value of both reactor water fission and corrosion products is 0.01 microcuries per cubic centimeters. With expected increases in operating activity proportional to the proposed power increase, the design shielding assumptions remain bounding at EPU conditions.

Feedwater Chemistry: The original design was based on an assumed value for nitrogen-16 (N–16) concentration of 100 microcuries per gram. To support the injection of hydrogen into the feedwater, the licensee conducted a special test in 1989 to evaluate the impact and efficacy of injection rates of up to 45 standard cubic feet per minute (scfm). The licensee stated that the results of this test led to an injection rate of 6 scfm, which yields an acceptable recirculating system electrochemical potential and no discernable N–16 dose rate increase. Between October 1994 and October 1996, the hydrogen injection rate was increased to 15 scfm to extend corrosion protection to portions of the core internals, with a resultant increase in dose rates of 3.3 times the rates without hydrogen injection. Although occupancy in some areas was restricted, no shielding modifications were required to maintain radiation levels within acceptable levels. Since 1996, DAEC has undertaken a noble metals injection program to protect the core internals from corrosion by reducing hydrogen use. As a result, the current operational hydrogen injection rate is 6.0 scfm. The 20-percent increase in the N–16 dose rate from EPU would not affect the acceptability of the shielding design.

The equilibrium activity concentration of corrosion products that have plated out on reactor coolant piping and other surfaces may theoretically increase by the square of the power uprate increase. This is primarily due to the linear increase in corrosion products in the primary system from the feedwater flow increase and the linear increase in activation events from the core average flux increase. However, this potential increase would be mitigated by four dose reduction programs at DAEC:

1. Oxygen injection in the condensate system started in 1987.
2. Recirculating system chemical decontaminations in 1990, 1992, 1993, and 1995.
3. Stellite reduction efforts started in 1993.
4. Depleted zinc addition started in 1994.

As a result of these efforts, the concentration of soluble cobalt-60 in the reactor water has decreased from 1.3E–04 microcuries per milliliter in early 1987 to 2.7 E–05 microcuries per milliliter in 2000. The potential increases in the volume and activity of activated corrosion products at EPU operating conditions would not negate these efforts, and it is expected that concentrations would continue to decline under EPU conditions. Consequently, operating and shutdown radiation levels would not increase under EPU conditions.

Plant Radiation Protection Program: The plant radiation protection program would be used to maintain individual doses consistent with as-low-as-reasonably-achievable policies and below the established limits of 10 CFR Part 20. Routine plant radiation surveys required by the radiation protection program would identify increased radiation levels in accessible areas of the plant, and radiation zone postings and job planning would be adjusted, if necessary. Time within radiation areas is controlled under the radiation protection program. Administrative dose control limits are established well below regulatory criteria and provide a significant margin to regulatory dose limits. The licensee stated that administrative dose limits were not routinely exceeded under present power conditions.

On the basis of the above information, the staff concludes that the expected annual collective dose for DAEC, following the proposed EPU, would still be bounded by the dose estimates in the FES.

Offsite Doses

The slight increase in normal operational gaseous activity levels under the EPU would not affect the large margin to the offsite dose limits established by 10 CFR Part 20. In addition, doses from liquid effluents, currently zero, would remain zero under EPU conditions.

The DAEC Technical Specifications implement the guidelines of 10 CFR Part 50, Appendix I, which are within the 10 CFR Part 20 limits. Adjusting current values for projected EPU increases, the offsite dose at EPU conditions is estimated to be 2.6 E–03 millirads for noble gas gamma air, 1.6E–02 millirads for noble gas beta air, and 6.8E–03 thyroid millirem for particulates and iodine. The Appendix I limits are 10 millirads, 20 millirads, and 15 thyroid millirem, respectively. The offsite dose would continue to be within the Technical Specification dose limits.

The EPU would not involve significant increases in an offsite dose from noble gases, airborne particulates, iodine, or tritium. Radioactive liquid effluents are not routinely discharged from DAEC. In addition, as stated by the Radiological Environmental Monitoring Program for DAEC, radiation from shine is not now a significant exposure pathway, and it would not be significantly affected by the proposed EPU.

The EPU would not create any new or different sources of offsite dose from DAEC operation, and the EPU would not involve significant increases in present radiation levels. Therefore, under EPU conditions, offsite dose would remain well within regulatory criteria and would not have a significant impact. The staff concludes that the estimated doses from both the liquid and gaseous release pathways resulting from EPU conditions are within the design objectives specified by 10 CFR part 50, appendix I, and the limits of 10 CFR part 20.

Accident Analysis Impacts

The staff reviewed the licensee's analyses and performed confirmatory calculations to verify the acceptability of the licensee's calculated doses under accident conditions. The staff concludes that the proposed EPU would not significantly increase the probability or consequences of accidents and would not result in a significant increase in the radiological environmental impact of DAEC under accident conditions. If the license amendment request is approved, the result of the staff's calculations will be presented in the safety evaluation issued with the license amendment.

Fuel Cycle and Transportation Impacts

The EPU would involve an increase in the average enrichment of the fuel bundle. The environmental impacts of the fuel cycle and of transportation of fuel and wastes are described in Table S–3 and S–4 of 10 CFR 51.51 and 10 CFR 51.52, respectively. Table S–3 of 10 CR 51.51 and S–4 of 10 CFR 51.52 were

adopted by the licensee after DAEC received its operating license. Consequently, the DAEC FES does not contain a uranium fuel cycle environmental analysis similar to Table S–3. The impacts of transportation are addressed in the Environmental Report and the FES, although the conclusions are not presented in the format of Table S–4. An NRC assessment (53 FR 30355, dated August 11, 1988, as corrected by 53 FR 32322, dated August 24, 1988) evaluated the applicability of Table S–3 and S–4 to higher burnup cycles and concluded that there is no significant change in environmental impacts for fuel cycles with uranium enrichments up to 5 weight-percent U–235 and burnups less than 60 gigawatt-day per metric ton of uranium (GWd/MTU) from the parameters evaluated in Tables S–3 and S–4. Because the fuel enrichment for the EPU would not exceed 5 weight-percent U–235 and the rod average discharge exposure would not exceed 60 GWd/MTU, the environmental impacts of the proposed EPU would remain bounded by these conclusions and would not be significant.

Summary

The proposed EPU would not significantly increase the probability or consequences of an accident, would not introduce any new radiological release pathways, would not result in a significant increase in occupational or public radiation exposures, and would not result in significant additional fuel cycle environmental impacts. Accordingly, the NRC concludes that no significant radiological environmental impacts are associated with the proposed action. Table 2 summarizes the radiological environmental impacts of the proposed EPU.

TABLE 2.—SUMMARY OF RADIOLOGICAL ENVIRONMENTAL IMPACTS OF EPU AT DAEC

Radiological Waste Stream Impacts:	
Gaseous Waste	An increase in release rate that is linearly proportional to the power increase would be expected.
Liquid Waste	No change in DAEC zero liquid release policy.
Solid Waste:	
Wet Waste	Backwashes would increase to create approximately 3 cubic meters of resin per year.
Dry Waste	No significant changes.
Irradiated Components	No significant changes.
Dose Impacts	May potentially increase radiation levels; dose would remain within permitted levels in-plant and offsite.
Accident Analysis Impacts	No significant increase in the probability or consequences of an accident.
Fuel Cycle and Transportation	Increase in bundle average enrichment; impacts would remain within the conclusions of Table S–3 and Table S–4 of 10 CFR Part 51.

Alternatives to the Proposed Action

As an alternative to the proposed action, the staff considered denial of the proposed action (i.e., the ''no-action'' alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

As stated previously, the estimated cost of adding this nuclear generating capacity is approximately half the cost projected for purchasing the power and one-third the cost of producing the power by constructing a new combined-cycle, natural-gas-fueled facility. Alliant concluded that increasing DAEC's capacity would be the most economical option for increasing power supply. Furthermore, unlike fossil fuel plants, DAEC does not routinely emit sulfur dioxide, nitrogen oxides, carbon dioxide, or other atmospheric pollutants that contribute to greenhouse gases or acid rain.

Alternative Use of Resources

This action does not involve the use of any resources different than those previously considered in the FES for DAEC, dated March 1973.

Agencies and Persons Consulted

In accordance with its stated policy, on August 23, 2001, the NRC staff consulted with the Iowa State official, Mr. D. McGhee of the Department of Public Health, regarding the environmental impact of the proposed action. The State official had no comment.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's application dated November 16, 2000, as supplemented April 16 (two letters) and 17; May 8 (two letters), 10, 11 (two letters), 22, and 29; June 5, 11, 18, 21, and 28; July 11, 19, and 25; and August 1, 10, 16, and 21; and October 17, 2001, and NMC's ''Supplement to DAEC Environmental Report,'' submitted on September 22, 2000. Documents may be examined and/or copied for a fee at the NRC's Public Document Room, at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Library component on the NRC Web site, *http://www.nrc.gov* (the Electronic Reading Room). If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room Reference staff at 1–800–397–4209, or 301–415–2737, or by e-mail at *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 31st day of October 2001.

For the Nuclear Regulatory Commission.

William D. Reckley,

Acting Chief, Section 1, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 01–27716 Filed 11–1–01; 8:45 am]

BILLING CODE 7950–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting of the Subcommittee on Reactor Fuels

Notice of Meeting

The ACRS Subcommittee on Reactor Fuels will hold a meeting on November

16, 2001, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Friday, November 16, 2001—8:30 a.m. until the conclusion of business.

The Subcommittee will discuss the Duke Cogema Stone Webster MOX Fuel Fabrication Facility construction application authorization. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineer named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the cognizant ACRS staff engineer, Ms. Maggalean W. Weston (telephone 301/415–3151) between 7:30 a.m. and 4:15 p.m. (EST). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any potential changes in the proposed agenda, etc., that may have occurred.

Dated: October 25, 2001.

Sher Bahadur,

Associate Director for Technical Support, ACRS/ACNW.

[FR Doc. 01–27537 Filed 11–1–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards and Advisory Committee on Nuclear Waste Joint Subcommittee Meeting; Notice of Meeting

The Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste (ACNW) Joint Subcommittee will hold a meeting on November 14, 2001, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, November 14, 2001—8:30 a.m. until the conclusion of business

The ACRS and ACNW Joint Subcommittee will continue its discussion on risk-informed regulation in the Office of Nuclear Material Safety and Safeguards (NMSS) including Standard Review Plan (SRP) Chapter 3 for integrated safety analysis (ISA), use of risk-informed case studies, and development of a PRA for dry cask storage. The purpose of this meeting is to gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the ACRS and ACNW full Committees.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman. Written statements will be accepted and made available to the ACRS and ACNW full Committees. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS/ACNW staff member named below five days prior to the meeting, if possible, so that appropriate arrangements can be made. During the initial portion of the meeting, the Subcommittee, along with any consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff, its consultants, and other interested persons regarding these matters.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, the Subcommittee's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the cognizant senior staff engineer, Michael T. Markley (telephone 301/415–6885) between 7:30 a.m. and 4:15 p.m. (EST) or by e-mail *MTM@NRC.gov.* Persons planning to attend this meeting are urged to contact the above-named individual one to two working days prior to the meeting to be advised of any potential changes in the proposed agenda, etc., that may have occurred.

Dated: October 26, 2001.

Howard J. Larson,

Acting Associate Director for Technical Support, ACRS/ACNW.

[FR Doc. 01–27574 Filed 11–1–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards Joint Meeting of the Subcommittees on Human Factors and Safety Research Program; Notice of Meeting

The ACRS Subcommittees on Human Factors and Safety Research Program will hold a joint meeting on November 15, 2001, in Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Thursday, November 15, 2001—8:30 a.m. until the conclusion of business

The Subcommittees will discuss the staff's proposed human reliability analysis (HRA) research plan for fiscal years 2001–2005. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittees, their consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineers named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittees, along with any of their consultants who may be

present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittees will then hear presentations by and hold discussions with representatives of the NRC staff and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, and the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor, can be obtained by contacting the cognizant ACRS staff engineer, Mr. Michael T. Markley (telephone 301/415–6885) between 7:30 a.m. and 4:15 p.m. (EST) or by e-mail *MTM@NRC.gov.* Persons planning to attend this meeting are urged to contact the above named individuals one or two working days prior to the meeting to be advised of any potential changes to the agenda, etc., that may have occurred.

Dated: October 26, 2001.

Howard J. Larson,

Acting Associate Director for Technical Support, ACRS/ACNW.

[FR Doc. 01–27575 Filed 11–1–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[SECY–01–0188]

Future Licensing and Inspection Readiness Assessment

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The Nuclear Regulatory Commission (NRC) is announcing, for information, the availability of SECY–01–0188, ''Future Licensing and Inspection Readiness Assessment,'' dated October 12, 2001. This document presents the staff's assessment of its readiness to review applications for licenses and to inspect new nuclear power plants in response to the Commission's February 13, 2001, staff requirements memorandum (SRM) for COMJSM–00–0003, ''Staff Readiness for New Nuclear Plant Construction and the Pebble Bed Modular Reactor.'' Because of the high level of external stakeholder interest in the assessment contained in SECY–01–0188, the Commission is announcing its public availability at this time.

ADDRESSES: SECY–01–0188 is available for inspection and copying for a fee at the Commission's Public Document Room, U.S. NRC's Headquarters Building, 11555 Rockville Pike (first floor), Rockville, Maryland, and electronically from the ADAMS Public Library component on the NRC web site, *http://www.nrc.gov* (the Electronic Reading Room). The ADAMS accession number for SECY–01–0188 is ML012640279. The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/NRC/ADAMS/index.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov.* A free single copy of SECY–01–0188 will be made available to interested parties until the supply is exhausted. Such copies may be requested by writing to the U.S. Nuclear Regulatory Commission, Distribution Services, Washington, DC 20555–0001 or submitting an e-mail to *distribution@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Nanette Gilles, U.S. Nuclear Regulatory Commission, Mail Stop O–11D17, Washington, DC 20555, Phone Number: (301) 415–1180, e-mail: *nvg@nrc.gov.*

SUPPLEMENTARY INFORMATION: In the SRM for COMJSM–00–0003 the Commission directed the staff to assess its technical, licensing, and inspection capabilities and identify enhancements, if any, that would be necessary to ensure that the agency can effectively carry out its responsibilities associated with an ESP application, a license application, and the construction of a new nuclear power plant. In addition, the staff was directed to critically assess the regulatory infrastructure supporting both part 50 and part 52, and other applicable regulations, and identify where enhancements, if any, are necessary. The Commission further directed the staff to incorporate into its planning the need for early interactions with the Advisory Committee on Reactor Safeguards and to integrate the tasks identified during this effort with the various related activities that are underway. The Commission also directed the staff to provide the Commission with a schedule and resource estimates for completing these tasks. The Commission stated that the staff should encourage the industry to be as specific as possible about its plans and schedules so that the agency can plan and budget for advanced reactor activities without disrupting other current important initiatives. The Commission also stated that the staff should work with NRC stakeholders to exercise, to the extent appropriate, the NRC's review process and identify potential policy issues that should be addressed by the Commission in a timely manner.

The staff provided its initial response to the February 13, 2001, SRM in a May 1, 2001, memorandum to the Commission. As the staff stated in that memorandum, the Future Licensing and Inspection Readiness Assessment (FLIRA) interoffice working group was established to address the ability of the NRC to support future application reviews under 10 CFR parts 50 and 52 and other applicable regulations. The FLIRA working group assessed the following matters:

- Licensing scenarios for the future application reviews, the durations of the reviews, and resource estimates to complete the reviews in full-time equivalents (FTE) for the NRC staff and in dollars for technical assistance support;
- Critical skills that must be available within the agency or that can be accessed through contractual agreements to perform these reviews; and
- Regulatory infrastructure needs to support future licensing reviews.

The attachment to SECY–01–0188 contains the FLIRA working group's assessment report. In developing its estimates of the durations and resources required to conduct the reviews discussed in the report, the staff considered (1) the results of a critical skills and resources survey taken of the staff in August 2001 to support this assessment, (2) industry plans and proposed schedules as discussed in public meetings and correspondence, (3) its past experience with licensing and pre-application reviews; (4) the effect of complex issues on these reviews; and (5) estimates from previous resource and schedule evaluations. The resource estimates developed reflect the most recent information received regarding industry plans and the staff's best estimate at this time regarding resource needs, recognizing that budget realities may not be consistent with the needs. Questions regarding the information contained in SECY–01–0188 should be directed to the contact point identified above.

Dated at Rockville, Maryland, this 26th day of October 2001.

For The Nuclear Regulatory Commission

James E. Lyons,

Director, New Reactor Licensing Project Office, Office of Nuclear Reactor Regulation.

[FR Doc. 01–27577 Filed 11–1–01; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Sunshine Act Meeting

AGENCY: Board of Governors, Postal Service.

ACTION: Notification of items added to meeting agenda and change in dates and times of meeting.

DATE OF MEETING: November 5 and 6, 2001.

STATUS: Closed and Open.

PREVIOUS ANNOUNCEMENT: By paper vote on October 26 and 29, 2001, the Board of Governors of the United States Postal Service voted unanimously to add these items to the agenda of its closed and open meeting and to change the times and dates and that no earlier announcement was possible. The General Counsel of the closed session item may be properly closed to public observation under the Government in the Sunshine Act.

STATUS: November 5–11 a.m. (Closed); November 6–8:30 a.m. (Open)

MATTERS TO BE CONSIDERED:

Monday, November 5–11 a.m. (Closed)

1. Rate Case R2001–1 Update.

Tuesday, November 6–8:30 a.m. (Open).

1. Minutes of the Previous Meetings, October 22, and October 1–2, 2001.
2. Remarks of the Postmaster General and CEO.
3. Report from the Chief Postal Inspector.
4. Human Resources/Report from the Surgeon General.
5. Report on Operations and Service.
6. Report on Equipment for Handling Hazardous Materials.
7. Report on Finances.
8. Tentative Agenda for the December 3–4, 2001, meeting in Washington, DC.

CONTACT PERSON FOR MORE INFORMATION: David G. Hunter, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza, SW., Washington, DC. 20260–1000. Telephone (202) 268–4800.

David G. Hunter,

Secretary.

[FR Doc. 01–27724 Filed 10–31–01; 2:15 pm]

BILLING CODE 7710–12–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of November 5, 2001:

An open meeting will be held on Wednesday, November 7, 2001, in Room 1C30, the William O. Douglas Room, at 10 a.m.

The subject matters of the open meeting scheduled for Wednesday, November 7, 2001, will be:

1. The Commission will consider whether to propose amendments to rule 17a–8 under the Investment Company Act of 1940. Rule 17a–8 permits certain affiliated investment companies to merge without obtaining individual exemptive relief. The amendments to Rule 17a–8 would expand the types of mergers that can proceed under the rule. The amendments would also add to the rule certain new conditions designed to protect the interests of fund shareholders.

For further information, please contact Hester Peirce, Attorney, Division of Investment Management, at (202) 942–0690.

2. The Commission will consider a recommendation to issue a concept release regarding actively managed exchange-traded funds. Currently, all exchange-traded funds are based on various equity market indices. The concept release would seek comment from a wide range of parties on potential issues raised by the prospect of an exchange-traded fund with an actively managed portfolio.

For further information, please contact David B. Smith, Associate Director, Division of Investment Management at (202) 942–0525, Nadya B. Roytblat, Assistant Director, Division of Investment Management at (202) 942–0564, or Michael W. Mundt, Branch Chief, Division of Investment Management at (202) 942–0564.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary at (202) 942–7070.

Dated: October 30, 2001.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–27679 Filed 10–31–01; 12:15 pm]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44900; File No. SR–Amex-2001–45]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change and Amendment Nos. 1, 2, 3, and 4 by the American Stock Exchange LLC, Relating to Listing Additional Funds of iShares, Inc. Based on Foreign Stock Indexes

October 25, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on July 2, 2001, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Amex. On October 5, 2001 the Amex filed Amendment No. 1 to the proposal.[3] On October 19, 2001, the Amex filed Amendment No. 2 to the proposal.[4] On October 24, 2001, the Amex filed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Michael Cavalier, Associate General Counsel, Legal & Regulatory Department, Amex, to Nancy Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated October 4, 2001 (''Amendment No. 1''). Amendment No. 1 provided additional information concerning the proposal, including (1) the minimum size and predicted price range of Creation Unit Aggregations; (2) in-kind exchange procedures; (3) the purpose of the Balancing Amount that is used in the creation of Creation Unit Aggregations; (4) iShare redemption procedures; (5) the final dividend amount and method of dissemination; (6) fees associated with buying and selling baskets of stocks in countries with local transfer restrictions; (7) a representation by Amex on preventing excessive weighting and reducing concern that an Index Fund could become a surrogate for trading in unregistered securities; (8) a representation that Barclays Global Fund Advisors seeks to minimize tracking error; (9) a representation that Morgan Stanley Capital International's (''MSCI'') has implemented procedures to prevent the misuse of material non-public information with regard to changes to the MSCI indexes underlying iShare Funds; and (9) the time of day when Net Asset Values will be determined for a given Index Fund.

[4] *See* letter from Michael Cavalier, Associate General Counsel, Legal & Regulatory Division, Amex, to Steven Johnston, Special Counsel, Division, Commission, dated October 18, 2001 (''Amendment No. 2''), Amendment No. 2: (1) Noted that iShares, Inc. had amended its application for certain exemptions under the Investment Company Act of 1940 (''1940 Act'') to add three funds not included in the original application; (2) clarified that Fund Participants must be a Depository Trust Company (''DTC'') Participant; (3) made technical changes to descriptions of Balancing Amount and redemption procedures; (4) clarified the level of the Funds' investment in their underlying indices.

Amendment No. 3 to the proposal.[5] On October 25, 2001, the Amex filed Amendment No. 4 to the proposal.[6] The Commission is publishing this notice to solicit comments on the proposed rule change and Amendment Nos. 1, 2, 3, and 4 from interested persons and is simultaneously approving the proposal, as amended, on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to list and trade under Amex Rules 1000A *et seq.* seven additional iShares℠ MSCI Index Funds (each an ''Index Fund'' or ''Fund''), with each Fund based on one of the following indices compiled by Morgan Stanley Capital International Inc. (''MSCI''): (1) MSCI Europe Index; (2) MSCI Emerging Markets (Free) Index; (3) MSCI Emerging Markets Latin America Index; (4) MSCI All Country World Ex USA Index; (5) MSCI All Country Far East (Free) Ex Japan Index; (6) MSCI Pacific (Free) Ex Japan Index; and (7) MSCI Israel Index. The text of the proposed rule change is available at the Amex 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 Amex 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 Amex has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

In 1996, the Commission approved an Amex proposal to list and trade under Amex Rules 1000A *et seq.* securities issued by an open-end management investment company that seeks to provide investment results that correspond generally to the price and yield performance of a specified foreign or domestic equity market index (''Index Fund Shares'').[7]

The first Index Fund Shares approved by the Commission and listed on the Exchange were seventeen series of World Equity Benchmark Shares™ (later re-named iShares℠ MSCI Index Funds) issued by Foreign Fund, Inc. (now iShares, Inc.), based on the following MSCI indices: Australia, Austria, Belgium, Canada, France, Germany, Hong Kong, Italy, Japan, Malaysia, Mexico (Free), Netherlands, Singapore (Free), Spain, Sweden, Switzerland and United Kingdom.[8] These funds have been trading on the Amex since March 18, 1996.[9]

On May 2, 2000, the Commission approved the listing of additional Index Funds of iShares Inc. based on the following MSCI Indices: MSCI EMU Index; MSCI Brazil (free) Index; MSCI South Korea Index; MSCI South Africa Index; MSCI Taiwan Index; and MSCI United States Index.[10]

The Amex now proposes to list and trade under Amex Rules 1000A *et seq.* the following additional MSCI Index Funds: (1) MSCI Europe Index Fund; (3) MSCI Emerging Markets (Free) Index Fund; (3) MSCI Emerging Markets Latin America Index Fund; (4) MSCI All Country World Ex USA Index Fund; (5) MSCI All Country Far East (Free) Ex Japan Index (Fund); (6) MSCI Pacific (Free) Ex Japan Index Fund; and (7) MSCI Israel Index Fund (each individually a ''Fund'' and collectively the ''Funds'').[11]

Issuances of iShares are made only in Creation Unit Aggregations of 50,000 shares or more. The size of the applicable Creation Unit Aggregation will be set forth in the Fund's prospectus, and it is currently anticipated that the price of a Creation Unit Aggregation will range from at least $450,000 to approximately $25,000,000. iShares, Inc. issues and sells shares of the Index Funds through SEI Investments Distribution Co., the Distributor and principal underwriter, on a continuous basis at the net asset value per share next determined after an order to purchase iShares in Creation Unit size aggregations is received in proper form. Creation Unit Aggregations may be purchased only by or through a participant that has entered into a participant agreement with the Distributor (''Authorized Participant'')[12]. Each Participant must be a Depository Trust Company participant (''DTC''). It is estimated that the initial net asset value per share for the proposed Index Funds will range from $20 to $120. Following issuance, iShares are traded on the Exchange like other equity securities by professionals, as well as retail and institutional investors.

Creation Unit Aggregations generally will be issued in exchange for an in-kind deposit of securities and cash. An Index Fund also may sell Creation Unit Aggregations on a ''cash only'' basis in limited circumstances. An investor wishing to make an in-kind purchase of a Creation Unit Aggregation from an Index Fund will have to transfer to the Fund a ''Portfolio Deposit'' consisting of (a) a portfolio of securities that has been selected by Barclays Global Fund Advisors (''Adviser'') to correspond generally to the price and yield performance of the relevant Underlying Index (''Deposit Securities''), (b) a cash payment equal per Creation Unit Aggregation to the dividends accrued on the Portfolio Securities of the Index Fund since the last dividend payment on the Portfolio Securities, net of expenses and liabilities (the ''Dividend Equivalent Payment''), and (c) an amount equal to the difference between (i) the net asset value (''NAV'') per Creation Unit Aggregation of the Index Fund and (ii) the sum of (I) the Dividend Equivalent Payment and (II) the total aggregate market value per Creation Unit Aggregation of the Deposit Securities (the ''Balancing Amount,''

[5] *See* letter from Michael Cavalier, Associate General counsel, Legal & Regulatory Division, Amex, to Steven Johnston, Special Counsel, Division, Commission, dated October 23, 2001 (''Amendment No. 3''). Amendment No. 3: clarified that fees are assessed to offset market impact costs of buying and selling baskets of stocks in countries with local transfer restrictions.

[6] *See* letter from Michael Cavalier, Associate General Counsel, Legal & Regulatory Division, Amex, to Steven Johnston, Special Counsel, Division, Commission, dated October 25, 2001 (''Amendment No. 4''). Amendment No. 4: clarified (1) further the level of the Funds investment in their underlying indices; (2) the Exchange will disseminate certain information to the National Securities Clearing Coprporation (''NSCC'') every 15 seconds; (3) Fund tracking error will be disseminated via an internet website; and (4) further the description of Balancing amount.

[7] *See* Securities Exchange Act Release No. 36947 (March 8, 1996), 61 FR 10606 (March 14, 1996) (Order Approving file No. SR–Amex-95–43) (''1996 Order'').

[8] ''MSCI'' and ''MSCI Indices'' are service marks of Morgan Stanley & Co. Incorporated.

[9] Trading of these funds was specifically approved in the 1996 Order.

[10] Securities Exchange Act Release No. 42748 (May 2, 2000), 65 FR 30155 (May 10, 2000).

[11] iShares, Inc. has filed with the Commission an Application for Orders under Sections 6(c) and 17(b) of the Investment Company Act of 1940 (''1940 Act'') as amended, for the purpose of exempting the Index Funds referenced herein from various provisions of the 1940 Act and rules thereunder (File No. 812–12290). The iShares MSCI All Country World Ex USA Index Fund; iShares MSCI Pacific (Free) Ex Japan Index Fund; and iShares MSCI Israel Index Fund have been added to the Application by amendment. *See* Amendment No. 1., *supra,* footnote 3.

[12] *See* Amendment No. 1., *supra,* footnote 3.

and, together with the Dividend Equivalent Payment, the ''Cash Component''). The Balancing Amount serves the function of compensating for differences, if any, between the net asset value per Creation Unit Aggregation and the value of the Deposit Amount. The Deposit Amount is the sum of (i) the Dividend Equivalent Payment and (ii) the market value per Creation Unit Aggregation of the Deposit Securities. If the Balancing Amount is a positive number (*i.e.,* the net asset value per Creation Unit Aggregation of the Index Fund exceeds that of the Deposit Amount), the Balancing Amount will be paid to the Fund by the Creator. If the Balancing Amount is a negative number (*i.e.,* the NAV per Creation Unit Aggregation of the Index Fund is less than that of the Deposit Amount) the creator will receive cash in an amount equal to the differential.[13]

On each business day, the Adviser will make available through the Distributor, immediately prior to the opening of trading on the Amex, the list of the names and the required number of the shares of each Deposit Security for each Index Fund that offers in-kind purchases of Creation Unit Aggregations. The Portfolio Deposit will be applicable to purchases of Creation Unit Aggregations until a change in the Portfolio Deposit composition is next announced. On a daily basis, the Adviser provides NSCC with the names and required number of shares of the Deposit Securities in a Creation Unit Aggregation, the Balancing Amount and the estimated cash amount. The NSCC, in turn, makes this information available to NSCC members through an electronic file the NSCC members can download. In addition, the Amex will disseminate at regular intervals (every 15 seconds) throughout the trading day, via the facilities of the Consolidated Tape Association (''CTA''), an amount representing on a per iShare basis, the sum of the Cash Component effective through and including the prior business day, plus the current value of the Deposit Securities.

Each Index Fund reserves the right to permit or require the substitution of an amount of cash or the substitution of any security to replace any Deposit Security that may be unavailable or unavailable in sufficient quantity for delivery to iShares, Inc., or which may be ineligible for trading by an Authorized Participant or the investor on whose behalf the Authorized Participant is acting.

It is anticipated that the deposit of Deposit Securities and the Cash Component in exchange for iShares will be made primarily by institutional investors, arbitrageurs, and the Exchange specialist. Creation Units are separable upon issuance into identical shares which are listed and traded on the Amex. iShares will be traded on the Exchange by professionals as well as institutional and retail investors.

Individual iShares will not be redeemable.[14] iShares will only be redeemable in Creation Unit Aggregations through each Index Fund. To redeem, an investor will have to accumulate enough iShares to constitute a Creation Unit Aggregation. An investor redeeming a Creation Unit Aggregation generally will receive (a) a portfolio of Portfolio Securities in effect on the date the request for redemption is made (''Redemption Securities''), which may not be identical to the Deposit Securities applicable to the purchase of Creation Unit Aggregations, and (b) a ''Cash Redemption Payment,'' consisting of an amount calculated in the same manner as the Cash Component, although the actual amounts may differ if the Redemption Securities are not identical to the Deposit Securities. To the extent that the Redemption Securities have a value greater than the NAV of the iShares being redeemed, the redeeming beneficial owner must make a compensating cash payment to the Fund equal to the differential between the value of the Redemption Securities and the NAV of the iShares being redeemed.[15] An investor may receive the cash equivalent of a Redemption Security in certain circumstances, such as where a redeeming entity is restrained by regulation or policy from transacting in the Redemption Security. An Index Fund may redeem Creation Unit Aggregations in cash in limited circumstances, such as when it is impossible to effect deliveries of Redemption Securities in the applicable jurisdiction.[16]

An Index Fund may make periodic distributions of dividends from net investment income, including net foreign currency gains, if any, in an amount approximately equal to accumulated dividends on securities held by the Fund during the applicable period, net of expenses and liabilities for such period. The final dividend amount for each Fund, which is made available on amextrader.com, is the amount of dividends to be paid by a Fund for the appropriate period (usually annually). The final dividend amount is also disseminated by the Funds to Bloomberg and other sources. iShares, Inc. will not make the DTC book-entry Dividend Reinvestment Service (the ''Service'') available for use by beneficial owners for reinvestment of their cash proceeds but certain individual brokers may make the Service available to their clients.[17]

The net asset value for each Index Fund is calculated by the Fund's Administrator (PFPC Inc.). After calculation, such net asset values are available to the public from the Fund's Distributor via a toll free telephone number, and are also available to NSCC participants through data made available from NSCC.

Fund shares are registered in book entry form through The Depository Trust Company and the Index Funds will not issue individual share certificates. DTC or its nominee will be the record or registered owner of all outstanding iShares. Beneficial

[13] *See* Amendment No. 4., *supra,* footnote 6.

[14] *See* Amendment No. 2., *supra*, footnote 4.

[15] Telephone conversation between Michael Cavalier, Associate General Counsel, Legal & Regulatory Division, Amex and Florence E. Harmon, Senior Special Counsel, Division of Market Regulation (''Division''), Commission, October 25, 2001.

[16] For example, local restrictions on transfers of securities to and between certain types of investors exist in Korea, Malaysia, Taiwan and Brazil. These restrictions currently preclude ''in kind'' creations and redemptions of Creation Units of iShares MSCI Korea, Malaysia, Taiwan and Brazil Index Funds. (*See* SR–Amex–98–49). Accordingly, creations and redemptions of Creation Units of other iShares MSCI Index Funds that hold shares of Korean, Malaysian, Taiwanese and Brazilian companies i.e., iShares MSCI Emerging Markets Latin America; iShares MSCI All Country Far East (Free) Ex Japan; iShares MSCI Emerging Markets (Free); iShares MSCI Pacific (Free) Ex Japan; and iShares MSCI All Country World Ex USA) will involve a combination of ''for cash'' and ''in kind'' transfers. In such cases, the Fund will charge creation and redemption fees intended to offset the transfer and other transaction costs incurred by the Fund, including market impact expenses (primarily associated with creations and redemptions for cash), related to investing in or disposing of the basket of stocks held by the Fund. The Exchange will disclose this information in the Information Circular sent to members and member organizations about the Funds. The Exchange further notes that the Fund prospectus will disclose: (1) The time that the NAV for each fund is calculated; (2) the possible market impact of a Fund buying or selling securities in Brazil, South Korea, Malaysia and Taiwan prior to calculation of the NAV, and (3) the creation and redemption fees for the Fund. The Exchange will also disclose in the Information Circular issued to members and member organizations in connection with start-up of trading in the Funds. *See* Amendment No. 3, *supra*, footnote 5. It is expected that continuous sales and redemptions of Funds that hold shares of Korean, Malaysian, Taiwanese and Brazilian companies will result in their trading close to net asset values. These Funds should ordinarily be able to buy and sell Creation Unit Aggregations shortly after receipt of an order (ordinarily on the business day after receipt of an order). *See* Amendment No. 2, *supra*, footnote 4.

[17] Telephone conversation between Michael Cavalier, Associate General Counsel, Legal & Regulatory Division, Amex and Florence E. Harmon, Senior Special Counsel, Division, Commission, October 25, 2001.

ownership of iShares will be shown on the records of DTC or DTC participants.[18] Trading in shares of iShares MSCI Index Funds on the Exchange is effected until 4 p.m. (New York Time) each business day. The minimum trading increment for such shares is $.01.

MSCI Indices. Each MSCI Index on which a Fund is based is calculated by MSCI for each trading day in the applicable foreign exchange markets based on official closing prices in such exchange markets. For each trading day, MSCI publicly disseminates each index value for the previous day's close. MSCI Indices are reported periodically in major financial publications worldwide, and are also available through vendors of financial information. The information includes an Index description, Index capitalization and concentration, size range of Index companies, Index characteristics, industry group weightings, country weightings and top ten companies and their weightings.

iShares MSCI Index Funds. As noted in the iShares MSCI Index Fund prospectus (Registration No. 33–97598), the investment objective of each Fund is to seek to provide investment results that correspond generally to the price and yield performance of public securities traded in the aggregate in particular markets, as represented by specific MSCI benchmark indices. Each Fund utilizes a ''passive'' or indexing investment approach (a ''representative sampling'' strategy) which attempts to approximate the investment performance of its benchmark index through quantitative analytical procedures. Each Fund has the policy to remain as fully invested as practicable in a pool of securities the performance of which will approximate the performance of the benchmark MSCI Index taken in its entirety. Each Fund will maintain regulated investment company compliance.[19]

Each Fund will normally invest at least 95% of its total assets in component securities that are represented in the underlying index, and will at all times invest at least 90% of its total assets in such stocks, except that in order to permit the Adviser additional flexibility to comply with the requirements of the Internal Revenue Code and other regulatory requirements and to manage future corporate actions and index changes in the smaller markets, certain Funds, identified in each Fund's prospectus, will at all times invest at least 80% of their assets in such stocks and at least half of the remaining 20% in such stocks or in stocks included in the relevant market, but not in the relevant underlying index. iShares, Inc. expects that the iShares MSCI Emerging Markets (Free), Emerging Markets Latin America and Israel Index Funds will be subject to the ''80%/20%'' exception described above. Each Fund may invest its remaining assets in money market instruments (subject to applicable limitations under the 1940 Act), in repurchase agreements, in stocks that are in the relevant market but not in the relevant underlying index, and/or in combinations of certain stock index futures contracts, options on futures contracts, stock index options, stock index swaps, cash, local currency and forward currency exchange contracts that are intended to provide a Fund with exposure to a stock. The Adviser may attempt to reduce tracking error by using futures contracts whose behavior is expected to represent the market performance of the Fund's underlying securities. A Fund will not use these instruments to leverage, or borrow against, its securities holdings or for speculative purposes.

As noted in the iShares MSCI Index Fund prospectus, the Exchange expects that, over time, the ''expected tracking error'' of an Index Fund relative to the performance of the relevant MSCI Index will be less than 5%. An expected tracking error of 5% means that there is a 68% probability that the net return on the asset value for the Index Fund (including dividends and without reflecting expenses) will be between 95% and 105% of the return of the subject MSCI Index after one year without rebalancing the portfolio composition. While no particular level of tracking error is assured, the Adviser monitors the tracking error of each Fund on an ongoing basis and seeks to minimize tracking error to the maximum extent possible. Semi-annual and annual reports of the Fund disclose tracking error over the previous six month periods, and in the event that tracking error exceeds 5%, the Adviser will notify the Fund's Board of Directors and the Board will consider what action might be appropriate.

The Index Funds do not intend to concentrate in any particular industry, except that each Fund will attempt to concentrate its investment (*i.e.,* hold generally 25% or more of its total assets in the stocks of a particular industry or group of industries)[20] to approximately the same extent that its underlying index concentrates in the stocks of such particular industry or group of industries.[21] For purposes of this limitation, securities of the U.S. Government (including its agencies and instrumentalities), repurchase agreements collateralized by U.S. Government securities, and securities of state or municipal governments and their political subdivisions are not considered to be issued by members of any industry.

The Exchange believes that these requirements and policies prevent any Index Fund from being excessively weighted in any single security or small group of securities and significantly reduce concerns that trading in an Index Fund could become a surrogate for trading in unregistered securities.

The Funds have chosen to pursue a representative sampling strategy which, by its very nature, entails some risk of tracking error. (It should also be noted that fund expenses, the timing of cash flows, and other factors all contribute to tracking error.) With this in mind, the Adviser seeks to minimize tracking error consistent with the Fund's decision to use a representative sampling strategy. The website for the Funds, *www.ishares.com,* contains detailed information on the performance and the tracking error for each Fund. Consistent with the current practice of other index funds, the Funds' annual and semi-annual report will not contain any specific item designated ''tracking error.'' The annual and semi-annual report will contain all total return

[18] Telephone conversation between Michael Cavalier, Associate General Counsel, Legal & Regulatory Division, Amex and Florence E. Harmon, Senior Special Counsel, Division, Commission, October 25, 2001.

[19] In order for a Fund to qualify for tax treatment as a regulated investment company, it must meet several requirements under the Internal Revenue Code. Among these is the requirement that, at the close of each quarter of the Fund's taxable year, (i) at least 50% of the market value of the Fund's total assets must be represented by cash items, U.S. government securities, securities of other regulated investment companies and other securities, with such other securities limited for purpose of this calculation in respect of any one issuer to an amount not greater than 5% of the value of the Fund's assets and not greater than 10% of the outstanding voting securities of such issuer, and (ii) not more than 25% of the value of its total assets may be invested in the securities of any one issuer, or of two ore more issuers that are controlled by the Fund (within the meaning of section 851(b)(4)(B) of the Internal Revenue Code) and that are engaged in the same or similar trades or businesses of related trades or business (other than U.S. government securities or the securities of other regulated investment companies).

[20] Each Fund will maintain regulated investment company compliance, which requires, among other things, that, at the close of each quarter of the Fund's taxable year, not more than 25% of its total assets may be invested in the securities of any one issuer. *See supra,* footnote 19.

[21] For the iShares MSCI Israel Index Fund, the MSCI Index seeks to reflect at least 60% of Israel's stock market capitalization.

performance information required by the Investment Company Act of 1940, Form N–1A and the standard conditions for the 1940 Act exemptive relief which we expect to be granted to the Funds. This information includes disclosure of the Funds' total return and each underlying index's total return for 1, 5 and 10 year periods, and line graphs comparing values of hypothetical $10,000 investments in the Fund and its Underlying index.

MSCI has implemented procedures to prevent the misuse of material non-public information regarding changes to the MSCI indexes underlying the Index Funds. These procedures, which will also apply to the MSCI indexes that are the subject of this filing, were submitted to the Commission by MSCI in connection with approval of additional series of World Equity Benchmark Shares (the previous name for iShares MSCI Index Funds).[22]

Dissemination of Index Information. The daily closing index value and the percentage change in the daily closing index value for every MSCI country and regional index is publicly available on the MSCI Web site at *www.mscidata.com.* In addition, MSCI advises that various news publications (*e.g.,* Barron's, Business Week, Forbes, Global Finance, Investor's Daily, The New York Times and The Wall Street Journal in the United States) publish data for certain MSCI Indices. For example, The Wall Street Journal recently has been publishing the closing index value, for MSCI Indices covering the United States, the United Kingdom, Canada, Japan, France, Germany, Hong Kong, Switzerland, Australia, the World and EAFE (*i.e.,* European, Australian and Far Eastern markets).

Data regarding each MSCI Index is available to MSCI subscribers through various methods of delivery. MSCI index data may be delivered to subscribers directly from MSCI on a daily or monthly basis via electronic delivery methods. MSCI subscribers also may receive index data on a daily, monthly, or quarterly basis in print format via express mail. Several independent data vendors package and disseminate MSCI data in various value-added formats (including vendors displaying both securities and index levels, such as FAME, FactSet, Datastream, RIMES, DSC Data Services and QUANTEC, and vendors displaying index levels only, such as Bloomberg, Bridge/Knight Ridder, Dow Jones Markets, DRI/McGraw Hill, Lipper Analytical, Quick, Quotron, Reuters and Telekurs). According to the iShares, Inc., compared to the MSCI data available free of charge from the MSCI website, the data available to users subscribing to quote vendors such as Bloomberg, Bridge and Reuters includes more frequent calculation and dissemination of index levels, including ''real-time'' feeds for certain indices, while the data available to MSCI paid subscribers (either directly from MSCI or from an independent ''full data'' vendor) includes more detailed information in respect of the securities included in a given index and/or more frequent calculations and dissemination of index levels and securities levels.

Availability of Information Regarding iShares. The Web site for iShares, Inc., which will be publicly accessible at no charge, will contain the following information, on a per iShare basis, for each Index Fund: (a) The prior business day's NAV and the reported closing price, and a calculation of the premium or discount of such price against such NAV; and (b) data in chart format displaying the frequency distribution of discounts and premiums of the daily closing price against the NAV, within appropriate ranges, for each of the four previous calendar quarters.

According to MSCI, the value of each Index Fund's underlying MSCI Index will be updated intra-day on a real time basis as individual component securities of that Index change in price. The intra-day values of these MSCI Indices will be disseminated every 15 seconds[23] throughout the trading day by organizations authorized by MSCI. In addition, these organizations will disseminate values for each Index once each trading day, based on closing prices in the relevant exchange market.

The NAV for each Index Fund will be calculated and disseminated daily. The NAV for the iShares MSCI Pacific (Free) Ex Japan Index Fund will be determined as of 8:30 a.m. Eastern Time. The time for NAV determination for the other Index Funds that are the subject of this filing will be established by iShares, Inc. prior to start-up of trading and will be publicly disclosed by the Funds. The Amex also intends disseminate for each Index Fund on a daily basis by means of CTA and CQ High Speed Lines information with respect to the Indicative Optimized Portfolio Value (as discussed below) and shares outstanding, prior to the opening of the Amex.[24] The Exchange will also disseminate the NAV and final dividend amounts to be paid for each Fund on the Web site *amextrader.com.* The closing prices of the Index Funds' Deposit Securities are readily available from, as applicable, the relevant exchanges, automated quotation systems, published or other public sources in the relevant country, or on-line information services such as Bloomberg or Reuters. The exchange rate information required to convert such information into U.S. dollars is also readily available in newspapers and other publications and from a variety of on-line services.

With each distribution, iShares, Inc. will furnish to the DTC Participants for distribution to Beneficial Owners of iShares of each Index Fund through the DTC Participants a statement setting forth the amount being distributed, expressed as a dollar amount per iShare of such Index Fund. Beneficial Owners also will receive annually notification as to the tax status of the distributions of iShares, Inc.

Promptly after the end of each fiscal year, iShares, Inc. will furnish to the DTC Participants, for distribution to each person who was a Beneficial Owner of iShares at the end of the fiscal year, an annual report of iShares, Inc. containing financial statements audited by independent accountants of nationally recognized standing and such other information may be required by applicable laws, rules and regulations.

Dissemination of Indicative Optimized Portfolio Value. As noted above, MSCI disseminates values for each MSCI Index once each trading day, based on closing prices in the relevant exchange market. In addition, the Fund causes to be made available on a daily basis the names and required number of shares of each of the securities to be deposited in connection with the issuance of Fund shares in Creation Unit size aggregations for each Fund, as well as information relating to the required cash payment representing, in part, the amount of accrued dividends applicable to such Funds. This information is made available by the Fund's Adviser to any NSCC participants requesting such information. In addition, other investors can request such information directly from the Fund's Distributor. The net asset value for each Fund is calculated daily by the Fund's Administrator (PFPC Inc.).

In order to provide updated information relating to each Fund for use by investors, professionals and persons wishing to create or redeem iShares MSCI Index Fund shares, the Exchange disseminates through the facilities of CTA an updated ''indicative optimized portfolio value'' (''Value'') for each of the Funds currently traded as

[22] Securities Exchange Act Release No. 42748 (May 2, 2000), 65 FR 30155 (May 10, 2000) (Order Approving File No. SR–Amex–98–49).

[23] *See* Amendment No. 4, *supra,* footnote 6.

[24] *See* Amendment No. 3, *supra,* footnote 5.

calculated by Bloomberg, LP. The Exchange will also disseminate a Value for the proposed seven new Funds over CTA facilities (Network B) as calculated by a securities information provider (''Value Calculator''). The methodology utilized in connection with the iShares MSCI Index Funds currently traded will also be utilized for the proposed seven new Funds. The Value is disseminated on a per Fund share basis every 15 seconds during regular Amex trading hours of 9:30 a.m. to 4 p.m. New York time. The equity securities values included in the Value are the values of the designated portfolio of equity securities (''Deposit Securities'') constituting an optimized representation of the benchmark MSCI foreign index for each Fund, which is the same as the portfolio that is to be utilized generally in connection with creations and redemptions of Fund shares in Creation Unit size aggregations on that day. The equity securities included in the Value reflects the same market capitalization weighting as the Deposit Securities in the optimized portfolio for the particular Fund. In addition to the value of the Deposit Securities for each Fund, the Value includes a cash component consisting of estimated accrued dividend and other income, less expenses. The Value also reflects changes in currency exchange rates between the U.S. dollar and the applicable home foreign currencies.

The Value does *not* reflect the value of *all* securities included in the applicable benchmark MSCI index. In addition, the Value does not necessarily reflect the precise composition of the current portfolio of securities held by the Fund for each Fund at a particular point in time. Therefore, the Value on a per Fund share basis disseminated during Amex trading hours should not be viewed as a real time update of the net asset value of the Fund, which is calculated only once a day. While the Value disseminated by the Amex at 9:30 a.m. is generally very close to the most recently calculated Fund net asset value on a per Fund share basis [25], it is possible that the value of the portfolio of securities held by the Fund for a particular Fund may diverge from the Deposit Securities Values during any trading day. In such case, the Value will not precisely reflect the value of the Fund portfolio. Following calculation of net asset value by the Fund's Administrator, the Value on a per Fund share basis can be expected to be the same as the net asset value of the Fund on a per Fund share basis.

However, during the trading day, the Value can be expected to closely approximate the value per Fund share of the portfolio of securities for each Fund except under unusual circumstances (*e.g.,* in the case of extensive rebalancing of multiple securities in a Fund at the same time by the Adviser). The circumstances that might cause the Value to be based on calculations different from the valuation per Fund share of the actual portfolio of a Fund would not be different than circumstances causing any index fund or trust to diverge from an underlying benchmark index.

The Exchange believes that dissemination of the Value based on the Deposit Securities provides additional information regarding each Fund that is not otherwise available to the public and is useful to professionals and investors in connection with Fund shares trading on the Exchange or the creation or redemption of Fund shares.

• MSCI All Country Far East Free Ex Japan Index; MSCI Pacific (Free) Ex Japan

For these Indexes there is no overlap in trading hours between the foreign markets and the Amex. Therefore, for these Funds, the Value calculator will utilize closing prices (in applicable foreign currency prices) in the principal foreign market for securities in the Funds portfolio, and convert the price to U.S. dollars. This Value will be updated every 15 seconds during Amex trading hours to reflect changes in currency exchange rates between the U.S. dollar and the applicable foreign currency. The Value will also include the applicable estimated cash component for the Fund.

• MSCI Emerging Markets Latin America Index; MSCI All Country World Ex USA Index; MSCI Emerging Markets Free Index; MSCI Europe Index; MSCI Israel Index

For the above noted MSCI Indexes, which include companies trading in markets with trading hours overlapping regular Amex trading hours, the Value calculator will update the applicable Value every 15 seconds to reflect price changes in the principal foreign market, and convert such prices into U.S. dollars based on the current currency exchange rate. When the foreign market is closed but the Amex is open, the Value will be updated every 15 seconds to reflect changes in currency exchange rates after the foreign market closes. The Value will also include the applicable estimated cash component for each Fund.

Criteria for Initial and Continued Listing. The Index Funds are subject to the criteria for initial and continued listing of Index Fund Shares in rule 1002A. For each of the Funds, it is anticipated that a minimum of two Creation Units will be required to be outstanding at the start of the trading. The minimum number of shares of each Fund required to be outstanding at the start of trading will be comparable to requirements that have been applied to previously listed series of Portfolio Depository Receipts and Index Fund Shares. The Exchange believes that the anticipated minimum number of iShares outstanding for each Fund at the start of trading is sufficient to provide market liquidity and to further the Fund's objective to seek to provide investment results that correspond generally to the price and yield of a specified MSCI Index.

Original and Annual Listing Fees. The Amex original listing fee applicable to the listing of iShares MSCI Index Funds is $5,000 per Fund (*i.e.,* $35,000 for the seven Funds listed above). In additional, the annual listing fee applicable to the Funds under section 141 of the Amex *Company Guide* will be based upon the year-end aggregate number of outstanding shares in all iShares MSCI Index Funds listed on the Amex, including existing Funds and the seven additional Funds proposed herein.

Stop and Stop Limit Orders. Amex rule 154, Commentary. 04(c) provides that stop and stop limit orders to buy or sell a security (other than an option, which is covered by rule 950(f) and Commentary thereto) the price of which is derivatively priced based upon another security or index of securities, may with the prior approval of Floor Official, be elected by a quotation, as set forth in Commentary .04(c) (i-v). The Exchange has designated Index Fund Shares, including iShares MSCI Index Funds, as eligible for this treatment [26]

Rule 190. Rule 190, Commentary .04 applies to Index Fund Shares listed on the Exchange, including iShares MSCI Index Funds. Commentary .04 states that nothing in rule 190(a) should be construed to restrict a specialist registered in security issued by an investment company from purchasing and redeeming the listing security, or securities that can be subdivided or converted into the listed security, from the issuer as appropriate to facilitate the

[25] A slight different between the Value disseminated at 9:30 a.m. and the most recently calculated Fund net asset value can be expected because the Value will include an estimated cash amount consisting principally of any divided accruals for the Deposit Securities going ''ex-dividend'' on that day.

[26] *See* Securities Exchange Act Release No. 29063 (April 10, 1998), 56 FR 15652 (April 17, 2001) (Oder Approving File No. SR–Amex-90–31), and *supra,* footnote 9.

maintenance of a fair and orderly market.

Prospects Delivery. The Exchange, in an Information Circular to Exchange members and member organizations, will inform members and member organizations, prior to commencement of trading, of prospectus or product description delivery requirements applicable to iShares MSCI Index Funds. IShares, Inc. has on file with the Division of Investment Management a separate request for an exemptive order granting relief from certain prospectus delivery requirements under section 24(d) of the 1940 Act. Any product description used in reliance on an section 24(d) exemptive order will comply with all representations made therein and all conditions thereto.

Purchase and Redemptions in Creation Unit Size. In the Information Circular referenced above, members and member organizations will be informed that procedures for purchases and redemptions of iShares in Creation Unit size are described in the Fund prospectus and Statement of Additional Information, and that iShares are not individually redeemable but are redeemable only in Creation Unit size aggregations or multiples thereof.

Trading Halts. In addition to other factors that may be relevant, the Exchange may consider factors such as those set forth in rule 918C(b) in exercising its discretion to halt or suspend trading in Index Fund Shares, including iShares. These factors would include, but are not limited to, (1) the extent to which trading is not occurring in stocks underlying the index; (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. (See Amex rule 918C). In addition, trading in iShares will be halted if the circuit breaker parameters under Amex rule 117 have been reached.

Suitability. The Information Circular referenced above will inform members and member organizations of the characteristics of the specific Index Fund and of applicable Exchange rules, as well as of the requirements of Amex rule 411 (Duty to Know and Approve Customers). The Information Circular will also disclose the time that the NAV is determined for a particular Fund and will disclose that for Funds holding shares of Korean, Malaysian, Taiwanese and Brazilian companies that the Fund will charge creation and redemption fees intended to offset brokerage costs associated with cash creations and redemptions, (as discussed in footnote 16 above).

Surveillance. Exchange surveillance procedures applicable to trading in the proposed iShares MSCI Index Funds are the same as those applicable to iShares currently trading on the Exchange.

(2) Statutory Basis

The proposed rule change is consistent with section 6(b) of the Act in general and furthers the objection of section 6(b)(5) in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transaction in securities, and, in general to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will impose no 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 solicited or received with respect to the proposed rule change.

III. Solitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change and Amendment Nos. 1, 2, 3, and 4 are consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with the respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to file number SR–Amex–2001–45 and should be submitted by November 23, 2001.

IV. Commission Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Amex has requested that the Commission approve the proposal on an accelerated basis. The Amex notes that the proposed iShares are similar in structure and operation to Index Fund Shares approved previously by the Commission and that the component securities of the Underlying Indexes are among the stocks with the highest liquidity and market capitalization in their respective countries. The Amex believes that the proposal does not raise issues that the Commission has not considered in connection with previous proposed rule changes relating to Index Fund Shares.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, with the requirements of section 6(b)(5).[27] Specifically, the Commission finds that the proposal to list and trade the proposed iShares will provide investors with a convenient and less expensive way of participating in the foreign securities markets. The Commission believes that the Amex's proposal should advance the public interest by providing investors with increased flexibility in satisfying their investment needs by allowing them to purchase and sell single securities at negotiated prices throughout the business day that represent the performance of several portfolios of stocks.[28] Accordingly, the Commission finds that the Amex's proposal will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in clearing, settling, processing information with respect to, and facilitating transactions in securities, and, in general, protect investors and the public interest, consistent with section 6(b)(5) of the Act.[29]

[27] 15 U.S.C. 78f(b)(5). In approving the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[28] The Commission notes that unlike typical open-end investment companies, where investors have the right to redeem their fund shares on a daily basis, investors in iShares can redeem in Creation Unit size aggregations only.

[29] Pursuant to section 6(b)(5) of the Act, the Commission must predicate approval of exchange trading for new products upon a finding that the introduction of the product is in the public interest. Such a finding would be difficult with respect to a product that served no investment, hedging or other economic functions, because any benefits that might be derived by market participants would likely be outweighed by the potential for manipulation, diminished public confidence in the

Amex Rules 1000A *et seq.* provide for the listing and trading of Index Fund Shares. The Commission has approved the listing and trading of various Index Fund Shares on the Amex, including the following: 15 series of iShares Trust;[30] 23 series of iShare MSCI Index Funds (formerly MSCI World Equity Benchmark Shares (''WEBS''));[31] series of the iShares Trust based on the S&P Europe 350 Index and the S&P/TSE 60 Index;[32] nine series of Select Sector SPDRs and one series of the Technology 100 Index Fund;[33] and shares of the street Tracks Dow Jones Global Titans Index Fund.[34]

Similar to these Index Fund Shares, the Commission believes that the proposed iShares will provide investors with an alternative to trading a broad range of securities on an individual basis, and will give investors the ability to trade a product representing an interest in a portfolio of securities designed to reflect substantially the applicable Underlying Index. The estimated cost of individual iShares, approximately $20 to $120, should make them attractive to individual retail investors who wish to hold a security representing the performance of a portfolio of stocks. In addition, unlike the case with standard open-end investment companies specializing in such stocks, investors will be able to trade iShares continuously throughout the business day in secondary market transactions at negotiated prices.[35] Accordingly, the proposed iShares will allow investors to: (1) Respond quickly to market changes through intraday trading opportunities; (2) engage in hedging strategies similar to those used by institutional investors; and (3) reduce transaction costs for trading a portfolio of securities.

Although the value of iShares will be derived from and based on the value of the securities and cash held in the Fund, iShares are not leveraged instruments. Accordingly, the level of risk involved in the purchase or sale of iShares is similar to the risk involved in the purchase or sale of traditional common stock, with the exception that the pricing mechanism for the iShares is based on a portfolio of securities. Nevertheless, the Commission believes that the unique nature of iShares raises certain product design, disclosure, trading and other issues that must be addressed.

A. Generally

The Commission believes that the proposed iShares are reasonably designed to provide investors with an investment vehicle that substantially reflects in value their Underlying Indexes and, in turn, the performance of: (1) The component securities comprising the MSCI All Country World Ex USA Index;[36] (2) the component securities comprising the MSCI All Country Far East (Free) Ex Japan Index;[37] (3) the component securities comprising the MSCI Emerging Markets (Free) Index;[38] (4) the component securities comprising the MSCI Emerging Markets Latin America Index;[39] (5) the component securities comprising the MSCI Europe Index;[40] (6) the component securities comprising the MSCI Pacific (Free) Ex Japan Index;[41] and (7) the component securities of the MSCI Israel Index.[42]

The Commission notes that each Fund will normally invest at least 95% of its total assets in component securities that are represented in the underlying index, and will at all times invest at least 90% of its total assets in such stocks, except that in order to permit the Adviser additional flexibility to comply with the requirements of the Internal Revenue Code and other regulatory requirements and to manage future corporate actions and index changes in the smaller markets, certain Funds, identified in each Fund's prospectus, will at all times invest at least 80% of its assets in such stocks and at least half of the remaining 20% in such stocks or in stocks included in the relevant market, but not in the relevant underlying index. iShares, Inc. expects that the iShares MSCI Emerging Markets (Free), Emerging Markets Latin America and Israel Index Funds will be subject to the ''80%/20%'' exception described above. Each Fund may invest its remaining assets in money market instruments (subject to applicable limitations under the 1940 Act), in repurchase agreements, in stocks that are in the relevant market but not in the relevant underlying index, and/or in combinations of certain stock index futures contracts, options on futures contracts, stock index options, stock index swaps, cash, local currency and forward currency exchange contracts that are intended to provide a Fund

integrity of the markets, and other valid regulatory concerns.

[30] Securities Exchange Act Release No. 4470 (August 14, 2001), 66 FR 43927 (August 21, 2001) (order approving File No. SR–Amex–2001–34).

[31] *See* 1996 Order (approving the listing and trading of Index Fund Shares under Amex Rules 1000A *et seq.* and 17 series of WEBS based on MSCI foreign indexes); and Securities Exchange Act Release No. 42748 (May 2, 2000), 65 FR 30155 (May 10, 2000) (order approving File No. SR–Amex–98–49) (approving the listing and trading of six series of WEBS based on MSCI Indexes).

[32] *See* Securities Exchange Act Release No. 42786 (May 15, 2000), 65 FR 33586 (May 24, 2000) (order approving File No. SR–Amex–99–49).

[33] *See* Securities Exchange Act Release No. 40749 (December 4, 1998), 63 FR 68483 (December 11, 1998) (order approving File No. SR–Amex–98–29).

[34] *See* Securities Exchange Act Release No. 433338 (September 25, 2000) 65 FR 59235 (October 4, 2000) (order approving File No. SR–Amex–00–53).

[35] Because of the potential arbitrage opportunities, the Commission believes that iShares will not trade at a material discount or premium in relation to their NAV. The mere potential for arbitrage should keep the market price of iShares comparable to their NAV; therefore, arbitrage activity likely will not be significant.

[36] The MSCI All Country World Ex USA Index, is comprised of securities trading on the exchanges of 49 of the 51 countries for which MSCI has indices. The index represents world stock markets (not including markets in the United States). The index included 1849 constituent companies as of May 31, 2001.

[37] The MSCI All Country Far East (Free) Ex Japan Index comprises 9 of the 51 countries for which MSCI has indices. The index represents Asian stock markets (not including markets in Japan). The index included 407 constituent countries as of May 31, 2001. Approximately 45% of the index is comprised of securities traded on the combined markets in Korea, Malaysia, and Taiwan. Those countries have restrictions that preclude in-kind redemptions and creations. Therefore, the MSCI Pacific (Free) Ex Japan Index Fund will charge fees to offset related transfer and transaction costs. Those costs include market impact costs because there is a possibility, which the Exchange will disclose in its prospectus, of market impact as a result of the Fund buying or selling securities in those countries.

[38] The MSCI Emerging Markets (Free) Index comprises 25 of the 51 countries for which MSCI has indices. The index included 696 constituent companies as of May 31, 2001. Approximately 40% of the index is comprised of securities trading in Brazil, Korea, Malaysia, and Taiwan. Those countries have restrictions that preclude in-kind redemptions and creations. Therefore, the Emerging Markets (Free) Index Fund will charge fees to offset related transfer and transaction costs. Those costs include market impact costs because there is a possibility, which the Exchange will disclose in its prospectus, of market impact as a result of the Fund buying or selling securities in those countries.

[39] The Emerging Markets Latin America Index comprises 7 of the 51 countries for which MSCI has indices. The index included 127 constituent companies as of May 31, 2001. Approximately 40% of the index is comprised of securities trading in Brazil, which has restrictions that preclude in-kind redemptions and creations. Therefore, the Emerging Markets Latin America Fund will charge fees to offset related transfer and transaction costs. Those costs include market impact costs because there is a possibility, which the Exchange will disclose in its prospectus, of market impact as a result of the Fund buying or selling securities in Brazil.

[40] The MSCI Europe Index comprises 7 of the 51 countries for which MSCI has indices. According to MSCI, the index included 127 constituent companies as of May 31, 2001.

[41] The MSCI Pacific (Free) Ex Japan Index represents markets in Australia, Hong Kong, New Zealand and Singapore. There were 151 constituent companies included in the index as of May 31, 2001.

[42] The MSCI Israel Index includes country constituents that are classified using the Global Industry Classification Standard (GICS), which has 10 sectors drawn from 23 Industry groups. Over 70% of the index is comprised of securities in three industry groups: Software & Services; Pharmaceuticals & Biotechnology; and Banks. There were 33 constituent companies as of May 31, 2001.

with exposure to a stock. The Adviser may attempt to reduce tracking error by using futures contracts whose behavior is expected to represent the market performance of the Fund's underlying securities. A Fund will not use these instruments to leverage, or borrow against, its securities holdings or for speculative purposes. The Exchange expects that each Fund does not intend to concentrate in any particular industry except to the extent that its Underlying Index concentrates in the stocks of a particular industry or industries.[43] In addition, each Fund will maintain regulated investment company compliance, which requires, among other things, that, at the close of each quarter of the Fund's taxable year, not more than 25% of its total assets may be invested in the securities of any one issuer. While the Commission believes that these requirements should help to reduce concerns that the Funds could become a surrogate for trading in a single or a few unregistered stocks, in the event that a Fund were to become such a surrogate, the Commission would expect the Amex to take action immediately to delist the securities to ensure compliance with the Act.

As noted above, each Fund will use a representative portfolio sampling strategy to attempt to track its Underlying Index. Although a representative sampling strategy entails some risk of tracking error, the Advisor will seek to minimize tracking error. It is expected that each Fund will have a tracking error relative to the performance of its Underlying Index of no more than 5%. If the tracking error for a Fund exceeds 5%, the Advisor will notify the Board and discuss appropriate actions with the Board.[44] The Commission notes that the Exchange will disseminate the NAV and final dividend amounts to be paid for each Fund on the website amextrader.com.[45] In addition, the Funds' annual and semiannual reports will include disclosures regarding the Funds' total return and each Underlying Index's total return for one-, five-, and 10-year periods, and graphs comparing hypothetical $10,000 investments in the Funds and their Underlying Indexes.[46] While the Commission believes that the proposed requirements for the Funds, and the expected tracking error of less than 5%, should be adequate to characterize the proposed Funds as bona fide index funds, the Commission would be concerned if a Fund's portfolio failed to substantially reflect its Underlying Index.[47]

B. Disclosure

The Commission believes that the proposal should ensure that investors have information that will allow them to be adequately apprised of the terms, characteristics, and risks of trading iShares. Investors purchasing the proposed iShares will be required to receive either a prospectus or, as discussed below, a product description of the iShares.[48] If the proposed iShares are not granted relief from the prospectus delivery requirements of the 1940 Act, then investors purchasing iShares will be required to receive a prospectus prior to or concurrently with the confirmation of a transaction therein. Because iShares will be in continuous distribution, the prospectus delivery requirements of the Securities Act of 1933 will apply both to initial investors and to all investors purchasing such securities in secondary market transactions on the Amex.

Alternatively, if the proposed iShares are granted relief from the prospectus delivery requirements of the 1940 Act, they will be subject to Commentary .03 to Amex Rule 1000A, which provides for delivery of a product description for series of Index Fund Shares that have been granted relief from the prospectus delivery requirements of the 1940 Act. Under Commentary .03, the delivery requirement will extend to a member or member organization carrying an omnibus account for a non-member broker-dealer, who must notify the non-member to make the product description available to its customers on the same terms as are directly applicable to members and member organizations. In addition, Commentary .03 provides that a member or member organization must deliver a prospectus to a customer upon request.

The Commission notes that prior to the commencement of trading in the proposed iShares, the Amex will issue a circular to its members explaining the characteristics of the specific Index Fund and of applicable Exchange rules, as well as the requirements of Amex rule 411. Amex rule 411 generally requires that member use due diligence to learn the essential facts relative to every customer, every order or account accepted.[49]

The Information Circular will also disclose the time that the NAV is determined for a particular Fund and will disclose that for Funds holding shares of Korean, Malaysian, Taiwanese and Brazilian companies that the Fund will charge creation and redemption fees intended to offset brokerage costs associated with cash creations and redemption. It will also inform members and member organizations, prior to commencement of trading, of prospectus or product description delivery requirements applicable to iShares MSCI Index Funds.

C. Listing and Trading of iShares

The Commission finds that adequate rules and procedure exist to govern the listing and trading of iShares. iShares will be deemed equity securities subject to Amex rules governing the trading of equity securities,[50] including, among others, rules governing trading halts,[51] responsibilities of the specialist, account opening and customer suitability requirements, and the election of stop and stop limit orders.

In addition, the Funds will be subject to Amex listing and delisting/suspension rules and procedures governing the trading of Index Fund Shares on the Amex. As the Commission has noted previously,[52] the listing and delisting criteria for Index Fund Shares should help to ensure that a minimum level of liquidity will exist in each series of Index Fund Shares to allow for the maintenance of fair and orderly markets. The de listing criteria also will allow the Amex to consider the suspension of trading and the delisting of a series of iShares if an event were to occur that made further dealings in such securities inadvisable. This will give the Amex flexibility to delist iShares if circumstances warrant such action. For example, as noted above, in the vent that iShares became a surrogate for trading a single or few unregistered

[43] *See* Amendment No. 1, *supra,* footnote 3; Amendment No. 2, *supra,* footnote 4.

[44] *See* Amendment No. 1, *supra,* footnote 3.

[45] *See* Amendment No. 1, *supra,* footnote 3.

[46] *See* Amendment No. 1, *supra,* footnote 3.

[47] Among other issues that may arise under the federal securities laws, such an occurrence could raise the issue of whether trading of the proposed iShares would remain consistent with Amex listing standards for Index Fund Shares, as well as the surrogate trading issue discussed above.

[48] As noted above, iShares, Inc. has requested an exemptive order granting relief from the prospectus delivery requirements imposed by section 24(d) of the 1940 Act.

[49] *See* Amex Rule 411.

[50] Telephone conversation between Michael Cavalier, Associate General Counsel, Legal & Regulatory Division, Amex and Steven Johnston, Special Counsel, Division, Commission, October 25, 2001.

[51] In addition to other factors that may be relevant, the Amex may consider factors such as those set forth in Amex Rule 918(b) in exercising its discretion to halt or suspend trading in iShares. These factors would include, but are not limited to: (1) The extent to which trading is not occurring in stocks underlying the index; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. In addition, trading in iShares will be halted if the circuit breaker parameters under Amex Rule 117 have been reached.

[52] *See* 1996 Order.

securities, such an event could raise issues that would require the delisting of iShares to ensure compliance with the Act. Accordingly, the Commission believes that the rules governing the trading of iShares provide adequate safeguards to prevent manipulative acts and practices and to protect investors and the public interest.

As noted above, the Amex expects to require that a minimum of two Creation Units (100,000 iShares) to outstanding at the start of trading. The Commission believes that this minimum number is sufficient to help to ensure that a minimum level of liquidity will exist at the start of trading.

The Commission believes that the Amex's proposal to trade iShares with a minimum price variation of $.01 is consistent with the Act. The Commission believes that such trading may enhance market liquidity and should promote more accurate pricing, tighter quotations, and reduced price fluctuations. The Commission also believes that such trading should allow customers to receive the best possible execution of their transactions in the Funds. Additionally, the Commission believes that the proposed original listing fee of $5,000 is reasonable, as is the proposed method for calculating the annual fee.

D. Specialists

The Commission finds that it is consistent with the Act to allow a specialist registered in a security issued by an Investment Company to purchase or redeem the listed security from the issuers as appropriate to facilitate the maintenance of a fair and orderly market in that security. The Commission believes that such market activities should enhance liquidity in such securities and facilitate a specialist's market making responsibilities. In addition, because the specialist will only be able to purchase and redeem iShares on the same terms and conditions as any other investor in accordance with the terms of the Funds prospectus and statement of additional information (''SAI''), the Commission believes that concerns regarding potential abuse are minimized.[53] The Amex's existing surveillance procedure also should ensure that such purchases are only for the purpose of maintaining fair and orderly markets, and not for any improper or speculative purposes. Finally, the Commission notes that its approval of this aspect of the Amex's proposal does not address any other requirements or obligations under the federal securities laws that may be applicable.

E. Stop and Stop Limited Orders

The Commission believes that the Amex's proposal to designate the proposed iShares as eligible for election by quotation with the prior approval of a Floor Official is consistent with the Act. Amex rule 154, Commentary .04(c) generally provides that stop and stop limit orders to buy or sell a security or index of securities may, with prior approval of a Floor Official, be elected by quotation, as set forth in Amex rule 154, Commentary .04. Amex rule 154, Commentary .04(c)(v) states that election by quotation only is available for such derivative securities as are designated by the Amex as eligible for such treatment. The Amex has so designated Index Fund Shares, including the proposed iShares.

The Commission believes that allowing stop and stop limit orders in iShares to be elected by quotation, a rule typically used in the options context, is appropriate because, as a result of their derivative nature, iShares are in effect equity securities that have a pricing and trading relationship to the underlying securities similar to the relationship between options and their underlying securities.[54]

F. Surveillance

The Amex represents that the Exchange surveillance procedures applicable to trading in the proposed iShares MSCI Index Funds are the same as those applicable to iShares currently trading on the Exchange.

The Commission believes that the surveillance procedures developed by the Amex for Index Fund Shares are adequate to address the concerns associated with the listing and trading of the iShares, including any concerns associated with purchasing and redeeming Creation Units.

G. Use of Non-Public Information

The Commission notes that when a broker-dealer's affiliate, such as MSCI, is involved in the development and maintenance of a stock index upon which a product such as iShares is based, the broker-dealer and its affiliate should have procedures designed specifically to address the improper sharing of information. The Commission notes that MSCI has implemented procedures to prevent the misuse of material non-public information regarding changes to the MSCI indexes underlying the Index Funds. The Commission believes,[55] as it has concluded previously, that the information barrier procedures put in place by MSCI address the unauthorized transfer and misuse of material, non-public information.

H. Dissemination of Information Regarding the Funds

The Commission believes that the Value that the Amex proposes to have disseminated for the Funds will provide investors with timely and useful information concerning the value of the individual Funds. The Exchange represents that Indicative Portfolio Value will be disseminated through the facilities of the CTA every 15 seconds from 9:30 a.m. to 4 p.m.Eastern time. The Commission expects that the Amex will monitor the disseminated Value and, if the Amex were to determine that the Value does not closely track the applicable iShares series, it would arrange to disseminate an adequate alternative value.

The daily index value and the percentage change in the daily closing index value for every MSCI country and regional index will be publicly available on the MSCI website at www.mscidata.com. In addition the website for the Funds, 222.ishares.com, contains detailed information on the performance of each Fund, and the tracking error for each fund.

The NAV for each Index Fund will be calculated and disseminated daily. The NAV for the iShares MSCI Pacific (Free) Ex Japan Index Fund will be determined as of 8:30 a.m. Eastern Time; the time for NAV determination for the other Index Funds that are the subject of this filing will be established by iShares, Inc. prior to start-up of trading and will be publicly disclosed by the Funds. In addition, the Funds' annual and semi-annual report will include disclosure of the Funds' total return and each Underlying Index's total return for one—, five—, and 10-year periods, and graphs comparing value of hypothetical $10,000 investments in the Fund and its Underlying Index.[56]

The Amex also will disseminate for each Index Fund on a daily basis by means of CTA and CQ High Speed Lines information with respect to the Indicative Optimized Portfolio Value (as discussed below) and shares

[53] Telephone conversation between Michael Cavalier, Associate General Counsel, Legal & Regulatory Division, Amex and Florence E. Harmon, Senior Special Counsel, Division, Commission, October 25, 2001.

[54] *See generally* Securities Exchange Act Release No. 29063 (April 10, 1991), 56 FR 15652 (April 17, 1999) (order approving File No. SR–Amex–90–31) (relating to stop and stop limit orders in certain equity securities).

[55] *See* Securities Exchange Act Release No. 42748 (May 2, 2000), 65 FR 30155 (May 10, 2000) (order approving File No. SR–Amex–98–49)

[56] *See* Amendment No. 1, *supra,* footnote 3.

outstanding, prior to the opening of the Amex. The Exchange will also disseminate the NAV and final dividend amounts to be paid for each Fund on amextrader.com.

As described more fully above, the Advisor will make available through the Distributor on each business day prior to the opening of trading on the Exchange the list of the names and the required number of shares of each Deposit Security included in the current Portfolio Deposit for each Fund to effect purchases of Creation Unit Aggregations of the Fund.

In addition, the Advisor will provide the NSCC on a daily basis with the names and required number of shares of the Deposit Securities in a Creation Unit Aggregation and the Balancing Amount, which the NSCC will make available to NSCC members through an electronic file that NSCC members can download.[57]

I. Scope of the Commission's Order

The Commission is approving the 7 series of iShares described herein. Other similarly structured products, or additional iShares Funds based on indexes that include securities not listed on a national securities exchange of The Nasdaq Stock Market, would require review by the Commission pursuant to Section 19(b) of the Act prior to being traded on the Amex.

J. Accelerated Approval of the Proposal and Amendment Nos. 1, 2, 3, and 4

The Commission finds good cause for approving the proposed rule change and Amendment Nos. 1, 2, 3, and 4 to the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. As discussed more fully above, the Commission has approved the listing and trading of various Index Fund Shares on the Amex. Several of the Amex's previous proposals to list and trade Index Fund Shares were published for comment and the Commission received no comments regarding the proposals. Accordingly, the Commission believes that it is reasonable to make the proposed iShares available to investors as soon as possible. Amendment No. 1 strengthens the Amex's proposal by, among other things, stating that the Exchange will disclose, in an Information Circular that Funds holding shares of Korean, Malaysian, Taiwanese and Brazilian companies will charge creation and redemption fees intended to offset brokerage costs associated with cash creations and redemptions; and representing that MSCI has implemented procedures to prevent the misuse of material non-public information regarding MSCI indices. Amendment No. 2 clarifies the proposal by, among other things, noting that Fund Participants are limited to DTC Participants and clarifying the level of the Funds' investment in their Underlying Indices. Amendment No. 2 further clarified the proposal explaining that fees assessed in connection with Funds trading in countries where in-kind purchases of securities are precluded, are assessed in part to cover market impact costs. Amendment No. 4 also strengthened the proposal by requiring, among other things, that the Fund prospectus will disclose the possible market impact of a Fund buying or selling securities in those countries prior to calculation of the NAV. Amendment No. 4 clarified the proposal by, among other things, further delineating the level of the Funds investment in their Underlying Indices. Accordingly, the Commission believes that there is good cause, consistent with sections 6(b)(5) and 19(b)(2) of the Act,[58] to approve the proposal and Amendment Nos. 1, 2, 3, and 4 to the proposal on an accelerated basis.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (SR–Amex–2001–45), as amended, is approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[59]

Margaret H. McFarland,

Deputy Secretary.

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[57] *See* Amendment No. 4, *supra,* footnote 6.

[58] 15 U.S.C. 78f(b)(5) and 78s(b)(2).

[59] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44994; File No. SR–CBOE–2001–22]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Chicago Board Options Exchange, Incorporated Relating to Permanent Approval of the Pilot Program To Eliminate Position and Exercise Limits for OEX, SPX, and DJX Index Options and Flex Options on These Indexes

October 26, 2001.

I. Introduction

On May 14, 2001, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4 thereunder,[2] a proposed rule change seeking permanent approval of the pilot program eliminating position and exercise limits for S&P 500 Index (''SPX''), S&P 100 Index (''OEX''), and Dow Jones Industrial Average (''DJX'') as well as for FLEX options overlying these indexes.

The proposed rule change was published for comment in the **Federal Register** on June 25, 2001.[3] The Commission received no comments on the proposal. This order approves the proposal.

II. Description of Proposal

On January 22, 1999, the Commission approved a two-year pilot program (''Pilot Program'') that allowed for the elimination of position and exercise limits for options on the OEX, SPX, DJX index options as well as for FLEX options overlying these indexes.[4] On January 22, 2001, the Commission extended the Pilot Program until May 22, 2001.[5] On May 22, 2001, the Commission again extended the Pilot Program until September 22, 2001.[6] On September 24, 2001, the Commission extended the pilot program until March 24, 2002.[7] The Exchange now seeks

[1] 15 U.S.C. 78(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 42862 (May 30, 2000), 65 FR 36481.

[4] *See* Securities Exchange Act Release No. 40969, 64 FR 49111 (Feb. 1, 1999) (approving SR–CBOE–98–23) (''Pilot Approval Order'').

[5] *See* Securities Exchange Act Release No. 43867, 66 FR 8250 (January 30, 2001).

[6] *See* Securities Exchange Act Release No. 44335, 66 FR 33728 (May 25, 2001).

[7] *See* Securities Exchange Act Release No. 44837, 66 FR 49988 (October 1, 2001).

permanent approval of the Pilot Program.

III. Discussion

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[8] Specifically, the Commission believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities and to remove impediments to and perfect the mechanism of a free and open market and a national market system.[9]

The Commission believes for the same reasons discussed in the Pilot Approval Order, in addition to the lack of any problems identified during the pilot period as discussed below, that the pilot should be approved on a permanent basis.[10] The Commission notes that the Pilot Approval Order required the Exchange to submit a report to the Commission on the status of the Pilot Program so that the Commission could use this information to evaluate any consequences of the program and to determine whether to approve the elimination of position and exercise limits for these products on a permanent basis.[11] The CBOE submitted the required report to the Commission on December 21, 2000.[12]

The report represents that during the review period, CBOE did not discover any instances where an account maintained an unusually large unhedged position. The data from the report found that only 12 accounts established positions in excess of 10% of the standard limit applicable to each index at the time the Pilot Program was approved. These positions were all in SPX and most were established by firms and market makers. All of the accounts were hedged, although to different degrees. CBOE represented that it did not discover any aberrations caused by large unhedged positions during the life of the Pilot Program.[13]

In addition to no identifiable problems during the pilot program, the Commission also believes that the factors for approval of the pilot program continue to be met. For example, in approving the pilot, the Commission stated, among other things, that the enormous capitalization of and deep, liquid markets for the underlying securities contained in the OEX, SPX and DJX significantly reduces concerns regarding market manipulation or disruption in the underlying market. In this regard, we note that the indexes continue to have enormous capitalizations. Indeed, the current capitalizations' of the indexes are currently higher than the capitalizations we relied on in originally approving the pilot.[14]

The Commission also continues to believe that the financial requirements imposed by CBOE and the Commission help to address concerns that a CBOE member or is customer may try to maintain an inordinately large unhedged position in the indexes. As noted in the Pilot Approval Order, the CBOE has the authority to impose additional margin and/or assess capital charges and should be able to monitor accounts to determine when such action is warranted.[15]

Finally, in addition to the other basis for approval of the pilot as discussed in the Pilot Approval Order, the Commission relied heavily on the enhanced surveillance[16] and reporting safeguards that would allow CBOE to detect and deter trading abuses arising from the elimination of position and exercise limits in options and Flex options on the subject indexes.[17] The Commission continues to believe that these enhanced procedures are critical in our determination to permanently approve the pilot. While the pilot did not note any aberrations or concerns about large unhedged positions, the Commission continues to believe that these procedures will enable the CBOE to adequately assess and respond to market concerns at an early stage. In this regard the Commission continues to expect CBOE to take prompt action, including timely communication with the Commission and other marketplace self-regulatory organizations responsible for oversight of trading in component stocks, should any unanticipated adverse market effects develop.

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[18] that the proposed rule change (SR–CBOE–2001–22) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[19]

Margaret H. McFarland,

Deputy Secretary.

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[8] In approving this rule proposal, the Commission notes that it has also considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[9] 15 U.S.C. 78f(b)(5).

[10] The bases for approving the pilot as discussed in the Pilot Approval Order are incorporated herein to this permanent approval order.

[11] In the prior Approval Order, the Commission stated, "CBOE will provide the Commission with a report detailing the size and different types of strategies employed with respect to positions established in those classes not subject to position limits. In addition, the report will note whether any problems resulted due to the no limit approach and any other information that may be useful in evaluating the effectiveness of the pilot program. The Commission expects that CBOE will take prompt action, including timely communication with the Commission and other marketplace self-regulatory organizations responsible for oversight of trading in component stocks, should any unanticipated adverse market effects develop."

[12] Letter from Patricia L. Cerny, Director, Office of Trading Practices, CBOE, to Elizabeth King, Division of Market Regulation, Commission, dated December 21, 2000.

[13] In its latest filing extending the pilot program, CBOE again represented that it had not discovered any aberrations caused by large unhedged positions during the pilot program. *See supra* note 7.

[14] The Pilot Approval Order stated that, as of August 1998, the market capitalizations for the SPX, OEX, and DJX were $8.5 trillion, $3.8 trillion and $2.2 trillion, respectively. As of October 2001, these figures had increased to $9.81 trillion, $5.7 trillion and $3.23 trillion, respectively.

[15] As originally noted in the Pilot Approval Order, the Commission's net capital rule, Rule 15c3–1 under the Exchange Act, imposes a capital charge on members to the extent of any margin deficiency. More specifically, Exchange Act Rule 15c3–1 requires a capital change equal to the maximum potential loss on a broker-dealer's aggregate index position over a +(−) 10% market move. Exchange margin rules require margin on naked index options which are in or at-the-money equal to a 15% move in the underlying index; and a minimum 10% charge for naked out-of-the money contracts. At an index value of 9,000 this approximates to a $135,000 to $90,000 requirement per each unhedged contract.

[16] It is inappropriate to discuss the details of CBOE's enhanced surveillance program because the disclosure of specific surveillance procedures could provide market participants with information that could aid potential attempts at avoiding regulatory detection of inappropriate trading activity.

[17] CBOE's reporting requirements subject SPX, OEX and FLEX options on those indexes to a 100,000 contract hedge reporting requirement, and DJX, which is one-tenth the size of a full value index contract, and FLEX options on the DJX, are subject to a 1 million contract hedge reporting threshold. Each member or member organization that maintains a position on the same side of the market in excess of these contract thresholds for its own account or for the account of a customer must file a report that includes, but is not limited to, data related to the option position, whether such position is hedged and if so, a description of the hedge. If applicable, the report must contain information concerning collateral used to carry the position.

[18] 15 U.S.C. 78f(b)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44995; File No. SR–GSCC–2001–06]

Self Regulatory Organizations; Government Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Placement of Highly Leveraged Members on Surveillance Status

October 26, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] notice is hereby given that on May 14, 2001, the Government Securities Clearing Corporation (''GSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by GSCC. The Commission is published 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

GSCC proposes to add new definitions and procedures to its rules that relate to how GSCC will monitor its members' clearing fund status. In addition, GSCC proposes to add a rule that would permit GSCC to exchange information with other clearing organizations concerning a member that is on any surveillance status.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, GSCC included statements concerning the purpose of and basis for the proposed rules changes and discussed any comments it received on the proposed rules changes. The text of these statements may be examined at the places specified in Item IV below. GSCC has prepared summaries, set forth in sections A, B, C below of the most significant aspects of such statements.[2]

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Rule 4, section 3 of GSCC's rules states that a member whose clearing fund deposit obligation represents a significant portion of its net worth or net capital will be placed on a ''class 1 (advisory list) surveillance status'' and thus be subjected to a more thorough monitoring of its financial condition and activities. Until recently, GSCC has not routinely monitored its members' use of leverage. Now, due to factors such as the increasingly high level of members' clearing fund deposit requirements and the growing number of executing firms[3] for whose trades members are responsible, the amount of clearing fund deposit required of certain GSCC netting members can represent a significant proportion of their excess capital. Consequently, GSCC believes that it has become appropriate for risk management purposes to more closely monitor members' relative use of leverage.

Specifically, GSCC believes that it is important to compare the ratio of each member's clearing fund requirement to that member's level of excess regulatory capital[4] and to advise its membership of specific actions that it plans to take pursuant to Rule 4 with respect to any member that has a ratio in excess of certain defined parameters.[5]

To accomplish this, GSCC's approach under this proposed rule change would be analogous to the early warning concept applied by the Commission with respect to its net capital rule.[6] Examining authorities utilize parameters established within the net capital rule to provide an early warning of any broker-dealer that may be at risk of not having sufficient liquid capital to meet current obligations.[7] Deposits to GSCC's clearing fund are included in broker-dealers' net capital balances since such deposits are allowable assets.[8] Despite its liquidity, these amounts are deposited with and retained by GSCC to support GSCC-related trading and, therefore, are not available for other use. Therefore, GSCC believes that it is meaningful to measure the portion of a member's excess capital that is deposited to the clearing fund against its overall excess capital.

If a significant portion of the excess net capital of a netting member is committed to GSCC's clearing fund, it may be more likely than other members to have difficulty in meeting obligations in general and may therefore deemed to pose a greater likelihood of default with respect to its obligations to GSCC in particular.

To compensate for this potentially higher-than-ordinary risk of default, GSCC will place a member with a clearing fund requirement to excess net capital ratio of greater than .050 on Class 1 Surveillance Status.[9] Rule 4 permits GSCC to more thoroughly monitor such a highly leveraged member's financial condition and activities and to require the member to make more frequent financial disclosures. GSCC will require a highly leveraged member to provide GSCC with a satisfactory explanation of its leverage and it may seek to obtain information with respect to such member's margin requirements at other clearing organizations to better enable GSCC to assess whether the member will be able to meet its obligations to GSCC.

GSCC believes that the proposed rules change is consistent with the requirements of section 17A of the Act[10] and the rules and regulations thereunder because they serve to clarify rights that GSCC currently possesses with respect to highly leveraged participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

GSCC does not believe that the proposed rules change will impact or impose a burden on competition.

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by GSCC.

[3] An executing firm is a non-GSCC member that contracts with a GSCC member to submit trades on its behalf to GSCC.

[4] In this context, the term ''excess regulatory capital'' is used to include excess net capital, excess liquid capital, or excess adjusted net capital, all of which are measures of an organization's net worth after adjusting for the liquidity of its balance sheet.

[5] Inter-dealer brokers (''IDBs'') and bank members are excluded from this analysis because IDBs, which have fixed clearing fund requirements and limited capital, are subject to different types of risk management considerations and because banks do not perform net capital computations.

[6] 17 CFR 240.15c3–1. The net capital rule is designed to ensure the liquidity of broker-dealers by requiring that they maintain minimum levels of liquid assets to support the volume and risk of the business in which they are engaged.

[7] In order to derive net capital under the net capital rule, a firm's net worth is reduced to give effect to the elements of market, credit, or operational risk inherent in the business in which the firm is engaged. Net capital is the broker-dealer's net worth adjusted for illiquid (''nonallowable'') assets, certain operational capital charges, and potential adverse fluctuations in the value of securities inventory (known as ''haircuts''). The purpose of the net capital computation is to determine that the broker-dealer's net liquid assets (minimum capital base) are adequate in the event of sudden adverse business conditions. Excess net capital is the amount by which the member's net capital exceeds its minimum capital requirement.

[8] Letter from Richard L. Gregg, Commissioner of the Bureau of the Public Debt of the Department of the Treasury, to Jeffrey F. Ingber, General Counsel of the Government Securities Clearing Corporation (August 30, 1989) (permitting registered government securities brokers or dealers to treat clearing fund collateral as allowable assets for capital calculation purposes).

[9] For purposes of this analysis, the separate clearing fund requirements of members with multiple accounts will be combined into a single aggregate number.

[10] 15 U.S.C. 78q–1.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rules changes have not yet been solicited or received. Members will be notified of the rule change filing and an Important Notice will solicit comments. GSCC will notify the Commission of any written comments received by GSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) [11] of the Act and Rule 19b–4(f)(1) [12] thereunder because the proposed rule change constitutes a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule. At any time within sixty 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 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, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room in Washington, DC. Copies of such filing will also be available for inspection and copying at GSCC's principal office. All submissions should refer to File No. SR–GSCC–2001–06 and should be submitted by November 23, 2001.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(1).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–27557 Filed 11–1–01; 8:45 am]

BILLING CODE 8010–01–M

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44993; File No. SR–NYSE–2001–41]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the New York Stock Exchange, Inc. Amending the Exchange's Floor Conduct and Safety Guidelines and Exchange Rule 35 To Allow Specialists' Trading Assistants To Assist Specialist in Capturing Trades and Quotes During Active Market Conditions

October 26, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 15, 2001, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. 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 Exchange proposes to amend the Exchange's Floor Conduct and Safety Guidelines (the ''Guidelines'') with respect to policies and procedures on clerical employees entering a trading crowd. The Exchange believes that the Guidelines are a ''stated policy, practice or interpretation'' concerned with the administration of the Exchange. In addition, the exchange proposes a corresponding amendment to Exchange Rule 35.20 to cross-reference the proposed amendment to the Guidelines.

The text of the proposed rule change is available at the Office of the Secretary, the NYSE, and the Commission.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Exchange 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 Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The purpose of the Guidelines is to ensure that the behavior and practices of individuals on the Floor of the Exchange contribute to the efficient, undisrupted conduct of business on the Floor and do not jeopardize the safety or welfare of others. The Exchange believes the proposed rule change would enable the Exchange to keep its Guidelines consistent with current and new Exchange policy and procedures.

Entering or Crossing Trading Floor

The Guidelines prohibit Floor clerical employees entering a Trading Crowd [3] for any purpose, other than the resolution of Question Trade [4] or open items, from ten minutes prior to the opening until five minutes after the close. This is popularly known as the prohibition against crossing the ''blue line.''

The Exchange believes that with the elimination of Exchange reports,[5] there may be a need, under active market conditions, for specialist' trading assistants to stand in front of the post to assist in capturing trades and quotes.

[3] A trading crowd is defined as a group of Exchange members with a defined area of function tending to congregate around a trading post pending execution of orders. These are specialists, floor traders, odd-lot dealers, and other brokers as well as smaller groups with specialized functions (Barron's Dictionary of financial and Investment Terms).

[4] Indicates a trade in which, during the comparison process, one participant is discovered to be incorrectly identified. *See* Glossary, New York Stock Exchange Web page, *www.nyse.com* (visited October 23, 2001). *See also* NYSE Rule 134.

[5] According to the NYSE, it was the duty of Exchange reporters to report trades to the tape. As of August 2, 2001, this position has been eliminated by the Exchange. Telephone conversation between Jeff Rosenstrock, Senior Special Counsel, NYSE, and Christopher Solgan, Law Clerk, and Lisa Jones, Staff Attorney, Division of Market Regulation, Commission (October 25, 2001).

Accordingly, the Exchange is proposing to amend its Guidelines to permit specialists' trading assistants to act in this capacity, provided that prior Floor official approval is obtained.

Exchange Rule 35

Exchange Rule 35.20 provides that ''Floor employees of members and member organizations are not allowed to be upon or to cross the trading area of the Floor for any purpose during the period between ten minutes preceding the opening of the market and five minutes following the close of the market.'' In order to conform the above rule to the Guidelines, the Exchange is proposing to amend this paragraph by cross-referencing the proposed amendment to the Guidelines.

(2) Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act[6] in general and furthers the objectives of section 6(b)(5) of the Act[7] in particular in that it is designed to facilitate transactions in securities and remove impediments to and perfect the mechanism of a free and open market. The Exchange believes the revisions to the Guidelines support these goals by promoting the efficient, undisrupted conduct of business on the Trading Floor.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(i) of the Act[8] and subparagraph (f)(1) of Rule 19b-4[9] thereunder because the proposed rule change is a ''stated policy, practice or interpretation'' concerned with the administration of Exchange Rule 35. 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 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, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR–NYSE–2001–41 and should be submitted by November 23, 2001.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–27526 Filed 11–1–01; 8:45 am]

BILLING CODE 8010–01–M

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A)(i).

[9] 17 CFR 240.19b-4(f)(1).

[10] 17 CFR 200.30–3(a)(12).

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Determinations Under the African Growth and Opportunity Act

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The United States Trade Representative has determined that Uganda has adopted an effective visa system and related procedures to prevent unlawful transshipment and the use of counterfeit documents in connection with shipments of textile and apparel articles and has implemented and follows, or is making substantial progress toward implementing and following, the customs procedures required by the African Growth and Opportunity Act. Therefore, imports of eligible products from Uganda qualify for the textile and apparel benefits provided under the AGOA.

EFFECTIVE DATE: October 23, 2001.

FOR FURTHER INFORMATION CONTACT: Leslie S. Yang, Director for African Affairs, Office of the United States Trade Representative, (202) 395–9612.

SUPPLEMENTARY INFORMATION: The African Growth and Opportunity Act (Title I of the Trade and Development Act of 2000, Pub. L. 106–200) (AGOA) provides preferential tariff treatment for imports of certain textile and apparel products of beneficiary sub-Saharan African countries. The textile and apparel trade benefits under the AGOA are available to imports of eligible products from countries that the President designates as ''beneficiary sub-Saharan African countries,'' provided that these countries (1) have adopted an effective visa system and related procedures to prevent unlawful transshipment and the use of counterfeit documents, and (2) have implemented and follow, or are making substantial progress toward implementing and following, certain customs procedures that assist the Customs Service in verifying the origin of the products.

In Proclamation 7350 (Oct. 2, 2000), the President designated Uganda as a ''beneficiary sub-Saharan African country.'' Proclamation 7350 delegated to the United States Trade Representative (USTR) the authority to determine whether designated countries have met the two requirements described above. The President directed the USTR to announce any such determinations in the **Federal Register** and to implement them through modifications of the Harmonized Tariff Schedule of the United States (HTS). Based on actions that Uganda has taken, I have determined that Uganda has satisfied these two requirements.

Accordingly, pursuant to the authority vested in the USTR by Proclamation 7350, U.S. note 7(a) to subchapter II of chapter 98 of the HTS and U.S. note 1 to subchapter XIX of chapter 98 of the HTS are each modified by inserting ''Uganda'' in alphabetical sequence in the list of countries. The foregoing modifications to the HTS are effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the effective date of this notice. Importers claiming preferential tariff treatment under the AGOA for entries of textile and apparel articles should ensure that those entries

meet the applicable visa requirements. *See Visa Requirements Under the African Growth and Opportunity Act,* 66 FR 7837 (2001).

Robert B. Zoellick,

United States Trade Representative.

[FR Doc. 01–27494 Filed 11–1–01; 8:45 am]

BILLING CODE 3190–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–99–5867]

Parts and Accessories Necessary for Safe Operation; Renewal of Fuel Tank Exemptions for Vehicles Manufactured by the Ford Motor Company

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of intent to renew exemptions; request for comments.

SUMMARY: The FMCSA is announcing its intent to renew exemptions granted in response to applications from the Ford Motor Company (Ford), from certain fuel tank design and certification labeling requirements in the Federal Motor Carrier Safety Regulations (FMCSRs). Renewal of the exemptions would enable motor carriers to continue operating commercial motor vehicles (CMVs) manufactured by Ford, and equipped with fuel tanks that do not meet the FMCSA's requirements that fuel tanks be capable of receiving fuel at a rate of at least 20 gallons per minute, and be labeled or marked by the manufacturer to certify compliance with the design criteria. The FMCSA believes the terms and conditions of the exemptions have ensured a level of safety that is equivalent to the level of safety that would be achieved by complying with the regulations, and that renewing the exemptions would not adversely affect highway safety. The exemptions, if renewed, would continue to preempt inconsistent State and local requirements applicable to interstate commerce.

DATES: Comments must be received on or before December 3, 2001.

SUPPLEMENTARY INFORMATION:

Electronic Access

You can mail or deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. You can also submit comments electronically at *http://dms.dot.gov*. Please include the docket number that appears in the heading of this document. You can examine and copy this document and all comments received at the same Internet address or at the Dockets Management Facility from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you want to know that we received your comments, please include a self-addressed, stamped postcard or include a copy of the acknowledgement page that appears after you submit comments electronically.

FOR FURTHER INFORMATION CONTACT: Ms. Deborah M. Freund, Office of Bus and Truck Standards and Operations, (202) 366–4009, Federal Motor Carrier Safety Administration, 400 Seventh Street, SW., Washington, DC 20590–0001. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

Background

Ford's Applications for Exemptions

Ford applied for exemptions from 49 CFR 393.67(c)(7)(ii), which requires that certain fuel tank systems on CMVs be designed to permit a fill rate of at least 20 gallons (75.7 liters) per minute, and 49 CFR 393.67(f)(2) and (f)(3), which require that liquid fuel tanks be marked with the manufacturer's name and a certification that the tank conforms to all applicable rules in § 393.67.

On August 10, 1999 (64 FR 43417), the FHWA published a notice of intent to grant Ford's applications. The FHWA requested public comment on Ford's applications and the agency's safety analysis, and presented other relevant information known to the agency. After considering all the comments received, the agency granted the exemptions on December 20, 1999 (64 FR 71184). In that notice, the agency noted that the 20 gallon per minute rate referenced in the FMCSA's regulations, while appropriate for diesel fuel-powered vehicles, also mandates that fill pipes on gasoline-powered vehicles be capable of receiving fuel at the same rate, which is twice the maximum rate gasoline pumps are designed to dispense fuel. The vehicles in question are gasoline-fueled and are capable of receiving fuel at a rate of 17 gallons per minute.

The exemptions covered § 393.67(c)(7)(ii), Construction of liquid fuel tanks; fill pipe, and §§ 393.67(f)(2) and (f)(3)(ii) which require that liquid fuel tanks be marked with the manufacturer's name, and a certification that the tank conforms to all applicable rules in § 393.67.

Reason for Renewing the Exemptions

The FMCSA intends to renew the exemptions because the commercial motor vehicles covered by the exemptions are still in operation, and the agency is not aware of any information, anecdotal or otherwise, that would suggest that the level of safety for the exempted vehicles is not equivalent to the level of safety that would have been achieved if the vehicles complied with §§ 393.67(c)(7)(ii), 393.67(f)(2), and 393.67(f)(3)(ii). No interested parties have contacted the FMCSA or submitted comments to the docket since December 20, 1999, the date the exemption was granted, indicating that any aspects of the exemptions have had an adverse effect on highway safety. Accordingly, the agency is proposing to renew the exemptions for another two-year period.

Terms and Conditions for the Exemption Renewal

The FMCSA would continue to provide exemptions to §§ 393.67(c)(7)(ii), 393.67(f)(2), and 393.67(f)(3)(ii) for motor carriers operating Ford Econoline-based vehicles. The exemption renewal would be effective upon publication in the **Federal Register** pursuant to 5 U.S.C. 553(d)(1) and would be valid for two years from the date of approval, unless revoked earlier by the FMCSA. Ford, or any of the affected motor carriers, may apply to the FMCSA for another renewal of the exemption. The exemption would continue to preempt inconsistent State or local requirements applicable to interstate commerce.

As with the original exemption, the motor carriers operating these vehicles would not be required to maintain documentation concerning the exemption because the vehicles and fuel tanks have markings that would enable enforcement officials to identify them. The vehicles covered by the exemptions can be identified by their vehicle identification numbers (VINs). The VINs contain E30, E37, E39, E40, or E47 codes in the fifth, sixth, and seventh positions. The fuel tanks are marked with Ford part numbers F3UA–9002–G*, F3UA–9002–H*, F4UA–9002–V*, F4UA–9002–X*, F5UA–9002–V*, F5UA–9002–X*, F6UA–9002–Y*, F6UA–9002–Z*, F7UA–9002–C*, and F7UA–9002D* where the asterisk (*) represents a ''wild card'' character (any character of the alphabet).

Request for Comments

In accordance with 49 U.S.C. 31315 and 31136(e), the FMCSA is requesting public comment from all interested

persons on the exemption renewal. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the address section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable, but the FMCSA may renew the exemptions at any time after the close of the comment period.

Issued on: October 29, 2001.

Julie Anna Cirillo,

Acting Deputy Administrator.

[FR Doc. 01–27551 Filed 11–1–01; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2001–10923]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD's) intentions to request extension of approval for three years of a currently approved information collection.

DATES: Comments should be submitted on or before January 2, 2002.

FOR FURTHER INFORMATION CONTACT: Christopher Krusa, Maritime Administration, 400 Seventh Street, SW., Washington, DC 20590. Telephone: 202–366–2648 or FAX: 202–493–2288.

Copies of this collection can also be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: Supplementary Training Course Application.

Type of Request: Extension of currently approved information collection.

OMB Control Number: 2133–0030.

Form Numbers: MA–823.

Expiration Date of Approval: May 31, 2002.

Summary of Collection of Information: Section 1305 (a) of the Maritime Education and Training Act of 1980 indicates that the Secretary of Transportation may provide maritime-related training to merchant mariners of the United States and to individuals preparing for a career in the merchant marine of the United States. Also, the U.S. Coast Guard requires a fire-fighting certificate for U.S. merchant marine officers. This collection provides the information necessary for the maritime schools to plan their course offerings and for applicants to complete their certificate requirements.

Need and Use of the Information: This information collection is necessary for eligibility assessment, enrollment, attendance verification and recordation. Without this information, the courses would not be documented for future reference by the program or individual student.

Description of Respondents: U.S. Merchant Seamen, both officers and unlicensed personnel, and other U.S. citizens employed in other areas of waterborne commerce.

Annual Responses: 2,000.

Annual Burden: 100 hours.

Comments: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW, Washington, DC 20590. Comments may also be submitted by electronic means via the Internet at *http://dmses.dot.gov/submit*. Specifically address whether this information collection is necessary for proper performance of the functions of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance the quality, utility, and clarity of the information to be collected. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m. EDT, Monday through Friday, except Federal Holidays. An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov*.

By order of the Maritime Administrator.

Dated: October 30, 2001.

Joel C. Richard,

Secretary.

[FR Doc. 01–27624 Filed 11–1–01; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Financial Management Service; Proposed Collection of Information: CMIA Annual Report and Direct Cost Claim

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Financial Management Service, 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 a continuing information collection. By this notice, the Financial Management Service solicits comments concerning the report ''CMIA Annual Report and Direct Cost Claim.''

DATES: Written comments should be received on or before January 2, 2002.

ADDRESSES: Direct all written comments to Financial Management Service, 3700 East West Highway, Programs Branch, Room 144, Hyattsville, Maryland 20782.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Birdie McKay, Program Compliance Division, 401–14th Street, SW, Room 424, Washington, DC 20227, (202) 874–6630.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995, (44 U.S.C. 3506(c)(2)(A), the Financial Management Service solicits comments on the collection of information described below.

Title: CMIA Annual Report and Direct Cost Claim.

OMB Number: 1510–0061.

Form Number: None.

Abstract: This report is used to gather information from States and territories on interest owed to and collected by the Federal Government for major Federal assistance programs.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: States and territories.

Estimated Number of Respondents: 56.

Estimated Time Per Respondent: 500 hours.

Estimated Total Annual Burden Hours: 28,000.

Comments: Comments submitted in response to this notice will be summarized and/or included in a request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: October 26, 2001.

Bettsy H. Lane.

Assistant Commissioner, Federal Finance.

[FR Doc. 01–27623 Filed 11–1–01; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Proposed Collection: Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork 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). Currently the Bureau of the Public Debt within the Department of the Treasury is soliciting comments concerning the U.S. Treasury Auction Submitter Agreement.

DATES: Written comments should be received on or before January 8, 2002, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of the Public Debt, Vicki S. Thorpe, 200 Third Street, Parkersburg, WV 26106–1328.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Vicki S. Thorpe, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106–1328, (304) 480–6553.

SUPPLEMENTARY INFORMATION:

Title: U.S. Treasury Auctions Submitter Agreement.

OMB Number: None.

Form Number: PD F 5441.

Abstract: The information is requested from entities wishing to participate in U.S. Treasury Securities Auctions via TAAPSLink.

Current Actions: None.

Type of Review: New.

Affected Public: Depository Institutions, Brokers/Dealers, Assessment Management Companies, Pension Funds, and other Institutional Investors.

Estimated Number of Respondents: 1000.

Estimated Time Per Respondent: 5 minutes.

Estimated Total Annual Burden Hours: 80.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: October 29, 2001.

Vicki S. Thorpe,

Manager, Graphics, Printing and Records Branch.

[FR Doc. 01–27552 Filed 11–1–01; 8:45 am]

BILLING CODE 4810–39–P

Federal Register

Friday,
November 2, 2001

Part II

Nuclear Regulatory Commission

10 CFR Parts 2, 19, 20, 21, etc.

Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 19, 20, 21, 30, 40, 51, 60, 61, 63, 70, 72, 73, and 75

RIN 3150–AG04

Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, NV

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing licensing criteria for disposal of spent nuclear fuel and high-level radioactive wastes in the proposed geologic repository at Yucca Mountain, Nevada. As mandated by law, this final rule changes the Commission's technical requirements and criteria, as necessary, to be consistent with final environmental standards for Yucca Mountain issued by the U.S. Environmental Protection Agency (EPA). The criteria address how a repository system at Yucca Mountain must perform and specify that the system must comprise both natural and engineered barriers. The final rule includes licensing criteria; participation in license reviews by the State, affected units of local government, and Indian Tribes; records and reporting; monitoring and testing programs; performance confirmation; quality assurance; personnel training and certification; and emergency planning. Criteria set out in this final rule apply specifically and exclusively to the proposed repository at Yucca Mountain. Consistent with this intent, the Commission is also changing its generic criteria for disposal of spent nuclear fuel and high-level radioactive wastes in geologic repositories. These changes make clear that the generic criteria, specified elsewhere in the regulations, do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain.

EFFECTIVE DATE: December 3, 2001.

FOR FURTHER INFORMATION CONTACT: Timothy McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–7285, e-mail tjm3@nrc.gov; Janet Kotra, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6674, e-mail jpk@nrc.gov; or Clark Prichard, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6203, e-mail cwp@nrc.gov.

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I. Background

On February 22, 1999 (64 FR 8640), the Commission published a proposed rule for public comment that would establish licensing criteria for disposal of spent nuclear fuel and high-level radioactive waste in the proposed geologic repository at Yucca Mountain, Nevada. The Energy Policy Act of 1992, Pub. L. 102–486 (EnPA) directed the Commission to make its requirements for geologic disposal consistent with new standards for Yucca Mountain the Environmental Protection Agency (EPA) would develop. The legislation also specifies the type of standards the NRC is to implement [that is, standards which limit individual dose and which are based on and consistent with the National Academy of Sciences' (NAS) 10 recommendations]. The Commission proposed a new, separate part of its regulations, 10 CFR part 63, that would apply only to the proposed repository at Yucca Mountain. The Commission also proposed to leave its existing, generic regulations at Part 60 in place, changed only to state that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain.

In setting forth these criteria, the Commission sought to establish a coherent body of risk-informed, performance-based criteria for a Yucca Mountain facility that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation. Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment, and performance history are used to (1) focus attention on the most important activities, (2) establish objective criteria based upon risk insights for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, and (4) focus on the results as the primary basis for regulatory decision making. The Commission believes that creating a new part of its regulations accomplishes these objectives better than modifying the generic requirements. The Commission prefers a wholly new part 63 that reflects the fundamentally different approach laid out for Yucca Mountain by EnPA and the final EPA standards, an approach unlike that contemplated when the generic criteria were issued. Specifically, EnPA defined an approach that requires the performance of a Yucca Mountain repository to comply with health-based standards, developed by EPA and based on the recommendations of the NAS. EPA has established standards for Yucca Mountain that consider risk to a hypothetical individual and are to be the only such standards for the postclosure performance of the repository. This approach differs from that taken in the existing generic criteria which relies on quantitative, subsystem performance standards.

The public comment period, originally ending on May 10, 1999, was

extended to June 30, 1999, in response to many requests for extension (64 FR 24092; May 5, 1999). During the public comment period, the NRC staff held a series of public meetings in Nevada to discuss the proposed rule and solicit public comment. Meetings were held at Las Vegas and Beatty, Nevada, on March 23 and 25, respectively. Later, NRC held more meetings at Amargosa Valley, Las Vegas, and Caliente, Nevada, on June 15, 16, and 17, respectively. In developing this final rule, NRC considered comments received at these meetings along with written comments sent to NRC. The NRC also held a facilitated round table discussion on defense in depth as applied to a possible repository at Yucca Mountain on November 2, 1999, in Las Vegas.

The EPA published final radiation protection standards for the potential Yucca Mountain repository (40 CFR part 197) on June 13, 2001 (66 FR 32073). The EPA standards differ from the performance objectives proposed by the Commission at 10 CFR part 63. EPA established an annual individual protection dose limit of 0.15 mSv (15 mrem), and EPA included separate ground-water protection criteria in its final standards for the purpose of protecting ground water. In formal comments on EPA's proposed standards, dated November 3, 1999, the NRC staff supported a somewhat different approach. The NRC approach, which the Commission believes is adequately protective of public health and safety and ground water, used a comprehensive, all-pathway limit. However, the ultimate decision was EPA's to make and, as called for under the EnPA, the Commission will change its technical requirements and criteria to be consistent with EPA's final standards.

II. Implementation of the Environmental Protection Agency Final Standards

The U.S. Environmental Protection Agency (EPA) published Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada, at 40 CFR part 197 on June 13, 2001 (66 FR 32073). The Energy Policy Act of 1992, Pub. L. 102–486 (EnPA) directs the Commission to modify its technical requirements and criteria to be consistent with these standards. The Commission has imported the EPA standards into its final 10 CFR part 63 regulations in as transparent a manner as possible. Three categories of changes were necessary to accomplish this. First, the two subparts of the EPA standards—subpart A for storage and subpart B for disposal—have been added to part 63 as subparts K and L, respectively. Second, in most cases, the Commission adopted wording precisely as it appears at 40 CFR part 197. The Commission also made nonsubstantive changes that conformed to the regulatory style of the proposed part 63, and other U.S. Nuclear Regulatory Commission (NRC) regulations; removed unnecessary references to NRC; and adapted or removed redundant definitions. Lastly, as the implementing authority for the EPA standards, we have provided additional specifications and requirements based on the proposed part 63 rule and public comments we received in the areas where it is appropriate to do so. Indeed, EPA has acknowledged NRC's authority to add implementing requirements. As part of its rulemaking process, the Commission proposed and received comments on many aspects of radiation exposure scenarios, including several matters relevant to implementation of the EPA standards. Although EPA publication of the standards postdated the formal comment period for proposed part 63, the Commission has provided further specifications in subpart L, where needed, for clarification. We believe these additions are consistent with EPA's intent and are responsive to public comments we received. A brief summary of key aspects of the Commission's implementation of EPA's Standards in the final part 63 regulations appears below.

Radiation Standards for Storage

NRC has adopted the 0.15 mSv/year (15 mrem/year) dose limit for members of the public, during the storage period, and the associated requirements for determining compliance with the standards. The EPA standards identify the standards for storage as applicable at Yucca Mountain during the time period before closure of the proposed repository. In proposed part 63, NRC characterized this phase as ''preclosure.'' Therefore, we are implementing EPA's standards for storage to apply to the preclosure time period.

Radiation Standards for Disposal

The NRC has adopted the 0.15 mSv/year (15 mrem/year) dose limit for the reasonably maximally exposed individual, during the disposal period, and the associated requirements for determining compliance with the standards.

Ground-Water Protection Standards

NRC has adopted the ground-water protection standards and the associated requirements for determining compliance with the standards.

Radiation Standards for Human Intrusion

NRC has adopted the 0.15 mSv/year (15 mrem/year) dose limit for the reasonably maximally exposed individual as a result of a human intrusion and the associated requirements for determining compliance with the standards. One aspect of EPA's final standards is the specification of the characteristics of a postulated scenario for evaluating the consequences of human intrusion. NRC fully supports and has adopted the characteristics of the human intrusion scenario as specified in 40 CFR part 197 and has specified one additional requirement to further characterize the scenario. Specifically, part 63 provides that no particulate waste material falls into the borehole, and that DOE should assume the exposure scenario includes only those radionuclides transported to the saturated zone by water (e.g., water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone). This change responds to a public comment seeking clarification of this aspect of the human intrusion scenario in proposed part 63. The Commission considers the additional requirement to be appropriate for addressing the comment and to be a matter of implementation of the EPA final standards. Further, the requirement is consistent with the human intrusion scenario as specified in 40 CFR part 197.

Reference Biosphere

The EPA standards for Yucca Mountain specify criteria that pertain to the characteristics of a reference biosphere, for use in the performance assessments that are required to show compliance with the postclosure standards for disposal. NRC fully supports and has adopted, in part 63, the characteristics of the reference biosphere as specified in 40 CFR part 197 and has included an additional requirement on characteristics of the biosphere that are consistent with EPA's final standards and that were discussed in proposed part 63 (64 FR 8640; February 22, 1999). Specifically, part 63 provides a further requirement for biosphere pathways by stating these pathways * * * ''must be consistent with arid and semi-arid conditions.'' This addition, from proposed part 63 (64 FR 8677), clarifies the bounds on what DOE needs to consider and is consistent with present knowledge of

how the climate could change over the next 10,000 years.

Reasonably Maximally Exposed Individual

The EPA standards specify characteristics of the reasonably maximally exposed individual (RMEI) for use in the performance assessments used to demonstrate compliance with standards for disposal. The NRC fully supports and has adopted the characteristics of the reasonably maximally exposed individual from 40 CFR part 197, and has included requirements specifying additional characteristics that are consistent with the EPA standards and were discussed in proposed part 63 (64 FR 8640). First, part 63 provides that the reasonably maximally exposed individual * * * ''is an adult with metabolic and physiological considerations consistent with present knowledge of adults.'' This addition, suggested for the average member of the critical group in proposed part 63 (64 FR 8677), clarifies assumptions DOE must make in estimating the radiation exposure to the reasonably maximally exposed individual. This addition is considered to be consistent with EPA's standards because: (1) The standards specify a consumption rate for water (i.e., 2 liters per day) that corresponds with that of an adult; and (2) a dose limit of 0.15 mSv (15 mrem) for an adult is protective of children as well as other age groups. The requirement that metabolic and physiological considerations are consistent with present knowledge of adults is consistent with EPA's final standards, which state that DOE should not project changes in human biology (66 FR 32133).

Second, although the EPA standards specify a representative volume approach for demonstrating compliance with the separate ground-water protection standards, they leave to NRC the approach for demonstrating compliance with the individual protection standard for disposal. EPA's approach for ground-water protection specifies a representative volume of 3,000 acre-feet for estimating the concentrations of radionuclides. The 3,000 acre-feet representative volume of ground water is consistent with assumptions for the critical group described in proposed part 63 (64 FR 8646). Specifically, in the proposed part 63, we suggested consideration of a farming community of up to 100 individuals, living on 15 to 25 farms. Fifteen to 25 farms are consistent with current conditions in the town of Amargosa Valley, Nevada, and would be the number needed to produce the range of locally produced food that is currently consumed in this area. The purpose of identifying 15 to 25 farms and specifying 100 individuals was to provide DOE with flexibility in determining an appropriate water demand consistent with a farming community of that size. A community of 15 to 25 farms would pump a sufficiently large volume of water and involve a broad range of exposure pathways. Of primary importance is the ingestion pathway, through consumption of water, crops, and animal products. The Commission considers that the water demand of between 15 and 25 farms can be represented by a volume of at least 3,000 acre-feet and, thus, is consistent with the farming community proposed for comment in part 63. Additionally, the preamble to EPA's final standards stated the NRC could use an approach to assess water usage in the hypothetical community, in which the RMEI resides, that was similar to the representative volume approach used for ground-water protection (i.e., consider a representative volume of 3,000 acre-feet). Therefore, the Commission removed the flexibility provided DOE to determine an appropriate water demand. This revised approach limits speculation on water demand and provides DOE with a specific value for the water demand that the NRC staff finds acceptable to estimate the RMEI dose. Part 63 specifies that the reasonably maximally exposed individual uses well water with an average concentration of radionuclides based on a representative volume of water of 3,000 acre-feet.

Unlikely Features, Events, and Processes

The EPA standards exclude unlikely features, events, and processes (including sequences of events and processes) from analyses for estimating compliance with the standards for human intrusion and ground-water protection. However, the EPA standards do not specify a frequency for unlikely features, events, and processes, and acknowledge that a value is to be specified by NRC (66 FR 32135). NRC fully supports excluding unlikely features, events, and processes from analyses for estimating compliance with the standards for human intrusion and ground-water protection. Although we have provided no specific quantitative value for determining when exclusion of unlikely features, events, and processes is appropriate, the final regulations require DOE to exclude unlikely features, events, and processes from the specified analyses upon prior approval of the Commission for the probability limit used for unlikely features, events, and processes. The Commission recognizes that specification of a probability limit for unlikely features, events, and processes, as is done for ''very'' unlikely features, events, and processes, would be a more direct approach. Although the Commission considers a frequency for unlikely features, events, and processes would fall somewhere between 10^{-8} to 10^{-4} per year, the Commission has decided not to specify a value in the regulations at this time. The Commission plans to conduct an expedited rulemaking to quantitatively define the term ''unlikely.'' Consideration will be given to whether a range of values or a single specific value should be used as well as the appropriate numerical value(s). The expedited rulemaking will provide an opportunity for public comment to assist the Commission in determining an appropriate approach.

Total Effective Dose Equivalent

The EPA and the NRC use different quantities to assess the total dose to exposed members of the public (including the RMEI). EPA uses the annual committed effective dose equivalent (annual CEDE), defined as the sum of the committed effective dose equivalent from internal doses resulting from one year's exposure to radioactive materials, and the effective dose equivalent from external radiation exposure during the year. The NRC uses the total effective dose equivalent (TEDE) for the same purpose. There are differences between TEDE and annual CEDE in some contexts. Specifically, in determining the external dose component of TEDE, NRC specifies use of the deep-dose equivalent at 10 CFR 20.1003. The deep-dose equivalent is a point measurement that does not sum the doses to the organs or tissue through use of weighting factors. This approach may reflect the fact that compliance with part 20 is customarily assessed using a Thermo-Luminiscent Device (TLD) or a film badge, and the results of such measurements reflect deep-dose equivalent. By contrast, in determining annual CEDE, the external dose component is determined using the effective dose equivalent, which involves summing the products of organ doses and weighting factors. In those situations in which the two measures of external dose differ, the effective dose equivalent approach probably provides a better estimate for measuring radiation risk.

Nonetheless, NRC's part 20 does allow for consideration of weighting factors for individual organs in the case of external exposures on a case-by-case

basis. *See* 10 CFR 20.1003, Footnote 2 to Table on Organ Dose Weighting Factors. In practice, computer codes used by NRC in decommissioning and HLW disposal currently calculate external doses using effective dose equivalent and not deep-dose equivalent. *See* NUREG/CR 6676, ''Probabilistic Dose Analysis Using Parameter Distributions Developed for RESRAD and RESRAD-Build Codes,'' 3–1 (July 2000); NUREG–1464, ''NRC Iterative Performance Assessment,'' 7–5 (October 1995); and NUREG/CR–5512, ''Residual Contamination from Decommissioning, User's Manual DandD Version 2.1,'' Vol. 2, E–1 (April 2001). Consequently, use of organ doses and organ weighting factors, from Federal Guidance Report 12 and ICRP in its Publication 26, for external doses in assessing compliance with dose limits for members of the public in the general environment and the individual protection standard in connection with a geologic repository will yield exactly the same result as applying annual CEDE. As a result, in assessing compliance with the individual protection standard, the staff intends to use effective dose equivalent for assessing external exposure.

For purposes of assessing actual doses to workers at the Yucca Mountain repository, however, the Commission has directed that deep-dose equivalent be used in determining TEDE. This ensures consistency with NRC's regulations for limiting doses to occupationally exposed workers.

Requirements for Environmental Impact Statement

EPA's standards require DOE to estimate peak dose under the evaluations for individual protection and human intrusion. The results of these evaluations are to be included in DOE's environmental impact statement (EIS). The Commission has modified part 63 to include the provision that DOE must include peak dose estimates in its EIS, but notes that there is no standard that must be met with respect to these peak dose calculations, and that there is no finding that the NRC must make with respect to these peak dose calculations nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain. However, DOE still must carry out its responsibilities under the National Environmental Policy Act in accordance with the final EPA standards.

Definitions

Barriers

Proposed part 63 and EPA's final standards define ''barriers'' slightly differently. The Commission believes there is no substantive difference between the two definitions and has adopted the EPA definition at § 63.2. The EPA definition, among other things, provides that the Commission would determine a time period over which a material, structure or feature would perform its intended function. The regulation at § 63.115 requires DOE to describe the capability of each barrier to isolate waste. The description would include information on the time period over which DOE asserts that each barrier will perform its intended function including any changes during the compliance period. This information on expected performance will enable NRC to determine the period of time that any particular material, structure or feature prevents or substantially reduces the rate of movement of water or radionuclides from the Yucca Mountain repository to the accessible environment, or prevents the release or substantially reduces the release rate of radionuclides from the waste.

Ground Water

Proposed part 63 and EPA's final standards define ''ground water'' differently. To implement the EPA standard, part 63 has adopted the EPA definition for ground water and revised the use of the term ''ground water'' in the proposed rule accordingly. The single definition for ground water is provided at § 63.302.

High-Level Waste

Proposed part 63 and EPA's final standards define ''high-level waste'' slightly differently. The Commission believes there is no substantive difference between the two definitions and has modified its definition to more closely reflect the definition provided in the Nuclear Waste Policy Act of 1982 and the final standards.

Important to Waste Isolation

Proposed part 63 defined ''important to waste isolation'' in the context of meeting the individual dose limit for the postclosure period of the repository (i.e., disposal). This use of the term is important in defining the scope of the requirements for: DOE's quality assurance program (specified at subpart G); multiple barriers (specified at 10 CFR 63.113); performance confirmation (specified at subpart F); and changes, tests, and experiments (specified at 10 CFR 63.44). The Commission has expanded the definition of the term, ''important to waste isolation'' to include both the dose limit and the separate ground-water protection limits contained in the EPA standards.

Performance Assessment

Proposed part 63 and EPA's final standards define ''performance assessment'' slightly differently. The Commission believes there is nosubstantive difference between the two definitions and has adopted the EPA definition at § 63.2.

III. Public Comments and Responses

In preparing the final rule, the NRC staff carefully reviewed and considered more than 700 discrete comments enclosed in about 160 individual letters received during the public comment period. The NRC staff also identified and evaluated an additional 193 comments made at public meetings. To simplify the analysis, the NRC staff grouped all written and oral comments on the rule into the following six major topic areas:

(1) Regulatory Process and Licensing Process;

(2) Requirements for the Preclosure Period;

(3) Requirements for the Postclosure Period;

(4) General Requirements;

(5) Selected Topics; and

(6) Beyond the Scope of This Rulemaking.

1 Regulatory Process and Licensing Process

1.1 Promulgation in Advance of EPA Standards

Issue 1: Is NRC's action in promulgating part 63 in advance of EPA standards beyond the scope of its authority?

Comment. Many of those who commented on the NRC's proposed part 63 expressed concern that NRC was ''usurping'' EPA's authority by declaring its own standards and technical requirements in advance of EPA's issuance of final standards. For example, the State of Nevada pointed out the EnPA does not mandate a new Commission rule specific to Yucca Mountain to replace its general rule for licensing geologic repositories. It only requires modification of NRC's technical requirements and criteria, as necessary, to be consistent with new EPA standards once they are published. Further, the State pointed out that EnPA does not authorize the Commission to expand its licensing jurisdiction to include proposing standards for human safety and environmental protection

that are within the statutory mandate and jurisdiction of EPA.

Response. The Commission acknowledges the statutory role given to EPA for setting standards for Yucca Mountain. It is with full recognition of that role that the Commission is publishing final criteria that are consistent with EPA's published standards. In the supplementary information published with the proposed rule, the Commission stated clearly that ''* * * the authority and responsibility for setting public health and safety standards for radioactive waste disposal rest with EPA'' (64 FR 8643; February 22, 1999). The Commission went on to say that ''* * * [w]hen EPA issues final standards for Yucca Mountain or if new HLW legislation is enacted into law, the Commission will amend its criteria at 10 CFR part 63, if necessary, to be consistent with the final standards'' (ibid. 8644).

It is true the EnPA did not direct the NRC to develop a new rule specific to Yucca Mountain to replace its general rule for licensing geologic repositories. It is also true the EnPA does not diminish NRC's authority under the Atomic Energy Act to conduct rulemaking nor to select the manner in which it will revise regulatory requirements. In the proposed rule, the Commission explained that since the initial technical criteria at 10 CFR part 60 were promulgated more than 15 years ago, there has been notable evolution in the capability of technical methods for assessing the performance of a geologic repository at Yucca Mountain. The Commission stated that ''(t)hese new methods were not envisioned when the part 60 criteria were established and their implementation for Yucca Mountain will avoid the imposition of unnecessary, ambiguous, or potentially conflicting criteria that could result from the application of some of the Commission's generic requirements at 10 CFR part 60'' (64 FR 8641). The Commission recognized that its generic part 60 requirements will need updating if applied to sites other than Yucca Mountain. However, the Commission elected not to conduct an update of part 60 now but, instead, decided to place all the regulations needed for the licensing of a repository at Yucca Mountain in a separate CFR part. *See* Response to Issue 3. The Commission explained that it ''believes this to be the most direct and time-efficient approach to the specification of concise, site-specific criteria for Yucca Mountain that are consistent with current assumptions, with site-specific information and performance assessment experience, and with forthcoming EPA standards that must also apply solely to Yucca Mountain'' (64 FR 8643). Consistent with the views expressed by most commenters, the Commission has awaited EPA's publication of final standards for Yucca Mountain and has changed its technical requirements and criteria to conform to EPA's standards, as required by law.

Issue 2: Should NRC wait for EPA to release final standards before completing part 63?

Comment. Commenters differed on the issue whether NRC should proceed with proposed part 63 or wait until after EPA publishes final standards. Commenters in favor of NRC moving forward with the proposed part 63 supported the proposed approach as protective of public health and safety and the environment. They cited timely specification of NRC regulations for the potential repository as a benefit for the national program. Others, however, believed that it was premature for NRC to publish final regulations. They felt that doing so would be contrary to the sequence set by Congress in the EnPA which directs EPA to issue radiation standards first and then for NRC to conform its technical requirements to those standards. These commenters saw no reason for NRC to act outside this time sequence and favored withdrawal of the proposed rule and resubmittal with any necessary adjustments after promulgation of EPA standards.

Response. The EnPA specified that EPA was to publish radiation standards for Yucca Mountain not later than 1 year after receipt of the findings and recommendations of the National Academy of Sciences (NAS). It also directed NRC to modify its technical requirements and criteria not later than 1 year after EPA publishes final standards. The Commission believes that this schedule reflects Congress' intent to have a final regulatory structure before DOE would start preparation of a license application if Yucca Mountain were recommended as a site for a geologic repository. The NAS published its recommendations in August 1995. The NRC explained when it published its proposed rule, on February 22, 1999, that it had decided to proceed, even in the absence of EPA standards, because of the short time period allotted NRC to conduct its own rulemaking. In one year, NRC would have to modify its standards and requirements and to implement certain assumptions in the EnPA related to the effectiveness of postclosure oversight of the repository. The Commission also believed it was in the best interest of the national program to proceed, given that DOE could be in a position to submit a license application to NRC in 2002 (64 FR 8641). It is important to recognize that most of the requirements proposed at part 63 involve matters that are unaffected by the final EPA standards (e.g., licensing procedures, records and reporting, monitoring and testing programs, performance confirmation, quality assurance, personnel training and certification, and emergency planning). Now that EPA has published final standards, NRC is prepared to complete its implementing regulations at part 63 with due regard to the requirement in EnPA to be consistent with EPA's standards.

Issue 3: Why is there a need to develop a site-specific disposal regulation for the Yucca Mountain site?

Comment. Several commenters questioned NRC's need to develop a whole new body of site-specific regulations as opposed to revising its generic regulations at part 60, as necessary, to conform to the new, site-specific standards to be developed by EPA. These same commenters noted that certain portions of proposed part 63 depart significantly from part 60 (e.g., there are no quantitative subsystem requirements) and, in the view of several commenters, weaken the safety requirements for any proposed repository at Yucca Mountain.

Response. The Commission is establishing a new, separate part of its regulations (at part 63) that would apply only to the proposed repository at Yucca Mountain. The Commission will leave existing, generic regulations at part 60 in place, modified only to state that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain. The Commission believes this to be the most direct and efficient approach for specifying concise, site-specific criteria for Yucca Mountain that are consistent with current assumptions, with site-specific information and performance assessment experience, and with EPA standards that apply solely to Yucca Mountain.

In developing these criteria, the Commission sought to establish a coherent body of risk-informed, performance-based criteria for Yucca Mountain that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation [''Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities—Final Policy Statement'' (60 FR 42622; August 16, 1995)]. Stated succinctly, risk-informed, performance-based regulation is an

approach in which risk insights, engineering analysis and judgment (e.g., defense in depth), and performance history are used to: (1) Focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision making. The Commission believes that creating a new part of its regulations to accomplish these objectives is preferable to modifying its generic requirements, given that EnPA and NAS laid out a fundamentally different approach for Yucca Mountain than was contemplated when the generic criteria were promulgated. Specifically, EnPA and NAS outlined an approach that would require the performance of a Yucca Mountain repository to comply with health-based standards established in consideration of risk to individuals in a hypothetical group. The law also stated that the new health-based standards were to be the only quantitative standards for the postclosure performance of the repository. This approach departs from the approach taken in the existing generic criteria which rely on compliance with cumulative release limits and separate, quantitative, subsystem performance objectives. Further, the Commission's current approach is consistent with EPA standards for Yucca Mountain. Therefore, after carefully considering the public comments, the Commission remains of the view that it is best to develop site-specific regulations—regulations that reflect an improved scientific understanding of the site; are based on state-of-the-art analyses; are consistent with the Commission's philosophy to implement risk informed regulation; and implement the separate, site-specific standards that EPA has issued for Yucca Mountain.

Commenters correctly pointed out that there are significant differences between part 60 and part 63. In the Commission's view, the part 63 regulations do not in any way lessen DOE's responsibility to site, design, and operate the proposed repository safely. Much has been learned regarding the expected performance of geologic repositories in general (Nuclear Energy Agency, Lessons Learnt from Ten Performance Assessment Studies, Paris, France, NEA/OECD Working Group on Integrated Performance Assessments for Geologic Repositories, 1997), and a potential Yucca Mountain repository in particular over the nearly two decades since part 60 was written. Part 63 reflects and incorporates much of this new information. The risk-informed, performance-based approach used to develop the rule (see SECY–97–300, ''Proposed Strategy for Development of Regulations Governing Disposal of High-Level Radioactive Wastes in a Proposed Repository at Yucca Mountain,'' U.S. NRC, December 24, 1997) eliminates arbitrary or prescriptive siting and design criteria, as well as detailed requirements such as quantitative subsystem performance objectives. That being said, however, part 63 still requires DOE to demonstrate reliance on multiple barriers and defense in depth, preservation of the retrieval option, implementation of a performance confirmation program, transparency in decision making, and application of rigorous quality assurance (QA). Moreover, as a result of public comments, other provisions have been added to part 63 to ensure the adequacy and sufficiency of DOE's compliance demonstrations. (See Multiple Barriers and Defense in Depth for additional discussion on quantitative subsystem requirements.)

1.2 Differences Between Part 63 and EPA Standards for WIPP

Issue: Why is there a difference between the performance objectives in NRC's proposed 10 CFR part 63 for Yucca Mountain and EPA's 40 CFR part 191 standards used to certify the Waste Isolation Pilot Project (WIPP)?

Comment. Many commenters expressed concern that NRC's proposed regulations for Yucca Mountain provided less protection than EPA's standards for WIPP. They regarded NRC's proposed regulations as less stringent than the standards for WIPP. Many cited the absence of separate criteria for protection of ground water in NRC's proposed regulation as evidence that the WIPP standards, which include separate requirements for protection of ground water, are more restrictive. Commenters also cited the differences in the individual protection limits [0.15 mSv/year (15 mrem/year) for WIPP compared to 0.25 mSv/year (25 mrem/year) limit for Yucca Mountain], and the compliance location (5 km for WIPP compared to approximately 20 km for Yucca Mountain). Generally, commenters asked NRC to set standards similar to, or more stringent than, those for WIPP. Some argued that a greater level of protection for people near Yucca Mountain was needed to offset potential exposures from other sources in the region (i.e., the Beatty low-level waste site and the Nevada Test Site, NTS).

Response. Final EPA standards adopted numerical limits that are comparable to those applied at WIPP. Consistent with the views expressed by a majority of commenters, the Commission has awaited EPA's publication of final standards for Yucca Mountain and is adopting final part 63 criteria that are consistent with those limits, as required by law.

1.3 Multi-Staged Licensing

Issue 1: Should DOE be allowed to begin to place waste in the repository or to store waste in surface facilities once NRC has determined that there is enough space for initial operations, or should DOE have to wait until site construction is complete?

Comment. Many commenters indicated that NRC should not allow DOE to place waste in the repository until construction is complete. These commenters had general concerns that only after construction is completed would emergency equipment and safety precautions be available in case of an accident; and that any waste, if emplaced before completing construction, may pose an unnecessary risk to the construction workers. Alternatively, other commenters suggested that storage of waste at the repository should be allowed during construction as long as it does not pose any additional health or safety risk. The Nuclear Energy Institute (NEI) suggested that part 63 should be changed so that NRC could authorize DOE to construct all or part of the geologic repository operations area (GROA), and could authorize early use of the surface facilities to store waste.

Response. The proposed rule retained the licensing phases as described at part 60. Once construction of the GROA is substantially complete (as specified at § 63.41), DOE may update its application and the Commission may issue a license to receive and possess source, special nuclear, or byproduct material at the GROA. Prior to issuing such a license, the Commission must make certain findings, such as: (1) Activities to be conducted at the GROA comply with the rules and regulations of the Commission, which will include radiation protection for workers; (2) adequate protective measures can and will be taken in the event of a radiological emergency; (3) there is no unreasonable risk to the health and safety of the public; and (4) construction of the GROA has been substantially completed. Construction is deemed

substantially complete, for this purpose, if among other things, DOE has completed construction of sufficient underground storage space for *initial* operations. Thus, part 63 provides DOE flexibility to plan for efficient repository operations for receipt and emplacement of waste because of the significant length of time required to complete excavation of the entire underground facility.

The DOE has not indicated to the Commission any intention to seek an authorization for early use of the surface facilities for storage of spent nuclear fuel. Such an authorization likely would necessitate a change to (or an exemption from) the regulations. Before NRC would make changes of this type to its regulations, NRC would need to publish the proposed changes and seek public comment.

Issue 2: Should DOE have to prepare a second EIS to support a decision to issue a license amendment for permanent closure, as this may constitute a major Federal action?

Comment. Commenters stated that the license amendment for permanent closure is a major Federal action and should require a new EIS (i.e., not rely upon the EIS prepared for the license application). They expressed the view that a decision to issue an amendment for permanent closure would include a decision that retrieval of the waste is not necessary and that the expected impacts of the waste affecting the environment far into the future and far beyond the site are acceptable. They also pointed out that the decision to issue the license amendment will be based, in part, on performance confirmation data collected after the original EIS is submitted. One commenter was concerned that the proposed requirement at § 51.67 did not explicitly state the need to include measures to mitigate impacts including transportation.

Response. The regulations require DOE to supplement its EIS, if necessary, when the application for the license amendment for permanent closure is submitted [§ 63.51(b)]. The decision involved in granting the amendment would be a subset of decisions made in the original EIS and any supplements. A supplement to the EIS would need to address such things as substantial changes to the proposed action or significant new circumstances or information relevant to environmental concerns. The Commission believes the commenters' request for requiring DOE to consider these matters at the time of permanent closure is adequately covered by the regulations.

The Commission did not adopt the suggested change to § 51.67 to include a specific requirement to consider mitigation measures that the Council on Environmental Quality (CEQ) regulations dictate for the contents of the EIS, which include requirements for consideration of measures to mitigate impacts including transportation. DOE would need to comply with applicable CEQ requirements, and the Commission does not believe any regulatory changes are necessary to ensure compliance by DOE.

Issue 3: Is there any limit on the types and amounts of radioactive materials (e.g., tons of HLW) that DOE would be allowed to receive and possess at Yucca Mountain if these materials were for site characterization activities or testing during construction?

Comment. EPA suggested that, under the proposed rule (§§ 63.7(a) and 63.74(a)(1)), DOE could take any types and amounts of radioactive materials onto the site if it claimed that the materials were for site characterization activities.

Response. EPA correctly notes that proposed part 63 does not place any specific quantitative limit on the amount of radioactive materials DOE might use for site characterization or testing. However, a specific numerical limit is unnecessary. Section 113(c)(2)(A) of the NWPA prohibits the DOE from using radioactive material in conducting site characterization activities unless the Commission concurs that such use is necessary. Under § 63.16(a), if DOE's planned site characterization activities include onsite testing with radioactive material, the Commission must determine whether the proposed use of radioactive material is necessary. The Commission would not concur in any DOE proposal to bring radioactive materials on site unless it was convinced that both the types and amounts were needed for site characterization. The proposed part 63 would not have allowed DOE to receive and possess ''any types or amounts'' of radioactive materials as suggested by EPA. Thus, changes to the proposed regulations are not needed.

Issue 4: In a multi-staged licensing approach, does the NRC require that all information be available at the first stage (i.e., construction authorization) or will DOE be allowed to provide certain information in a ''staged'' manner consistent with that particular stage of the licensing process?

Comment. DOE commented that it intends to provide a sufficient level of information to allow the NRC to make a finding of reasonable assurance at the time of the construction authorization in accordance with § 63.31. However, DOE stated that it would be helpful if the Commission would clarify its intent regarding the level of information required in the license application. In particular, DOE recommended three changes to proposed subpart B: (1) The language of § 63.21(b)(3) calling for ''a detailed plan'' to provide physical protection for HLW should be changed to a ''description of the plan'' to provide physical protection for HLW because this would be more consistent with the language used in other provisions of § 63.21(b) and would reflect what DOE believes to be an adequate level of detail on this subject; (2) the proposed § 63.24(a) requirement that the application be as complete as possible at the time of docketing based on reasonably available information should be moved to § 63.21(a) because this section provides requirements for the content of the license application; and (3) the proposed finding that the Commission would make to authorize construction at § 63.31(a)(6) that ''DOE's proposed operating procedures to protect health and to minimize danger to life or property are adequate'' should be changed to ''DOE's proposed plan to develop operating procedures'' because, at the time of construction authorization, details of the repository design will not, in some cases, be sufficient to support development of operating procedures and DOE does not believe that the procedures need to be in place at this stage of the licensing process. Another commenter suggested that the regulations for each licensing stage should be modified to state explicitly that the corresponding Commission finding must take into account ''the scope of the authorization requested and the information available.''

Response. part 63 provides for a multi-staged licensing process that affords the Commission the flexibility to make decisions in a logical time sequence that accounts for DOE collecting and analyzing additional information over the construction and operational phases of the repository. The multi-staged approach comprises four major decisions by the Commission: (1) Construction authorization; (2) license to receive and emplace waste; (3) license amendment for permanent closure; and (4) termination of license. The time required to complete the stages of this process (e.g., 50 years for operations and 50 years for monitoring) is extensive and will allow for generation of additional information. Clearly, the knowledge available at the time of construction authorization will be less than at the subsequent stages. However,

at each stage, DOE must provide sufficient information to support that stage. DOE has stated its intent to submit, and NRC expects to receive, a reasonably complete application at the time of construction authorization to allow the Commission to make a construction authorization decision. This is reflected in the requirement at § 63.24(a) that the application be as complete as possible in light of information that is reasonably available at the time of docketing. The Commission believes the regulations, as proposed, provide the necessary flexibility for making licensing decisions consistent with the amount and level of detail of information appropriate to each licensing stage. However, we agree with DOE that the proposed requirement at § 63.24(a) speaks to the content of the initial application, as well as to all subsequent updates, and, therefore, it has been included at the end of § 63.21(a).

Regarding DOE's recommendation that the requirement for a ''detailed plan'' to provide physical protection be changed to require a ''description of the plan,'' the Commission agrees that the suggested revision provides greater consistency with other provisions of § 63.21(b) and with § 72.24(o) and has revised § 63.21(b)(3) to require ''(a) description of the detailed security measures for physical protection of high-level radioactive waste in accordance with § 73.51 of this chapter.'' Notwithstanding this change, DOE must provide sufficient information at each stage of the licensing process to support that stage, and DOE must provide sufficient detail necessary to allow NRC to review DOE's design.

Regarding DOE's recommendation that the requirement that ''DOE's proposed operating procedures'' are adequate be changed to require the adequacy of ''DOE's proposed plan to develop operating procedures,'' the Commission believes a proposed plan to develop operating procedures is not sufficient to meet the requirement at § 63.31(a)(6). However, to support the construction authorization, the DOE must provide a sufficient level of information to allow NRC to review DOE's design, which would include any operating procedures that affect design.

Issue 5: Is there any control over the site after license termination?

Comment. Commenters expressed general concern regarding oversight of the site after license termination. One commenter supported the approach in proposed part 63 that leaves a single agency (DOE) responsible for control over the site after license termination.

Response. License termination represents the end of NRC involvement with the repository. However, the Commission would not terminate the license unless and until all requirements have been met by DOE. License termination removes NRC oversight of the Yucca Mountain site, leaving DOE as the single Federal authority responsible for the site. Under the proposed part 63, the license amendment for permanent closure must include a DOE program for continued oversight to prevent any activity at the site that poses an unreasonable risk of breaching the geologic repository's engineered barriers or increasing radiation exposure of individual members of the public beyond allowable limits. The final part 63 continues to retain these same requirements. This is consistent with statutory direction in section 801(b)(2) of EnPA that the Commission's requirements assume that, following repository closure, the inclusion of engineered barriers and DOE's postclosure oversight will be sufficient to prevent any activity at the site that poses an unreasonable risk of breaching the repository's engineered or geologic barriers, and prevent any increase in the exposure of individual members of the public to radiation beyond allowable limits. The NRC will review the adequacy of DOE's program for continued oversight at the time DOE submits an application to amend the license for permanent closure.

Issue 6: Are the standards for issuance of a license sufficiently clear?

Comment. EPA asked why the term ''unreasonable risk'' was used at § 63.41(c) and suggested that reference to the dose limit may be more appropriate. EPA also asked what the basis was for judging what is necessary for ''common defense and security'' at § 63.42.

Response. The standards for issuance of a license specified at § 63.41 and conditions of the license at § 63.42 provide a general description of standards and conditions that the Commission will apply to a license application for an HLW repository at Yucca Mountain. They would include, among other things, compliance with dose limits established by EPA in its final standards for Yucca Mountain. Although the terms identified by EPA (i.e., ''unreasonable risk'' and ''common defense and security'') are general terms, clarification for what is required is provided earlier in the regulation. In particular, requirements for the content of the license application (specified at § 63.21) describe and clarify the types of analyses and information that would be necessary for DOE's demonstration of compliance with these standards and conditions including, among other things, reference to dose limits and physical protection of the repository (i.e., common defense and security). Revision of § 63.21 in the proposed rule to provide additional clarification of these terms is considered unnecessary.

1.4 Reasonable Assurance

Issue 1: Should a concept other than ''reasonable assurance'' be incorporated into the implementing regulations for Yucca Mountain?

Comment. EPA commented that generic disposal standards at 40 CFR Part 191 require compliance to be demonstrated with ''reasonable expectation,'' and that proposed NRC implementing regulations for Yucca Mountain at Part 63 require demonstration with ''reasonable assurance.'' EPA believes that a connotation has developed around ''reasonable assurance'' that could lead to an extreme approach of selecting worst case values for important parameters. EPA believes that ''reasonable assurance'' is appropriate for operating facilities or in the context of the nuclear power plant licensing program where facilities operate under active institutional controls during their lifetime. It is not appropriate, in EPA's view, for the licensing of a repository where projections of performance have inherently large ranges of uncertainty. EPA prefers ''reasonable expectation'' because it believes ''reasonable assurance'' has come to be associated with a level of confidence that is not appropriate for the very long term analytical projections that will be necessary for evaluating Yucca Mountain.

Another commenter expressed the view that the majority of people in the HLW field view ''reasonable assurance'' as being more stringent than ''reasonable expectation.'' This commenter expressed the concern that it is likely that by requiring ''reasonable assurance'' the NRC will be seen as implementing EPA's standards in a manner more stringent than intended by the EPA. The commenter also indicated that if it is NRC's position that the two terms are synonymous in the context of HLW disposal, then this should be made more explicit.

Response. Confidence that DOE has, or has not, demonstrated compliance with EPA's standards is the essence of NRC's licensing process. It is the Commission's responsibility to determine whether DOE has or has not demonstrated compliance. The Commission does not believe that NRC's use of ''reasonable assurance'' as a basis

for judging compliance compels focus on extreme values (i.e., tails of distributions) for representing the performance of a Yucca Mountain repository. Further, if DOE is authorized to file a license application, and if the Commission is called on to make a decision, irrespective of the term used, the Commission will consider the full record before it. That record will include many factors in addition to whether the site and design comply with the performance objectives (both preclosure and postclosure performance standards) contained in Subparts E, K and L. The Commission could consider the QA program, personnel training program, emergency plan and operating procedures, among others, in order to determine whether it has confidence that there is no unreasonable risk to the health and safety of the public.

To avoid any misunderstanding and to achieve consistency with final EPA standards, the Commission has decided to adopt EPA's preferred criterion of ''reasonable expectation'' for purposes of judging compliance with the postclosure performance objectives. The Commission is satisfied that a standard of ''reasonable expectation'' allows it the necessary flexibility to account for the inherently greater uncertainties in making long-term projections of a repository's performance. The Commission agrees with EPA and others that it is important to not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence. By adopting what EPA has characterized as a more flexible standard of ''reasonable expectation'' for determining compliance with postclosure performance objectives, the Commission hopes to make clear its expectations. The Commission expects that the required analyses of postclosure performance will focus on the full range of defensible and reasonable parameter distributions, and that they should not be constrained only to extreme physical situations and parameter values. For other determinations regarding compliance of the repository with preclosure objectives, the Commission will retain a standard of ''reasonable assurance,'' consistent with its practice for other licensed operating facilities subject to active licensee oversight and control.

Issue 2: Does the term ''reasonable assurance'' denote a specific statistical parameter related to either the probability distribution of calculated individual doses or important variables used in that calculation?

Comment. EPA commented that a connotation has developed around ''reasonable assurance'' that could lead to an extreme approach to selecting worst case values for important parameters used to calculate individual dose (for example, precipitation rates, seepage rates, and flow in the unsaturated zone). According to the EPA, that approach, coupled with an equally extreme approach in selecting engineered barrier performance factors, would lead to assessments that represent situations with little or no probability of occurring but which become the basis for licensing decisions. The EPA concludes that the application of the ''reasonable assurance'' standard: (1) Is inconsistent with the NAS recommendation to use ''cautious, but reasonable'' assumptions when projecting the performance of the geologic repository; and (2) would result in applying margins of safety beyond the standard for individual protection set by EPA, which, in effect, alters that standard.

Another commenter noted that the proposed part 63 makes it clear that compliance is to be based on calculations of ''expected annual dose'' and that this requirement is completely consistent with the recommendation in the NAS report on ''Technical Basis for Yucca Mountain Standards,'' which recommends that the mean values of calculations be the basis for comparison with the NAS recommended standards. However, the commenter was concerned that ''reasonable assurance'' may be interpreted to be more stringent than the mean values of calculations of individual dose and recommended that it be made clear that, in the context of Yucca Mountain, ''reasonable assurance'' refers to the mean or expected value of the relevant probability distribution.

Response. As stated previously, in order to avoid further misunderstanding of its intent, the Commission will adopt EPA's preferred standard of ''reasonable expectation'' for purposes of judging compliance with the numerical postclosure performance objectives. However, the Commission wants to make clear that its proposed use of ''reasonable assurance'' as a basis for judging compliance was not intended to imply a requirement for more stringent analyses (e.g., use of extreme values for important parameters) or for comparison with a potentially more stringent statistical criteria (e.g., use of the 95th percentile of the distribution of the estimate of dose).

2 Requirements for the Preclosure Period

2.1 Preclosure Safety Analysis

Issue 1: Is the use of an Integrated Safety Assessment (ISA) appropriate for evaluation of the preclosure safety of a repository at Yucca Mountain?

Comment. One commenter questioned the use of an ISA, as derived from chemical process safety analyses, to evaluate preclosure safety because there is not yet much experience in regulating with the ISA and suggested that requirements for monitored retrievable storage (as contained in part 72) should be applicable to the GROA and should be used in place of the proposed requirements of part 63.

Response. The Commission considers necessary the analysis referred to in the proposed rule as an ''integrated safety analysis''. However, for clarity, in the final rule, the Commission has changed the name of the analysis to ''preclosure safety analysis'' (PSA).

The proposed rule identifies the need for, and general scope of, the analysis to be done to demonstrate compliance with the performance requirements for the operational phase of the repository (§§ 63.111(a) and (b) and 63.112(e)). The Commission did not intend to imply, however, that a particular approach, such as that used for chemical process safety analyses, was required. The Commission's intention was to identify ISA as a broad category of analyses to be used by DOE in its evaluation of repository operations and design in the context of meeting the preclosure performance objectives. ISA was proposed as a general term for these preclosure analyses, much as the general term ''performance assessment'' is used to denote the analyses used to evaluate postclosure performance. To avoid confusion with any particular type of analysis associated with other industrial facilities, the term ''ISA'' will be replaced by the more general term ''preclosure safety analysis (PSA).'' The Commission intends that DOE have broad flexibility in structuring its PSA for purposes of demonstrating compliance with the requirements at § 63.112.

The Commission recognizes that there are similarities between a facility regulated by Part 72 and the GROA facilities proposed for Yucca Mountain. However, there are important differences (e.g., Part 72 does not consider a mined facility) that make it impractical to merely adopt the requirements of the current part 72. The Commission has used and adopted relevant portions of existing regulations (e.g., part 50), including part 72, to the

extent practical, during the development of proposed part 63.

Issue 2: Is the probability of a design basis event (DBE) based on the event sequence or just an initiating event? Are the criteria for Category 2 DBEs too stringent?

Comment. DOE suggested that the rule should be clarified as to whether event sequences or single initiating events are to be used in determining the probabilities of DBEs. DOE also noted that the proposed rule would define Category 2 DBEs as those that have one chance in 10,000 of occurring before permanent closure of the repository or an annual probability of about 10^{-6}. DOE stated that:

> Designing to this probability is a reasonable goal in general, but that there are specific concerns with applying the definition to natural events, which have existing precedent for the magnitude and frequency of events to be included *ensp;* *ensp; A 1010^{-6} earthquake is far beyond normal design considerations.

DOE suggested the following definitions of DBEs:

Definition for Category 1 DBEs should be revised to read: ''natural events and human-induced event sequences.''

Definition for Category 2 DBEs should be revised to read: ''other human-induced event sequences that have at least one chance in 10,000 of occurring before permanent closure of the geologic repository, and (b) appropriate consideration of natural events (phenomena) that have been historically reported for the site and the geologic setting (referred to as Category 2 events).''

Response. The Commission agrees that the basis for determining the probability for design basis events and what initiating events should be considered in the safety analysis should be clarified. The Commission considers that the changes to the rule suggested by DOE are not sufficiently clear and has not adopted these changes in the final rule. However, the Commission has revised the rule for clarity as follows: (1) A new term ''initiating event'' is defined; (2) the present term ''design basis event'' is replaced with a new term ''event sequence;'' and (3) § 63.102(f) is revised to clarify the scope of the PSA and the requirements for the inclusion or exclusion of specific, naturally-occurring, and human-induced hazards in the safety analysis.

The proposed rule described the ISA (referred to as PSA in final part 63) as a systematic examination of the hazards and their potential consequences [see § 63.102(f)]. In the Supplementary Information for the proposed rule, Category 2 design basis events were discussed as follows:

> The analysis of a specific Category 2 design basis event would include an initiating event (e.g., an earthquake) and the associated combinations of repository system or component failures that can potentially lead to exposure of individuals to radiation. An example design basis event is a postulated earthquake (the initiating event) which results in (1) the failure of a crane lifting a spent fuel waste package inside a waste handling building, (2) damage to the building ventilation (filtration) system, (3) the drop and breach of the waste package, (4) damage to the spent fuel, (5) partitioning of a fraction of the radionuclide inventory to the building atmosphere, (6) release of some radioactive material through the damaged ventilation (filtration) system, and (7) exposure of an individual (either a worker or a member of the public) to the released radioactive material.

The Commission intended that the probability of the entire event sequence, including initiating event(s) and the associated combinations of repository system or component failures, be considered in dose calculations. The proposed rule has been revised by replacing the previous term ''design basis event'' with new terms ''initiating event'' and ''event sequence'' and associated definitions. These changes clarify that the appropriate probability is based on the entire event sequence, which includes the initiating event(s) and associated combinations of repository system or component failures relating to the potential release of radioactive material.

The two critical aspects of the PSA in the context of this issue are (1) the identification of the event sequences that have probabilities greater than or equal to one chance in 10,000 of occurring before permanent closure and (2) the associated dose consequences. Following the intent of risk-informed performance-based regulation, designation of specific design basis criteria in the regulation is not appropriate. The goal of the DOE design activity should be to demonstrate that the dose limits expressed in § 63.111 will be met, taking into consideration site-specific information regarding the geologic setting and human activities in the surrounding environs. For example, if a hazard (or the low probability events of the hazard spectrum) is deemed unreasonable for the Yucca Mountain site, DOE can exclude it from consideration in the PSA provided proper technical justification is presented in accordance with § 63.112(d). Thus, while the regulation specifies a lower limit on the probability of event sequences, the risk-informed NRC regulation anticipates that DOE will develop a clear technical basis for the event sequences included/excluded from the PSA. The Commission did not intend to specify cut-off probabilities for initiating events but recognizes that certain initiating events may not be appropriate for inclusion in the PSA. Therefore, the rule, at § 63.102(f), has been revised to include the following description of considerations that can be used by the DOE to limit the inclusion of initiating events in the PSA:

> Initiating events are to be considered for inclusion in the preclosure safety analysis for determining event sequences only if they are reasonable (i.e., based on the characteristics of the geologic setting and the human environment, and are consistent with precedents adopted for nuclear facilities with comparable or higher risks to workers and the public).

Issue 3: How should doses be estimated in evaluating repository operations during the time before permanent closure? Can different approaches be used for evaluating Category 1 and Category 2 DBEs (event sequences)?

Comment. Further clarification is needed on the scope of the dose calculations associated with DBEs (event sequences).

For Category 1 DBEs [event sequences], DOE recommended a realistic or best-estimate analysis for direct exposures from a single event. For airborne pathways, DOE proposed including submersion, inhalation, and ingestion. DOE also recommended that the doses from all Category 1 DBEs (event sequences) be aggregated.

For Category 2 DBEs (event sequences), DOE recommended dose calculations be based on suitably conservative values for direct exposure and airborne pathways including submersion, and inhalation, but not ingestion. DOE recommended that ingestion not be considered because the focus is on an acute dose, not a dose that occurs slowly over time as is the case for ingestion. Also, the emergency planning would mitigate, if necessary, contamination relevant to ingestion. DOE also recommended that Category 2 DBEs [event sequences] be analyzed on an event sequence by event sequence basis.

Response. The Commission has revised the proposed rule, at § 63.111(b)(1) and (2), to clarify that (1) the doses from consequence analyses for Category 1 event sequences are to be aggregated to a single estimate and (2) the dose from the consequence analysis for each Category 2 event sequence is to be estimated for that specific event sequence only. Thus, each Category 2 event sequence dose is to be evaluated

separately. The doses from Category 2 event sequences that might occur at different times during the preclosure period are not to be aggregated.

DOE raised a number of concerns with the scope of the dose calculations associated with event sequences. Generally, DOE called for details that are typically found in regulatory guidance rather than regulation. Although such guidance is expected to be included in the Yucca Mountain Review Plan (YMRP) rather than in the regulation, the NRC staff response to DOE's concerns regarding dose calculations associated with event sequences is summarized below.

Within the context of the ISA (PSA), DOE is expected to identify the relevant initiating events and event sequences and estimate potential radiologic exposures. Part 63 provides flexibility to DOE in selecting an appropriate approach for estimating doses, including selection of pertinent exposure pathways and the degree of conservatism or realism to include in the analysis. DOE will need to defend and support whatever approach it selects for identifying initiating events and analyzing event sequences. In the selection of a particular approach, DOE will need to consider the uncertainties and limitations associated with a particular method of analysis and data.

DOE suggested that a ''realistic or best-estimate'' analysis is appropriate for Category 1 event sequences, and a ''suitably conservative'' analysis is appropriate for Category 2 event sequences. Once again, the approach in the rule is to provide DOE flexibility to select the type of analysis it believes most appropriate for the license application. Whatever approach DOE uses will need to be supported, taking into account uncertainties. Therefore, analyses relying on point values (e.g., best estimate values) will need to discuss how uncertainties are taken into account.

DOE suggested that dose estimates for Category 1 DBEs (event sequences) should be aggregated into a single annual dose estimate. This approach is consistent with historical practices and is acceptable to NRC. DOE also suggested that the potential dose arising from the occurrence of each Category 2 DBE (event sequence) should be estimated separately (i.e., not be aggregated). The Commission agrees that each Category 2 event sequence is to be evaluated individually, as this approach is consistent with historical practices. Also, analyzing each event sequence separately provides a high degree of transparency in the analysis, thus allowing NRC to evaluate the postulated events, the associated event sequences, and the engineered components that affect the likelihood and magnitude of potential releases of radioactive material. The Commission has revised the rule at § 63.111(b)(1) and (2) to clarify that dose estimates for Category 1 event sequences are to be aggregated, but those of Category 2 event sequences are to be analyzed and documented individually.

DOE also suggested that, for Category 2 DBEs (event sequences), dose calculations for ingestion are not necessary. The Commission sees no compelling logic for the specific pathways for dose calculations being different for Category 1 and Category 2 event sequences. Dose should be calculated considering all pathways relevant to an event sequence. Consistent with the Commission requirements elsewhere, the DOE must consider all pathways in demonstrating compliance with § 63.111. The risk-informed regulation anticipates that DOE will present in its license application the magnitude of, and the technical basis for, the dose contribution of various pathways, including the technical bases for eliminating any pathway.

Issue 4: What precedents, if any, do NRC regulatory guides developed for other applications, such as nuclear power plants, have for use in developing DBEs (event sequences) for a potential repository at Yucca Mountain?

Comment. DOE asked for clarification about the role of precedents in other regulatory guides (e.g., consideration of earthquakes, aircraft crashes, tornadoes, and flooding) in determining what should be considered in the development of DBEs (event sequences) (especially for Category 2). DOE also commented that development of credible natural events, for Category 2 DBEs (event sequences), would require only following applicable regulatory precedents and considering severe natural phenomena that have been historically reported for the site and geologic setting.

Response. The applicability of regulatory guidance developed for facilities other than a high-level waste repository will need to be considered on a case-by-case basis for applicability to high-level waste disposal at Yucca Mountain. For the guidance to be appropriate, it should be generally applicable to nuclear facilities with comparable or higher risks to workers and the public than the potential repository at the Yucca Mountain site (see discussion under Issue 2).

Issue 5: What is the status of NRC's provisional acceptance of DOE's Topical Report on Seismic Design for Yucca Mountain with respect to event sequences in part 63?

Comment. DOE inquired about the status of NRC's provisional acceptance of DOE's Topical Report on Seismic Design for Yucca Mountain with respect to event sequences in Part 63.

Response. DOE's Topical Reports 1 and 2 on Seismic Design for Yucca Mountain were provisionally accepted prior to NRC's issuance of proposed requirements at part 63. The applicability of DOE's seismic design methodology will be reviewed after final part 63 requirements are in place and DOE has completed Topical Report 3.

Issue 6: Should there be an explicit requirement for an analysis of the effects of any plans for use of the air space above the GROA?

Comment. One commenter recommended an analysis of the effects of any plans for use of the air space above the GROA.

Response. Any plans for use of the air space above the GROA that would affect compliance with the performance objectives should be included in the PSA. The Commission finds no reason for a separate requirement for such an analysis.

Issue 7: Will NRC have its own experts to evaluate what can happen during repository operations or will NRC rely on the DOE analysis?

Comment. One commenter inquired whether NRC had independent experts to develop probabilities for DBEs, or would NRC simply rely on DOE analyses.

Response. The Commission will perform an audit review of the DOE license application including a review of the technical basis for initiating events and event sequences. In performing the audit review, the NRC will use a variety of its technical staff with appropriate technical experience and skills, and experience with comparable activities for other facilities (handling of nuclear fuel at nuclear reactors and fuel fabrication facilities) regulated by NRC. Additionally, the NRC's HLW contractor (The Center for Nuclear Waste Regulatory Analyses, CNWRA) has a wide range of technical expertise to assist NRC staff in any review conducted.

Issue 8: Is the terminology in the rule consistent and adequate to convey what is required?

Comment. DOE identified instances where particular words or phrases in Part 63 lacked clarity and suggested the following changes:

Section 63.112(b) should be revised to read: ''An identification and systematic analysis of naturally-occurring and

human-induced hazards at the geologic repository operations area, including a comprehensive identification of potential design basis events'' (The definition of DBEs makes no link to consequence, whereas § 63.112(b) inappropriately implies such a link).

The word ''accidents'' in § 63.112(e) should be replaced with ''design basis events'' (the word ''accidents'' is not defined (also in § 63.161)—use of DBE is consistent with language elsewhere in part 63).

Response. The Commission agrees that the use of the word ''accident'' in § 63.112(e) is vague and will replace ''accident'' by ''event sequence.'' Additionally, the Commission has revised the language at § 63.112(b) to remove the inappropriate reference to consequences.

Issue 9: Should the proposed rule prescribe requirements for the ISA (PSA)?

Comment. DOE noted that prescribing requirements for the ISA (PSA) at § 63.112 was inconsistent with the overall performance-based approach in the rule.

Response. The rule identifies topics that need to be included in the PSA but does not prescribe either the methodology to use or the depth to which these topics need to be addressed. part 63 appropriately identifies the topics that need to be included in the PSA to ensure DOE's analysis is complete and yet gives DOE flexibility to determine the level of detail needed to address each topic properly. This performance-based approach provides DOE latitude to adjust the technical rigor of its evaluation of any particular topic in a manner that is consistent with the topic's importance to safety.

2.2 Retrievability

Issue 1: Will NRC require DOE to demonstrate that the waste package is retrievable?

Comment. Some commenters were concerned that NRC's proposed regulations required DOE to submit plans for retrievability, but did not require an actual demonstration that the plans were feasible. Some commenters suggested that the NRC should require DOE to demonstrate the feasibility of its retrieval plans.

Response. If necessary to protect public health and safety, waste package retrieval in a deep geologic repository would be a first-of-a-kind endeavor with unique engineering and geotechnical challenges. The Commission recognizes that the retrieval operation would be an unusual event, and may be an involved and expensive operation (U.S. Nuclear Regulatory Commission, ''Staff Analysis of Public Comments on Proposed Rule 10 CFR part 60, 'Disposal of High-Level Radioactive Wastes in Geologic Repositories','' Office of Nuclear Regulatory Research, NUREG–0804, December 1983; p. 11). As such, DOE can expect that its plans and procedures in this area will receive extensive, detailed review by the NRC staff as part of any construction authorization review. The feasibility and reasonableness of DOE's retrieval plans will be reviewed by the NRC staff at the time of the license application submittal.

However, the Commission does not envision that DOE will need to build full-scale prototypes of its retrieval systems to demonstrate that its retrieval plans are practicable at the time of construction authorization. Rather, DOE needs to design (and build) the repository in such a way that the retrieval option is not rendered impractical or impossible.

Issue 2: Why did NRC set an upper limit for retrieval at 50 years after waste emplacement operations are initiated?

Comment. Some commenters expressed a belief that the period of waste package retrieval could be accomplished beyond 50 years, and there should be flexibility for extending the period of retrievability to longer time periods. One commenter suggested that the repository should be monitored to determine if there will be problems (e.g., too high a temperature, too much water inflow) that would require the waste to be retrieved. The same commenter suggested that stewardship of the waste be maintained (indefinitely) so that waste could be made available for future energy needs.

Response. The 50-year limit on waste retrieval operations was adopted from the generic requirements found at part 60. At the time part 60 was first promulgated, the Commission solicited comment on what was then a proposed 110-year retrieval period (46 FR 35282; July 8, 1981). However, after an analysis of public comments, it was determined that the Commission's earlier proposal was excessive, and the shorter 50-year period was decided upon (U.S. Nuclear Regulatory Commission, ''Staff Analysis of Public Comments on Proposed Rule 10 CFR part 60, 'Disposal of High-Level Radioactive Wastes in Geologic Repositories','' Office of Nuclear Regulatory Research, NUREG–0804, December 1983). In specifying this time period, the Commission noted that the 50-year period was ''provisional'' and subject to possible modification (i.e., longer periods) in light of both the planned waste emplacement schedule and completion of the performance confirmation program and a review of those results. After 50 years of waste emplacement operations and performance confirmation, the Commission previously reasoned, it is likely that significant technical uncertainties will be resolved, thereby providing greater assurance that the performance objectives will be met. It should be noted that DOE is free to design the repository for retrieval periods greater than 50 years. In fact, the Commission understands that DOE is contemplating working designs that may provide for a retrieval period of up to 300 years (see ''Supplement to the Draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada,'' Office of Civilian Radioactive Waste Management, DOE/EIS–0250DS, May 2001). Thus, as recommended in this comment, allowance for longer waste retrieval periods greater than 50 years is permitted under the regulation.

As for longer retrieval periods that would permit the recovery of the HLW as a potential resource, the Commission has previously noted that its retrieval provision is not intended to facilitate recovery. Waste retrieval is intended to be an unusual event only to be undertaken to protect public health and safety.

Issue 3: If retrieval is necessary, what happens to the retrieved waste?

Comment. One commenter inquired as to the disposition of the waste if it is determined that retrieval is necessary.

Response. Proposed Part 63 does not specifically address any required actions for the handling of retrieved waste from an operating geologic repository, but § 63.21(c)(19) [moved to § 63.21(c)(7) in the final rule] does require that DOE's Safety Analysis Report include a description of its plans for the alternate storage of the radioactive wastes, should retrieval be necessary. Retrieved waste would need to be controlled in compliance with applicable regulations at the time of retrieval.

2.3 Performance Confirmation

Issue 1: What is the objective of the performance confirmation program?

Comment. DOE commented that the general requirements for performance confirmation at § 63.131(a) and requirements for confirmation of geotechnical and design parameters at § 63.132(a) do not reflect the Commission's risk-informed, performance-based approach to regulation because the requirements do

not explicitly focus the performance confirmation program on data linked to the performance assessment. DOE stated that the performance confirmation program, when tied to a performance-based approach, should focus on the verification of the performance assessment. DOE stated that this approach would allow DOE and NRC to focus attention and resources on those parameters and processes that are significant contributors to repository performance and to uncertainties in that performance.

Response. The objective of the performance confirmation program is to confirm the assumptions, data, and analyses that led to the findings that permitted construction of the repository and subsequent emplacement of the wastes. Consistent with NRC's performance-based approach, the NRC will make findings with respect to each of the performance objectives in Part 63, Subpart E, and not just the postclosure performance objective specified at § 63.113(b). The general requirements for the performance confirmation program at § 63.131(a)(1) and (a)(2) state that the program must provide data that indicate whether: (1) Subsurface conditions encountered and changes in those conditions during construction and waste emplacement are within limits assumed in the licensing review and (2) natural and engineered systems and components required for repository operation, and that are designed or assumed to operate as barriers after permanent closure, are functioning as intended and anticipated. These requirements are intended to encompass subsurface conditions and design assumptions related to both operational (preclosure) and postclosure repository performance. Should the Commission authorize construction of a geologic repository at Yucca Mountain, the NRC staff will conduct an ongoing, performance-based inspection program to evaluate DOE's compliance with the performance objectives and any conditions established in that construction authorization per § 63.75.

The general requirements at § 63.131(a) explicitly link the performance confirmation program to DOE's performance assessment, albeit in terms of the barriers designed or assumed to function after permanent closure. Although the primary focus of the performance confirmation program is on postclosure performance of the repository, and the NRC recognizes DOE's desire to focus on verifying the performance assessment (e.g., postclosure performance), it is important that the general requirements also include consideration of operational aspects of repository performance, for example, the ability to retrieve waste as required at § 63.111(e). An organized program of collecting subsurface information during repository construction and operation that confirms the design assumptions regarding the ability to retrieve waste is therefore an important performance confirmation activity. The NRC believes that the general requirements at § 63.131(a) allow DOE the flexibility to develop and implement an effective performance confirmation program focused on confirming assumed subsurface conditions and assumed functionality of geologic and engineered systems and components important to postclosure performance (i.e., performance of barriers important to isolation) and/or preclosure repository operations (e.g., retrievability). In the proposed rule, the definition of performance confirmation in § 63.2 and the discussion of performance confirmation in § 63.102(m) do not clearly reflect the intent of § 63.131(a) and have been revised accordingly in the final rule. To adopt the changes to §§ 63.131(a) and 63.132(a) requested by DOE would remove consideration of operational aspects of repository performance from the performance confirmation program. For these reasons, the Commission does not agree that these changes are appropriate and has not adopted them.

Issue 2: Are the requirements for the performance confirmation program too prescriptive?

Comment. Some commenters were concerned with the level of detail provided in the requirements for the performance confirmation program. NEI commented that the regulation should provide for ongoing programs of monitoring and testing to improve information but also stated that the specified requirements should be made less prescriptive. NEI stated that §§ 63.132–134 (respectively, Confirmation of geotechnical and design parameters, Design testing, and Monitoring and testing waste packages) were inconsistent with the overall performance-based nature of the regulation. NEI recommended that these requirements be deleted because they are unnecessary and counterproductive to § 63.131 in that they provide more detail and remove flexibility already in the rule. NEI also recommended minor word changes to the definition of performance confirmation in § 63.2 and the discussion of performance confirmation in § 63.102(m) to lessen the potential for overly prescriptive interpretations of what is expected of the performance confirmation program. DOE commented that the minimum list of geotechnical parameters in § 63.132(c) is overly prescriptive and is not needed or appropriate. DOE recommended revising the requirement to state that DOE will determine the parameters, measurements, and observations appropriate for inclusion in the program. DOE also recommended revising § 63.133, which restricted design testing to in situ testing, to allow performance of some of the design testing at other locations, such as laboratories, other test facilities, or boreholes outside of the repository block. In addition, DOE also suggested revising the wording of § 63.133(c) to make it clear that testing of backfill is required only if backfilling the emplacement drifts is planned. Another commenter noted that while § 63.134 requires a program to monitor and test waste packages, the commenter found no statement of objectives or criteria for the monitoring and test program. The commenter was concerned that the regulation could be used to drive a very large and costly full scale test program and recommended that the objectives and criteria be stated.

Response. The Commission agrees with the commenters that §§ 63.132–134 were too prescriptive and has modified these sections accordingly. However, the Commission does not agree with the comment that §§ 63.132–134 are inconsistent with the overall performance-based nature of the rule and therefore should be deleted. The Commission believes the requirements for performance confirmation set forth in §§ 63.132–134 are consistent with the overall performance-based approach to part 63. Consistent with this approach, the rule does not prescribe specific subsystem requirements. The absence of subsystem requirements is a concern to a number of commenters. Some commenters believe that the rule places too much reliance on the total system performance assessment (refer to discussion of issues under Postclosure Safety Assessment and Multiple Barriers and Defense in Depth). The Commission believes these concerns are partly addressed through an effective performance confirmation program focused on confirming assumed subsurface conditions and assumed functionality of geologic and engineered systems and components important to postclosure performance and the related performance assessment. Specific concerns that these requirements are either too prescriptive or too limiting are discussed in the following paragraphs.

Section 63.132 (Confirmation of geotechnical and design parameters)

provides additional requirements related to the underground facility including comparing the original design bases and assumptions to information obtained during construction and operation, determining their significance to performance, and reporting this information, including recommended design changes, to the Commission. Section 63.132(c) does prescribe specific measurements and observations to be made by DOE. Because the design of the repository is evolving, it is not clear that, in the future, this list will be an acceptable minimum list of measurements and observations to be made. For the same reason, it is not clear that, in the future, all items in the list will be technically justifiable within the context of operational and postclosure performance of the repository. The Commission believes that it is DOE's responsibility to specify the important geotechnical and design parameters to be evaluated through observation and measurement during construction and operation, subject to NRC approval through review and evaluation of the license application. DOE will provide this information in their performance confirmation plan included in the license application. If necessary, the NRC staff will provide guidance to DOE in this area through pre-licensing interactions and/or the YMRP. Section 63.132(c) has been revised to reflect these considerations.

Section 63.133 (Design testing) provides requirements for in situ testing of seals and backfill and the thermal interaction effects of waste packages, backfill, rock, and ground water. DOE's recommendation that § 63.133 be revised so as to not limit testing to in situ testing only is reasonable. Section 63.133(a) has been revised accordingly. The NRC has also revised § 63.133(a) to generally reference ''engineered systems and components,'' with examples, so as to not limit tests to specific features that may or may not be included in the final design of the repository. Finally, the Commission has revised § 63.133(c) to require specific testing of the effectiveness of backfill placement and compaction only if backfill is included in the repository design.

Section 63.134 (Monitoring and testing waste packages) provides specific requirements for monitoring and testing waste packages consistent with the objectives of the performance confirmation program established at § 63.131(a). Waste packages are important engineered components designed to operate as barriers after permanent closure. Because the assumed long-term performance of waste package materials is based on short-term experimental data, monitoring waste package performance and related laboratory experiments are appropriate performance confirmation activities. Although the NRC recognizes the need for reasonable cost constraints, it is important to note that it is DOE's responsibility to develop the details of a performance confirmation plan that focuses on those natural and engineered systems and components important to repository performance and operation. The requirements allow DOE the flexibility to develop a focused and effective performance confirmation program. An alternative approach would be to prescribe in detail the specifics and limits of that program. The Commission does not want to limit DOE's options regarding testing methodologies and has chosen not to follow that approach. Note, however, that NRC will evaluate the adequacy of the performance confirmation program in the course of its review of the license application.

Issue 3: Is the performance confirmation data required to be used in the updating of the performance assessment?

Comment. EPA recommended that performance confirmation data should be explicitly identified as information to be included in the update of the performance assessment required at the time of the amendment for permanent closure [§ 63.51(a)(1)].

Response. The Commission agrees with the commenter and has modified the rule accordingly.

2.4 Preclosure Operations Activities

Issue: Should the proposed rule specify environmental monitoring requirements for regulating releases from the preclosure operational activities?

Comment. The EPA commented that requirements for environmental monitoring during the operational phase of the repository were not in the proposed rule and there were no methods stated in the rule for enforcement of the preclosure requirements.

Response. The Commission considers that proposed part 63 has sufficient requirements for environmental monitoring during the operational phase of the repository and is not revising the rule on this issue. The Commission has included environmental monitoring requirements for radioactive releases in part 63. Sections 63.111 and 63.112 require DOE to account for, design against, and monitor any potential event sequences that could lead to radioactive releases. As part of the PSA (§ 63.112), for example, DOE is to describe its design and operating procedures for monitoring and controlling radioactive releases. Consistent with its National Environmental Policy Act (NEPA) responsibilities, DOE has already described its plans and procedures for the monitoring (and mitigation) of environmental impacts due to the operation of the geologic repository, including radioactive releases, in its DEIS for Yucca Mountain.

Regarding the comment on the lack of enforcement methods in the rule, subpart J of part 63 addresses enforcement at a level of detail that the Commission has typically used in all its regulations. Specific policy and procedure issues for enforcement activities are described in NRC's ''General Statement of Policy and Procedure for NRC Enforcement Actions,'' the NRC enforcement manual, and supplemental guidance. The Commission believes this is an appropriate approach for its regulations and will retain the current language as in the proposed rule under subpart J. The Commission plans to develop specific changes to the enforcement policy and procedures as part of development of inspection and oversight plans for implementation of part 63.

2.5 Emergency Planning Criteria

Issue 1: If local emergency first-responder capabilities and emergency medical services are not sufficient for reacting to nuclear accidents at the geologic repository, will the NRC require DOE to enhance existing local capabilities in the Yucca Mountain region?

Comment. Commenters expressed concern that current local emergency and medical services are not adequate to respond to potential nuclear accidents at a geologic repository at Yucca Mountain. Accordingly, it was suggested that NRC include, as a license condition to operate the repository, a requirement that DOE enhance local capabilities for responding to potential nuclear accidents.

Response. Part 63 (Subpart I) requires DOE to submit an emergency plan for coping with radiological accidents. NRC's review of DOE's emergency plan will evaluate the adequacy of the plan including such things as the capability to respond to accidents and medical assistance for treatment of radiological injuries. Where DOE's emergency plan is found to be inadequate, the NRC, if necessary, can impose license conditions that require DOE to correct any deficiencies. (See also response to Issue 3 below.)

Additionally, U.S. Federal Emergency Management Agency (FEMA) regulations, as well as DOE orders, require that DOE have an emergency response capability that is adequate to meet anticipated accidents, including potential radiological accidents. DOE is responsible for ensuring that the emergency treatment capability exists and is documented in its emergency plan, which is subject to NRC review in accordance with § 63.161.

Issue 2: Will DOE's emergency plans be sufficiently comprehensive to include such scenarios as emergency evacuation procedures and responses to terrorist activity?

Comment. Some commenters were concerned whether DOE would have adequate, effective, and sufficiently comprehensive plans and procedures to address most, if not all, potential accidents, incidents, and/or contingencies.

Response. The rule requires DOE to have plans to cope with radiological accidents (emergency planning at § 63.161) and provide for physical protection (§ 63.21(b)(3)). These plans are required to address a number of criteria to ensure that DOE is prepared to respond, both on site and off site, to accidents, and that DOE has the capability to detect and respond to unauthorized access and activities that could threaten the physical protection of HLW. As noted in the previous response, NRC and FEMA regulations, as well as DOE orders, require that DOE have adequate plans and procedures in place to address any potential accidents and incidents. DOE's emergency plan and physical protection plan are subject to NRC review. The Commission believes that the requirements for DOE's plans for emergencies and physical protection expressed in the proposed part 63 are appropriate and has retained them in the final rule. In light of the terrorist attacks of September 11, 2001, the Commission has directed the staff to conduct a comprehensive reevaluation of NRC physical security requirements. If this effort indicates that NRC's regulations or requirements warrant revision, such changes would occur through a public rulemaking or other appropriate methods.

Section 63.161 requires DOE to develop an emergency plan based on the criteria of § 72.32 (i.e., criteria provided for an Emergency Plan for an Independent Spent Fuel Storage Installation (ISFSI)). The required Emergency Plan includes: Identification of each type of accident, description of the means of mitigating the consequences of each type of accident; prompt notification of offsite response organizations; and adequate methods, systems, and equipment for assessing and monitoring actual or potential consequences of a radiological emergency condition. If particular types of accidents require evacuation procedures to ensure the protection of public health and safety, they will be included in the Emergency Plan.

Section 63.21(b)(3) requires DOE to submit a detailed plan to provide physical protection of HLW in accordance with § 73.51 (requirements for physical protection of stored spent nuclear fuel and HLW). The requirements for physical protection include: (1) Capabilities to detect and assess unauthorized access or activities and protect against loss of control of the facility; (2) limiting access to HLW by means of two physical barriers; (3) providing continual surveillance of the protected area in addition to protection by an active intrusion alarm; and (4) providing a primary alarm station located within the protected area and have bullet-resisting walls, doors, ceiling, and floor. These requirements provide high assurance that physical protection of the repository includes appropriate measures to prevent and respond to unauthorized access and activities, including the potential for armed intruders (e.g., terrorist activity).

Issue 3: Will Federal funding be available to upgrade emergency first-responders and emergency medical services so as to allow local communities to be better prepared to respond to potential transportation accidents?

Comment. Counties in the Yucca Mountain region expressed concern with their ability to respond to medical emergencies resulting from a transportation accident involving nuclear waste. Local communities suggested that DOE be required to enhance local emergency capabilities for responding to transportation accidents.

Response. Section 180(c) of the NWPA requires DOE to provide technical assistance and funding for training State and local governments and Tribes for safe routine transportation and emergency response. However, NRC's responsibility for oversight and review of DOE's emergency plans (see discussion under Issues 1 and 2) does not include responsibility for how DOE provides for technical assistance and funding. Additionally, under NEPA, the potential for (environmental) impacts due to transportation, including accidents, is the responsibility of DOE to assess and mitigate.

3 Requirements for the Postclosure Period

3.1 Postclosure Safety Assessment

Issue 1: Can performance assessments be relied on as the sole quantitative technique for evaluating compliance with postclosure safety requirements?

Comment. DOE and NEI supported the risk-informed, performance-based approach. Additionally, NEI supported requirements in proposed Part 63 intended to ensure that DOE conducts and documents a high-quality performance assessment (e.g., features, events, and processes (FEPs) be described; relevant conceptual models be considered) and NEI also expressed a need for the NRC to effectively and clearly articulate this approach in future regulatory efforts. However, other commenters indicated that, although performance assessment is a highly informative methodology, its capability to model complex, coupled geologic systems over extended time periods has yet to be demonstrated. Confidence in performance assessments could be improved through testing on actual geologic systems and conducting suitable, long-term studies.

Response. Although repository postclosure performance is evaluated with respect to a single performance measure for individual protection, the NRC considers a broad range of information in arriving at a licensing decision. In the case of the proposed repository at Yucca Mountain, Part 63 contains a number of requirements (e.g., qualitative requirements for data and other information, the consideration and treatment of uncertainties, the demonstration of multiple barriers, performance confirmation program, and QA program) designed to increase confidence that the postclosure performance objective is satisfied. The Commission will rely on the performance assessment as well as DOE's compliance with these other requirements in making a decision, if DOE submits a license application for disposal of HLW at Yucca Mountain. The Commission believes the approach for performance assessment in the proposed rule is appropriate and it is retained in the final rule. However, requirements for QA, multiple barriers, and performance confirmation have been revised to clarify the Commission's intent for these requirements (see discussion under Quality Assurance, Multiple Barriers and Defense in Depth, and Performance Confirmation for more details).

The Commission believes that there have been significant advances in, and experience with, risk assessment in the

past 20 years (see Commission's white paper on Risk-Informed and Performance-Based Regulation, March 1999). The Commission continues to believe that a performance assessment, developed with sufficient credibility, is the best means to provide useful information to the Commission for making an informed, reasonable licensing decision. The Commission recognizes, however, the uncertainties inherent in evaluating a first-of-a-kind facility like the repository and in estimating system performance over very long time periods (i.e., 10,000 years). Thus, proposed part 63 contained requirements to ensure that: (1) Uncertainties inherent in any performance assessment are thoroughly articulated and analyzed or addressed; (2) DOE's performance assessment is tested (corroborated) to the extent practicable; and (3) there are additional bases, beyond the performance assessment, that provide confidence that the postclosure performance objectives will be met. For example:

1. Requirements for Addressing Uncertainty in Performance Assessment

Section 63.114 provides a number of requirements for DOE's performance assessment to thoroughly address uncertainty. Part 63 requires consideration of uncertainties in DOE's representation of the repository (uncertainty and variability in parameter values must be taken into account—§ 63.114(b)) and the events that can happen during the compliance period (consideration of potentially disruptive events with a probability of occurrence as low as one chance in 10,000 of occurring over 10,000 years—§ 63.114(d)) to be directly included in the quantitative estimate of performance. Additionally, DOE is required to provide additional assurances that uncertainty in the information (e.g., evaluation of site characterization data) used to develop the performance assessment have been evaluated by consideration of alternative conceptual models of features and processes that are consistent with available data and current scientific understanding (§ 63.114(c)); and the basis for inclusion or exclusion of FEPs that would have a significant effect on performance (§ 63.114(e) and (f)). (See discussion under Issue 2 for further details on uncertainty in performance assessment.)

2. DOE's Performance Assessment Is Tested (Corroborated) to the Extent Practicable

DOE must test or corroborate, to the extent practicable, the confidence in (validity of) the performance assessment models. Part 63 requires DOE to provide the technical basis for the models used in the performance assessment (§ 63.114(g)). Approaches for providing the technical basis would include comparisons of these models with information relevant to the conditions of geologic disposal and time periods of the assessment (e.g., results from detailed process-level models, field investigations, and natural analogs). Additionally, a performance confirmation program is required (part 63, subpart F) to confirm that the behavior of the barriers of the repository system is consistent with what has been assumed in the performance assessment (see discussion under Performance Confirmation for more details).

3. Basis for Confidence That the Postclosure Performance Objectives Will Be Met

As a basis for confidence that the postclosure performance objectives will be met, the Commission plans to rely on requirements in addition to that for the performance assessment. Specifically, part 63 requires a multiple barrier approach for the repository, and a QA program. A requirement that multiple barriers make up the repository system ensures that repository performance is not wholly dependent on a single barrier. As a result, the system is more tolerant of failures and external challenges such as disruptive events (see discussion under Multiple Barriers and Defense in Depth for more details). The required QA program enhances confidence in the design and characterization of barriers important to waste isolation.

In summary, any determination that the postclosure performance objectives will be met will be based on a comprehensive set of regulatory requirements. Thus, reliance on the performance assessment for assisting regulatory decisions is supported by a range of considerations. The Commission believes this comprehensive approach (i.e., requirements for addressing uncertainty, providing technical basis for models, and additional requirements, beyond expected performance, for increasing confidence that the performance objectives will be met) is appropriate and it is retained in the final rule.

Issue 2: Should a requirement for the level of uncertainty and performance that is acceptable for performance assessment of the proposed repository be included in part 63?

Comment. A number of comments were received concerning uncertainty in estimating postclosure performance of the repository. Commenters were concerned with the level or degree of uncertainty in performance calculations and approaches for analyzing uncertainty in performance calculations. Some specific concerns were: (1) The acceptable level of uncertainty should be clearly stated in part 63 (results that depend mainly on assumptions rather than actual properties are unacceptable); (2) the many orders of magnitude of uncertainty in performance projections are, and will continue to be, too high for assuring long-term safety; and (3) whether DOE is required to predict ''actual'' performance.

Response. The first-of-a-kind nature of the repository and the evaluation over a very long time period result in significant uncertainty being included in the performance assessment. Part 63 not only requires DOE to account for uncertainty in its performance assessment but also contains a number of other requirements (e.g., use of multiple barriers, performance confirmation program) to compensate for residual uncertainties in estimating performance. The Commission will consider all these requirements in determining whether it has sufficient confidence (i.e., reasonable expectation) that DOE has demonstrated or has not demonstrated the safety of the repository. Specification of an acceptable level of uncertainty is neither practical nor appropriate due to the limited knowledge currently available to support any such specification and the range of uncertainties that would need to be addressed. The Commission believes the approach to performance assessment in the proposed rule, which includes the treatment of uncertainty, is appropriate and has retained this approach in the final rule.

The previous response under Issue 1, discussed the requirements for the performance assessment. Many of these requirements address uncertainty in the performance assessment. Some of these uncertainties will be directly included in the DOE's estimate of performance. For example, DOE is expected to conduct uncertainty analyses (i.e., evaluation of how uncertainty in parameter values affects uncertainty in the estimate of dose), including the consideration of disruptive events and associated probability of occurrence. Other uncertainties are not necessarily quantified but are considered during the development of the conceptual models for the performance assessment (e.g., consideration of alternative models, inclusion and exclusion of FEPs). If NRC were to specify an acceptable level of uncertainty, the specified value would be somewhat arbitrary because:

(1) Understanding of the site is evolving as site studies continue; (2) repository design options are still being evaluated; and (3) differences in the types of uncertainties (e.g., variability in measured parameters, modeling assumptions, expert judgment, etc.) complicate the specification. The approach defined in part 63, which requires DOE to fully address uncertainties in its performance assessment rather than requiring DOE to meet a specific level of uncertainty, is appropriate. The treatment of uncertainty in DOE's performance assessment will be an important part of NRC's review.

Regardless of the uncertainty in the performance assessment, part 63 contains additional provisions to increase confidence that the postclosure performance objectives will be met. These provisions include requirements for multiple barriers, a performance confirmation program, and implementation of a QA program (see discussion under Issue 1). However, it should be kept in mind that the performance assessment evaluates ''potential'' doses, not ''actual'' doses. For example, part 63 requires the performance assessment to assume for the next 10,000 years that the reasonably maximally exposed individual (RMEI) is a member of a community that: (1) Exists where it will intercept potential releases from the repository and (2) uses ground water but never tests the quality of this water nor treats the ground water to remove any contaminants. This specification is considered appropriately conservative for evaluating performance but most likely is not an ''accurate'' prediction of what will happen during the next 10,000 years (see discussion under RMEI Characteristics and Reference Biosphere for more information on the RMEI). Although the Commission does not require an ''accurate'' prediction of the future, uncertainty in performance estimates cannot be so large that the Commission cannot find a reasonable expectation that the postclosure performance objectives will be met (see discussion under Reasonable Expectation). At this time, the Commission is not aware of any information that suggests the uncertainties are so large that NRC will be unable to make a regulatory decision regarding the safety of a potential repository at Yucca Mountain.

Issue 3: Do known conditions at the Yucca Mountain site and/or the potential for other adverse conditions make Yucca Mountain an unacceptable location for an HLW repository?

Comment. Commenters expressed opinions/concerns regarding the impact of certain FEPs (e.g.; Yucca Mountain lies in an area that is seismically and tectonically active; volcanic activity in the recent geologic past; potential for fast ground-water pathways to the water table; the effect of heat and radiation on the surrounding rock; microbial-induced corrosion of the waste package; and the potential for a significant rise of the water table as the water table may rise and interact with the proposed repository) that could have a deleterious effect on repository performance. Given these concerns, many of the commenters recommended the Yucca Mountain site be withdrawn from further consideration as a potential repository.

Response. Consideration of all FEPs, especially those with the potential to have an adverse effect on performance, is an important part of the evaluation of repository performance. Commenters have correctly identified a number of conditions that have been or are being considered by DOE in performance assessments for Yucca Mountain, such as seismic activity, thermal effects, volcanic activity, microbial-induced corrosion of the waste package, and the potential for a significant rise of the water table. Section 63.114 requires DOE to consider all FEPs pertinent to a repository at Yucca Mountain and fully justify how they are treated in the performance assessment. In reviewing DOE's performance assessment, the NRC will evaluate how well DOE has accounted for those FEPs that could have an adverse effect on the repository. Based on current information, the Commission is not aware of any specific feature, event, or process that so adversely affects repository performance that Yucca Mountain must be withdrawn from further consideration by DOE as a potential repository site.

Issue 4: How will NRC ensure DOE properly documents its performance assessment?

Comment. One commenter discussed the need for DOE to provide a traceable and transparent analysis in support of its demonstration of compliance with the performance standard. The commenter recommended that plain English should be used to document the performance assessment to improve overall understanding of the risks.

Response. The Commission agrees that DOE's performance assessment needs to be clearly documented. Part 63 provides the requirements for DOE's performance assessment at § 63.114 and requirements for the content of the application at § 63.21. These requirements provide a general description of the types of information that need to be included in the license application but do not prescribe specific details for the format of the documentation. The Commission believes it is inappropriate and unnecessary to prescribe, in the regulations, further details for DOE's documentation. The performance assessment is DOE's analysis, and DOE needs flexibility in deciding how best to document its analysis. However, the NRC staff is developing a YMRP to provide guidance to DOE on approaches for documenting performance assessment results that are both transparent and traceable. The Commission agrees with improving overall understanding of performance assessment through better documentation and will interact with the public and DOE to improve the YMRP in this important area.

Issue 5: Why does NRC require DOE to evaluate alternative designs?

Comment. DOE questioned the regulatory basis of § 63.21(c)(7) that requires DOE to evaluate alternative designs. DOE believes evaluation of alternative designs goes beyond typical licensing practice by implying a need for DOE to justify selection of one design over another. DOE suggested they should be allowed to select the design that best suits their purposes consistent with the approach given other NRC-regulated activities at § 50.109(a)(7). Another commenter suggested that the consideration of alternative designs be limited to present-day technology.

Response. The Commission agrees with the comments and has removed this requirement from the regulations. The NRC review should focus on the safety aspects of DOE's proposed approach. DOE should only be required to propose alternatives from its proposed approach in areas where the NRC review determines DOE's approach is deficient.

When developing proposed part 63, the NRC staff adopted this requirement from 10 CFR part 60, the existing generic NRC HLW disposal regulation, which contains a similar requirement in 10 CFR 60.21 (c)(1)(ii)(D). At the time of the issuance of part 60, DOE objected to this specific requirement with basically the same argument presented for part 63. In the Statement of Considerations for part 60 (published in **Federal Register** on June 21, 1983; 48 FR 28194), the Commission justified the requirement by stating ''If the Commission finds, on the basis of its review, that the adoption of some alternative design feature would significantly increase its confidence that the performance objectives would be

satisfied, and that the costs of such an approach are commensurate with the benefits, it should not hesitate to insist that the alternative be adopted.''

The decision to require DOE to submit alternatives for certain site design features was a discretionary action on the part of the Commission as nothing (in either the Atomic Energy Act of 1954, as amended, or the Nuclear Waste Policy Act of 1982, as amended) required the Commission to obtain information on alternative designs at the site level. At the time part 60 was initially published (1983), the Commission implemented an appropriate regulatory framework for a generic program facing many uncertainties. Multiple sites with very different geological settings were under consideration. The NRC's generic HLW regulations had to address the resolution of a large number of technical issues in the relative short licensing review period established by the Nuclear Waste Policy Act of 1982. With all the uncertainties in the program, the Commission believed it was important to require design alternatives be submitted with the application to increase the probability of NRC approval of the license application within the three-year schedule mandated by Congress.

The Commission has revisited the decision to require submission of alternative designs. Specifically, the Commission no longer believes this information should be submitted with a license application and, accordingly, has removed this requirement. To protect public health and safety and the common defense and security, which is the NRC's mandate under the Atomic Energy Act of 1954 as amended, the Commission will closely scrutinize the design proposed by DOE. Consistent with this mandate, the new part 63 is designed to be a risk-informed, performance-based regulation which establishes overall repository performance objectives. DOE must demonstrate that the repository meets the performance objectives. The NRC review is an audit of the DOE demonstration to determine if we agree that the performance objectives have been met. If the NRC believes that the site does not meet the performance objectives within uncertainties addressed in the analysis, then it is DOE's responsibility to either defend its current design or propose an alternative design that can meet the NRC acceptance criteria.

3.2 Individual Dose Limit

Issue 1: How is the protection of future generations considered as part of setting the dose limit?

Comment. A number of commenters expressed concern that the dose limit specified in the proposed rule provided inadequate protection for future generations. Commenters suggested that (1) selection of the dose limit should consider the unpredictability of the future, particularly where and how an individual would be exposed, and (2) the dose limit should reflect impacts from either future energy development or past releases on the local community, such as ground-water releases from the NTS or the Beatty Low-Level Waste facility, in developing the standard.

Response. The purpose of the postclosure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission has incorporated, an individual dose limit of 0.15 mSv/year (15 mrem/year). The Commission is confident that this limit is fully protective and that it provides an added margin of safety beyond what is necessary to ensure public health and safety. The Commission has long held that an individual dose limit of 0.25 mSv/year (25 mrem/year) TEDE is (1) a reasonable and appropriate level of protection for future generations, (2) within the range of dose limits used for current sources of public exposure, and (3) accounts for the possibility of dose from other sources.

In judging the adequacy of a dose limit for waste management and other related activities, NRC considers recommendations from the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), EPA, and International Atomic Energy Agency (IAEA). The ICRP's and NCRP's recommendations are developed by recognized experts in the fields of radiation protection and health effects. The NCRP is a nonprofit corporation chartered by the U.S. Congress to develop and disseminate information and recommendations about radiation protection and to cooperate with the ICRP and other national and international organizations with regard to these recommendations. The ICRP is an international panel of radiation experts from all fields that provides estimates of radiation risk and recommendations on radiation protection and has continued to update and revise its risk estimates and radiation protection recommendations since its inception in 1928. In its deliberations, ICRP maintains relationships with United Nations health and labor organizations.

The IAEA is a United Nations agency involved in assisting member states to establish consistent radiation protection standards. In 1995, the IAEA identified a number of principles with the express purpose of giving a common basis for the development of more detailed standards and a basis for national waste management programs (The Principles of Radioactive Waste Management, IAEA Safety Series No.111–F, International Atomic Energy Agency, Vienna (1995)). Two of the principles are:

1. Protection of Future Generations. Radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than the relevant levels of impact that are acceptable today.

2. Burdens on Future Generations. Radioactive waste shall be managed in such a way that will not impose undue burdens on future generations.

In support of the proposed part 63 dose limit, the NRC considered other current regulations for consistency and the potential effects of other sources of radiation to select a limit that would be acceptable today for releases of radiation. The EPA, ICRP, and NCRP have all supported the use of source-specific constraints (i.e., a margin of safety) below the 1 mSv/year (100 mrem/year) public dose limit to account for the potential effect of multiple sources of radiation exposure. In addition, use of the critical group concept or the RMEI provides an additional margin of safety because it is difficult for the same individual to be a member of the critical group or to be the RMEI for multiple diverse sources.[1] The final regulations, which specify use of the RMEI concept and limit individual dose to 0.15 mSv/year (15 mrem/year) (15% of the public dose limit), are sufficiently protective that potential exposures from other sources (e.g., past releases from operations at NTS and future hospitals or research centers) would not be expected to result in exposures above the 100 mrem/year public dose limit.

Issue 2: Why does NRC prefer an individual dose limit over a total release limit like part 60?

Comment. Some commenters, while noting that the EnPA specified a dose limit for Yucca Mountain, expressed their support for a total release limit like

[1] Although an individual might be exposed to more than one source of radiation, it would be a very rare circumstance for that individual to retain the lifestyle and other characteristics of the RMEI for more than one source.

part 60. The commenters believed that a total release limit is more understandable, easier to implement, and a simpler way to measure compliance of the repository's performance.

Response. The EPA has established a dose limit for individual protection, expressed in terms of a limit on dose to the RMEI. The NRC is incorporating this limit as required by law. A total release limit may appear to be more straightforward and understandable. In fact, however, nearly all of the same issues, such as dose or risk limit, human behavior, or volume of water mixed with the release, must be addressed to determine an appropriate release standard that is protective of the health and safety of the public and environment. Furthermore, a release standard is more difficult to relate directly to site-specific risk.

To set a release limit, the regulatory agency would first need to establish a risk or dose goal and calculate the risk or dose per unit release (e.g., per curie). The risk/dose goal would need to be the collective risk/dose over the entire compliance time for any release into the environment based on some assumed level of waste (e.g., for 40 CFR part 191, EPA used a risk goal of 1,000 premature cancer deaths in 10,000 years per 100,000 metric tons of heavy metal contained in spent fuel (High-Level and Transuranic Radioactive Wastes: Background Information Document for Final Rule, Office of Radiation Programs, EPA 520/1–85–023, August 1985, Page 7–13)). To calculate the risk per unit release, a model estimating the individual dose from a release will need to be used. To develop the model and data parameters, assumptions about the type of release (e.g., for 40 CFR part 191, a release to surface water was assumed (ibid, pg. 7–13)), which biosphere processes to include, resource usage by the local population (e.g., for 40 CFR part 191, 65 percent of drinking water is assumed to be from the contaminated surface water (ibid, pg. 7–7)), and individual habits and characteristics (e.g., for 40 CFR part 191, annual individual intake of drinking water is assumed to be 600 liters (ibid, pg. 7–7)) will need to be made. In its current form, part 63 requires all the same calculations to be done, but the defense of many of the assumptions is the responsibility of DOE and will be subject to review and approval by NRC.

Use of a release limit also provides less information than calculating the dose from a release. The dose calculation combines the intake and exposure from all radionuclides in the environment into one term. The dose from one scenario or calculation can be readily compared to another. When release limits are used, it is very difficult to compare results if more than one radionuclide is involved because each radionuclide provides a different dose/risk per unit activity. For example, consider a review of two alternate designs. For design number one, the total release results in radionuclide A being released at 60 percent of its limit and radionuclide B is at 30 percent of its limit. For design number two, radionuclide A is 20 percent of its limit and radionuclide B is 70 percent of its limit. Without knowing the relative risk from a release per unit activity for each radionuclide, it would be difficult, if not impossible, to state which design results in a lower risk to the public. Thus, the total release limit yields less information in its application than a dose limit.

Issue 3: How does the use of an individual dose limit protect the entire population?

Comment. A few commenters supported either the use of collective dose limits or requiring dose distributions over the population to be calculated based on a concern that a single dose limit requiring only calculation of dose to the critical group would not adequately protect the overall population. Commenters: (1) Suggested that the collective dose is more important than the individual dose, (2) disagreed with the use of a negligible individual dose value to screen possible release scenarios, and (3) viewed a dose distribution over the population as more informative to the regulators and public, allowing a more risk-informed decision to be made.

Response. The Commission agrees with NAS that ''a health-based individual standard will provide a reasonable standard for protection of the general public'' (p. 65 of the NAS report). The final regulations, which specify characteristics of an RMEI and an individual dose limit of 0.15 mSv/year (15 mrem/year), are protective of the RMEI. The general public includes the small number of individuals within the RMEI's community as well as all other individuals residing near the Yucca Mountain area. Because the community in which the RMEI resides will have a higher estimated dose than the highest exposed individual who does not live in that community, an individual dose limit for the RMEI is protective of all individuals.

Although a distribution of individual doses for the entire population arguably can provide more information to consider in making a decision, the speculation and uncertainty regarding a representative population dose distribution would generally make the results inadequate to use in decision making. The difficulty lies in developing the habits, characteristics, location, and exposure time for the entire population. For analyses of possible future releases, such as from degrading waste in Yucca Mountain, the assumptions about the location, habits, and characteristics for each individual (or group of individuals) would be speculative. The Commission believes that it is possible to develop and defend a reasonable exposure scenario for a small group of individuals that would likely receive the largest doses based on current practices in the region because analyzing doses received by the RMEI living in a community at the 18-km (11-mile) location with a diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada, would bound any doses received by other individuals in the population. Because of the uncertainty in the distribution and range of activities, including location and number of individuals, for other less exposed groups, unbounded speculation could make any resulting population dose distribution unsupportable.

Although the Commission could require performance assessments of the potential dose distribution to hypothetical individuals, at the same locations and with the same habits as the current residents, the Commission believes that the uncertainty in the doses calculated for those not subject to the largest expected exposures would make the results difficult to interpret. In the end, the speculation would lead NRC, DOE, EPA, and other interested parties to expend resources without a commensurate increase in public health and safety or protection of the environment.

Collective dose is useful for comparing options but it does not provide adequate protection of the individual. Collective dose is the total dose received by all exposed people, regardless of distance or magnitude of exposure, over all time from a source. In general, most analyses tend to truncate the dose by calculating over a certain time frame and a given environmental area. Truncated collective dose can provide an overall measure of radiological impact on society or on parts of society but is only useful as an aid to compare options (e.g., DOE has considered individuals living within 84 km (52 miles) of the Yucca Mountain site for evaluating population doses in the DEIS). Because the calculation of collective dose results in a single value (in person-Sv (person-rem)), it gives no

indication of the range or variability of individual doses or the time when the doses could occur. Meanwhile, the use of an individual dose limit to the RMEI assures that the vast majority of the population receive lower doses. The Commission believes that using an individual all-pathway dose assessment provides to the regulator and the public a meaningful measure for making decisions regarding public health and safety.

Issue 4: How is the ''As Low As Reasonably Achievable'' (ALARA) principle incorporated in part 63?

Comment. A few commenters suggested that the ALARA principle be explicitly part of the long-term compliance dose limit in part 63. Others supported the proposed rule for not including the ALARA principle in the requirements for the long-term performance requirements because the cost-benefit analysis would be highly speculative.

Response. The Commission believes that, although it is appropriate to explicitly require the application of the ALARA principle to the operational and decommissioning phases of the repository, the application of ALARA to achievement of the long-term performance objective is not appropriate.

The ALARA principle deals with optimizing the reduction of potential doses from radiation to members of the general public and workers. It is a principal component of the radiation protection philosophy during operations and decommissioning activities and it helps to ensure that no individual will receive a dose in excess of the annual dose limit (i.e., 1 mSv/year (100 mrem/year) for the public and 50 mSv/year (5,000 mrem/year) for radiation workers). Application of ALARA during operations compels the consideration of the benefits of further reduction in potential doses to present-day populations and workers relative to impacts to present-day populations (e.g., increased cost to reduce potential doses further). The application of ALARA to the achievement of the postclosure performance objective would involve considerations far more complicated than those evaluated for operations. The reasonableness of further reduction of potential doses would need to evaluate benefits and impacts that span many generations (e.g., costs incurred today versus a reduction of potential doses thousands of years in the future; repository designs that reduce potential doses in the future but increase doses to present-day workers during fabrication of the design such as installing a special backfill). By adopting the EPA's dose limit for long-term performance, the Commission implements a constraint that is a small fraction (15 percent) of the public dose limit, and which provides a significant margin of safety to ensure that public health and safety and the environment are protected.

In its 1995 findings and recommendations, NAS noted that there is no scientific basis for incorporating the ALARA principle into NRC's Yucca Mountain regulations. In summary, their reasoning was that deep geologic disposal, by its very nature, was ALARA, and there were few technological alternatives in repository design. They also noted it would be problematic to evaluate compliance with the application of ALARA principles in the postclosure phase of the repository. The Commission agrees with NAS in this regard. Therefore, although the Commission will require ALARA considerations for the operational phase and decommissioning of the surface facilities, NRC will not explicitly require an ALARA analysis as part of the postclosure performance assessment.

Issue 5: Why did NRC select 0.25 mSv/year (25 mrem/year) as the proposed dose limit?

Comment. A large number of commenters addressed the 0.25 mSv/year (25 mrem/year) dose limit in proposed part 63. A large number either disagreed with the limit, saying it was too high, or supported a lower standard such as the EPA's 0.15 mSv/year (15 mrem/year) standard in 40 CFR part 191 and proposed 40 CFR part 197. Some commenters (1) expressed confusion on whether the dose limit was for workers or members of the public, (2) requested additional clarification on what ''fully protect'' meant as part of the dose limit, or (3) supported the 0.25 mSv/year (25 mrem/year) dose limit.

Response. The purpose of the postclosure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission has incorporated, a dose limit of 0.15 mSV/year (15 mrem/year). The Commission has long held that its proposed dose limit of 0.25 mSv/year (25 mrem/year) to an individual is (1) a reasonable and appropriate fraction of the annual public dose limit to protect future generations from receiving doses greater than 1 mSv/year (100 mrem/yr), (2) within the range of dose limits used for current sources of public exposure, and (3) accounts for the possibility of dose from other sources. However, the Commission has changed the dose limit in the final rule because it is required to be consistent with EPA's final standards, and not because the Commission is persuaded that its earlier proposal is unsafe, inadequate, or not appropriate in any way. The Commission is confident that the 0.15 mSv/yr (15 mrem/yr) limit is also amply protective. Both limits ensure that no member of the public would be exposed to more than 1 mSv/yr (100 mrem/yr) from all sources of radiation, except background radiation. Both protect future generations. During the operational phase, the repository will be required to comply with part 20 for worker and public health and safety, except that the permitted public dose will be limited to 0.15 mSv/yr (15 mrem/yr).

Issue 6: How is NRC's proposed limit different than the dose limits in older rules (i.e., part 61) and how do they compare?

Comment. Many commenters were concerned that the proposed part 63 would relax health and safety standards. They (1) disagreed with the comparisons with other waste-related safety standards discussed in the Statements of Consideration of the proposed rule, especially with rules using an older dose methodology and (2) expressed concern that the use of the single limit on the TEDE did not adequately protect the organs. They pointed to regulations requiring specific organ limits. While not a dose limit, some commenters disagreed with the use of the national value for background radiation for comparison for the Nevada area because of impacts from past practices.

Response. Part 63 does not change the 1 mSv/yr (100 mrem/yr) public dose limit from part 20, which is the health and safety standard for protection of members of the public. The Commission adopts, in part 63, a limit specifically for the repository that is well below the public dose limit, and that is similar to, but more stringent than a number of other waste management-related dose limits. As noted in the proposed rule, the Commission considers 0.25 mSv/yr (25 mrem/yr) TEDE to be the appropriate dose limit to compare with the range of potential doses represented by the older limits that had whole body dose limits of 0.25 mSv/yr (25 mrem/yr). The single limit does account for each organ's sensitivity to radiation, and each organ is limited to the same risk as the whole body.

Different sources of radiation can have different constraints placed on them. The 0.25 mSv/yr (25 mrem/yr) dose limit is in a similar range as a number of other constraints for waste management facilities or

decommissioning requirements (e.g., 40 CFR 191.03(a), 10 CFR 72.104, 10 CFR 61.41, and 10 CFR 20.1402). Furthermore, during the operational and surface facility decommissioning phases, the facility will need to meet the ALARA requirements in 10 CFR 20.1101(b). This includes an 0.1 mSv/yr (10 mrem/yr) additional constraint on air emissions (10 CFR 20.1101(d)).

A number of the current regulations were published before the early 1990s when the NRC (and other Federal agencies) began using current knowledge about radiation risks and internal dosimetry. These older regulations generally have two or three limits associated with them. They tend to have separate limits for the dose to the whole body, the organs, and possibly, a specific limit for the thyroid (e.g., 10 CFR 72.104 limit of 0.25 mSv/yr (25 mrem/yr) whole body, 0.75 mSv/yr (75 mrem/yr) thyroid dose, and 0.25 mSv/yr (25 mrem/yr) to any other critical organ). At the time these older regulations were published, the Federal government was using a dosimetry system (i.e., a model that calculates the dose if a person ingests or inhales radioactive material) that did not account for the sensitivity to radiation of the various organs (also known as radiosensitivity) nor how the dose to an organ compared to a whole body dose. Because one could not add the various organ doses together, each needed its own limit. With little information on the radiosensitivity of different organs, most organs were given the same limit.

In the early 1990s, the Federal government began using a newer dosimetry system that accounted for how radiosensitive the various organ systems are. In addition to being able to compare the doses between organs, one can calculate what whole body dose would result in the same cancer risk. This whole body dose is known as an effective dose equivalent. By summing each organ's dose, weighted by its relative radiosensitivity, and adding in any whole body exposure, one could calculate the total dose received, which is called the TEDE. Therefore, by using the TEDE dosimetry system, not only the whole body but each of the organs are protected from an increased chance of cancer. They are also all protected at the same level of risk, which was not true of the earlier system.

Because each of the organs had the same limit under the older system even though each had a different level of radiosensitivity, it is very difficult to directly compare the old standards with the new standards. As noted in the proposed rule, the Commission considers 0.25 mSv/yr (25 mrem/yr) TEDE as the appropriate dose limit to compare with the range of potential doses represented by the older limits that had whole body dose limits of 0.25 mSv/yr (25 mrem/yr). However, to conform to the EPA standard, the Commission has incorporated a dose limit of 0.15 mSv/yr (15 mrem/yr) in final part 63.

In the proposed rule, as a point of reference, it stated that the national average background radiation is approximately 3 mSv/yr (300 mrem/yr). Some commenters questioned whether this was valid for the Nevada area considering past practices in the area. The average background radiation stated in the proposed rule did not include variations due to the geology, relative altitude above sea level, or past practices in the region around Yucca Mountain. The Commission does not consider dose from the residual radioactivity left by past practices to be part of the background radiation.

3.3 Calculation of Expected Dose

Issue: Is the ''expected annual dose'' an appropriate quantitative measure for demonstrating compliance?

Comment. The public noted that while a specialist may know that the ''expected dose'' and the ''mean dose'' are equivalent, to many people ''expected'' implies the most likely outcome. The same commenter asserted that the mean value derived from the performance assessment is not the most likely, but rather a value that is unlikely to be exceeded. The commenter sought clarification on whether the ''expected annual dose'' is the mean or the median dose or some other statistical measure. Some members of the public approved of the use of the mean dose rather than the median or mode and noted that the mean should provide a reasonable degree of conservatism. Furthermore, some commenters asserted that use of the ''expected annual dose'' is completely consistent with NAS recommendations that the mean value of the calculations be used for comparison to the standard. Finally, one commenter supported the use of a 25 mrem performance objective, but suggested that it be bolstered with the addition of a 100 mrem limit on the 95th percentile of the probabilistic dose distribution.

Response. Final EPA standards at 40 CFR part 197 specify that NRC determine compliance based upon the mean of projected doses of DOE's performance assessments. The Commission has incorporated this requirement at § 63.303 in subpart L. The mean of the projected annual dose is therefore the appropriate quantitative measure for demonstrating compliance with the dose limit. NAS recommended a performance objective for Yucca Mountain based on risk to an individual. Proposed part 63 defined ''risk'' to an individual as being proportional to two factors: (1) The dose to the individual from exposure to ionizing radiation and (2) the probability of the individual receiving that dose. Analyses conducted by NRC staff demonstrate that the mean annual dose correctly expresses the risk from radioactive exposure to the individual.

The Commission expects that performance assessments conducted by the applicant in support of any potential license application will use probabilistic methods to simulate a wide range of possible future behaviors of the repository system. Each possible future behavior of the repository system is represented by a curve describing the annual dose to the RMEI as a function of time. Generally, but not necessarily, each of the possible curves is assumed to be equally likely. Because none of these possible futures can be demonstrated to describe the actual future behavior of the repository system, the Commission requires that the applicant calculate the mean of these dose versus time curves, properly weighted by their individual probabilities.

In addition, NRC performance assessment experience indicates that the mean already reflects a high degree of confidence that dose limits will not be exceeded. For example, preliminary analysis of the proposed repository at Yucca Mountain (Mohanty, S., R. Codell, R. Rice, J. Weldy, Y. Lu, R. Byrne, T. McCartin, M. Jarzemba, and G. Wittmeyer, ''System-Level Repository Analyses using TPA Version 3.2 Code,'' Center for Nuclear Waste Regulatory Analyses, CNWRA 99–002, August 1999) indicates that the mean exceeds the 95th percentile at early times (i.e., less than 600 years), the 80th percentile prior to 6,000 years and greater than the 70th percentile at 10,000 years. For this reason, NRC does not believe that addition of a 100-mrem limit on the 95th percentile would provide significant additional protection to the public.

3.4 Infant and Children Dose Standard

Issue: Is the dose limit protective of children (and other sensitive populations) and the environment?

Comment. Many commenters were concerned that the dose limits in part 63 may not be sufficiently protective of sensitive populations such as children or infants that may be more susceptible to the effects of radiation. Others were

concerned that by focusing the dose limit on protecting humans, the environment was not adequately protected.

Response. The international community and the Federal agencies (including EPA) follow ICRP's current guidelines that the overall annual dose to members of the public from all sources should not exceed 1 mSv (100 mrem), in order to be protective of all individuals and the environment. These guidelines also hold that exposures from a single practice should be limited to a fraction of this overall dose. The purpose of the public dose limit is to limit the lifetime risk from radiation to a member of the general public. The conversion factor used to equate dose into risk is based on data from various populations exposed to very high doses of radiation such as the atomic bomb survivors, and these populations contained individuals of all ages. Therefore, variation of the sensitivity to radiation with age and gender is built into the standards which are based on a lifetime exposure. A lifetime exposure includes all stages of life, from birth to old age. For ease of implementation, the radiation standards, which are developed to minimize the lifetime risk, limit the annual exposure that an individual may receive. For more information on the selection of the 0.15 mSv/yr (15 mrem/yr) limit, see the discussion under the Individual Dose Limit.

Experimental studies have shown that many flora and fauna tend to be much more resistant to radiation than humans (Casarett, Alison, P., ''Radiation Biology,'' Prentice-Hall, 1968, pages 220 and 300–302 and Nias, A.H.W., ''An Introduction to Radiobiology,'' John Wiley and Sons, 1990, page 231). Therefore, except in cases where large concentrations of radionuclides can enter the environment and no reasonable exposure scenarios exist for humans, one of the principles of radiation protection is that by protecting the public, the environment is protected. In the case of Yucca Mountain and long-term releases, the primary pathway will be through the ground water. Although the contaminated ground water may rise up to the surface environment around Ash Meadows (approximately 40 km (25 miles) from Yucca Mountain), the contaminants will be diluted to much lower concentrations than those used in calculating the dose to the RMEI. Therefore, if the RMEI is protected from doses in excess of the dose limit, the environment is also protected.

3.5 Location of the Critical Group or RMEI

Issue 1: Should the NRC staff consider alternative locations to the proposed 20-km location of the proposed critical group?

Comment. Some commenters recommended that the critical group be located closer than 20 km (up to and including the outline of the repository footprint). Some commenters recommended distances greater than 20 km. Commenters suggested that locations downwind from Yucca Mountain should be considered under critical group locations. Another commenter suggested that NRC's limitation on well depths, based on 1950's–1960's drilling practices, in defining a critical group, was outdated and needed to be revised based on modern drilling practices and pumping technology.

Response. As required by law, the Commission will adopt a compliance location consistent with that established by EPA in its standards for Yucca Mountain. The EPA standards limit the permissible dose to the RMEI, an individual who resides in the ''accessible environment'', above the highest concentration of radionuclides in the plume of contamination. EPA has also established ground-water protection limits for a representative volume of water which includes the highest concentration level in the plume of contamination in the accessible environment. EPA defines the accessible environment as any point outside of the ''controlled area.'' As defined by EPA the controlled area is a 300 square-kilometer surface area that extends no further south than 36° 40′13.6661″ north latitude, or roughly 18 kilometers, in the predominant direction of ground-water flow, and not beyond 5 kilometers in any other direction.

In its 1995 findings and recommendations, NAS recommended that dose calculations be performed, for specific populations, to avoid unlimited speculation about the behavior of future human society. Specifically, in performing the requisite calculations, NAS recommended consideration of the local biosphere, using the ''critical group approach'' specified by the ICRP and employing ''cautious but reasonable assumptions.'' The ICRP has generally defined the critical group to be a relatively homogenous group of people whose location and habits are such that they are representative of those individuals expected to receive the highest doses as a result of radionuclide releases (International Commission on Radiological Protection, ''Recommendations of the ICRP,'' Annals of the ICRP, Vol. 1, No. 3 (1977). (ICRP Publication 26) and International Commission on Radiological Protection, ''Radiological Protection Principles for the Disposal of Solid Radioactive Waste,'' Pergamon Press, Oxford, 1985. (ICRP Publication 46))

Both EPA and NRC have identified the ground-water pathway as the most likely pathway for radiological exposures at Yucca Mountain. EPA's standards, which specify the location for the RMEI at 18 kilometers in the predominant direction of ground-water flow, is consistent with the most likely pathway for radiological exposure. This location is generally considered the nearest location to Yucca Mountain where farming activities can reasonably be expected to occur. At distances less than 18 km to the Yucca Mountain site, there is evidence of intermittent or temporary occupation in modern (historic) times in and around the site—for prospecting or ranching (see ''Preliminary Performance-Based Analyses Relevant to Dose Based Performance Measures for a Proposed Geologic Repository at Yucca Mountain,'' T. McCartin and M. Lee (eds.), NUREG–1538, 2001 (in press)). There also are a number of Native American archeological sites reported throughout NTS closer to the site than the Lathrop Wells location. However, the literature indicates that these were never permanently occupied, and most were abandoned by the end of the 1800's. Overall, the literature suggests many reasons for the absence of permanent inhabitation at distances much closer than 18 km to the site—unfavorable agricultural conditions, inhospitable terrain, the scarcity of mineral resources, and limitations on water availability.

As discussed in the proposed regulation, farming activities are considered to be representative of those individuals expected to receive the highest dose because (1) farming activities involve more exposure pathways than other known human activities in the region (e.g., ingestion pathway through consumption of contaminated water, crops, and animal products) and (2) the relatively large water demand for ground water for irrigation increases the likelihood of drawing contaminated water to the surface where human exposures could occur (64 FR 8645; February 22, 1999).

Finally, with regard to the suggestion that the NRC staff's understanding of drilling and pumping practices in the area is outdated, the Commission does not share this view. Rotary drilling technology, first introduced into the

U.S. in the early 1900's, is still used to drill most wells in the U.S., including those in the Amargosa Desert area. The Commission also is aware that there are now more efficient submersible pumps capable of pumping ground water from greater depths. However, the costs of developing deep ground-water resources increase proportionally with depth, regardless of pump efficiencies.

Issue 2: Should alternatives to the proposed farming community critical group be considered?

Comment. A few commenters objected to the NRC staff's proposed farming community critical group type and noted that parameters used by the NRC staff to define it were themselves controversial and speculative. Overall, the commenters recommended that the NRC staff give more consideration to the criteria used to define the characteristics of the critical group and, in doing so, other critical groups could be identified and situated at locations closer than 20 km to the proposed repository. A question was also raised whether doses would be higher if a farming critical group were located closer than 20 km to Yucca Mountain.

Response. EPA's standards specify the RMEI as the appropriate basis for application of the individual protection standard and adopted certain characteristics for the RMEI representative of the Town of Amargosa Valley. The Commission has added an additional requirement that DOE should assume the RMEI uses contaminated water with average concentrations of radionuclides in a volume of water reflective of the water demand associated with the community in which the RMEI resides (*i.e.,* 3,000 acre-feet/yr). EPA selected a rural-residential RMEI that is assumed to drink two liters per day of contaminated water and consume some locally produced food (based on surveys) (66 FR 32092; June 13, 2001). As noted in the preamble to the EPA standards (66 FR 32093; June 13, 2001), commercial farming occurs today in the southwestern portion of the Town of Amargosa Valley. Thus any survey of consumption of locally produced food for this area will include a variety of lifestyles including some full-time farmers, however, the RMEI is not assumed to be a full-time farmer. NRC proposed an average member of a farming community, in part, to ensure locally produced food was accounted for as a potential exposure pathway. The Commission considers the RMEI, as specified in the EPA's standards, to be protective and consistent with the Commission's intent of including locally produced food as a potential exposure pathway. Also, as noted in the response to the previous issue, EPA limits the location of the RMEI to any point outside of the ''controlled area,'' which EPA defines as 300 square kilometer surface area that extends no further south than 36° 40′13.6661″ north latitude, or roughly 18 kilometers, in the predominant direction of ground-water flow, and not beyond 5 kilometers in any other direction. It is possible, of course, to postulate some other RMEI, however, doing so would be difficult to defend based on the pattern of historic development in the area prior to the establishment of NTS, and would also be inconsistent with NAS' overall recommendations.

In order to avoid boundless speculation, the NAS recommended that the characteristics of the exposure scenario be specified by rule. Thus, the EPA standards specify certain characteristics of the biosphere and the RMEI. NRC's proposed regulation also specified many of these same characteristics in addition to specifying a farming community of approximately 100 individuals (residing on 15 to 25 farms). This specification of the farming community provided flexibility to DOE in determining an appropriate water demand consistent with the specified farming community. It is reasonable to assume, based on current activities and water usage in the area, that the annual water demand for a farming community of this size could range from a few thousand to as much as ten thousand acre-feet. The final regulations specify a water demand of 3,000 acre-feet as a conservative value for use in estimating the dose to the RMEI. Specification of this value is consistent with: (1) The NAS recommendations for specifying the exposure scenario by rule; (2) NRC's proposed critical group (*i.e.,* farming community of 100 individuals); and (3) the criteria for the RMEI specified in the EPA standards (*i.e.,* diet and lifestyle representative of the people who now reside in the Town of Amargosa Valley, Nevada). Finally, the specification of the use of an average concentration is both consistent with the proposed regulation, which specified the use of an average dose, and the EPA standards that specify the use of a mean (average) dose.

Regarding the consideration of other types of critical groups, examination of the literature suggests that the pattern and nature of development in Amargosa Valley has been influenced by two types of factors—natural and engineered. Foremost among the natural factors is the physical geography of the area—particularly the type of climate and the availability of water. Amargosa Valley is considered a mid-latitude desert; it receives on average 4 inches of rain per year. Moreover, there are few naturally-occurring sources of drinking water supply; surface water supplies are restricted to a few natural springs and, although ground water is available, one has to drill for it. Because of costs associated with drilling and pumping ground water, agricultural development has tended to favor areas where the ground water is shallow. Thus, despite almost 100 years of improvements in farming technology, practical limitations in soil fertility combined with the economics of irrigation-based agriculture continue to restrict farming activities to the same basic location within Amargosa Valley.

Man-made developments, such as the introduction of commercial electricity in Amargosa Valley in the early 1960s, have made the economics of irrigation-based agriculture somewhat more attractive and led to diversification of the local economic base which now includes a dairy, a turf farm, a hotel, a casino, and a golf course. The availability of commercial electricity has also led to a moderate increase in the permanent, non-farming resident population. Non-farming activities, as one commenter pointed out, are generally unaffected by ground-water depth, soil type, and other similar factors and could take place anywhere in the Yucca Mountain area, but have not, because the lands immediately surrounding Yucca Mountain are Federally-owned. It is likely that in addition to the existence of infrastructure (roads and commercial electricity) other factors as significant as the physical ones, also have contributed to diversification of the local economic base in Amargosa Valley. However, decisions to pursue diverse business ventures are typically made privately, by business persons or corporations, taking into account economic forces in the market place. In the Commission's view, it is impossible to predict the future behavior of the national or local economy and translate this behavior into specific human actions in the Yucca Mountain area.

In summary, the requirement that the RMEI use water of average contaminant concentration, in a volume of water (3,000 acre-feet) reflective of a farming community, is conservative. Because the RMEI is defined as that person reasonably likely to receive the highest doses, the selection of RMEI characteristics must take into consideration both the magnitude of the dose likely to be received and the likelihood that a dose will actually occur at that location. The Commission believes that EPA selected the characteristics of the RMEI based on

cautious and reasonable assumptions for the community of individuals likely to receive the highest doses. For these reasons, the Commission has adopted EPA's definition of the RMEI, as it appears at 40 CFR part 197 and added the additional requirement for water usage by the RMEI.

Issue 3: How will potential doses from the air-pathway be evaluated during the period of repository operations (preclosure period)?

Comment. A subject of continuing concern for any possible geologic repository at Yucca Mountain is the potential effects of unexpected (low probability) releases of gaseous/particulate radionuclides during the preclosure phase of operations (*i.e.,* DBEs). As a matter of background, it was noted that radioactive fallout from atmospheric tests of nuclear weapons conducted at the NTS during the 1950's was transported by prevailing westerly winds to communities east of the NTS, such as Caliente (Nevada). Because prevailing wind patterns are unlikely to change, concerns were expressed that health effects similar to those assumed to have resulted from atmospheric testing may arise from potential repository operations. Accordingly, it was suggested that a critical group based on exposure to an air-pathway should be evaluated.

Response. The Commission is aware of the effects of local atmospheric conditions on past nuclear testing activities (which were not subject to NRC regulation). During operations, DOE is required to control releases from all potential pathways, including atmospheric, such that no member of the public is exposed to more than 0.15 mSv/year (15 mrem/year). To comply with this requirement (at § 63.111) DOE will need to account for potential gaseous and particulate releases to existing members of the public (including current down-wind communities, such as Caliente). This requirement also directs DOE to conduct a preclosure safety assessment (§ 63.112) that shows (1) that the GROA design and normal operations at the site will limit the release of gaseous and particulate radionuclides so that the public dose will remain below 0.15 mSv/yr (15 mrem/yr) dose and (2) that in the event of an unlikely, but credible emergency situation, the design is robust enough to constrain potential doses to within acceptable public health and safety standards.

3.6 Critical Group Characteristics and Reference Biosphere

Issue 1: Is the average member (of a critical group) an appropriate measure to protect public health and safety?

Comment. A number of commenters focused on the proposed approach of calculating doses to an average member of a critical group. Commenters noted: (1) Use of the average member results in some people (aside from those with extreme habits) receiving less protection than others (*i.e.,* individuals protected by assuming current conditions may not be protected under potentially different future conditions); (2) the proposed rule does not provide a definition of the average member of the critical group; (3) the appropriate measure is the average of calculated doses to members of the critical group rather than a single dose calculated for a single member with average characteristics; and (4) a subset of the farming group that would be more likely to experience health effects (*e.g.,* children) should be used.

A few commenters suggested use of a subsistence farmer. One commenter added that sensitivity studies should be done for a subsistence farmer (*i.e.,* all food locally grown) located closer than 20 km from the proposed repository site to gain insights into risk, even though such a scenario would be unlikely.

Response. Although the Commission finds that limiting the dose received by the average member of the critical group is protective of current and future populations in the vicinity of the site, the final rule has been changed, as required by EnPA, to use 40 CFR part 197's mean dose to the RMEI as the measure to compare with the dose limit. The RMEI approach has been characterized as providing a similar level of protection to that achieved by protecting the average member of the critical group, as was proposed for part 63. In its comments to EPA on the proposed 40 CFR part 197, the NAS noted that the reasonably maximally exposed individual is very similar to the internationally used critical group approach. Additionally, in the proposed rule, NRC quoted the International Commission on Radiological Protection, which stated that it may be convenient to define the critical group in terms of a single hypothetical individual. The International Atomic Energy Agency's (IAEA's) Biosphere Modeling and Assessment working group has taken it further and calls such a hypothetical individual a reasonably maximally exposed individual (BIOMASS, 1999). Although there are slight differences between the EPA's reasonably maximally exposed individual and NRC's proposed average member of the critical group, they are virtually the same (especially in view of the IAEA's guidance). As noted earlier, the Commission has adopted the RMEI approach to be consistent with 40 CFR part 197.

The issue of whether children are protected has been taken into consideration in developing the rule (see discussion under Infant and Children Dose Standard). In summary, the standards were developed with sufficient conservatism to protect all members of the public regardless of age or gender.

The Commission disagrees with the recommendation that the NRC should use the admittedly unlikely subsistence farmer approach as the basis to test sensitivities (for additional information on the subsistence farmer approach, see the response to Issue 2, below). The NRC expects that sensitivity studies based on unrealistic and unlikely exposure scenarios would provide results that would be difficult to interpret and relate to the actual anticipated conditions of exposure. The NRC, however, agrees with the commenters' recognition of the value of sensitivity analysis as a tool to gain insight into uncertainties and the importance of parameters and models. NRC conducted extensive sensitivity analyses with an independently developed total performance assessment code (Nuclear Regulatory Commission, ''Sensitivity and Uncertainty Analysis for a Proposed Repository at Yucca Mountain, Nevada, Using TPA 3.1, Volume 2: Results and Conclusions,'' NUREG 1668, Vol. 2, Washington DC: Nuclear Regulatory Commission) in the development of the proposed rule.

Issue 2: Has NRC made cautious and reasonable assumptions about the characteristics of the proposed critical group?

Comment. A variety of comments were received which are related to critical group assumptions specified in the proposed NRC rulemaking. A few commenters disagreed with specification of critical group characteristics based on current conditions, noting that over long time frames such conditions are likely to change. Another commenter asserted that the assumption that all locally grown food is contaminated is vague because the proposed rule does not state all food consumed by the critical group is locally grown (the commenter disagreed with the use of a subsistence farmer approach that would result from assuming all consumption was local). The commenter further stated that the expected plume dimensions and

number of farms make the assumption that all local food is contaminated excessively conservative (*i.e.,* tends to overestimate dose). The commenter noted local surveys show that not all food consumed in Amargosa Valley is locally grown. Other commenters offered that the critical group should be a subsistence farmer because that approach is conservative and bounding (suggesting that no dose would be allowed higher than the critical group's and therefore it would be protective of all). Another commenter stated the reasonably maximally exposed individual for a subsistence farmer also provides broad protection of all people (excepting those with extreme habits), and its conservatism would lessen the effect of assuming constancy of future behaviors. Still another commenter tentatively approved the NRC choice for critical group noting the actual critical group is likely to involve commercial, light industrial activities and, therefore, assuming a farming community is conservative (*i.e.,* protective). One commenter questioned the accuracy of the reported population count for Amargosa Valley.

Some commenters suggested alternative critical groups as being more representative or protective of the local population. Representatives of the Western Shoshone people suggested their long existence in the region and lifestyle in close proximity to the land support selection of a Western Shoshone critical group. They noted a long history of a hunting and gathering ''subsistence'' lifestyle that is expected to remain into the future. Farming and livestock activities were also discussed as recent introductions to the Western Shoshone lifestyle.

Response. Although the Commission considers the proposed assumptions about the characteristics of the critical group to be protective of current and future populations in the vicinity of the site, the final rule has been changed, as required by EnPA, to use the mean dose to the RMEI, as defined at 40 CFR part 197, as the measure to compare with the dose limit. Although there are slight differences between the characteristics of EPA's reasonably maximally exposed individual and the proposed average member of the critical group, they are practically the same. However, as noted, the Commission has adopted the characteristics of the RMEI as specified in 40 CFR 197 and added two additional requirements.

Regarding the two additional requirements, the final regulations specify: (1) The water demand to be used in estimating exposure to the RMEI (see response to Issue 2 under Critical Group Location); and (2) that the RMEI is an adult with metabolic and physiological considerations consistent with present knowledge. Specification of the RMEI as an adult is: (1) Consistent with the NAS recommendations for specifying the exposure scenario by rule; (2) consistent with the proposed regulation characteristics for the exposure scenario; (3) consistent with the criteria for the RMEI specified in the EPA standards (*i.e.,* drinks 2 liters of water per day); and (4) consistent with the EPA's Draft Federal Radiation Protection Guidance for Exposures of the General Public (59 FR 66422; December 23, 1994). The Commission considers the RMEI approach and associated characteristics of the RMEI to be protective of the health and safety of the public and environment (see also responses under Infant and Children Dose Standard and Location of the Critical Group or RMEI).

The Commission disagrees with the suggestions that a subsistence farming critical group should be used in dose calculations or that the RMEI be a subsistence farmer. As noted above, the Commission considers the RMEI approach from 40 CFR part 197 to be fully protective. The RMEI approach requires DOE to use diets and lifestyles representative of the people who now reside in the Town of Amargosa Valley, Nevada. Therefore, a variety of diets and lifestyles, including farming as it occurs today, will be represented in the characteristics of the RMEI. The Commission considers the use of local, present day conditions to be the most realistic basis for RMEI behavior assumptions, and present evidence indicates that there are no subsistence farmers in the vicinity of Yucca Mountain. NRC disagrees with the suggestion that the excessive conservatism of the subsistence approach is needed to offset any presumed lack of conservatism from the assumption of current conditions.

The Commission also disagrees with the suggestion that a Shoshone critical group should be used in dose calculations or that the RMEI be a Western Shoshone. In defining the critical group for the proposed rule, the Commission considered the possibility of a Native American based critical group. To date, based on all the information including the information provided by public comments, NRC has not been able to identify a suite of common characteristics of Native American groups in the region that is both different from the proposed farming critical group and likely to lead to greater exposures than the proposed farming critical group or the RMEI. Thus, the NRC believes the use of a RMEI for postclosure exposures protects Native Americans as well as other members of the public.

Issue 3: Should NRC include potential future climate changes in the specification of a reference biosphere?

Comment. One commenter asked that the NRC clarify whether it has determined with certainty that a future ice age will occur and, if so, provide the supporting documentation. If such a determination has not been made, NRC should revise the proposed rule to reflect greater uncertainty with regard to climate change. DOE recommended that NRC move proposed § 63.115(a)(3) and (4) to proposed § 63.114 to remove the implication that climate change needs to be considered for biosphere assumptions. Both DOE and another commenter claimed that because NRC expects that climate change (from arid to semi-arid) will not alter the biosphere sufficiently to cause major changes in potential exposure pathways, climate change should be removed from the biosphere requirements. DOE noted that climate change and changes in the geologic setting affect the performance assessment and, thus, should be moved to § 63.114. Another commenter recommended deleting proposed § 63.115(a)(3) and revising proposed § 63.115(a)(2) to reflect current climate conditions. Yet another commenter stated that evolution of the geologic setting should not be part of the reference biosphere, and thus the requirements should be moved under performance assessment (proposed § 63.114).

A commenter stressed the need to emphasize present-day conditions for defining the biosphere and provided a number of supporting points for NRC consideration. The commenter agreed with NRC that use of future human behavior is speculative and, thus, it is appropriate to limit assumptions to present-day behavior. The commenter noted risks to future generations should be based on levels deemed tolerable by present day society. The commenter claimed such analyses of future risk can only be done by assuming present-day behavior. The commenter also noted that using present-day characteristics provides confidence to the local community.

Another commenter believed that the emphasis on present-day conditions, while adequate for the time of site characterization, does not take into consideration processes and events currently taking place in Southern Nevada which could lead to different futures. Cited examples include the rapid growth that has occurred (and

continues) in Southern Nevada over the past 30 years and the increase in urban growth of southern Nye County (*e.g.,* Pahrump). Such growth was noted as important because it increases demand for, and pumping rates of, ground water, which could lead to changes in gradients that would accelerate contamination. It was further mentioned that ground-water sources north of Clark county have long been considered options to meet future water demands. For these reasons, the NRC should consider such future possibilities as alternatives to present-day biosphere conditions.

Response. Because some commenters questioned the Commission's basis for including climate change in the performance assessment requirements of the proposed rule, the Commission responds by providing additional information supporting the theory that climate change is possible during the proposed period of performance. The inclusion of climate change in biosphere requirements is consistent with the EPA standards and is also further justified based on a reasonable likelihood that climate change will occur in the future and the fact that such changes have the potential to impact the biosphere. However, comments suggesting that NRC consider future economic growth trends ignore inherently large uncertainties in predictions of such futures over both short and long time frames. The Commission finds that the inclusion of such future predictions would add inappropriate speculation into the requirements, would not enhance public safety, and is likely inconsistent with the EPA standards. Therefore, the language of the proposed rule, which requires DOE to consider climate change and precludes consideration of changes to assumptions of lifestyle and land use, that could be subject to speculation about future economic growth, is retained in the final rule, with the exception that the critical group has been replaced with the RMEI for consistency with EPA's standards.

Although it is beyond the capabilities of present-day science to determine ''with certainty'' that a future ice age will occur, the present paleoclimatic data support that (1) ice ages have occurred in past history, (2) climate changes in the past have exhibited a cyclical pattern, and (3) the cycle is likely to lead back to another ice age. The NRC has extensively investigated relevant research on future climate change in the vicinity of Yucca Mountain and has summarized the available information in an Issue Resolution Status Report (Nuclear Regulatory Commission, ''Issue Resolution Status Report Key Technical Issue: Unsaturated and Saturated Flow Under Isothermal Conditions,'' Revision 2, Vol 1, Washington DC: Nuclear Regulatory Commission, June 1999). (For more information about obtaining reports from the NRC PDR, mail a request to U.S. Nuclear Regulatory Commission, Public Document Room, Mail Stop O1F13, Washington DC 20555, or e-mail pdr@nrc.gov.) The NAS committee also was familiar with the science behind future climate changes and stated, in its recommendations on Yucca Mountain standards, that a future ice age in the next few hundred years is unlikely but not impossible, in the next 10,000 years is probable but not assured; however, over a million-year time frame, the climate is virtually certain to pass through several glacial-interglacial cycles (*i.e.,* ice ages). The Commission believes there is sufficient information in the paleoclimate record to justify including climate change in the final regulations regarding effects on repository performance.

Climate change was included in the proposed regulations for the reference biosphere in § 63.115 because the NRC believed there was sufficient scientific evidence supporting the potential for climate change over the long time frames considered by the performance assessment calculations. Although NRC analyses suggest that inclusion of climate change in the biosphere is not likely to significantly change the assumed local climate conditions and assumed exposure conditions, the Commission believes it is important to include the consideration of climate change in both the geosphere and the biosphere performance assessment calculations to ensure that the conceptual model of the environment is consistent with our scientific understanding of reasonably anticipated natural events. The NRC also believes it is important for DOE to include these processes in its performance assessment calculations and do the necessary technical analyses to ensure the processes have been adequately considered and addressed.

The NRC agrees there is a need to emphasize current conditions when applied to behavioral characteristics of the RMEI. The natural systems of the biosphere are allowed to vary (*e.g.,* climate change) because the geologic record provides evidence of past climate over a long time frame, which provides a strong basis for predicting future changes. Because human behavior cannot be similarly predicted, a similar approach cannot be used for the RMEI and the influence the local population has on the biosphere. Thus, it is necessary to emphasize current conditions for the RMEI (see response to Issue 1 for more information). The suggestion that NRC consider alternative futures related to human behavior is speculative and leads to problems deciding which alternative futures are credible and which are unrealistic. Such questions have no scientific or technical answer. It is DOE's responsibility to demonstrate that the RMEI and biosphere assumptions in performance assessment calculations are consistent with local conditions. During the review of the license application, the NRC will evaluate DOE's assumptions to ensure they are consistent with current information. Given the uncertainties associated with local economics, NRC believes it is unreasonable to expect DOE to predict future growth conditions in local areas and the consequences of growth trends.

3.7 Absence of Separate Ground-Water Protection Criteria

Issue: Why are there no separate requirements for the protection of ground water given the importance of ground water in the arid environment of Yucca Mountain and the fact that the most likely pathway for radionuclides to escape from the repository is via the ground-water pathway?

Comment. Commenters were divided on whether separate requirements for protection of ground water are necessary. Commenters supporting separate requirements for protection of ground water provided various rationales for instituting separate requirements, such as: (1) Ground water represents a valuable resource deserving separate protection; (2) ground water is the most likely source of contamination to Yucca Mountain residents; and (3) ground water at Yucca Mountain should be provided the same level of protection afforded other sites around the country that are subject to separate ground-water protection requirements under the Safe Drinking Water Act (SDWA). Generally, these commenters recommended protecting ground water by either limiting individual exposure from drinking water to 4 mrem per year or using EPA's maximum contaminant levels (MCLs). However, some commenters opposed the imposition of separate requirements for protecting ground water. One commenter opposed to separate requirements for protection of ground water stated: (1) An overall system approach for safety is appropriate, and separate requirements for protection of ground water represent unnecessary subsystem requirements and (2) such requirements would not be consistent with the recommendations of

NAS and go beyond the health-based standards mandated in section 801 of the EnPA.

Response. The Commission has commented previously that an individual, all-pathway dose limit of either 0.15 mSv (15 mrem) or 0.25 mSv (25 mrem) TEDE ensures that the risks from all radionuclides and all exposure pathways, including the ground-water pathway, are acceptable and protective. The EPA itself acknowledged, in publishing final standards for Yucca Mountain, that an '' * * * Individual Protection Standard is adequate in itself to protect public health and safety.'' However, ultimately, the EPA had to make the decision whether to include separate requirements for groundwater protection and the final EPA standards for Yucca Mountain include such requirements for the purpose of protecting groundwater. Therefore, as required by law, final part 63 requirements incorporate final EPA standards for Yucca Mountain at 40 CFR part 197, including separate ground-water protection requirements. These requirements, §§ 197.30 and 197.31, appear in the final 10 CFR part 63 regulations as §§ 63.331 and 63.332, respectively.

3.8 Multiple Barriers and Defense in Depth

Issue 1: Should NRC set quantitative limits (that is, subsystem requirements) for specific barriers that make up the repository system?

Comments. The NRC received comments both supporting and opposing the approach proposed in part 63, which would provide a single overall, health-based, performance objective and avoid setting arbitrary, quantitative limits on individual barriers. Commenters in favor of a single system performance goal stated that risk-informed and performance-based regulations allow the applicant and the regulator to place greatest emphasis on issues important to health and safety. Commenters supporting quantitative limits for specific subsystems expressed concern that reliance on quantitative performance assessments to show compliance with a single measure of performance is less protective than setting specific numerical criteria for the performance of individual barriers. They argued that quantitative limits for individual barriers are needed to provide greater assurance for overall repository performance and, in general, supported keeping the quantitative limits at part 60.

Response. The Commission believes that it presented a sound basis for the proposed approach to multiple barriers and defense in depth in the Supplementary Information accompanying the proposed part 63. The final rule adopts a single quantitative performance goal for individual protection and separate limits for ground-water protection as specified by the EPA standards. Beyond these, the final rule does not place quantitative limits on individual barriers. After considering the comments received, however, the Commission recognizes a need to clarify the multiple barrier requirements in the proposed rule. The response to the next issue discusses the specific clarifications adopted.

The Commission based its proposed treatment of multiple barriers on the following:

1. Consistent with the Commission's risk-informed and performance-based regulatory philosophy, DOE is provided flexibility for deciding the extent and focus of site characterization. As the repository designer, DOE may place greater or lesser reliance on individual components of the repository system when deciding how best to achieve the overall safety objective.

2. Estimates of subsystem performance are subject to many, if not all, of the same sources of uncertainty as are estimates of overall system performance. It is questionable, therefore, whether the subsystem criteria in part 60, or any other criteria, could provide truly independent assurance of total system performance.

3. The Commission recognizes that techniques of performance assessment have improved a great deal because of significant advances in knowledge and experience achieved since part 60 was developed. These advances in performance assessment technology support the use of performance assessment results for estimating long-term repository performance. They also obviate, in the Commission's view, the need to prescribe arbitrary, minimum performance standards for subsystems to build confidence in a system's overall performance.

The Commission's goal is to protect public health and safety and to ensure compliance with EPA's standards. NRC's evaluation of DOE's compliance demonstration will examine how all components of the repository system work together to achieve this goal. Therefore, the emphasis should not be on the isolated performance of individual barriers but rather on ensuring the repository system is robust, and is not wholly dependent on a single barrier. Further, the Commission supports an approach that would allow DOE to use its available resources effectively to achieve the safest repository without unnecessary constraints imposed by separate, additional subsystem performance requirements. It is also important to remember that part 63 requires DOE to carry out a performance confirmation program to provide further confidence that barriers important to waste isolation will continue to perform as expected (see Section 2.4 on Performance Confirmation).

Issue 2: How does the multiple barrier provision fulfill NRC's philosophy of defense in depth in evaluating repository performance?

Comments. Some commenters asked the NRC to explain how we apply defense in depth to the repository without specific calculations or numerical limits for meeting this requirement. They stated that the proposed part 63 is not clear about how DOE must demonstrate defense in depth for repository performance.

Response. In general, the Commission believes that a repository system should reflect the philosophy of defense in depth. The Commission expects that if a repository system is made up of multiple barriers, then it will be more tolerant of unanticipated failures and external challenges. The final regulations specify criteria for quantitatively evaluating postclosure performance (*e.g.,* individual protection, ground-water protection, and evaluation of human intrusion). These criteria help ensure defense in depth by requiring calculations that provide risk insights into the impact on performance of specific system attributes and external conditions. DOE must evaluate the performance of the repository system, as it performs as a result of compliance with general design criteria (*e.g.,* required use of multiple barriers and identification of the repository by markers). DOE must also evaluate the system's response to various external challenges (*e.g.,* disruptive events treated in the performance assessment, as well as a specified human intrusion scenario).

Commenters on the proposed rule pointed out that neither the intent of the multiple barrier provision, mandated by the Nuclear Waste Policy Act, nor how NRC would determine compliance with this provision, were clear. To clarify this intent, the final rule explains the concepts associated with the multiple barrier provision in § 63.102, and provides the criteria in § 63.115.

The proposed rule would have required and the final rule requires DOE to: (1) Identify barriers; (2) describe quantitatively each barrier's ability to contribute to waste isolation; and (3)

provide technical bases for the barriers' capabilities as part of the overall demonstration of compliance with the individual protection standard (see § 63.114 (h)–(j) of the proposed rule). Although not necessarily required as a separate demonstration, this required information on the capability of barriers, integral to the performance assessment, illustrates the resilience or lack of resilience of the repository to unanticipated failures or external challenges. Also, quantitative insights about the defense in depth of the proposed repository emerge directly from the quantitative evaluations in the performance assessment. The performance assessment must include analyses of the effects of unlikely, but credible, external challenges on overall performance. (In its analyses, DOE must consider disruptive events that have an annual probability of occurrence greater than 10^{-8}.) Disruptive events may degrade performance of the engineered barriers or reduce the effectiveness of natural barriers or both. Also, DOE must evaluate uncertainty about the performance of both engineered and natural barriers in the performance assessment. For example, uncertainty about the corrosion rate of the waste package will necessarily affect the estimated lifetime of the package. Likewise, uncertainty about geochemical sorption will affect estimates of the time it takes specific radionuclides to travel in the geosphere. As with the disruptive events, the proper consideration of uncertainty in the performance assessment should ensure an evaluation of the range of response of individual barriers to various challenges (*e.g.,* higher than normal corrosion rates, lower than normal geochemical sorption). Thus, a complete performance assessment (*i.e.,* one that complies with § 63.114) will illustrate the effectiveness of the multiple barriers, and the implementation of the philosophy of defense in depth, such that the individual protection standard is shown to be met even when barriers are challenged.

The Commission has clarified how DOE is to develop the technical basis for each barrier's technical capability. The change makes clear that a description of relevant information about a given barrier's characteristics and performance, which DOE has used to support the overall performance assessment, is sufficient to show compliance with this requirement. The language of the proposed rule was not intended to imply that an acceptable technical basis for multiple barriers need be (or even could be) derived separately from the basis for the performance assessment itself. Rather, the technical basis for the barriers should be presented in a focused, clear description. This description should be derived from pertinent information contained in the technical basis for the performance assessment.

Quantitative or Qualitative Assessment?

Consistent with the proposed rule, the final rule allows DOE to select from various methods to describe the capabilities of the barriers. Regardless of the method selected, DOE must describe the capability of each barrier to perform its intended function and the relationship of that barrier's role to limiting radiological exposure in the context of the overall performance assessment. The Commission has considered the comment that an evaluation of each barrier's capability should be quantitative. The Commission continues to believe a qualitative approach, as proposed, is appropriate for the following reasons:

1. It provides the Commission with information to be considered in its decisions without constraining its considerations to a specific limit for a particular barrier, which could result in less favorable overall system performance.

2. It gives the Commission the flexibility to consider the nature and extent of conservatism in the evaluations used for compliance demonstration, and to decide whether there is a need to require DOE to reduce uncertainties in its assessment (*e.g.,* collecting more site data) or to include further mitigative measures.

3. Quantitative evidence of the capability of individual barriers to contribute to waste isolation is an integral part of the performance assessment. Therefore, an additional quantitative limit is not necessary to show that overall performance reflects a system of multiple barriers.

The Commission understands that establishment of explicit, quantitative limits for individual barriers might be considered a desirable and more easily explained approach. That being said, however, the Commission knows of no scientific basis for setting such limits for particular barriers at Yucca Mountain, or at any other site, independent of the complex repository system in which they must perform. The Commission is confident that evidence for the resilience, or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior of the overall repository system. Such an assessment must consider credible and supportable ranges of individual parameters and modeling assumptions, and must include multiple evaluations of a wide range of combinations of resulting barrier performance.

Finally, the required description of barrier capability provides information that will aid in the interpretation of the performance assessment results, while at the same time providing information that is independent from the condition of the other barriers. For example, the unsaturated and saturated zones could provide significant retardation to many radionuclides such that radionuclides will not reach the RMEI within 10,000 years regardless of when the waste package fails. This capability of geologic systems to ''retard'' or slow the movement of contaminants exists whether or not the waste package is breached. Thus a geologic barrier can provide defense in depth irrespective of releases from the waste package. Describing the capabilities of the system's component barriers (*e.g.,* retardation of specific radionuclides in specific geologic media) can be accomplished by describing the applicable conceptual models and parameters used in the performance assessment. It does not require quantitative calculations beyond those performed to demonstrate compliance with the postclosure performance objectives. The Commission believes that understanding the capability of the system's component barriers provides an understanding of the repository system that can increase confidence that the postclosure performance objectives are met. The Commission is satisfied that the clarifying additions discussed above, along with other requirements at §§ 63.114 and 63.115, if met, will provide sufficient basis to determine whether a proposed repository system acceptably provides a system of multiple barriers.

3.9 Compliance Period

Issue 1: Is a 10,000-year compliance period reasonable in light of the NAS recommendations?

Comment. Several commenters stated that a 10,000-year compliance period conflicts with the NAS recommendation that the time over which compliance should be assessed should include the time when greatest risk occurs, within the limits imposed by the stability of the geologic system, and that rejecting the NAS recommendation is arbitrary.

Response. The EPA standards for Yucca Mountain provide for a demonstration of compliance over a 10,000-year time frame. Moreover, the

Commission agrees that a 10,000-year compliance period is reasonable for the reasons identified in the supplementary information provided with the proposed criteria at part 63 (64 FR 8647; February 22, 1999). The fact that it is feasible to calculate performance of the engineered and geologic barriers making up the repository system for periods much longer than 10,000 years does not mean that it is possible to make realistic or meaningful projections of human exposure and risk, attributable to releases from the repository, over comparable time frames. NAS acknowledged that projecting the behavior of human society over long periods is beyond the limits of scientific analysis and recommended that ''cautious, but reasonable'' assumptions, based upon current knowledge, be made with regard to the selection of biosphere and critical group parameters for Yucca Mountain. Determining just how far into the future current knowledge can no longer support ''reasonable'' assumptions about pathways affecting human exposure is clearly a subjective, policy judgment. NRC believes that, for periods approaching 1,000,000 years, as suggested by NAS, during which significant climatic and even human evolution would almost certainly occur, it is all but impossible to make useful and informed assumptions about human behaviors and exposure pathways. NAS explicitly acknowledged that selection of a time period over which compliance should be evaluated necessarily involves both technical and policy considerations (see p. 56, ''Technical Bases for Yucca Mountain Standard,'' National Research Council, 1995).

Issue 2: Should NRC require DOE to provide supplemental analyses of repository performance at times other than 10,000 years?

Comment. One commenter stated that although a 10,000-year compliance period is well justified, it would be beneficial to require, either by rule or guidance, a supplemental analysis for performance at 1,000 years. This analysis would help to identify vulnerabilities such as juvenile failures of waste packages, so that DOE can reduce the likelihood and consequences of such vulnerabilities. The same commenter also stated that a supplemental analysis at 100,000 years, or even later, can provide a useful projection of the final transport of waste from the repository, particularly for the very long-lived isotopes.

Response. The Commission will not require DOE to provide supplemental analyses of repository performance at times other than 10,000 years. To demonstrate compliance with the individual dose limit, the expected annual dose needs to be below the regulatory limit at all times within the 10,000-year compliance period. This requires a time history of repository performance throughout the 10,000-year compliance period. Therefore, repository performance at 1,000 years can be derived from the performance assessment provided by DOE in the license application. A separate, supplemental analysis at 1,000 years is not necessary. It may be useful to note that NRC pre-licensing activities include providing guidance that DOE (and other stakeholders) can use to develop a transparent performance assessment that will reveal an understanding of the relationship between the performance of individual components or subsystems of the geologic repository and the performance of the total system at all times over the 10,000-year compliance period.

In response to Issue 1 (Is a 10,000-year compliance period reasonable in light of NAS recommendations?), the Commission questions the realism and meaningfulness of projections of human exposure and risk, attributable to releases from the repository, over time frames much longer than 10,000 years. Requiring DOE to provide a separate analysis of repository performance over very long times in the license application would be inconsistent with our position on the utility of this information, as well as with EPA's standards for Yucca Mountain. The EPA standards require that DOE include an analysis of repository performance up through peak dose in the EIS which would accompany any potential license application. This provision is included in the final part 63 regulations at § 63.341. The Commission notes that there is no standard that must be met with respect to these peak dose calculations, and that there is no finding that the NRC must make with respect to these peak dose calculations nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain.

3.10 Human Intrusion Scenario

Issue 1: Is the Commission's proposal for the human intrusion calculation appropriate for evaluating the ability of the repository to withstand an intrusion event?

Comment. Some commenters noted that, because of the uniqueness of the repository, it is likely that institutions involved with the development, construction, and operation of a repository, and knowledge of its existence, are likely to persist longer than 100 years after the repository is permanently closed. Because some form of institutional, corporate, or anecdotal knowledge about the proposed repository, would exist well beyond closure, any drilling into the repository would be advertent, not inadvertent, contrary to the NAS'' recommendation. Thus, given the likelihood of multi-generational knowledge about any proposed repository that could persist well beyond permanent closure, there is no reason to believe that unintended human intrusion would occur shortly after the loss of institutional controls. Also, given the current waste package design, DOE asserted that current drilling techniques would likely not lead to waste package penetration without recognition by the drillers. Other commenters noted that any natural resource exploration campaign is likely to involve more than an exploratory borehole. Moreover, because of the potential for changing resource needs over the long period of regulatory concern, there is the possibility for multiple exploration campaigns and, thus, the potential for multiple boreholes breaching the repository. Consequently, the rule should be changed to require that effects of multiple boreholes on repository performance be evaluated.

One commenter questioned the rationale for not regulating the radioactive materials brought to the surface, in drill cuttings or captured in drill core, because these materials would enter the biosphere and have the potential for exposing members of the drilling crew and the public.

Response. The Commission supports and is implementing the approach for evaluation of human intrusion as specified in EPA's final standards. The Commission proposed at part 63 a stylized calculation that prescribed the timing of the intrusion (*i.e.,* 100 years after permanent closure), the repository barriers affected by the intrusion (*i.e.,* unsaturated zone and the waste package), and the relevant exposure pathway (*i.e.,* ground-water pathway). The comments received reflect the difficulties presented to EPA and to the Commission in selecting an appropriate approach for evaluating human intrusion. As noted by NAS, selecting an approach for evaluating human intrusion requires consideration of unknowns (*i.e.,* how and when intrusion into the repository will occur), ability to estimate the effect of a postulated intrusion into the repository, and policy considerations for setting an appropriate standard. In the proposed rule, the Commission specified a ''stylized'' calculation to test resilience of the repository and preclude

speculation on the form of the intrusion and when it may occur. However, the Commission also believes it is necessary to provide flexibility to DOE to support an alternative calculation such as the approach provided in EPA's final standards. The final EPA standards provide DOE the flexibility to identify the time of the intrusion as the earliest time that human intrusion into the waste package could occur without recognition by the drillers. The Commission has implemented this approach in the final regulations.

Responses to specific comments on the timing and frequency of the intrusion, details of the intrusion scenario regarding effects on the contents of the waste package, and exposure pathways for the intrusion are provided below:

Timing and Frequency of Intrusion

DOE commented that the proposed calculation was unrealistic because it is unlikely that a borehole would intersect a waste package because the cross-sectional area of the waste packages is small relative to the overall area of the repository footprint. DOE also noted that, at 100 years, it is unlikely the waste package could be penetrated, using current drilling techniques, without recognition by the drillers (DOE does not expect the waste packages to degrade significantly during the 10,000-year regulatory period). The final regulation, which implements the approach contained in the EPA standard, provides DOE with the flexibility to determine and to justify (subject to NRC review) its selection of the time of the intrusion event based on the condition of the waste package.

Another related issue is whether the stylized calculation should consider multiple intrusions. The final EPA standards resolve this issue in favor of a single intrusion. Moreover, in its findings and recommendations, NAS argued against analyses of whether and how often exploratory drilling would occur at Yucca Mountain because of the complexities associated in such assessments. Simply stated, the NAS felt that no one can accurately predict the characteristics of future human society and their technology. In the context of human intrusion, estimating the probability of exploratory drilling for a given resource relies on an ability to predict certain economic and technical factors that influence supply of, and demand for, that resource. In fact, NAS noted that the continued advances in noninvasive geophysical techniques may, in fact, reduce the number and frequency of exploratory boreholes. However, some evaluations of the resource potential of the site suggest that Yucca Mountain (and the area immediately around it) does not represent an attractive candidate for either random or systematic exploratory drilling at this time ((1) Raines, G.L., *et al.* (eds.), ''Geology and Ore Deposits of the Great Basin,'' Geological Society of Nevada/U.S. Geological Survey, Symposium Proceedings, April 1–5, 1990, Reno/Sparks, Nevada, 2 vols., 1991; (2) Schalla, R.A., and E.H. Johnson (eds.), Oil Fields of the Great Basin, Reno, Nevada, Geological Society of Nevada, 1994; (3) Sherlock, M.G., D.P. Cox, and D.F. Huber, ''Known Mineral Deposits and Occurrences in Nevada (Chapter 2),'' in D.A. Singer (ed.), ''An Analysis of Nevada's Metal-Bearing Mineral Resources,'' Reno, Nevada, Nevada Bureau of Mines and Geology, Open File Report 96–2, 1996; and (4) Singer, D.A. (ed.), ''An Analysis of Nevada's Metal-Bearing Mineral Resources,'' Reno, Nevada, Nevada Bureau of Mines and Geology, Open File Report 96–2, 1996; and (5) U.S. Department of Energy, ''Site Characterization Plan, Yucca Mountain Site, Nevada Research and Development Area, Nevada,'' Office of Civilian Radioactive Waste Management, Nevada, DOE/RW–0199, 9 vols., December 1988, pp. 1–256–1–313). Consequently, any consideration for the drilling of multiple exploratory boreholes or later drilling of more boreholes further increases the speculative nature of the intrusion scenario with potentially little increase in understanding repository resilience.

The EPA standards provide for consideration of a single borehole at the earliest time that human intrusion into the waste package can occur without recognition by the drillers. The Commission believes this is an appropriate test for evaluating repository resilience. Moreover, the suggested alternative to evaluate multiple intrusions for the human intrusion calculation fails to reflect the purpose of the human intrusion calculation, that is to test the resilience of the repository, not to evaluate the speculative issue of frequency of the intrusion.

Intrusion Scenario

The public comments on part 63 point out the need to clarify certain aspects of the prescribed human intrusion event at proposed § 63.113(d) with respect to the effects of human intrusion on the contents of the waste package. Consistent with current drilling practices, it can be reasonably assumed that material inside the waste package that is intercepted by the borehole would be taken to the surface. Proposed part 63 stated the borehole ''extends to the saturated zone, and is not adequately sealed.'' Some commenters suggested that particulate HLW inside the waste package would be free to fall to the saturated zone inside the inadequately sealed borehole. The Commission did not intend to imply that, contrary to current drilling practices, an inadequately sealed borehole would allow particulate waste to fall directly to the saturated zone. However, an inadequately sealed borehole would likely allow water to readily enter the waste package; release of radionuclides from the waste package by and in water, and transport of these radionuclides to the saturated zone by way of the borehole rather than through geologic units that could potentially retard the transport of radionuclides. NRC has clarified this point at § 63.322(e) and (f) in the final rule.

Exposure Pathways

Human intrusion has the potential for releasing particulate HLW to the surface with drill cuttings or providing a fast pathway for radionuclides to be transported to the saturated zone by water (*e.g.,* water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone). NAS concluded, and the Commission agrees, that analysis of the risk to the public or the intruders (*i.e.,* drilling crew) from radioactive drill cuttings left unattended at the surface for subsequent dispersal into the biosphere would not fulfill the purpose of the human intrusion calculation because it would not show how well a particular repository site and design would protect the public at large. Rather, an analysis of the hazard of particulate HLW left on the surface would be dominated by assumptions subject to significant speculation and uncertainty regardless of the particular site or design under evaluation. Additionally, the release to the surface represents a one-time release with no long-term effect on the repository barriers. Alternatively, releases to the ground-water pathway can be adversely influenced over a long period of time by an intrusion event that affects barriers of the repository (see the discussion on barriers). Therefore, an appropriate test of the resilience of the repository is an evaluation of the effects of intrusion on releases in the ground-water pathway.

Issue 2: Is a quantitative comparison between the individual dose limit and the results of the stylized human intrusion calculation appropriate for evaluating the impact of human intrusion?

Comment. Commenters questioned the value of comparing the results of what is essentially a deterministic ''bounding'' calculation for human intrusion with that of the probabilistic (risk) analysis of overall repository performance. Because risk is a function of both probability and consequence, evaluation of human intrusion, without accounting for the probability of the event taking place, must also apply judgment as to what constitutes an acceptable consequence. NEI suggested that selection of an acceptable consequence limit should be guided by the same logic that was used in establishing the proposed preclosure licensing requirements for DBEs found at § 63.111. This logic sets higher dose limits for those events that are unlikely to occur (*i.e.,* Category 2 DBEs) compared with the dose limit for those events expected to occur (*i.e.,* normal operations or Category 1 DBEs).

DOE suggested that the use of a highly speculative human intrusion scenario to evaluate the robustness of the repository is inappropriate and makes a poor criterion for potentially disqualifying the Yucca Mountain site. In particular, DOE noted that designing a repository to meet a restrictive human intrusion performance criterion may lead to suboptimization of the overall repository design. Therefore, DOE recommended that the results of the intrusion calculation be used as a qualitative indicator of repository ''resilience.''

Response. The objective of the human intrusion assessment is to inform any Commission decision regarding the need for DOE to reduce uncertainties in its estimates of performance or to provide more measures to mitigate consequences and protect public health and safety. As discussed in the previous response, the Commission is implementing the approach for evaluation of human intrusion as specified in EPA's final standards. This approach provides DOE flexibility in determining the timing of intrusion and sets an annual individual dose limit of 0.15 mSv/yr (15 mrem/yr).

3.11 Postclosure Aspects of Repository Design

Issue 1: Should the NRC limit the thermal energy output per unit area of the repository?

Comment. High-level waste (principally spent nuclear fuel) will continue to produce thermal energy following its disposal in a geologic repository. Host rock temperatures would be affected by the burn-up history of the waste, its age, and the density of waste package canisters within the repository. The resulting thermal load may result in a thermal-mechanical-hydrologic-chemical (T–M–H–C) response in the host rock and surrounding geologic setting, and thus may have a deleterious effect on repository performance. Given this concern, some commenters noted the proposed rule did not adequately account for the thermal output of the waste. In particular, some commenters suggested that the regulations should place a limit on the thermal output that would better ensure safe operation and long-term stability of the repository. One commenter even suggested that the waste be allowed to cool for 100 years prior to emplacement as a means of addressing this potential design issue.

Response. The Commission believes that it is inappropriate to specify a limit on the thermal energy output per unit area of the repository in the rule. This proposed regulation is performance-based and allows DOE wide latitude in how it designs any potential Yucca Mountain repository by requiring DOE to take into account likely site conditions, processes, and events expected during the time period of regulatory concern. Consequently, as a result of site characterization, DOE can be expected to come to some conclusion regarding the significance of T–M–H–C coupling to repository performance and account for it in both its preclosure design as well as in its postclosure performance assessment. The Commission recognizes that DOE is evaluating different thermal loading regimes in the context of its Supplemental Draft EIS. For its part, the Commission believes that it is inappropriate to specify a limit on the thermal energy output per unit area in advance of DOE's scientific decision making about the role and significance of T–M–H–C coupling at the Yucca Mountain site.

Issue 2: The repository design should be as robust as reasonably achievable.

Comment. A commenter suggested that although the ALARA principle should not be used in calculating doses, it should be used to design critical repository structures, systems, and components. By incorporating ALARA into the rule, the commenter proposed that the performance of certain design features, particularly barriers, would be optimized and made as robust as reasonably achievable.

Another commenter suggested that NRC should require that engineered barriers be designed to account for an oxidizing environment. The commenter stated that a ceramic waste package may function more effectively than a metal waste package in an oxidizing environment. One commenter was concerned that exceeding the Nelson limits could result in catastrophic failure of the waste package.

Finally, a commenter suggested that a repository with a natural-ventilation system may be safer and more sound. The commenter suggested that this design approach may be safer than complete closure of the repository.

Response. The Commission considers that part 63, as written, will ensure an adequate design and has not revised the proposed rule on this matter.

With regard to the public comment on the use of ALARA, in its 1995 findings and recommendations, NAS noted that there is no scientific basis for incorporating the ALARA principle into NRC's postclosure requirements. In summary, its reasoning was that deep geologic disposal, by its very nature, was ALARA, and there were few technological alternatives in repository design. They also noted that it would be problematic to evaluate compliance with the application of ALARA principles in the postclosure phase of the repository. The Commission agrees with NAS in this regard.

With regard to the comment concerning the potential oxidizing waste package environment, the Commission is aware of this concern and notes that, as the repository developer, the responsibility for designing an adequate engineered barrier system rests with DOE. As part of its responsibilities, DOE is required by the regulations to take into account applicable engineering limits, as well as likely site conditions, processes, and events, including those driven by thermal loads, when designing the waste package. As a result of its investigations, DOE is expected to reach some conclusion regarding the significance of the thermal pulse and its coupled effects on waste package lifetime. Thus, because DOE has some flexibility in how to design the repository and how it will allocate performance among the various natural and engineered barriers, DOE will have some flexibility in the choice of materials used to fabricate the waste package.

Lastly, with respect to the issue of repository ventilation, inasmuch as proposed part 63 is nonprescriptive, DOE has the responsibility to determine how to best design the geologic repository so that it complies with performance objectives. As noted above, DOE will be required by the regulations to take into account likely site conditions, processes, and events expected, including those driven by a thermal pulse. As a result of its

investigations, DOE would come to some conclusion regarding the significance of the thermal pulse to repository performance and account for such significance in both its preclosure design as well as in its postclosure performance assessment. For its part, the Commission will independently review this information in any potential license application, including the significance of thermal loading on the repository and how it has been accounted for in its design and in the context of overall performance of the repository, to ensure that the performance objectives are met.

Issue 3: Will NRC have sufficient information to evaluate DOE's repository design?

Comment. One commenter expressed the view that the amount of information being requested at § 63.21(c)(4)(i) in the proposed rule [moved to § 63.21(c)(3)(ii) in the final rule], the description and discussion of the engineered barrier system, is insufficient and inadequate for the NRC staff's requisite review. It was recommended that this section of the rule be expanded to include the requirements that DOE include detailed design drawings, including specifications and flow sheets for all manufacturing processes, etc., as part of any potential license application. One commenter asked whether the NRC will have access to classified information from other governmental agencies.

Response. The Commission believes that part 63 requires DOE to submit sufficient information to allow NRC to perform the necessary review but has revised the proposed rule to specify the level of detail required.

The rule requires that the general information of the license application shall include ''* * * a description and discussion of the engineered barrier system. * * *'' The types of information to be included in that ''description and discussion'' are currently being identified by the NRC staff as part of the development of the NRC's YMRP. Consistent with the rule, this review plan will identify the expected content of any potential license application. The guidance ensures that any potential license application submitted by DOE contains the information necessary for docketing and review by the NRC staff. However, to better assure that the information submitted by DOE is consistent with the level of detail being sought for the GROA design description for preclosure, the proposed rule has been revised to require that the design description include dimensions, material properties, specifications, and analytical and design methods used, along with any applicable codes and standards.

With regard to the comment on NRC access to classified information, all information (including classified information) used by DOE to support its license application is subject to NRC review. The Commission is capable of receiving, handling, and storing classified information.

4 General Requirements

4.1 Quality Assurance

Issue 1: Would the NRC rule weaken or undo the requirement that DOE systematically record its decisions that significantly concern safety, how those decisions were made, and what factors influenced them?

Comment. A number of comments expressed a concern that the NRC rule would weaken or undo the requirement that DOE systematically record its decisions that significantly concern safety, how those decisions were made, and what factors influenced them. The commenters further stated that systematic accountability on scientific and engineering decisions related to safety must be upheld.

Response. The regulations, while risk-informed and performance-based, contain provisions that require DOE to monitor and report on the types of potential concerns raised in this comment. These include reports on site characterization activities (§ 63.16); construction records (§ 63.72); potential site, design, and construction deficiencies (§ 63.73); the implementation of a program of continuing performance confirmation (§§ 63.131–63.134); and the application of a rigorous QA program to site characterization, design, construction, and operations (§§ 63.141–63.144).

Issue 2: Should the quality assurance program requirements contained in part 60 remain intact for part 63?

Comment. A number of comments identified a need for the QA requirements contained in part 60 to be applicable for part 63.

Response. The QA requirements initially proposed in Subpart G, ''Quality Assurance,'' to part 63 required that the licensee implement a QA program that meets the applicable requirements of Appendix B (''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants'') to part 50. However, rather than referencing Appendix B to 10 CFR part 50, as was done in the proposed rule, the final rule has incorporated quality assurance requirements from Appendix B that are specifically applicable to a geologic repository. Further, additional requirements are added in a new § 63.144 to address the controls that a licensee will have to meet for changing an NRC-approved QA program description.

Issue 3: Should there be requirements for qualification of data that existed prior to the implementation of QA programs?

Comment. One commenter expressed a concern that there are no requirements in the proposed rule to provide for the qualification of data that existed prior to the implementation of the QA program used by DOE.

Response. The Commission believes that the controls in §§ 63.141, 63.142, 63.143, and 63.144 are adequate. Based on these requirements, data related to structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto are subject to the applicable requirements of Appendix B to 10 CFR part 50 as incorporated into 10 CFR part 63. These provisions require DOE to evaluate data required to support its license application. If data related to structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto have not been collected in accordance with a QA program that meets these requirements, DOE would be required to show that such data have been qualified for its intended use.

The NRC recognized that some data supporting a license application for a high-level waste repository may not have been initially collected under a part 60, subpart G, QA program. In February 1987, the NRC published NUREG–1298, ''Qualification of Existing Data for High-Level Nuclear Waste Repositories.'' NUREG–1298 provides guidance on the use and qualification of data not initially collected under a Subpart G QA program.

Issue 4: Should the NRC conduct an inspection to verify proper execution of QA programs? What additional steps will the NRC take to ensure that problems which occurred during site characterization will not occur after a license is granted (will there be requirements for NRC inspections)?

Comment. Commenters suggested that the regulations should include a requirement for NRC to conduct inspections to verify proper execution of the DOE QA program and that there should not be a strict reliance upon DOE to implement the program properly. Commenters also expressed a concern that the problems occurring during site characterization would continue after NRC granted a license to DOE. The

question was asked, ''What additional steps will the NRC take to ensure that these same problems do not occur after a license is granted?'

Response. DOE is presently undertaking a comprehensive program that includes the proper steps to correct its QA program deficiencies, although some implementation issues remain to be resolved. Section 63.75, ''Inspection,'' requires, in part, that DOE allow the NRC to inspect the premises of the GROA at the Yucca Mountain site and adjacent areas to which DOE has right of access. Further, § 63.75 requires that DOE afford any NRC resident inspector assigned to the Yucca Mountain site or other NRC inspectors assigned to inspect the Yucca Mountain facility immediate unfettered access, equivalent to access provided regular employees, after proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety. If NRC were to issue a license to DOE, NRC would periodically perform inspections of selected DOE activities at the Yucca Mountain site, at DOE support facilities, and at DOE subcontractor facilities to ensure that DOE's QA program is being effectively implemented. The number and depth of the inspections would be based on: the risk significance of the structures, systems, or components; activities related to these structures, systems or components; and DOE's past performance.

Issue 5: Should the NRC require the use of Part 2.7 of NQA–1 or a similar standard for software QA?

Comment. A comment stated that it was proper to use Appendix B for QA requirements applicable for part 63. However, the commenter noted that Appendix B is weak regarding computer QA software and that the NRC should use Part 2.7 of NQA–1 or a similar standard for software QA.

Response. The proposed rule has been revised to emphasize that the QA program description needs to include how the requirements of Appendix B will be satisfied. In the final rule, § 63.143, ''Implementation,'' states: ''DOE shall implement a quality assurance program based on the criteria required by § 63.142.'' As discussed in § 63.142, DOE's QA program would be applicable to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. Further, these activities include site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Sections 63.142 and 63.21(c)(17) (§ 63.21(c)(11) in the proposed rule) have been changed to specifically require that the DOE QA program describe how the QA criteria contained in § 63.142 will be satisfied.

Presently, the DOE QA program for the Yucca Mountain site characterization (DOE Document No. DOE/RW–033P, Revision 8, dated June 5, 1998) includes a discussion of how the applicable requirements of Appendix B will be satisfied. Supplement 1, ''Software,'' to DOE/RW–033P describes the QA controls for software and addresses controls such as: (1) Software life cycles, baselines, and controls; (2) software verification and validation; (3) software configuration management; (4) defect reporting and resolution; (5) control of the use of software; and (6) software documentation. The software controls described in DOE's QA program were reviewed by the NRC and found acceptable. Although § 63.142 in the final rule does not specifically address software QA, it does require that the QA controls be applied to certain design and analysis activities. By inference, software used for such activities would be subjected to the applicable requirements of § 63.142. The NRC will provide, as necessary, additional guidance for software QA in the YMRP that may include elements similar to those in existing standards such as Part 2.7 of NQA–1. The level of detail for software QA in Part 2.7 of NQA–1 is considered inappropriate for inclusion in the rule.

Also, as a result of this and other comments, the final rule does not reference Appendix B, but incorporates Appendix B, with appropriate modifications, to address its applicability to the high-level waste repository.

Issue 6: The applicability of the QA program is not clear. What does safety include?

Comment. One comment identified a concern that the applicability of the QA program was unclear and that he believed the QA program was applicable to all items and activities important to the isolation of radioactive waste at Yucca Mountain and suggested adding text to Part 63 to better define the applicability of the QA program.

Response. The QA program applies to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. These activities include site characterization, acquisition and analysis of samples and data, scientific studies, performance of tests and experiments, controlling geological and engineering materials samples, facility design and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. These terms are defined in § 63.2.

Based on this discussion, the NRC considers the applicability of the QA program to be adequately described in subpart G to part 63. Because proposed part 63 referred to Appendix B for QA requirements and Appendix B does not use the terms important to safety and important to waste isolation, requirements from Appendix B have been incorporated into final part 63 and modified accordingly to address their applicability to the high-level waste repository.

Issue 7: Should Part 63 contain QA program change controls similar to those found in § 50.54(a), and should the proposed § 63.44 change control process be applicable for QA program changes?

Comment. DOE identified a problem with proposed part 63 requirements for controlling changes to the QA program and recommended that requirements similar to those contained in § 50.54(a) be used. DOE correctly pointed out that the NRC stated, in the discussion accompanying the final rule for Part 50 concerning changes to QA programs (64 FR 9030; February 23, 1999), that ''use of 10 CFR 50.59 criteria for QA program changes is not appropriate.'' DOE pointed out that, as written, proposed part 63 would permit QA program changes to be controlled in accordance with requirements similar to § 50.59 (as permitted by § 63.44). DOE suggested text changes to implement its comments. DOE also expressed a concern that as proposed, the location of § 63.21(c)(11) would cause the QA program description contained in the Safety Analysis Report to be subject to the change controls required by § 63.44.

Response. The Commission agrees that the use of the criteria specified at § 63.44 is not appropriate for changes to the QA program description included in the Safety Analysis Report. We also agree that the rule should identify change control requirements applicable to the licensee's QA Program and that those requirements should be similar to those contained in § 50.54(a)(3). The proposed rule has been revised to specifically address change control requirements for QA program descriptions.

We disagree that § 63.21(c)(11) should be relocated to § 63.21(b) because the QA program description is required to

specifically describe how the requirements of § 63.142 will be satisfied. By adding specific requirements in §§ 63.44 and 63.144 for the control of changes to the QA program description, the Commission believes it has resolved the expressed concern for relocating § 63.21(c)(11).

Note: The text at § 63.21(c)(11) in the proposed rule is specified at § 63.21(c)(17) in the final rule due to reordering of § 63.21 to achieve a more consistent order with the required analyses.

Issue 8: How will NRC ensure DOE properly implements its QA program and assures the quality of data it will use to support a license application?

Comment. A number of comments related to what actions the NRC would take to ensure that DOE is properly implementing its QA program and qualifying data.

Response. In early 1999, the NRC staff established a QA Task Force to review and evaluate the DOE QA program. The Task Force was created to address acknowledged concerns regarding the effective implementation of the DOE QA program. This task force includes a Senior QA Engineer, the NRC Onsite Representatives, and the CNWRA QA Director, under the direction of the Division of Waste Management (DWM) Division Director. The Task Force has been active in reviewing DOE's progress and issues.

With respect to data qualification, DOE has initiated corrective actions for the data qualification problems documented in 1998 and 1999. In September 1999, DOE committed to have 100 percent of all data fully qualified by the time of license application, should DOE submit a license application. DOE has made significant progress in confirming the adequacy of data collected before June 1999. In January 2001, DOE had qualified 80 percent of these data. As of June 13, 2001, DOE had qualified 86 percent of the data supporting the potential license application. Further, during the June 13, 2001 NRC/DOE Quarterly QA Breakout Session Meeting, DOE reported that its goal was to have all data fully qualified by site recommendation.

In late spring of this year, NRC and DOE identified further QA problems, this time affecting the processes controlling software verification and model validation. DOE acknowledged a need to revise and enhance some of its procedures, such as those controlling software development and model validation, and to provide needed training to its personnel. Further, DOE is evaluating traceability and transparency problems in its technical reports. The QA staff of DOE and their contractors have been successful in identifying the QA program deficiencies in the various participants' programs and, in many cases, highlighting the repetition of similar deficiencies. In the past, inadequate corrective action was taken, and the DOE organizations responsible for correcting the deficiencies were not held accountable. NRC has impressed upon DOE that correction of the QA program deficiencies is essential to any potential licensing of the Yucca Mountain repository and we are taking steps to ensure that NRC is able to evaluate the effectiveness of DOE action to correct the problem.

During fiscal year 2000 and through June 2001, the NRC staff evaluated the implementation of DOE's QA program by: (1) Continuing observation of DOE performance-based audits; (2) daily overviews by NRC Onsite Representatives assigned to the Yucca Mountain Project office in Las Vegas, Nevada; (3) enhanced participation of NRC's technical staff in activities at the various DOE facilities; and (4) interfacing with DOE during technical exchanges and management meetings. Through these activities, we are encouraged that many of the deficiencies are being corrected by DOE. Further, we have observed that DOE is continuing to adequately identify, process, and correct new problems. NRC believes its aggressive overview activities provide the ability to adequately evaluate whether the DOE QA program will continue to be effectively implemented.

4.2 Changes, Tests, and Experiments

Issue 1: Should the Commission adopt alternative criteria for changes, tests, and experiments?

Comments. Commenters who addressed the change process issue were generally supportive of applying alternative criteria, noting that the alternative criteria offered at § 63.44 were useful in clarifying the issues involved in evaluating the effects of changes, tests, and experiments on license conditions. Nonetheless, several commenters noted that the alternative criteria retained some terms that are ambiguous and that could be interpreted subjectively, and recommended that these terms be avoided or defined in the final rule.

Response. For nuclear reactors, ISFSIs, and holders of a certificate of compliance for a spent fuel storage cask, the Commission recently amended its regulations concerning the authority of these licensees and certificate holders to make changes to the facility or operating procedures, or to conduct tests or experiments, without prior NRC approval (64 FR 53582; October 4, 1999). The final rule clarified the specific types of changes, tests, and experiments conducted at a licensed facility and revised the criteria that must be used to determine when NRC approval is needed before such changes, tests, or experiments are made. The final rule also added certain definitions for terms that have been subject to differing interpretations. Requirements comparable to those recently amended were proposed at § 63.44 for a geologic repository at Yucca Mountain. In the Supplementary Information accompanying the proposed criteria, the Commission expressed its desire to establish a uniform policy approach for addressing the change process issue. To that end, the Commission sought comment on the suitability, for a repository at Yucca Mountain, of an approach substantially equivalent to that proposed for nuclear reactors and ISFSIs (63 FR 56098; October 21, 1998). Having taken into account the comments received on this approach for other NRC-licensed facilities and as applied to a potential repository at Yucca Mountain, the Commission is adopting final criteria for § 63.44 that are comparable, but not identical, to those recently applied to reactors and spent fuel storage facilities. Departures from the criteria applied to reactors and spent fuel storage facilities were made to reflect differences between the repository and such facilities (*e.g.,* replacement of ''facility or cask design'' with ''geologic repository operations area and design,'' and of ''importance to safety'' to ''importance to safety and important to waste isolation''). Other departures were necessary to reflect different administrative requirements of part 63 (*e.g.,* requirement that the Safety Analysis Report be updated rather than replaced with a Final Safety Analysis Report). Less obvious changes were needed to reflect the risk-informed, performance-based nature of the part 63 criteria, and the fact that part 63 contains fewer prescriptive requirements (*e.g.,* design basis limits).

Issue 2: Should the proposed, or alternate, requirements for changes, tests, and experiments at § 63.44 apply to the contents of the entire license application?

Comment. Some commenters felt that the requirements at § 63.44 should apply to the contents of the entire license application to ensure that the license application is maintained as a current reference document for describing activities at the geologic repository. Not all commenters agreed,

however, as some asserted that the proposed requirements should not apply to certain types of information that were unlikely to change (*e.g.*, General Information) or that which is already subject to control under separate NRC requirements incorporated by reference in part 63 (*e.g.*, parts 72, 73, and 74).

Response. The Commission intends to apply these criteria to the contents of the Safety Analysis Report (as updated). As the Commission noted in the Supplementary Information provided with the proposed regulations, the purpose of the criteria for changes, tests, and experiments is to ensure that the level of safety documented in the original licensing basis (*i.e.*, the Safety Analysis Report) is not eroded by subsequent modifications to the facility or operating procedures. Changes to other portions of the license application, provided under § 63.21(b), that have the potential to affect safety, *i.e.* the physical protection plan, the safeguards contingency plan, the security organization personnel training and qualification plan, along with the material control and accounting plan, are already subject to update and change control requirements elsewhere in NRC regulation (at parts 72, 73, and 74). Furthermore, as discussed earlier (under Quality Assurance), the Commission is adding additional requirements so that changes to DOE's QA program will be subject to explicit requirements at § 63.144.

Issue 3: Should specific modifications be made to the rule to exclude from reconsideration issues that have no bearing on public health and safety and to constrain NRC backfitting of the repository design after construction is authorized or imposition of additional tests under § 63.74?

Comment. One commenter recommended that once an issue is considered resolved for the purposes of the issuance of a license to commence with waste emplacement operations, license to amend for permanent closure, or license termination, it should not be subject to reevaluation by the Commission (and the ASLB) unless it can be demonstrated that the issue has a bearing on public health and safety, common defense and security, or the environment. To implement this proposal, alternative regulatory language was recommended to §§ 63.41, 63.51, and 63.52.

Consistent with other NRC regulations, the Commission should include provisions for backfitting of the repository design as well as any additional tests required under § 63.74. Specific regulatory language was recommended, and it was suggested that these new additional requirements would apply only following the issuance of a construction authorization. The commenter asserted that backfits should only be allowed under two conditions: (1) Where there would be a substantial increase in public health and safety; and (2) where the direct and indirect costs of the backfit are justified in view of this increased protection. In proposing backfits, the commenter recommended that the Commission first perform analyses that are systematic and documented.

DOE commented that regulatory changes may be needed to ensure that issues closed at the construction authorization stage would not be reopened at the receipt and possession stage absent significant new safety related information. DOE felt that such a change would allow NRC and DOE to keep their focus on the unresolved issues important to public health and safety. DOE understands that this change would need to be addressed in a subsequent rulemaking on the licensing process.

Response. The Commission agrees that the focus of a risk-informed, performance-based regulatory approach should be on those issues bearing on public health and safety, common defense and security, and protection of the environment. Clearly, the recently-adopted, generic approach (adapted in this rule for the repository) for defining a threshold of safety significance for changes, tests, and experiments, illustrates NRC's desire to confine its regulatory attention and resources to issues bearing on its regulatory responsibilities. That being said, however, the issue of imposing backfitting constraints on the Commission itself, as it proceeds to evaluate the license application for a proposed repository at Yucca Mountain, was not evaluated in developing the proposed part 63 criteria, and is therefore beyond the scope of this rulemaking.

Issue 4: How will DOE document its decision making as new information is obtained for the site?

Comment. No specifics are given regarding how the rule could be modified to address this concern. However, commenters suggested that in light of a proposed regulation that is performance-based, there is the potential for DOE's decision making related to safety issues to become less than transparent. The view expressed in this comment is that there needs to be transparency in safety-related decision making in order to have accountability for engineering and scientific decisions.

Response. The Commission agrees with the comment with regard to the importance of transparency and accountability of all safety significant decisions made in developing and licensing a geologic repository. It is for this very reason that part 63 includes extensive provisions for documenting new information and updating the SAR, in order to ensure that the technical bases for the Commission's licensing decisions are not eroded (§§ 63.22, 63.24, 63.32, 63.44, 63.46, and 63.51). In addition, part 63 also provides for the implementation of performance confirmation and quality assurance programs (subparts F and G), that help ensure the soundness of the data, assumptions, and modeling upon which DOE bases its safety case, and upon which the Commission bases its licensing judgments.

4.3 Land Ownership and Control

Issue 1: Must the U. S. Department of Energy (DOE) establish its ownership, title, or control of the Yucca Mountain site?

Comment. A number of commenters stated that under the Treaty of Ruby Valley of 1863, the Western Shoshone Nation never ceded the Yucca Mountain site to the United States and that title to the land therefore remains with the Western Shoshone Nation. These commenters further argue that all activities conducted by the United States at the Yucca Mountain site that are not within the specific privileges granted the United States under the Treaty of Ruby Valley constitute an illegal occupation of Western Shoshone territory and a violation of Western Shoshone sovereignty.

Response. The NRC is aware that the Western Shoshone National Council disputes the claim of the United States to have legal title to land that includes the Yucca Mountain site. However, there are Federal court decisions which have addressed these land claim issues and which are binding on both DOE and NRC. Section 63.121 requires that, before NRC licensing of a waste repository at the Yucca Mountain site, DOE must establish that the GROA and the site are located in and on land that is either acquired land under the jurisdiction and control of DOE or lands permanently withdrawn and reserved for DOE's use.

Issue 2: Does siting a waste repository at Yucca Mountain unfairly impose undue risks on the Western Shoshone People or adversely affect their culture?

Comment. Commenters believed that the Western Shoshone People were being unfairly asked to accept the risks of a waste repository while the benefits

went to the waste generators. One commenter believed that the Western Shoshone culture was being transformed from one of protecting the environment to one of being a steward of HLW.

Response. The Nuclear Waste Policy Amendments Act of 1987 (NWPAA), authorizes only Yucca Mountain, Nevada, as a location to be characterized as a potential repository site. Part 63 does not site the repository at Yucca Mountain. Rather, it provides criteria and regulations to provide reasonable assurance that public health and safety will be protected if a repository is constructed at this site. DOE and the President of the United States are responsible for making a site recommendation. If the Yucca Mountain site is recommended and Congress allows the recommendation to take effect, DOE is to file a license application accompanied by an EIS. To the extent practicable, the NRC will adopt DOE's EIS in accordance with the NWPA. In its licensing proceeding, the NRC will consider the costs and benefits of authorizing construction of a repository.

Issue 3: Should proposed § 63.121 be revised to require that DOE conform to State water law and to acknowledge the responsibilities of the Federal Government for compensation when initiating takings?

Comment. Commenters were concerned about whether DOE must conform to State water law to obtain water rights (one commenter indicated DOE is required, under State water law, to show beneficial use in order to obtain water). A commenter viewed § 63.121 as giving DOE the right to take water rights in order to achieve waste isolation and stated that the rule must acknowledge the responsibilities of the Federal Government for compensation when initiating takings.

Response. Section 63.121(c)(1) requires DOE to obtain such water rights as may be needed to accomplish the purpose of the GROA. The ''purpose of the geologic repository operations area'' is intended to be construed broadly to include the isolation of radioactive wastes after permanent closure as well as any water rights needed during the period of operations. Whether DOE is subject to State law in obtaining any water rights that may be needed for this purpose is a matter to be determined by DOE and the State. The NRC does not have the authority to require that DOE conform to State law.

Comment. One commenter suggested that § 63.121(b) directly state that additional controls include water rights, instead of specifying in § 63.121(c)(2) that water rights are included in the additional controls to be established under § 63.121(b).

Response. The Commission prefers to retain the present format for clarity because water rights would be dealt with explicitly in one paragraph of § 63.121. ''Controls'' referred to in § 63.121(b) would, of course, include water rights.

Comment. One commenter viewed § 63.121 as giving DOE the right to take water rights in order to achieve waste isolation and stated that the rule must acknowledge the responsibilities of the Federal Government for compensation when initiating takings. This commenter was also concerned that the rule permits the spread of radionuclides to areas far outside the boundaries of the repository and believes that the repository should be designed so that it is not necessary to take water rights to achieve waste isolation. Another commenter believed that this regulation would allow Yucca Mountain to operate as a delayed radioactive waste release facility and not a permanent disposal site.

Response. Section 63.121 does not give DOE the right to take water rights; rather, it requires DOE to have obtained any water rights needed to achieve waste isolation. DOE will need to comply with whatever laws apply with respect to obtaining any needed water rights. The purpose of the regulation is to make sure that DOE is in a position to establish appropriate controls outside of the site necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve waste isolation. The NRC will not license the facility unless there is reasonable expectation that releases of radioactivity will remain within regulatory limits.

Issue 4: Do requirements for land ownership and control of the site apply equally to repository operations (preclosure) and long-term safety (postclosure) activities?

Comment. DOE commented that requirements for land ownership and control (§ 63.121) are not sufficiently clear regarding their applicability to preclosure and postclosure activities. The lack of a clear distinction between preclosure and postclosure activities could imply that DOE must designate the same area for the evaluation of design basis events and for postclosure considerations for preventing adverse human actions. Part 60 provided flexibility in designating areas under preclosure and postclosure activities that should be retained in Part 63.

Response. The Commission agrees with DOE that land ownership and control requirements are not sufficiently clear regarding their application to preclosure and postclosure activities. The requirements have been clarified to indicate that: (1) The GROA shall be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use; (2) DOE has the flexibility to identify and establish additional controls for lands outside the GROA necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation (postclosure); and (3) DOE has the flexibility to identify and establish additional controls for lands outside the GROA to ensure the requirements at § 63.111(a) and (b) are met. These clarifications have been made in revisions to § 63.121 of the final rule.

5 Selected Topics

5.1 Public Out-Reach

Issue 1: What role do the public meetings serve in the rulemaking process?

Comment. Commenters questioned the use of the public meetings and were concerned about how the meeting record would be used in NRC's rulemaking process. Many commenters appreciated the efforts the NRC made to include the public in the promulgation of part 63. Based on listening to NRC staff presentations made at a public meeting, it appeared to some commenters that the objective was to convince the local populations about the safety of the Yucca Mountain Project and that NRC regulations will protect public health. Some commenters requested that sufficient time be given for the public to provide comments. One commenter asked if the dose limits would be lowered if public opinion favored a lower value.

Response. The purpose of the public meetings was to enhance the opportunity for the public to participate in NRC's rulemaking process. The public had an opportunity to question the NRC staff about the proposed rule and its decision making leading to it, as well as having the opportunity to express their views on the rule itself. To facilitate public interactions in this process, additional time was afforded to the public to comment on the proposed rule. Transcripts of the various public meetings were made as a way of accurately recording the public's views. These transcripts were later studied by the NRC staff so that the public's comments could be identified and responded to in this document. The Commission carefully considered the

issues raised by members of the public at the transcribed meetings, as well as the NRC staff's summary of written comments received, as part of its deliberations on the final form and content of part 63.

With regard to whether NRC would consider lowering the dose limits if public opinion favored it, the Commission has given serious consideration to the views of the public on this matter, and, consistent with its obligations under law, has adopted the dose limits published by EPA in its standards for Yucca Mountain.

Issue 2: Will there be more public meetings?

Comment. Commenters stated that it would be helpful for NRC to consider increasing its efforts in the area of public outreach and commit to holding more public meetings in the future. Another commenter suggested that the NRC program focus should be on public health and safety and not on political issues associated with the HLW program.

Response. The Commission agrees with the recommendation to increase its efforts in the area of public outreach. The NRC staff will continue to hold public meetings in Nevada. We continue to seek a better understanding of the views and concerns of the public on how we can best fulfill our independent regulatory responsibility to protect public health and safety.

As far as avoiding political issues associated with the Yucca Mountain site, the Commission notes that it has taken no position on the suitability of Yucca Mountain to host a potential geologic repository. That decision rests with DOE, with the subsequent approval of the President and Congress.

Issue 3: What is the role of NRC's local office in Nevada?

Comment. Some commenters asked if NRC had a local office in Nevada and if there was one, how could the public contact the staff there. One commenter suggested that the role of the local office be expanded to represent NRC in a manner more visible to the public.

Response. The NRC maintains a local onsite representative's office, with a small staff, in Las Vegas, Nevada, as a means of keeping abreast of DOE activities and interacting with other stakeholders. This office allows our onsite representatives physical proximity to the site and the opportunity to interact on various site characterization activities. At this time, the NRC has no plans to expand the size of the onsite representative's office. However, the size of the office, as well as the scope of NRC's activities conducted there, is subject to reexamination. Meanwhile, the public is encouraged to contact our staff at the onsite representative's office at: 1551 Hillshire Drive, Suite A, Las Vegas, Nevada 89137–1048, Telephone 702/794–5046.

Issue 4: Should AULGs and EPA be included in the regulations at part 63, subpart C, §§ 63.61–63.65, providing for participation in certain NRC regulatory activities?

Comment. One local government commenter noted that, under the NWPAA, there is a legal basis for the participation of affected units of local government (AULGs) in activities concerning a potential repository at the Yucca Mountain site and asked why AULGs have not been included in § 63.61 and subsequent sections dealing with participation in regulatory activities. Another local government commenter explicitly requested that AULGs be included in the requirement for provision of ''timely and complete information'' in § 63.61. EPA also requested that it be included in § 63.61(a) given its interest in the proper implementation of the standards.

Response. Section 116(c) of the NWPAA directs DOE to provide funding to AULGs so that they may participate in activities required or authorized under sections 116 and 117 of the NWPAA. Although these activities primarily involve DOE's interactions with the State, affected Indian tribes, and AULGs, the Commission believes that it would not be inconsistent with the intent of the statute to include AULGs at appropriate points in the regulations under part 63, subpart C, and has revised the regulations accordingly. The Commission is not adding EPA to § 63.61(a) because this provision is consistent with section 117(a)(1) of the NWPAA which does not include EPA. However, the information provided under § 63.61(a) is available to EPA.

Issue 5: Should the ''unquestionable legal right to participate as a party'' in a repository licensing hearing afforded to the State of Nevada and any affected Indian Tribe in proposed § 63.63(a) also include affected units of local government (AULGs)?

Comment. A local government commenter stated that AULGs should have the same ''unquestionable legal right to participate as a party'' in a repository licensing hearing as is provided to the State of Nevada and any affected Indian Tribe in proposed § 63.63(a).

Response. The Commission agrees. The hearing procedures in the current 10 CFR part 2, subpart J, have replaced the hearing procedures in 10 CFR part 2, subpart G (except for sections of subpart G specifically referenced in § 2.1000) with respect to a repository licensing proceeding. Under the subpart J rules for intervention in the licensing proceeding, AULGs are permitted to intervene as a matter of right (*see* 54 FR 14938; April 14,1989) in the same way as the State and an affected Indian Tribe. Thus, the Commission, in the final rule, has corrected the reference to ''Subpart G'' in the first sentence of § 63.63(a) to read ''Subpart J'' and has clarified the reference to local governments by changing it to ''affected units of local government.'' The Commission deleted the final sentence because it does not add any right not provided by the first sentence.

The proposed § 63.63(a) states: ''State and local governments and affected Indian Tribes may participate in license reviews as provided in subpart G of part 2 of this chapter. The State of Nevada and any affected Indian Tribe shall have an unquestionable legal right to participate as a party in such proceedings.'' This provision is modeled on, and virtually identical to, § 60.63(a). Section 60.63(a) was incorporated into NRC regulations prior to the Commission's adoption of part 2, subpart J, ''Procedures Applicable to Proceedings for the Issuance of Licenses for the Receipt of High-Level Radioactive Waste at a Geologic Repository'' (subpart J) (54 FR 14925; April 14, 1989). Section 2.1014(c) of subpart J permits intervention of AULGs in a repository licensing proceeding without the need to establish ''party'' status:

> ''Subject to paragraph (a)(3) of this section, the Commission, or the Presiding Officer designated to rule on petitions to intervene and/or requests for hearing shall permit intervention, in any hearing on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area, by an affected unit of local government as defined in section 2(31) of the Nuclear Waste Policy Act of 1982, as amended, 42 U.S. 10101.'' [§ 2.1014(c) (1999)]

See also the definition of ''party'' in § 2.1001 which, as amended in 1998 (63 FR 71729; December 30, 1998), defines a ''party'' to mean the DOE, the NRC staff, the host State, any AULG as defined in section 2 of the NWPA, any affected Indian Tribe as defined in section 2 of the NWPA, and a person admitted under the criteria in § 2.1014. These regulations relieve the State, affected Indian Tribes, and AULGs from the need to meet the standing requirements in order to be admitted as a party in the proceeding. The State, an affected Indian Tribe, and an AULG

must still submit contentions in accordance with the provisions of § 2.1014(a)(2)(ii) and (iii), and at least one contention must satisfy these requirements, or the State, affected Indian Tribe, or AULG shall not be permitted to participate as a party (§ 2.1014(a)(3) (1999)).

All the above is in the context of the existing hearing procedures in part 2. The Commission recently proposed revisions to part 2 (66 FR 19610; April 16, 2001). Even under the proposed revisions, however, a ''party'' in a subpart J proceeding continues to be defined as including the host State, any affected unit of local government and any affected Indian Tribe, provided that these entities file an acceptable contention. Thus, the Commission has not proposed any change to the ability of an affected unit of local government to participate as a party without the need to meet standing requirements.

Issue 6: What is the NRC's current approach to explaining the risks associated with the Yucca Mountain Project?

Comment. A commenter was concerned with how the NRC explains the risks associated with the Yucca Mountain Repository. The commenter stated that NRC bases its explanation of risk-informed regulation on comparison to other types of risks, such as exposure from other types of hazards or background levels of radiation. This commenter suggested that this relative risk explanation is not helpful or persuasive, and that the NRC should design a project that does not result in radioactive exposures. Other commenters complained that many of NRC's public documents, and the proposed rule in particular, are not written in language understandable to the public. For example, one commenter was confused about the intended meaning of ''individuals with unusual habits and sensitivities.''

Response. The Commission has the responsibility to establish disposal criteria that DOE must meet, consistent with the applicable environmental standards promulgated by EPA. As part of this responsibility, the Commission must explain the level of protection its regulations and regulatory programs provide. For its part, DOE, as the repository developer, is obliged to site and design the repository such that DOE can demonstrate, consistent with NRC regulations, that the proposed repository will perform as intended. In reaching any licensing decision, the Commission will need to perform an independent audit of DOE's analyses that show how DOE has complied with the established levels of protection, based on its independent review of DOE's license application and other confirmatory information and activities.

The NRC staff will continue to provide information to explain the risks that would be associated with a repository licensed in accord with its regulations by using a variety of comparisons. The potential health effects arising from any radiation exposure is a very complex subject. To provide a context for NRC's proposed criterion of 0.25 mSv/yr (25 mrem/yr) or EPA's final limit of 0.15 mSv/yr (15 mrem/yr) individual dose limit for Yucca Mountain, NRC staff members frequently draw comparisons with other dose limits applied in NRC's regulation for low-level waste disposal (part 61) as well as with national and international recommendations for radiation standards (see discussion under Individual dose limit). To provide some context for understanding what a radiation exposure at these levels represents, comparisons have been made to the values for more ''routine'' radiation exposures (*e.g.,* dental x-rays, increased radiation exposure from traveling in a plane). These comparisons are used to inform the public, not to persuade them.

With respect to the meaning of the term ''individuals with unusual habits and sensitivities,'' the Commission believes the commenter refers to the findings and recommendations of NAS. Both these recommendations and final EPA standards require that DOE base the characteristics of the representative group for postclosure dose calculations (the community in which the RMEI resides) on lifestyles and dietary habits (*i.e.,* reliance on well water, extent to which food is grown locally, types of foodstuffs eaten) of individuals currently living in the Yucca Mountain region. NAS explained that specification of the representative group should avoid extreme cases defined by unreasonable assumptions regarding the factors affecting dose. NAS also stated that a reasonable and practicable objective is to protect the vast majority of members of the public while also ensuring that the decision on the acceptability of a repository is not prejudiced by the risks imposed on a very small number of individuals with ''unusual habits or sensitivities'' (pp. 51–52, ''Technical Bases for Yucca Mountain Standard,'' National Research Council, 1995). Hence, the terms ''unusual habits'' and ''sensitivities'' were used to exclude unreasonable assumptions about the characteristics of a hypothetical, future population group or RMEI. The NAS did not use these words to imply any judgment with regard to the behaviors or mental state of individuals residing near the site today. The Commission will continue to strive to explain more clearly the risks associated with the potential repository at Yucca Mountain.

Issue 7: In the future, how is the NRC going to effectively communicate the risks of the Yucca Mountain Project to public health and safety?

Comment. One commenter requested one-on-one contact answering calls and letters and following through with questions and sending written responses. Another commenter was concerned that the people of Nevada are not suitably informed about the risks involved with the Yucca Mountain Project. Also, one commenter suggested that a bulletin be published quarterly or as an insert to a local paper about the Yucca Mountain Project. A few commenters were concerned that their fears are considered ''irrational'' regarding the safety of the Yucca Mountain Project and will not be taken seriously.

Commenters suggested that NRC use ''local'' sources (*e.g.,* local government and libraries) to provide information to the public regarding meetings and other information. Information should be written in plain English.

Response. The NRC understands the importance of a strong public outreach program. NRC held five public meetings in Nevada during the public comment period on proposed part 63. Comments made at those meetings were instrumental in NRC deciding to extend the public comment period for the proposed rule. However, these meetings also demonstrated to NRC that it can improve its public outreach efforts. The NRC has held seven additional public information workshops in Nevada since the public comment period closed on part 63. We will continue to meet with the people of Nevada and continue to seek the public's views on how we can carry out our responsibilities in a more effective manner. We also intend to keep the public better informed about our independent regulatory activities and oversight. The NRC will also continue to work on providing displays and fact sheets that use plain English.

The Commission notes also that DOE maintains three visitor centers that are intended to keep the public informed. They are located in Beatty, Pahrump, and Las Vegas. DOE also sponsors regular field trips to the Yucca Mountain site. DOE maintains an Internet web page with information that is regularly updated on activities at the site and developments in the program; it can be found at *http://www.ymp.gov.* With regard to the comments proposing that activities and future events be

published in local newspapers, the NRC staff will forward that recommendation to DOE. As the repository developer, DOE has the responsibility to keep interested members of the public informed about activities at the site as well as about the program. The State of Nevada, Nye County, Clark County, Eureka County, Inyo County, California, and others also maintain web sites with information about the Yucca Mountain program. They are located, respectively, at *http://www.state.nv.us/nucwaste, http://www.nyecounty.com, http://www.co.clark.nv/us/complan/Nucwaste.htm, http://Yuccamountain.org* and *http://sdsc.edu/Inyo/yucca-pg.htm.*

Finally, the Commission notes that the NRC staff has maintained a schedule of meetings with DOE on its Web page (*http://www.nrc.gov/nmss/dwm/hlw/htm*) for several years. Important NRC documents related to the HLW program also are distributed to DOE, the State, Affected Units of Local Government, and other stakeholders. Since November 1, 1999, NRC has made HLW program documents generated and received available on its Public Electronic Reading Room located at *http://www.nrc.gov/NRC/ADAMS/index.html.* Documents generated prior to November 1, 1999, can currently be found at the two designated library reading rooms (in Nevada): James R. Dickinson Library, Government Publications Department, University of Nevada at Las Vegas, 4505 Maryland Parkway, Las Vegas, NV 89154, (702) 895–1572 and Business and Government Information Center, University of Nevada Library, University of Nevada, Reno, Reno, NV 89557–0044, (702) 784–6500 ext. 257.

Issue 8: How do the NRC and DOE, both as government agencies, maintain a proper relationship, respectively, as the regulator and a potential licensee?

Comment. One commenter was concerned that constant care needs to be taken by both NRC and DOE to maintain a relationship that clearly delineates between the regulator and the licensee.

Response. The interactions of the NRC staff and the DOE staff with respect to all activities preparatory to DOE's submission of a license application are governed by the ''Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions,'' which was initially signed in 1983 and was revised in 1998, and by the NRC Staff's Policy Statement on Staff Meetings Open to the Public (65 FR 56964; September 20, 2000). These documents provide that meetings between the two staffs will be open to the public as specified in the Policy Statement and that management commitments will be documented in correspondence subsequent to the interactions. Thus, procedures are in place to ensure an appropriate open relationship between the potential regulator and the potential licensee.

Issue 9: Should different DOE organizations active in Nevada be required to better coordinate their activities and responses to questions from the public?

Comment. One commenter noted that the different DOE organizations operating within Yucca Mountain and the NTS need better coordination because the different organizations sometimes provide different answers to the same questions.

Response. The Commission is sensitive to the concern raised here, but this comment is beyond the scope of this particular rulemaking. This issue falls within DOE's purview as the overall operator of NTS and thus should be directed to it.

The Commission needs reliable information from DOE on its activities at Yucca Mountain in order to perform its independent regulatory role in the HLW program. DOE will be required to provide complete and accurate information for NRC's licensing decision. The Commission believes that the NRC licensing process for the repository will provide an adequate means to test the accuracy and reliability of the information submitted for licensing.

Issue 10: Where will the DOE license application be available for inspection by the public?

Comment. One commenter noted that the proposed rule (§ 63.22) stated that copies of the DOE license application will be made available for inspection by the public at ''appropriate locations'' near Yucca Mountain and inquired as to where these locations would be and how they would be determined.

Response. The determination as to what is an ''appropriate location'' has not been made at this time. In all likelihood, such a determination will be made in consultation with the State of Nevada and AULGs. Moreover, for those individuals who have access to the Internet, any potential DOE license application will also be available electronically for inspection on the NRC and DOE web pages.

Issue 11: Who is responsible for oversight and review of DOE's QA program?

Comment. The Western Shoshone Nation objected to DOE undertaking a QA program without strict oversight and review by the Western Shoshone Nation.

Response. NRC has the statutory responsibility for oversight and review of DOE's QA program for the proposed repository at Yucca Mountain. NRC cannot relinquish this authority to other groups or individuals. However, the Commission is interested in keeping the stakeholders informed of the results of the inspection process, including NRC's inspection of DOE's QA program. The Commission is interested in approaches for keeping the stakeholders informed and is interested in hearing from the stakeholders regarding their ideas for potential approaches.

5.2 Other Comments

Issue 1: Can the NWPA-mandated limit of 70,000 metric ton equivalent of uranium (MTU) for the proposed geologic repository at Yucca Mountain be exceeded?

Comment. Several comments were received in this area. Some commenters raised the possibility of the mass loading at the repository increasing from 70,000 MTU to 105,000 MTU. One commenter is concerned that such an increase may be approved by a Congressional action, without a scientifically-based recharacterization of the site. It appears that this comment was prompted as a result of published interviews with DOE officials quoted in June 1999 (in the Las Vegas Sun) that up to 105,000 MTU of waste may be destined for the repository. The comment concerns the effect of heat on the local geosphere given this alternative (higher) volume of waste.

Similarly, other commenters noted that a DOE report was published, which stated that there would likely be two repositories, and that the amount of waste emplaced in both would be a total of 126,000 metric tons plus 14,000 metric tons of defense waste.

Recognizing the potential need for additional repository disposal capacity, NEI suggested that the reference in § 63.42(d) (Conditions of License), to the NWPAA-mandated limit of 70,000 MTU for the proposed geologic repository at Yucca Mountain, should be deleted, and just refer to NWPA, as amended. This design limit is currently specified in legislation for the HLW program. If the legislation were to change, it would precipitate a need for an additional Yucca Mountain-specific rulemaking. By simply referring to NWPA, as amended, the need for a future rulemaking would be obviated if the legislation ever changes.

Response. The 70,000 MTU limit for the proposed geologic repository at Yucca Mountain is mandated by NWPAA. Specifically, NWPAA provides that no more than 70,000 MTU

can be placed in the first geologic repository. Whether the statutorily-imposed limit should be changed is an issue for Congress and the President to decide. Regardless of the limit, DOE must demonstrate in its license application that the types, kinds, and amounts of HLW to be disposed in any potential geologic repository at Yucca Mountain can be disposed in a way that ensures public health and safety. The Commission does agree that referencing the NWPA, as amended, is more appropriate than NRC providing the specific value of 70,000 MTU. The proposed rule has been revised accordingly.

Issue 2: Should there be specific requirements for postclosure monitoring of ground water?

Comment. Local ground water supplies the domestic and agricultural water needs for area residents and, therefore, needs to be part of a DOE postclosure monitoring program. The most likely exposure scenario to radionuclides released from a potential geologic repository at Yucca Mountain would be in the ground water, down-gradient from the site. Because of this potential hazard, some commenters expressed the view that there is a need for the NRC to require that DOE implement a postclosure ground-water monitoring system. It was noted that such a system would protect citizens living near the repository by providing early warning of the presence of radionuclides in the ground water.

Response. Consistent with the EnPA, § 63.51(a)(3)(iii) requires a program for continued oversight of the repository site after permanent closure. One objective of the oversight program is to ensure that exposure to individual members of the public does not exceed allowable limits. Because the ground-water pathway is the most likely exposure pathway, it is expected that ground water would be monitored.

Issue 3: Would local residents be compensated if radioactive contamination, due to transport of HLW to Yucca Mountain or to leakage from the repository, damages their health or property?

Comment. Several commenters were concerned about whether local residents would be able to obtain compensation if their health should be adversely affected by leaking of radiation from the repository or from casks being transported to the repository. They were also concerned about whether damage to land or ground water due to radioactive contamination or to the lowering of property values would be compensated.

Response. Part 63 does not alter whatever liability the Federal Government may have for damage to health or property caused by its activities. It is possible that compensation could be available for certain types of damage to health or property under Federal law, but it would be speculative to suggest that compensation would be available in any particular case.

Issue 4: Over what time period must physical security be maintained over the site and how would this be maintained?

Comment. Some comments were made regarding how security would be maintained over the site for very long time periods. One commenter asked if the site would be safeguarded against sabotage.

Response. NRC's regulation requires that DOE will have a system of active institutional controls and (passive) site markers, specified at § 63.21(c)(18) (§ 63.21(c)(15) in the proposed rule) and § 63.51(a)(3), that will prevent human intrusion into the repository by ensuring physical security indefinitely following permanent closure of any potential geologic repository at Yucca Mountain. That being said, by its very nature, geologic disposal is intended to provide a high degree of physical security by rendering the wastes difficult to access owing to their remote location deep underground (*i.e.,* about 300 meters/1000 feet). As a practical matter, once the repository is closed—*i.e.,* by sealing and possibly backfilling the underground drifts and access tunnels—the level of effort to reopen the repository and gain access to the wastes while preserving radiological safety will entail a substantial technical effort and expertise given current technology, and any action to do so would likely be detected.

As regards the potential risk of radiological sabotage to the repository during the preclosure phase of operations, the Commission's regulations for Yucca Mountain at § 63.21(b)(3) require that licensees have in place adequate physical security plans and attendant procedures to protect against radiological sabotage, consistent with § 73.51—NRC's requirements for the physical protection of stored spent nuclear fuel and high-level radioactive waste. In light of the terrorist attacks of September 11, 2001, the Commission has directed the staff to conduct a comprehensive reevaluation of NRC physical security requirements. If this effort indicates that NRC's regulations or requirements warrant revision, such changes would occur through a public rulemaking or other appropriate methods.

Issue 5: Terminology in the rule is not always as clear as it should be.

Comment. DOE indicated instances where particular words or phrases in Part 63 lacked clarity. The following specific changes to the proposed rule were suggested by DOE:

1. The phrase ''* * * could adversely affect safety * * *,'' found at § 63.32(b)(3), should be replaced with ''* * * could constitute a substantial safety hazard * * *'' as defined in part 21 of this chapter. (The phrase ''substantial safety hazard'' is well defined in NRC's part 21 regulations; there is no need to introduce a new, undefined term such as ''adversely impact safety''.)

2. DOE indicated that the location of the compliance point could be misinterpreted and recommended that the rule use ''the junction of U.S. Route 95 and Nevada Route 373'' and delete ''near Lathrop Wells, Nevada.''

Response. The Commission inadvertently used two different phrases (''could adversely affect safety'' [§ 63.32(b)(3)] and ''[b]e a substantial safety hazard'' (§ 63.73(a)(1))) when describing requirements for reporting deficiencies in proposed part 63. The Commission's intent was to specify a general level of concern (*i.e.,* could adversely affect safety) for deficiencies that would require reporting to the NRC as specified at §§ 63.32(b)(3) and 63.73(a)(1). Although the proposed rule used the phrase ''substantial safety hazard'' (§ 63.73(a)(1)), it was not the Commission's intent to imply the reporting requirements under § 63.73 were to be construed as the same as the part 21 requirements for reporting of defects. Accordingly, the Commission will clarify its intent by replacing ''[b]e a substantial safety hazard'' with ''adversely affect safety at any future time,'' and identify specific events and conditions that require reporting by reference to § 72.75 at § 63.73(c).

The location of the RMEI, for purposes demonstrating compliance with the postclosure performance objectives, is in the accessible environment above the highest concentration of radionuclides in the plume of contamination. EPA standards for Yucca Mountain define ''accessible environment'' as any point outside of the ''controlled area.'' To be consistent with EPA's standards, the Commission has incorporated EPA's definitions of ''accessible environment'' and ''controlled area'', as specified at 40 CFR 197.12, into subpart L of part 63.

Issue 6: Address the technical skills of the NRC staff to regulate a potential geologic repository at Yucca Mountain Project.

Comment. During the June 15, 1999, public meeting in Amargosa Valley, Nevada, one individual questioned the NRC staff's understanding of the fundamentals of the Yucca Mountain Project. This individual questioned how the NRC can regulate such a highly technical process without having its own highly technical personnel on staff. Commenters asked if NRC had its own experts or if NRC had to rely solely on information collected and developed by DOE. Although this comment is beyond the scope of the rulemaking, it questions the core technical expertise of the NRC staff to promulgate and implement this rule.

Response. The NRC (and its predecessor agency, the Atomic Energy Commission) has been regulating civilian uses of radioactive materials for nearly five decades. With increased awareness in the area of radioactive waste management, beginning in the late 1970s, the Commission's regulatory purview was expanded to include the disposal of HLW. As a complement to the existing NRC staff expertise in regulating nuclear activities and facilities, the Commission recruited and maintained a core staff with scientific expertise in those areas generally recognized to be important to radioactive waste management—the earth sciences, applied mathematics, geotechnical and materials engineering, and health physics. In the late 1980s, the Commission created a federally-funded research and development center, the CNWRA, to provide dedicated, conflict-of-interest-free technical assistance as a further complement to its scientific expertise.

In order to maintain an independent technical capability of the highest order, the NRC staff and its technical assistance consultants have been engaged over the years in scientific investigations and research necessary to understand how to properly regulate the management of radioactive wastes. The results of these efforts are widely published in the technical literature. In addition to these efforts, when there is a common interest, the NRC staff and its technical assistance consultants monitor or engage in international activities related to the regulation of radioactive wastes or the advancement of technical capability in radioactive waste management. To oversee these activities, the Commission's ACNW makes recommendations, when appropriate, to adjust or expand the technical capabilities needed by its staff.

In summary, the Commission believes that the qualifications and knowledge of the NRC staff and its technical assistance consultants with respect to the important technical aspects of the Yucca Mountain Project provide them with the credentials, skills, and state-of-the-art knowledge that are necessary and appropriate to ensure that NRC regulatory decisions with respect to public health and safety are made with the highest degree of scientific competence.

Issue 7: Does Yucca Mountain fail to comply with one of the [technical] criteria in the existing (Part 60) rule?

Comment. A commenter noted that it appears from DOE analyses that the Yucca Mountain site does not comply with one of the specific criteria in the existing rule, not the proposed new rule.

Response. DOE has not submitted an analysis to NRC for review that would fit the description of this comment. In addition, this final rule amends 10 CFR 60.1 to clearly state that Part 63, not Part 60, applies to licensing a disposal facility at Yucca Mountain, Nevada.

Issue 8: How should the material control and accounting program balance the need for inspections with worker exposures?

Comment. One commenter suggested that the program for maintaining material control and accounting should balance the need for periodic inspections with the potential for increased exposures of the inspectors. It was recommended that DOE and NRC should agree on how and when to terminate material control and accounting surveillance.

Response. The Commission agrees with the comment that workers should be protected from unnecessary doses due to repository operations. Although the requirement for conducting a physical inventory of HLW (reference to § 72.72 at § 63.78) extends over the operational period of the repository, the regulations provide flexibility to the Commission in determining the frequency for conducting the physical inventories. Determination of an appropriate frequency for conducting the inventories will consider such things as DOE's proposal for the material control and accounting program, the requirements for material control and accounting, and safety of inspectors. It is anticipated that the frequency for conducting inventories could vary due to significant changes in operations (*i.e.,* emplacement versus post-emplacement activities) over the long operational period (*e.g.,* 100 years) for the repository. The Commission considers a decision on how and when to terminate material control and accounting to be unnecessary and premature. The regulations provide the necessary flexibility for the Commission to determine how and when to terminate the material control and accounting that would consider the important issue raised by the commenter.

Issue 9: All references to "* * * decontamination or dismantlement * * *" of geologic repository facilities in the proposed rule (*e.g.,* § 63.21) should be revised to refer to "* * * decontamination or decontamination and dismantlement * * *" to avoid confusion about the need for decontamination.

Comment. EPA suggested that the reference to decontamination and dismantlement in the proposed rule needed clarification because the current language implies that facilities that needed dismantlement did not need to be decontaminated.

Response. The Commission agrees with this comment and has revised the proposed rule as suggested.

Issue 10: Should there be additional requirements for the content of the application?

Comment. One commenter recommended that the contents of the license application at § 63.21(c)(1)(iv) should also include information on the hydrology, geology, and climate at and near the chosen location for the critical group.

Response. In general, the Commission agrees with this comment to the extent that the Commission anticipates that it will need such information because it has a bearing on understanding the lifestyles and habits of the RMEI. However, in the Commission's view, the type of information suggested by the commenter is already included in the regulations at § 63.21(c)(1). Nonetheless, the Commission expects that this subject will be addressed in the YMRP, which describes the required contents and methods for the NRC staff review of any potential DOE construction authorization application, as well as DOE's compliance demonstration with the rule. At the appropriate time, the YMRP will be shared with interested stakeholders and published for public comment. Based on the public comments received, the staff will determine if additional revisions to the YMRP or regulations are necessary (*e.g.,* additional information to be included in the content of the application and a requirement for DOE to address all the issues in the YMRP).

Issue 11: Does the requirement for collecting information during construction (§ 63.72) take precedence over preservation of the design integrity?

Comment. It should be recognized that there is the possibility that the collection of certain types of data could

have a negative effect on the waste isolation capabilities of the site. The proposed requirements found in § 63.72 should be modified to recognize that data should be collected only when it is determined that the activities will have no adverse effect on the long-term performance of the repository.

Response. The Commission shares the commenter's concern that the collection of data could (potentially) have an adverse effect on the long-term performance of the repository. In this regard, it should be noted that the Commission is not in favor of any particular data collection techniques nor would it encourage data collection that could potentially affect the long-term performance of the repository or the effectiveness of its barriers be they natural or engineered. Nonetheless, during repository construction, DOE will need to collect data to confirm certain design (and performance) parameters as well as to identify previously undetected geologic conditions so as to have confidence that the repository will function as intended. To ensure that these activities have no effect on long-term repository performance, consistent with section 113(b)(1)(A)(ii) of the NWPAA, DOE will need to describe its data collection plans during construction in the manner described in § 63.72 so that their effect, if any, on containment and waste isolation can be independently evaluated by the NRC staff.

Issue 12: The reference to § 63.51(a)(2) (postclosure monitoring program) in §§ 63.71(b) (records and reports) and 63.72(a) (construction records) should be changed to refer to § 63.51(a)(3) (measures to regulate or prevent activities that could impair repository long-term performance).

Comment. Section 63.51(a)(3) refers to the description of the program for the postclosure monitoring program for the repository and not to record retention. The proposed requirements in §§ 63.71(b) and 63.72(a) also bear some relation to postclosure design, and this should be clarified in the rule.

Response. The commenter is correct, and the final rule contains the correct reference.

Issue 13: It is not clear how liquid HLW fits into DOE's disposal scenario.

Comment. From the definition of HLW found at § 63.2, it would appear that liquid HLW could also be disposed of at Yucca Mountain.

Response. Because of processing in the nuclear fuel cycle, some HLW can occur in the liquid (aqueous) state. However, this waste type is not expected to be disposed of at Yucca Mountain. Rather, liquid HLW will be vitrified—mixed with molten glass and solidified—to reduce the actual volume of waste and make it easier to handle. The definition of HLW found at § 63.2 was intended only to provide a technically correct definition of HLW in its various states. To provide further clarification, the definition has been revised to better reflect the language in the Nuclear Waste Policy Act of 1982 and final 40 CFR part 197, and continues to include the reference to irradiated reactor fuel consistent with the definition in the proposed rule.

Issue 14: Should climatological data be included for the update of the application and EIS?

Comment. EPA suggested that climatological data should be included in the types of data to be updated in the application and EIS [§ 63.24(b)(1)].

Response. The list of information to be updated at § 63.24(b)(1) includes meteorological data. Meteorological data are used as a general term indicating weather related information that would include information necessary to make inferences regarding climate. The addition of the word climatological is not needed; therefore, the language in proposed part 63 will be retained in final part 63.

6 Beyond the Scope of This Rulemaking

The following comments addressed issues that are beyond the scope of this rulemaking. Many of the comments in this category were directed at the hearing process, transportation, the selection of Yucca Mountain as a potential site for a geologic repository, or objected to deep geologic disposal as a method of managing HLW. Part 63 does not affect these issues because they already have been determined by legislation, are pertinent to other regulations or rulemakings but not to part 63, or because the provisions of part 63 are limited to specific regulatory areas while these issues are much broader.

6.1 Hearing Process

Issue: Will the Commission amend the hearing process for repository licensing to provide for informal, legislative-style hearings?

Comment. Some commenters, including EPA, urged NRC to change its hearing process to provide for informal, legislative-style hearings for repository licensing. One commenter suggested that the Commission itself be the hearing board. NEI expressed the view that a legislative-style hearing process is more conducive to effective scientific inquiry than formal adjudicatory procedures. NRC's decision on whether to adopt an informal process for repository licensing, in NEI's view, should not be tied to the generic question whether to revise the overall hearing process but, instead, should be the subject of a separate rulemaking. However, another commenter strongly opposed any suggestion to depart from formal trial-type adjudicatory and evidentiary hearing rules in 10 CFR part 2 for this potentially complex and first-of-a-kind licensing proceeding.

Response. In the proposed rule, the Commission told commenters that it had a broad study of the NRC hearing process underway, including the process that would be used for repository licensing. The Commission stated that it was inclined to provide for informal hearings for both construction authorization and licensing to receive and possess waste. If the Commission were to conclude that changes to the hearing process are warranted, the Commission stated that it would propose them for adoption in a separate notice and comment rulemaking. For that reason, the Commission did not seek comments on potential changes to the hearing process in this rulemaking. Subsequently, the Commission finished its study of the NRC hearing process and directed the staff to prepare a proposed rule to provide changes to that process. The proposed rule was published on April 16, 2001 (66 FR 19610) and the comment period closes on September 14, 2001 (extension of comment period, 66 FR 27045; May 16, 2001). In this recent notice, the Commission proposes to use formal hearing procedures in proceedings for the initial authorization to construct a geologic repository operations area and proceedings for initial authorization to receive and possess high-level waste at the repository. However, amendments to the construction authorization and to the authorization to receive and possess high-level waste may be conducted under informal hearing procedures. *See* proposed § 2.310(e). The Commission will make its final determinations on these issues in a final rule after it has considered all public comments received in this separate rulemaking.

6.2 Transportation

Issue 1: What regulations or controls will be used to ensure nuclear waste is transported safely including operations at an intermodal transfer facility?

Comment. Commenters raised concern that the risks for transporting nuclear waste were not being addressed in proposed part 63. Many commenters interpreted the absence of transportation criteria in proposed part 63 as an indication that NRC has deemphasized

transportation issues. One commenter raised concern over the possibility of terrorism and theft of spent fuel shipments.

Response. Nuclear waste transportation safety is not specifically addressed by the proposed part 63 because it is beyond the scope of this rulemaking. Issues related to terrorism or theft of spent fuel shipments during transport are also beyond the scope of this part 63 rulemaking. Nothing in this rule changes the existing regulatory regime governing the transportation of spent nuclear fuel and high-level radioactive waste. In light of the terrorist attacks of September 11, 2001, the Commission has directed the staff to conduct a comprehensive reevaluation of NRC physical security requirements. If this effort indicates that NRC's regulations or requirements warrant revision, such changes would occur through a public rulemaking or other appropriate methods.

Section 180 of the NWPA requires DOE to use packages that have been certified by NRC for transportation of spent nuclear fuel and HLW. The NRC regulations in 10 CFR part 71 specify the standards for certification. These standards provide that a package must prevent the loss or dispersion of radioactive contents, provide adequate shielding and heat dissipation, and prevent nuclear criticality under both normal and accident conditions of transportation.

Section 180 of the NWPA also requires that DOE abide by NRC regulations regarding advance notification of State and local governments prior to transportation of spent nuclear fuel or high-level radioactive waste. These advance notification requirements are set forth in 10 CFR 73.37. The NWPA also requires DOE to provide funds and technical assistance for training of local public safety officials (*e.g.,* emergency responders) along the routes.

In Volume II of the Draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High Level Radioactive Waste at Yucca Mountain, Nye County, Nevada, dated July 1999 (DEIS) (at J–23), DOE states that its proposed procedures for implementing Section 180 of the NWPA provide that routing for shipments to Yucca Mountain would comply with applicable regulations of the U.S. Department of Transportation (DOT) in effect at the time of such shipments. DOT regulations on route approval for transporting radioactive material by highway and State or Tribal designation of preferred routing [as an alternative to Interstate System highways] are contained in 49 CFR 397.101, 397.103, and 397.201.

A DOT–NRC Memorandum of Understanding (44 FR 38690; July 2, 1979) specifies that, in general, the DOT is responsible for regulating safety in transportation of all hazardous materials, including radioactive material. The NRC is responsible for regulating safety in receipt, possession, use, and transfer of radioactive materials. The NRC also reviews and approves package designs for transporting fissile material and other radioactive material in quantities exceeding Type A limits. Facilities which temporarily handle and store radioactive material during and incidental to their transport (*i.e.,* movement), such as operations at an intermodal transfer facility, are subject to DOT requirements.

Issue 2: How will transportation routes be selected and will local governments and communities be informed and consulted about the routes?

Comment. Commenters raised a number of questions regarding the selection of transportation routes for nuclear waste, such as: (1) Will DOE analyze the impacts of transportation routes; (2) Can rural roads be used to safely transport large nuclear waste shipments; (3) Will transportation route selection be addressed in DOE's license application; (4) Will local governments and communities be able to participate in route selection; and (5) Does NRC require DOE contractors to be responsible for transporting waste or are third-party contractors responsible for transporting waste.

Response. The routing requirements and practices largely depend upon whether a particular shipment is made by highway or railway. DOE is evaluating its options regarding the mix of road and rail shipments to the potential repository and will decide the appropriate level of analysis needed for transportation routes.

As noted, DOE has stated that routing of shipments of spent nuclear fuel and high-level waste will comply with applicable DOT regulations (DEIS, Vol. II, at J–23). The DEIS (Vol. I and Vol. II, Appendix J) also contains a discussion of the impacts associated with shipments to the proposed repository. The DOT regulations (49 CFR part 397) provide that shipments are to be on preferred routes (Interstate System highways and city bypasses) or State-or Tribal-designated preferred routes (i.e., alternate routes). These routing requirements were developed by the DOT considering the risks of transportation. Further, DOT has published guidelines (DOT/RSPA/HMS/92–02) for State or Tribal agencies to use in performing route analyses to ensure that the overall risk of the shipments to the public is considered in designating preferred routes. The degree of local participation in the State or Tribal routing agency's process may vary from State to State or from Tribe to Tribe.

NRC licensees, contractors of NRC licensees, DOE, and DOE contractors who are transporting spent fuel by highway must abide by the DOT's routing rules when they transport spent fuel by highway. There are no Federal regulations for selecting railway routing. Once a highway or railway route is selected, the route is reviewed by the NRC for physical protection purposes. NRC annually publishes a report, ''Public Information Circular for Shipments of Irradiated Reactor Fuel'' (NUREG–0725, Rev. 13, 1998), that describes the routes taken by commercial spent fuel shipments. For physical protection reasons, certain information on shipments is protected from general release until after the shipment (or series of shipments) is completed.

Issue 3: What criteria will be used to ensure the shipping cask can survive a variety of challenges during transportation?

Comment. Commenters inquired into how shipping casks were designed and who was responsible for manufacturing the casks. Additionally, one commenter asked whether the shipping cask design and testing consider specific accident scenarios, including sabotage.

Response. An application for a cask design is submitted to NRC by the cask vendor, and an approval certificate must be issued by NRC before a cask can be used to transport spent fuel. Typically, private firms manufacture a cask under contract to the cask's vendor. NRC requires that casks be designed, fabricated, used, and maintained under an NRC-approved QA plan. Activities under these plans are subject to NRC's inspection and enforcement programs. Safety standards, design criteria, and design test requirements for spent fuel casks are set forth in NRC regulations at 10 CFR part 71. Casks must be designed to withstand a series of impact, puncture, and fire environments, thereby providing reasonable assurance that packages will withstand serious transportation accidents. NRC regulations require that casks protect against the loss or dispersion of radioactive contents, provide adequate shielding and heat dissipation, and prevent nuclear criticality, under both incident-free and accident conditions of

transportation. NRC conducts an independent design review prior to issuing a cask certificate.

In the 1980's, NRC sponsored experiments and studies of the effects of sabotage on casks that meet NRC's safety standards. In addition, DOE has sponsored similar studies, most recently in 1999. The estimated performance of spent fuel casks during historically severe, actual accidents (viz., these severe accidents did not actually involve radioactive materials) was investigated as part of the NRC-sponsored study (*e.g.,* Fischer, L.E., *et. al.,* ''Shipping Container Response to Severe Highway and Railway Accident Conditions,'' NUREG/CR–4829, 1987). NRC's studies show that risks are low, from both incident-free shipments of radioactive material and possible accidents during transport. Therefore, the Commission has found that approved cask designs provide an adequate level of protection of public health and safety.

Issue 4: Will dose estimates be calculated for exposures from transportation and operations at an intermodal transfer facility?

Comment. A commenter asked that dose estimates be calculated for exposures from transportation and operations at an intermodal transfer facility.

Response. NRC has estimated the radiation doses to the population as a result of transportation of radioactive material. These estimates are performed as part of environmental impact studies such as NUREG–0170 (1977), ''Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes.''

The specific operations that would occur at an intermodal transfer facility related to the repository have not been identified. Consequently, NRC is not aware of radiation dose estimates that have been performed for that facility. Furthermore, the NRC notes that DOT requirements govern radiation safety for facilities which temporarily handle and store radioactive material during and incidental to their transport (*i.e.,* movement), such as operations at an intermodal transfer facility.

6.3 Other Comments

Issue 1: Should nuclear waste be sent somewhere else/out of Nevada?

Comment. A number of commenters believed that nuclear waste should be sent somewhere else (other than Yucca Mountain), or out of Nevada. Yucca Mountain was viewed as unsafe. Commenters did not want a nuclear waste repository constructed there and strongly objected to disposal of radioactive waste there. An opposing view was expressed by other commenters who stated that Yucca Mountain was the best place for disposal of radioactive waste. One commenter just wanted the waste kept safe.

Response. The NWPAA authorizes characterization of only Yucca Mountain, Nevada, as a potential repository site. Part 63 does not select Yucca Mountain as a site for a potential repository. Part 63 is being promulgated to provide reasonable assurance that, if a repository is built and operated at Yucca Mountain, public health and safety will be protected.

Issue 2: Is there a better solution for managing nuclear waste than geologic disposal?

Comment. There were a number of comments focused on whether an alternative should be used for management of radioactive waste. Some commenters stated that the use of onsite storage (*i.e.,* at nuclear reactors) of nuclear waste should be pursued. This would avoid transportation risks and be a suitable interim method of managing nuclear waste until a safe long-term disposal method was found. However, one commenter stated that it was appropriate and safe to place the waste in one location. Newly emerging technologies, such as transmutation, were cited by some commenters as methods that could reduce the hazard of the waste. A commenter noted that the materials making up the waste could be used in the future; there were numerous applications. Comments were received opposing underground disposal of spent fuel rods as unsafe, and not the best answer for disposal, and that only cooled spent fuel rods, but no plutonium, should be stored at Yucca Mountain or the NTS.

Response. The decision about how to manage HLW and spent fuel does not result from part 63. Deep geologic disposal of HLW was authorized by the NWPA. The NWPAA and the EnPA continue the U.S. government policy of disposal of HLW in a geologic repository. Nothing in part 63 changes this method of managing HLW authorized by existing law. The regulations in part 63 are designed to provide reasonable assurance of protection of public health and safety from any radioactive material disposed of, including surplus weapons plutonium.

Issue 3: Who should manage the Yucca Mountain project?

Comment. Commenters suggested that the University of Nevada at Las Vegas should manage the Yucca Mountain project.

Response. The NWPA gives DOE the responsibility for management of the Yucca Mountain project. DOE must address how to carry out its responsibility for management of the Yucca Mountain project.

Issue 4: Should nuclear power be used?

Comment. A commenter opposed the use of nuclear power as wasteful and the source of dangerous long-lived radioactive products. Another commenter said that sources of energy other than fission should be investigated.

Response. Part 63 establishes requirements for disposal of HLW at a potential repository at Yucca Mountain. It does not encourage or restrict the use of nuclear power. The NRC is establishing part 63 in accordance with its statutory responsibilities under the Atomic Energy Act (AEA), the NWPAA, and the EnPA.

Issue 5: How much money has been spent on Yucca Mountain?

Comment. A commenter wanted to know how much money had been spent on the Yucca Mountain project.

Response. The DOE publishes reports that give details of its budget and spending on the Yucca Mountain project. Expenditures are the subject of appropriations by Congress and oversight by both Congress and the General Accounting Office. In May 2001, DOE published its most recent cost estimates [see ''Analysis of the Total System Lifecycle Costs of the Civilian Radioactive Waste Management Program,'' DOE/RW–0533, May 2001; available on DOE's Web page at *http://www.rw.doe.gov*].

Issue 6: What happens if the Yucca Mountain project is developed and Congress cuts the budget for it? Or appoints a weaker agency to oversee the project?

Comment. A commenter noted that Congress had cut DOE's budget for Yucca Mountain in past years. What will NRC do, especially regarding monitoring, if construction of the project is underway, and a budget cut occurs?

Response. Responsibility for the Yucca Mountain project rests with DOE. Changes in budget levels for the Yucca Mountain project would have to be addressed by DOE in its planning for the project. If the Commission believes that it does not have sufficient funds to carry out its mission to protect public health and safety, it would ask Congress for additional funding.

Issue 7: Will the NRC staff seek input from local governments to assist it in providing comments to the DOE on the DEIS for Yucca Mountain?

Comment. One commenter asked the NRC to seek input from local governments to assist the NRC in providing comments on the DOE's DEIS.

Response. The NRC is expected, under the NWPA, to comment on the DEIS during the DEIS public comment period. The NRC provided comments for DOE to consider as part of the DEIS public comment process. In preparing these comments, the NRC staff observed DOE's DEIS public meetings to better understand what DEIS issues were of concern to the public. In addition, the NRC staff conducted its own meetings with AULG officials and conducted a public meeting in Caliente (Nevada) to discuss the NRC role with respect to the EIS, as it was formulating its comments. For its part, the Commission invited AULGs, stakeholders, and other interested parties to express their views on the DEIS during a public meeting on January 21, 2000. The Commission has considered these views before forwarding its comments to DOE.

Issue 8: Does the public have enough time to prepare comments on DOE's DEIS for Yucca Mountain and attend NRC meetings on part 63?

Comment. The NRC staff was asked at several public meetings to avoid scheduling future public workshops and meetings on part 63 during the DEIS public comment period.

Response. The Commission is sensitive to the issue being raised here and notes that the NRC is making every effort practical to schedule its public workshops and meetings in such a way so as to afford the public opportunity to participate in other agencies' activities. Accordingly, the Commission held only one meeting on part 63 during the public comment period on the DEIS.

Issue 9: What about the possibility that a waste repository at Yucca Mountain would be a target in the event of a nuclear war?

Comment. A commenter stated that the Air Force base and Hoover dam would be likely targets in the event of war. If a repository were developed at Yucca Mountain, that would also be a target.

Response. Consideration of the effects of wars and military actions is beyond the scope of NRC's responsibility. The NRC has not taken into account the effects of war in developing part 63.

Issue 10: Decisions regarding the licensing of a potential geologic repository at Yucca Mountain should be left to the voters to decide.

Comment. A commenter stated that important decisions, such as the potential geologic repository, should be placed on a nationwide ballot for the voters to decide.

Response. The NWPA and the EnPA establish the framework for licensing a potential geologic repository at Yucca Mountain. This legislation gives the NRC the responsibility for making a licensing decision on such a potential repository. Under this framework for licensing, there are opportunities for public input in the licensing process. The requirements promulgated here as part 63 do not make any change in public input opportunities already established.

Issue 11: How much radiation is being released from nuclear facilities?

Comment. Commenters wanted to know how much radiation was being released from nuclear facilities around the U.S. and what is being done to control those releases.

Response. The NRC's Annual Report—Reactors, NUREG–1272, Vol. 11, No.1, November 1998, gives annual exposures to the average person in the U.S. of less than 1 mrem (0.01 mSv) TEDE from the entire nuclear fuel cycle, including operation of reactors. All NRC licensees are required to limit radiation exposures from licensed activities in accordance with NRC regulations in 10 CFR part 20, 10 CFR part 50, Appendix I, and 10 CFR part 72.

Issue 12: Is radioactive material recycled into consumer products?

Comment. One commenter was concerned about potential exposure from radioactive material that has been recycled into consumer products.

Response. Part 63 is concerned only with disposal of HLW in a potential geologic repository at Yucca Mountain, Nevada. There are no provisions in this final rule that affect recycling of radioactive material into consumer products.

NRC is in the preliminary stages of examining its approach for controlling solid material. A paper that discusses issues associated with alternative courses of action was published in the **Federal Register** on June 30, 1999 (64 FR 35090). This issues paper is also available at NRC's web site.

Issue 13: Does NRC regulate the transportation of nuclear weapons?

Comment. One commenter inquired as to NRC's role in the transportation of nuclear weapons.

Response. The NRC does not have authority to regulate the transportation of nuclear weapons. The NRC's regulations for packaging and transportation of radioactive materials, 10 CFR part 71, do not apply to transportation of nuclear weapons.

IV. Changes from the Proposed Rule

Subpart A—General Provisions

Section 63.2 Definitions

Several terms have been deleted and definitions revised either to conform with the final EPA standard (40 CFR part 197) or to provide needed clarification. The terms annual dose and expected annual dose have been replaced by a single definition for TEDE (total effective dose equivalent) that provides for the use of organ weighting factors for assessing potential doses to members of the public. The term critical group has been deleted, and the term reasonably maximally exposed individual added and defined. The term design basis event has been deleted, and replaced with the terms event sequence and initiating event (the term design basis event has been replaced throughout the rule with event sequence). The term integrated safety analysis has been deleted, and replaced with the term preclosure safety analysis (the term integrated safety analysis has been replaced throughout the rule with preclosure safety analysis). The definition of performance confirmation has been revised to more clearly reflect the intent of the general requirements for performance confirmation at § 63.131(a). The definition of the engineered barrier system has been revised to include engineered components and systems other than the waste package (*e.g.,* drip shields). The definition of retrieval has been revised to clarify that retrieval means the act of ''permanently'' removing radioactive waste. The clarification to the definition of retrieval was done to differentiate it from operational activities (*e.g.,* DOE might intentionally remove one or several waste packages from its emplacement location and re-emplace them either at the same or a different location in the underground facility during the operational life of the repository as part of testing, demonstration, repair, maintenance or performance confirmation) that would not be considered as permanent retrieval. The definition for high-level waste has been modified to more closely reflect the definition provided in the Nuclear Waste Policy Act of 1982 and final 40 CFR part 197. The definition for the saturated zone has been revised to more accurately describe the intent of the definition. Other definitions have been modified in whole or in part to conform with the final 40 CFR part 197, including barriers, important to waste isolation, isolation, performance assessment, and reference biosphere. The definition for ground water has

been removed from this section because the definition for the same term provided in 40 CFR part 197 has been adopted into the regulations at § 63.302.

Section 63.4 Communications and Records

The section was revised to reflect the current address of the Commission.

Section 63.8 Information collection requirements: OMB approval

This section has been revised according to the current standard wording.

Section 63.10 Completeness and Accuracy of Information

The recipient of notification of information was changed from the Administrator of the appropriate Regional Office to the Director of the Office of Nuclear Material Safety and Safeguards.

Subpart B—Licenses

Section 63.16 Review of site Characterization Activities

Section 63.16(d) was clarified to specify that public comments would be sought on comments made by the Director of the Office of Nuclear Material Safety and Safeguards to DOE after the Director's comments had been sent to DOE. Section 63.16(d) essentially adopts 10 CFR 60.18(i) with the addition of performance assessment as a subject area for potential public comments. The Commission explained at the time it adopted § 60.18(i) that ''(j)ust as the Commission will solicit comments on its comments on DOE's initial S(ite) C(haracterization) P(lan), it wants to allow for public comment on any Commission comments on DOE's semi-annual reports (or on any other comments which the Director makes to DOE on site characterization)'' (51 FR 27161; July 30, 1986). Under § 60.18(f), the Director must publish in the **Federal Register** a notice of the availability of comments on DOE's Site Characterization Plan for public comment after the comments have been sent to DOE. Section 63.16(d) was clarified to reflect the Commission's intent that the timing of any public comment period remain the same as under § 60.18.

Section 63.21 Content of Application

Requirements associated with the description of the engineered barrier system, quality assurance program, physical protection, design criteria, and decontamination of surface facilities have been clarified. The requirements in this section have been regrouped in an order more consistent with the required analyses. The requirement for DOE to provide a comparative evaluation of alternatives to major design features has been removed. The level of information necessary to support each licensing stage has been clarified by stating the application must be as complete as possible in the light of information that is reasonably available at the time of docketing. The words ''principal design criteria'' have been replaced with ''design criteria'' to avoid any confusion with the meaning of the word ''principal;'' this was not intended as a substantive change. The design criteria to be described are those that relate to the preclosure and postclosure performance objectives. This provides DOE sufficient guidance as to which design criteria are to be provided. The reference to ''ground water'' at § 63.21(c)(10) was changed to ''water'' to maintain the intent of the proposed rule, which included both saturated and unsaturated zone water in the definition of ground water, and avoid conflict with the new definition for ''ground water'' in subpart L. Additional changes have been made to conform to the final 40 CFR part 197.

Section 63.31 Construction Authorization

This section was modified to reflect a finding of reasonable expectation for demonstration of compliance with the quantitative standards now specified in new Subpart L.

Section 63.41 Standards for Issuance of a License

Clarification has been made regarding decontamination of surface facilities.

Section 63.42 Conditions of License

Section 63.42(d) was modified to eliminate the specific reference to the NWPA limit of 70,000 MTU. Although this limit still applies, by simply referring to ''* * * NWPA, as amended * * *,'' the need for a future rulemaking would be obviated if the legislation ever changes this disposal volume restriction.

Section 63.44 Changes, Tests, and Experiments

This section has been extensively revised in accordance with NRC-wide programmatic changes in this area.

Section 63.51 License Amendment for Permanent Closure

This section has been revised to specifically require that performance confirmation data pertinent to compliance with § 63.113 be included in the update of the performance assessment in the application for a license amendment for permanent closure.

Section 63.52 Termination of License

Clarification has been made regarding decontamination of surface facilities.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

Section 63.61 Provision for Information

This section has been changed to include the affected units of local government.

Section 63.62 Site Review

This section has been changed to include the affected units of local government.

Section 63.63 Participation in License Reviews

This section has been changed to correct the reference to ''Subpart G'' to read ''Subpart J,'' and the reference to local governments has been clarified by changing it to ''affected units of local government.'' The final sentence in proposed § 63.63(a) has been deleted.

Section 63.65 Representation

This section has been changed to include the affected units of local government.

Subpart D—Records, Reports, Tests, and Inspections

Section 63.71 Records and Reports

The record retention requirements referenced at § 63.71(b) were incorrect in the proposed rule and have been modified to refer correctly to § 63.51(a)(3).

Section 63.72 Construction Records

The record retention requirements referenced at § 63.72(a) were incorrect in the proposed rule and have been modified to refer correctly to § 63.51(a)(3). Additionally, the design specifications and ''as built'' drawings have been added to the list of required records.

Section 63.73 Reports of Deficiencies

The phrase ''(b)e a substantial safety hazard,'' found at § 63.73(a)(1), was replaced with the phrase ''(a)dversely affect safety at any future time,'' to be consistent with terminology used at § 63.32(b)(3) and to avoid confusion with reporting requirements under 10 CFR part 21, which includes a very precise definition for what constitutes a ''substantial safety hazard.'' Specific requirements regarding DOE's implementation of a program for

evaluating and reporting deficiencies have been included to clarify the reporting requirements.

Subpart E—Technical Criteria

Section 63.101 Purpose and nature of findings

This section has been revised to address how the Commission intends to implement a finding of reasonable expectation. The discussion of postclosure performance objectives has been revised to conform with the public health and environmental radiation standards for geologic disposal now specified in Subpart L, which are referenced in § 63.113.

Section 63.102 Concepts

This section has been changed to clarify NRC's expectations for the demonstration of compliance with the requirements for multiple barriers, performance confirmation, and preclosure safety analysis. The discussion of multiple barriers has been modified to clarify the intent of the multiple barrier requirement. The discussion of preclosure safety analysis has been revised to clarify requirements for the dose calculations due to the event sequences and the selection of specific event sequences to be included in the analysis. The discussion of performance confirmation has been revised to more clearly reflect the intent of the general requirements for performance confirmation at § 63.131(a). Additional changes have been made to conform with the final 40 CFR part 197, including among others the discussion of the reference biosphere, reasonably maximally exposed individual, and human intrusion; and addition of a discussion on ground-water protection.

Section 63.111 Performance Objectives for the Geologic Repository Operations Area Through Permanent Closure

The performance objectives at § 63.111(b)(1) and (2) have been changed to clarify that (1) the doses from consequence analyses for Category 1 event sequences are to be aggregated to a single estimate and (2) the dose from the consequence analysis for each Category 2 event sequence is to be estimated for that specific event sequence only. Section 63.111(a)(2) has been modified to conform with the individual protection standard now specified in subpart K.

Section 63.112 Requirements for Preclosure Safety Analysis of the Geologic Repository Operations Area

This section has been revised to clarify that the objective of the analysis is to evaluate event sequences; as such, the phrase ''accidents that would result in unacceptable consequences'' has been replaced with ''event sequences.'' The consideration of criticality has been clarified by requiring analysis of the means to prevent and control criticality. The words ''principal design criteria'' have been replaced with ''design criteria'' to be consistent with the changes made at § 63.21 (as noted in the discussion under § 63.21, this change was not intended as a substantive change).

Section 63.113 Performance Objectives for the Geologic Repository After Permanent Closure

This section has been modified to conform with the public health and environmental radiation standards for geologic disposal now specified in subpart L.

Section 63.114 Requirements for Performance Assessment

The reference to features, events, and processes in this section has been changed by removing the words ''of the geologic setting.'' In addition, the requirements for multiple barriers have been moved to the revised § 63.115.

Section 63.115 Required Characteristics of the Reference Biosphere and Critical Group

Requirements related to characteristics of the reference biosphere and critical group have been deleted from this section in light of the definitions and concepts necessary to estimate dose to the reasonably maximally exposed individual, now specified in subpart L. This section now contains the requirements related to multiple barriers formerly at § 63.114. This section is now titled ''Requirements for multiple barriers'.

Section 63.121 Requirements for Ownership and Control of Interests in Land

This section has been revised to clarify the extent and manner of control over lands that DOE must exercise during the preclosure period.

Subpart F—Performance Confirmation Program

Section 63.131 General Requirements

This section has been revised to replace the word ''geologic'' with ''natural'' at § 63.131(a) to be consistent with terms used in the definition of important to isolation.

Section 63.132 Confirmation of Geotechnical and Design Parameters

This section has been revised to require DOE to identify parameters and interactions to be measured or observed rather than specifically prescribing such parameters and interactions.

Section 63.133 Design Testing

This section has been revised to clarify testing requirements such that testing is not limited to in situ testing only; to require specific testing of the effectiveness of backfill placement and compaction only if backfill is included in the repository design; to require ''tests'', rather than ''test sections,'' so as to be more general; and to generally reference ''engineered systems and components,'' with examples, so as not to limit tests to specific features that may or may not be included in the final design of the repository. The reference to ''ground water'' was changed to ''unsaturated zone and saturated zone water'' to maintain the intent of the proposed rule, which included both saturated and unsaturated zone water in the definition of ground water, and avoid conflict with the new definition for ''ground water'' in subpart L.

Subpart G—Quality Assurance

Section 63.141 Scope

This section was revised to clarify the extent of the geologic repository system by adding ''structures'' and ''systems'' and deleting the word ''subsystems.''

Section 63.142 Quality Assurance Criteria

This section has been revised to include previously referenced quality assurance requirements. Provisions of Appendix B to 10 CFR part 50, as applicable, have been brought into this section rather than merely referencing appendix B in the rule. The introduction of the language from Appendix B into the final part 63 has not changed any requirements in the proposed part 63. This approach specifies the quality assurance requirements and removes any ambiguity regarding which portions of Appendix B are applicable to Yucca Mountain.

Section 63.143 Implementation

This section has been revised to reference the criteria at § 63.142 rather than the criteria in Appendix B of 10 CFR part 50, as applicable.

Section 63.144 Quality Assurance Program Change

This section has been added to provide requirements for how changes to the quality assurance program description are to be processed.

Subpart K—Preclosure Public Health and Environmental Standards

Section 63.201 Purpose and Scope

New section that states the requirements in this subpart apply to the storage of radioactive material in the Yucca Mountain repository and on the Yucca Mountain site.

Section 63.202 Definitions for Subpart K

New section adopted from the final 40 CFR part 197 that contains definitions of terms as used in subpart K.

Section 63.203 Implementation of Subpart K

New section adopted from the final 40 CFR part 197 that states DOE must demonstrate that normal repository operations will meet the requirements of this subpart.

Section 63.204 Preclosure Standard

New section adopted from the final 40 CFR part 197 that establishes a 0.15 mSv (15 mrem) dose limit during the preclosure period.

Subpart L—Postclosure Public Health and Environmental Standards

Section 63.301 Purpose and Scope

New section that states the requirements in this subpart apply to the disposal of radioactive material in the Yucca Mountain repository.

Section 63.302 Definitions for Subpart L

New section adopted from the final 40 CFR part 197 that contains definitions of terms as used in subparts L and K.

Section 63.303 Implementation of Subpart L

New section adopted from the final 40 CFR part 197 that states DOE must demonstrate there is a reasonable expectation that the projected performance of any geologic repository at Yucca Mountain will meet the requirements of this subpart for 10,000 years after disposal.

Section 63.304 Reasonable Expectation

New section adopted from the final 40 CFR part 197 that defines what is meant by the reasonable expectation concept used in relation to projecting the long-term performance of any geologic repository at Yucca Mountain.

Section 63.305 Required Characteristics of the Reference Biosphere

New section adopted from the final 40 CFR part 197 that describes the characteristics of the reference biosphere DOE is to assume for the purpose of projecting the long-term performance of the geologic repository.

Postclosure Individual Protection Standard

Section 63.311 Individual Protection Standard After Permanent Closure

New section adopted from the final 40 CFR part 197 that establishes an annual, all pathway, individual protection standard of 0.15 mSv (15 mrem) for the reasonably maximally exposed individual from potential releases of radioactivity from any geologic repository at the Yucca Mountain site for 10,000 years following disposal.

Section 63.312 Required Characteristics of the Reasonably Maximally Exposed Individual

New section adopted from the final 40 CFR part 197 that defines the required characteristics of the reasonably maximally exposed individual to be used by DOE in the dose calculations necessary to assess the long-term performance of any geologic repository at the Yucca Mountain site.

Human Intrusion Standard

Section 63.321 Individual Protection Standard for Human Intrusion

New section adopted from the final 40 CFR part 197 that describes the stylized human intrusion calculation to be used by DOE to evaluate the resilience of any geologic repository at the Yucca Mountain site. Establishes an annual, all pathway, individual protection standard of 0.15 mSv (15 mrem) for the reasonably maximally exposed individual, from potential releases of radioactivity from the geologic repository for 10,000 years after disposal, as a result of the stylized human intrusion.

Section 63.322 Human Intrusion Scenario

New section adopted from the final 40 CFR part 197 that describes the assumptions related to a stylized human intrusion scenario DOE will use to estimate the dose to any reasonably maximally exposed individual from a human intrusion. Additionally, NRC has clarified that the human intrusion scenario is to include only those radionuclides transported to the saturated zone by water (*e.g.,* water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone); and not consider particulate waste material falling into the borehole.

Ground-Water Protection Standards

Section 63.331 Separate Standards for Protection of Ground Water

New section adopted from the final 40 CFR part 197 that establishes limits on the level of radioactivity that would be acceptable in a representative volume of ground water 10,000 years following repository closure.

Section 63.332 Representative Volume

New section adopted from the final 40 CFR part 197 that describes the assumptions DOE will use in the calculation to estimate the level of radioactivity in a representative volume of ground water, at a specified point, down-gradient from any geologic repository at Yucca Mountain.

Additional Provisions

Section 63.341 Projections of Peak Dose

New section adopted from the final 40 CFR part 197 that requires DOE to estimate peak dose and include the results in its Environmental Impact Statement. However, there is no standard that must be met with respect to these peak dose calculations, and there is no finding that the NRC must make with respect to these peak dose calculations, nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain.

Section 63.342 Limits on Performance Assessments

New section adopted from the final 40 CFR part 197 that describes how DOE will determine which features, events, and processes need to be considered in the dose assessments described in subpart L.

Section 63.343 Severability of Individual Protection and Ground-Water Protection Standards

New section adopted from the final 40 CFR part 197 that indicates the individual protection and ground-water protection standards are wholly severable.

Parts 2, 19, 20, 51, 70, 72, 73, and 75

The following changes are being made to other parts to add references to part 63 where appropriate. These changes are needed to reflect changes in NRC regulations that have occurred since development of the proposed rule and to correct omissions.

Section 2.714 Interventions

A reference to part 63 is added in the section on interventions in any hearing on a license application for a repository.

Section 2.1013 Use of the electronic docket during the proceeding

A reference to part 63 is added in the section on use of the electronic docket (Licensing Support Network) for a license application for a repository.

Section 2.1014 Intervention

A reference to part 63 is added in the section on procedures for intervention and for filing an amendment to a contention.

Section 2.1021 First Prehearing Conference

A reference to part 63 is added in the section on procedures for conducting the first prehearing conference.

Section 2.1023 Immediate Effectiveness

A reference to part 63 is added in the section containing criteria for immediate effectiveness of a decision on issuance or amendment of a construction authorization for a repository.

Section 19.20 Employee Protection

A reference to part 63 is added in the section on employee protection to make employee protection provisions applicable to employees engaged in protected activities under part 63.

Section 20.1003 Definitions

A reference to part 63 is added to the definition of ''License'' in the definitions section.

Section 20.1401 General Provisions and Scope

A reference to part 63 is added to the section on general provisions and scope of radiological criteria for license termination to make these provisions applicable to decommissioning facilities licensed under part 63.

Section 20.2001 General Requirements

A reference to part 63 is added to the section on general requirements for waste disposal.

Section 20.2206 Reports of Individual Monitoring

A reference to part 63 is added to the section on reports of individual monitoring to make requirements for individual monitoring applicable to a part 63 licensee.

Section 51.22 Criterion for Categorical Exclusion; Identification of Licensing and Regulatory Actions Eligible for Categorical Exclusion or otherwise Not Requiring Environmental Review

A reference to part 63 is added to the section on categorical exclusions to allow for technical requirements and criteria promulgated under part 63 to be included along with technical requirements and criteria promulgated under part 60 as actions eligible for categorical exclusions.

Section 70.17 Specific Exemptions

A reference to part 63 is added to the section on specific exemptions to include DOE activities that are subject to part 63 or part 60 to be exempt from the requirements of part 70.

Section 72.44 License Conditions

A reference to part 63 is added to the section on license conditions. Part 72 already contains a provision limiting the quantity of spent fuel at the site of a monitored retrievable storage facility until a repository authorized under NWPA and part 60 begins operations. This change allows for a repository authorized under part 63 as well.

Section 73.1 Purpose and Scope

A reference to part 63 is added to the section on purpose and scope. This makes certain requirements for the establishment and maintenance of a physical protection system applicable to a repository licensed under part 63 in addition to part 60.

Section 73.51 Requirements for the Physical Protection of Stored Spent Nuclear Fuel and High-Level Radioactive Waste

A reference to part 63 is added to the section on requirements for physical protection of spent fuel and HLW. Applicability of these requirements is extended to the GROA licensed under part 63.

Section 75.4 Definitions

A reference to part 63 is added to the definition of ''Installation'' in the definitions section. This identifies locations where possession of more than 1 effective kilogram of nuclear material requires certain safeguards requirements.

V. Section-by-Section Analysis of Part 63

Subpart A—General Provisions

This subpart, except for § 63.2, ''Definitions,'' contains general provisions that are similar to the provisions of part 60 with minor wording changes for simplification, clarification, or to refer specifically to the Yucca Mountain site, where appropriate. Definitions have been revised to reflect their use in this part, as appropriate.

Section 63.1 Purpose and Scope

This section limits the purpose and scope of part 63 to the licensing of DOE to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada. It states that generic regulations at part 60 of this title do not apply and cannot be the subject of any litigation in any licensing proceeding for the Yucca Mountain site.

Section 63.2 Definitions

This section contains definitions of terms as used in this part.

Section 63.3 License Required

This section prohibits DOE from receiving or possessing source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site without having a license issued by the Commission. It also prohibits DOE from beginning construction of the geologic repository operations area without authorization from the Commission.

Section 63.4 Communications and Records

This section describes requirements for communications and reports submitted to the Commission, including appropriate addresses for communications to be forwarded to NRC.

Section 63.5 Interpretations

This section specifies when interpretations of the meaning of the regulations in this part by NRC officers or employees will be considered binding on the Commission.

Section 63.6 Exemptions

This section states the bases on which the Commission may grant exemptions from the requirements of this part.

Section 63.7 License Not Required for Certain Preliminary Activities

This section allows DOE to possess source, special nuclear, or byproduct material at Yucca Mountain for the purposes of site characterization, and for use in certain construction activities.

Section 63.8 Information Collection Requirements: OMB Approval

This section indicates that the information collection requirements contained in this part have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act.

Section 63.9 Employee Protection

This section specifies requirements for protection of licensee or contractor and subcontractor personnel from certain adverse actions by employers.

Section 63.10 Completeness and Accuracy of Information

This section requires information provided to the Commission be complete and accurate. It also requires NRC notification of information having significant public health and safety implications.

Section 63.11 Deliberate Misconduct

This section prohibits certain licensee activities and describes resulting enforcement action.

Subpart B—Licenses

This subpart, except for § 63.15, ''Site characterization,'' § 63.16, ''Review of site characterization activities,'' and § 63.21, ''Content of application,'' contains provisions that are similar to the licensing provisions of part 60 with minor wording changes for simplification, clarification, or to refer to the Yucca Mountain site, where appropriate. Provisions related to the content of the license application have been developed to be consistent with the technical criteria of subpart E. Provisions related to site characterization have been simplified from similar sections of part 60 to reflect the maturity of site characterization at Yucca Mountain. For example, there are no provisions requiring DOE to prepare and submit a site characterization plan to NRC or any requirement for NRC to prepare a specific site characterization analysis inasmuch as both activities have been completed. However, provisions requiring DOE to undertake site characterization and submit semiannual progress reports to NRC and provisions allowing NRC to comment on any aspect of site characterization or performance assessment, at any time, are retained as indicated in the analysis of pertinent sections of subpart B that follows.

Section 63.15 Site Characterization

This section specifies that a program of site characterization is to be conducted prior to submittal of an application and that investigations are to be conducted in a manner that limits adverse effects on the performance of the geologic repository.

Section 63.16 Review of Site Characterization Activities

This section specifies that DOE must submit to the Commission semiannual reports on the progress of site characterization, that the NRC staff shall be permitted to visit, inspect, and observe site characterization activities at the Yucca Mountain site, and that the Director may, at any time, comment on any aspect of site characterization and performance assessment. This section further provides that the Director shall invite public comment on any comments made by the Director after the Director's comments have been sent to DOE. This section also specifies that the Commission will determine whether any proposed onsite testing with radioactive material during site characterization is necessary to provide data for the preparation of the environmental reports required by law and for the license application.

Section 63.21 Content of Application

This section specifies that the license application must include general information, a safety analysis report, and be accompanied by an environmental impact statement. This section also describes the detailed information to be included in the safety analysis report.

Section 63.22 Filing and Distribution of Application

This section describes requirements for filing and distribution of the license application, amendments to the license application, environmental reports, and related updates and supplements.

Section 63.23 Elimination of Repetition

This section allows DOE to incorporate by reference information in previous applications, statements, or reports filed with the Commission in its application or environmental statement.

Section 63.24 Updating of Application and Environmental Impact Statement

This section requires DOE to submit a complete application, to update or supplement the application or environmental impact statement in a timely manner, and certify that updated copies contain current information.

Section 63.31 Construction Authorization

This section states the bases on which the Commission may authorize construction of a geologic repository operations area at the Yucca Mountain site.

Section 63.32 Conditions of Construction Authorization

This section indicates that the Commission will include conditions in the construction authorization as necessary to protect the health and safety of the public, the common defense and security, and environmental values, and describes specific provisions and restrictions that will be included in the construction authorization. This section also indicates that a license will not be issued until DOE has updated its application as required at § 63.24 and the Commission has made the findings stated at § 63.41.

Section 63.33 Amendment of Construction Authorization

This section requires DOE to apply for an amendment of the construction authorization if changes are desired. This section also states the bases on which the Commission may approve an amendment of the construction authorization.

Section 63.41 Standards for Issuance of a License

This section states the bases on which the Commission may issue a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site.

Section 63.42 Conditions of License

This section indicates that the Commission will include conditions or specifications in the license as necessary to protect the health and safety of the public, the common defense and security, and environmental values. This section also identifies general conditions that will be considered conditions of the license, whether stated in the license or not.

Section 63.43 License Specification

This section indicates that the Commission will include conditions in the license that are derived from the analyses and evaluations included in the application and amendments made before a license is issued. This section also describes specific categories of restrictions, requirements, and controls that will be included as conditions of the license.

Section 63.44 Changes, Tests, and Experiments

This section states the bases on which DOE may change the geologic repository operations area or procedures as described in the application, and conduct tests or experiments not described in the application, without prior Commission approval. This section also requires DOE to maintain records of changes made and tests undertaken under this section.

Section 63.45 Amendment of License

This section requires DOE to apply for an amendment of the license if changes are desired. This section also states the bases on which the Commission may approve an amendment of the license.

Section 63.46 Particular Activities Requiring License Amendment

This section describes specific activities that require amending the license prior to being performed, unless expressly authorized in the license.

Section 63.51 License Amendment for Permanent Closure

This section requires DOE to apply for an amendment of the license to permanently close a geologic repository at the Yucca Mountain site. This section also requires DOE to submit an update of the license application and describes the detailed information to be included in the update.

Section 63.52 Termination of License

This section requires DOE to apply for an amendment to terminate the license following permanent closure of the geologic repository and the decontamination or decontamination and dismantlement of surface facilities at the Yucca Mountain site.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

This subpart contains provisions that are similar to the State and affected Indian Tribe participation provisions of 10 CFR part 60, with some wording changes to refer to the State of Nevada, the Yucca Mountain site, and to include the AULGs, where appropriate.

Section 63.61 Provision of Information

This section states that the NRC shall provide to the Governor, the Nevada State legislature, AULGs, and any affected Indian Tribe timely and complete information regarding determinations made by the Commission with respect to the Yucca Mountain site. The NRC shall also make this information available to the public and DOE.

Section 63.62 Site Review

This section states that the NRC shall consult with the State of Nevada, AULGs, and affected Indian Tribes regarding site characterization activities.

Section 63.63 Participation in License Reviews

This section sets forth procedures for the State, AULGs, and affected Indian Tribes to participate in license review activities.

Section 63.64 Notice to State

This section notes that, if the Governor and legislature of the State of Nevada have designated a joint person or entity to receive information from NRC, the NRC will send such information to the jointly designated addressee.

Section 63.65 Representation

This section allows the Commission to request that any person acting as a representative of the State, Governor, or legislature of Nevada, or any AULG, or any affected Indian Tribe provide the Commission with the authority basis for such a representation.

Subpart D—Records, Reports, Tests, and Inspections

This subpart contains provisions that are similar to the records, reports, tests, and inspection provisions of part 60 with minor wording changes for simplification, clarification, or to refer to the Yucca Mountain site, as appropriate.

Section 63.71 Records and Reports

This section requires DOE to make and maintain records and reports as required by conditions of the license or rules, regulations, and orders of the Commission.

Section 63.72 Construction Records

This section requires DOE to maintain records of the construction of the geologic repository operations area and describes the types of records to be maintained.

Section 63.73 Reports of Deficiencies

This section requires DOE to notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site and the design and construction of the geologic repository operations area, if the uncorrected deficiency could adversely affect safety, represent a deviation from the design criteria or design bases, or represent a deviation from conditions of the construction authorization or license.

Section 63.74 Tests

This section requires DOE to perform such tests, or to allow the Commission to perform such tests, as the Commission determines necessary for administration of the regulations in this part. This section also describes the types of tests that may be included under this section.

Section 63.75 Inspections

This section requires DOE to afford the Commission opportunity for inspection of the geologic repository operations area and adjacent areas. This section also requires DOE to provide office space for Commission inspection personnel.

Section 63.78 Material Control and Accounting Records and Reports

This section requires DOE to establish a material inventory system, whereby material and accounting procedures are developed, physical inventories are performed, loss of special nuclear material or accidental criticality is reported, and material status and nuclear material transfer reports are generated. This section notes that the material and accounting program is to be the same as that specified at §§ 72.72, 72.74, 72.76, and 72.78.

Subpart E—Technical Criteria

This subpart, except for § 63.101, ''Purpose and nature of findings,'' § 63.102, ''Concepts,'' and § 63.121, ''Requirements for ownership and control of interests in land,'' contains performance objectives for the geologic repository operations area through permanent closure (preclosure) and the geologic repository after permanent closure (postclosure), separate requirements for protection of ground water (postclosure), and requirements for the analyses used to demonstrate compliance with the performance objectives. The preclosure performance objective is similar to the provisions in part 60. However, the postclosure performance objective and other requirements differ significantly from part 60. This subpart requires compliance to be demonstrated in the context of safety analyses of total system performance and does not prescribe general design or siting criteria, or specific quantitative subsystem performance objectives as was done in part 60. Performance requirements from the final 40 CFR part 197, incorporated into subparts K and L, are referenced in this subpart.

Section 63.101 Purpose and Nature of Findings

This section describes the Commission's expectations for demonstration that the geologic repository will be in conformance with the performance objectives.

Section 63.102 Concepts

This section provides a functional overview of this subpart.

Section 63.111 Performance Objectives for the Geologic Repository Operations Area Through Permanent Closure

This section requires DOE to design the geologic repository operations area

to comply with the exposure limits given in this section, conduct a preclosure safety analysis, permit implementation of a performance confirmation program, and preserve the option for waste retrieval.

Section 63.112 Requirements for Preclosure Safety Analysis of the Geologic Repository Operations Area

This section specifies the requirements for the preclosure safety analysis used to demonstrate compliance with the performance objective through permanent closure provided at § 63.111(a)(1) and (a)(2).

Section 63.113 Performance Objectives for the Geologic Repository After Permanent Closure

This section requires DOE to include a system of multiple barriers for the geologic repository, comply with the limits on radiological exposures to the reasonably maximally exposed individual, comply with limits on releases of radionuclides into the accessible environment, comply with the limits on radiological exposures to the reasonably maximally exposed individual as a result of a specified human intrusion event, and conduct related assessments.

Section 63.114 Requirements for Performance Assessment

This section specifies the requirements for the performance assessment used to demonstrate compliance with the requirements specified at § 63.113(b), (c), and (d).

Section 63.115 Requirements for Multiple Barriers

This section requires DOE to identify and describe the natural features of the geologic setting and design features of the engineered barrier system that are considered barriers important to waste isolation.

Section 63.121 Requirements for Ownership and Control of Interests in Land

This section requires DOE to have permanent control of the geologic repository operations area. It states that DOE shall set up controls necessary to prevent adverse human actions that could affect the repository. Appropriate controls shall be established outside the geologic repository operations area. DOE is required to obtain water rights needed for the repository.

Subpart F—Performance Confirmation Program

This subpart contains provisions that are similar to the performance confirmation provisions of 10 CFR part 60.

Section 63.131 General Requirements

This section states the objectives of the performance confirmation program and specifies that the program be started during site characterization and continue until permanent closure.

Section 63.132 Confirmation of Geotechnical and Design Parameters

This section requires DOE to monitor subsurface conditions during repository construction and operation to confirm original design assumptions and to ensure that performance of geologic and engineered features is within design limits. DOE is also required to inform the Commission of any design changes needed to accommodate actual field conditions encountered.

Section 63.133 Design Testing

This section requires DOE to undertake a program of testing of such features as borehole and shaft seals, backfill, drip shields, and the thermal interaction effects of waste packages, backfill, rock, and ground water.

Section 63.134 Monitoring and Testing Waste Packages

This section requires DOE to establish a program for monitoring and testing waste packages at the geologic repository operations area that is to continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

This subpart contains provisions that are similar to the quality assurance provisions of 10 CFR part 60. Rather than referencing Appendix B to 10 CFR part 50, as was done in 10 CFR part 60, 10 CFR part 63 has incorporated quality assurance requirements from Appendix B that are specifically applicable to a geologic repository.

Section 63.141 Scope

This section requires DOE to establish a quality assurance program to be applied at the geologic repository at the Yucca Mountain site.

Section 63.142 Quality Assurance Criteria

This section indicates that the quality assurance program applies to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. This section specifies the applicability and criteria for DOE's quality assurance program description.

Section 63.143 Implementation

This section indicates that the quality assurance program is to be based on the criteria required by § 63.142.

Section 63.144 Quality Assurance Program Change

This section specifies when DOE is allowed to make a change to a previously accepted quality assurance program without prior NRC approval.

Subpart H—Training and Certification of Personnel

This subpart contains provisions that are similar to the training and certification provisions of 10 CFR part 60.

Section 63.151 General Requirements

This section specifies that operations of systems and components important to safety are to be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operations. This section also specifies that supervisory personnel who direct operations that are important to safety are to be certified in such operations.

Section 63.152 Training and Certification Program

This section specifies that a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel is to be established.

Section 63.153 Physical Requirements

This section specifies physical requirements for personnel certified for operations that are important to safety.

Subpart I—Emergency Planning Criteria

This subpart contains provisions for emergency planning.

Section 63.161 Emergency Plan for the Geologic Repository Operations Area Through Permanent Closure

This section requires DOE to develop and be prepared to implement a plan to cope with radiological emergencies. The section indicates that the emergency plan is to be based on criteria at § 72.32(b).

Subpart J—Violations

This subpart contains provisions that are similar to the violation provisions of 10 CFR part 60.

Section 63.171 Violations

This section specifies actions the Commission may take, including obtaining a court order to prevent a violation, and contains civil penalty provisions.

Section 63.172 Criminal Penalties

This section specifies criminal sanctions for violations. For purposes of section 223 of the Atomic Energy Act of 1954, as amended, that provides for criminal sanctions, all regulations in part 63 are issued under one or more of sections 161b, 161i, or 161o except for the sections listed in § 63.172(b).

Subpart K—Preclosure Public Health and Environmental Standards

This subpart contains provisions that are consistent with the public health and environmental standards for storage specified at 40 CFR part 197.

Section 63.201 Purpose and scope

This section stipulates that, to the extent that there may be a conflict, the requirements in this subpart take precedence over other requirements in subparts A through J.

Section 63.202 Definitions for Subpart K

This section contains definitions of terms as used in this subpart and subpart L.

Section 63.203 Implementation of Subpart K

This section provides a functional overview of this subpart.

Section 63.204 Preclosure Standard

This section specifies the dose limits that DOE must meet when storing waste at a geologic repository.

Subpart L—Postclosure Public Health and Environmental Standards

This subpart contains provisions that are consistent with the public health and environmental standards for disposal specified at 40 CFR part 197.

Section 63.301 Purpose and Scope

This section stipulates that, to the extent that there may be a conflict, the requirements in this subpart take precedence over other requirements in subparts A through J.

Section 63.302 Definitions for Subpart L

This section contains definitions of terms as used in this subpart.

Section 63.303 Implementation of Subpart L

This section provides a functional overview of this subpart.

Section 63.304 Reasonable Expectation

This section defines what is meant by the reasonable expectation concept.

Section 63.305 Required Characteristics of the Reference Biosphere

This section specifies characteristics of the reference biosphere to be used by DOE in its performance assessment to demonstrate compliance with the requirements specified at § 63.113(b) and (d).

Postclosure Individual Protection Standard

Section 63.311 Individual Protection Standard After Permanent Closure

This section specifies the dose limit for any geologic repository at the Yucca Mountain site.

Section 63.312 Required Characteristics of the Reasonably Maximally Exposed Individual

This section specifies characteristics of the reasonably maximally exposed individual to be used by DOE in the performance assessment used to demonstrate compliance with the requirements specified at § 63.113(b) and (d).

Human Intrusion Standard

Section 63.321 Individual Protection Standard for Human Intrusion

This section directs DOE to estimate the dose resulting from a stylized human intrusion drilling scenario and specifies the dose limit that any geologic repository at the Yucca Mountain site must meet as the result of any such hypothetical human intrusion.

Section 63.322 Human Intrusion Scenario

This section specifies the assumptions related to a stylized human intrusion scenario DOE will use to estimate the dose to any reasonably maximally exposed individual from a human intrusion.

Ground-Water Protection Standards

Section 63.331 Separate Standards for Protection of Ground Water

This section specifies limits on the levels of radioactivity that would be acceptable in a representative volume of ground water found in the accessible environment for up to 10,000 years following repository closure.

Section 63.332 Representative Volume

This section specifies the assumptions DOE will use to estimate the levels of radioactivity in a representative volume of ground water, at a specified point, down-gradient from any geologic repository at the Yucca Mountain site for up to 10,000 years following repository closure.

Additional Provisions

Section 63.341 Projections of Peak Dose

This section specifies that DOE will estimate peak dose and include the results in its Environmental Impact Statement. However, there is no standard that must be met with respect to these peak dose calculations, and there is no finding that the NRC must make with respect to these peak dose calculations, nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain.

Section 63.342 Limits on Performance Assessments

This section specifies how DOE will identify which features, events, and processes will be considered in the dose assessments described in Subpart L.

Section 63.343 Severability of Individual Protection and Ground-Water Protection Standards

This section stipulates that calculations required by §§ 63.311 and 63.331 can be performed independently of each other.

VI. Section-by-Section Analysis of Corresponding Changes to Other Parts

Section-by-section analysis of changes to parts 2, 19, 20, 21, 30, 40, 51, 61, 70, 72, 73, and 75.

10 CFR Part 2

Section 2.101, Filing of applications, is amended to add a reference to part 63 in the procedures for filing of applications.

Section 2.103, Action on applications for byproduct, source, special nuclear material, and operator licenses, is amended to add a reference to part 63 in the procedures for notification in this section.

Section 2.104, Notice of hearing, is amended to add a reference to part 63 in the procedures for notification of hearings.

Section 2.105, Notice of proposed action, is amended to add a reference to part 63 in the procedures for notification of proposed actions in this section.

Section 2.106(c), Notice of issuance, is amended to provide for public notification of any action with respect to a license application or license amendment under part 63.

Section 2.714—A reference to part 63 is added in the section on interventions in any hearing on a license application for a repository.

Section 2.1013—A reference to part 63 is added in the section on use of the

electronic docket (Licensing Support Network) for a license application for a repository.

Section 2.1014—A reference to part 63 is added in the section on procedures for intervention and for filing an amendment to a contention.

Section 2.1021—A reference to part 63 is added in the section on procedures for conducting the first prehearing conference.

Section 2.1023—A reference to part 63 is added in the section containing criteria for immediate effectiveness of a decision on issuance or amendment of a construction authorization for a repository.

10 CFR Part 19

Section 19.2, Scope, is amended to make part 63 subject to the regulations in part 19.

Section 19.3, Definitions, is amended to add part 63 to the definition of ''license.''

Section 19.20—A reference to part 63 is added in the section on employee protection to make employee protection provisions applicable to employees engaged in protected activities under part 63.

10 CFR Part 20

Section 20.1002, Scope, is amended to make part 63 subject to the regulations in part 20.

Section 20.1003—A reference to part 63 is added to the definition of ''License'' in the definitions section.

Section 20.1401—A reference to part 63 is added to the section on general provisions and scope of radiological criteria for license termination to make these provisions applicable to decommissioning facilities licensed under part 63.

Section 20.2001—A reference to part 63 is added to the section on general requirements for waste disposal.

Section 20.2206—A reference to part 63 is added to the section on reports of individual monitoring to make requirements for individual monitoring applicable to a part 63 licensee.

10 CFR Part 21

Section 21.2(a), Scope, is amended to make part 63 subject to the regulations in part 21.

Certain definitions in § 21.3 are amended to include part 63.

Section 21.21 is amended to make part 63 subject to the regulations for reporting defects and noncompliance.

10 CFR Part 30

Section 30.11, Specific exemptions, is amended to exempt DOE from part 30 regulations for activities subject to part 63.

10 CFR Part 40

Section 40.14, Specific exemptions, is amended to exempt DOE from part 40 regulations for activities subject to part 63.

10 CFR Part 51

Section 51.20, Criteria for and identification of licensing and regulatory actions requiring environmental impact statements, is amended to add a reference to part 63 under actions requiring environmental impact statements.

Section 51.22, Criteria for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review, is amended to add a reference to part 63 in requirements for categorical exclusion from environmental review.

Section 51.26, Requirement to publish notice of intent and conduct scoping process, is amended to add a reference to part 63 in procedures for receipt of an application and accompanying environmental impact statement from DOE.

Section 51.67, Environmental information concerning geologic repositories, is amended to add a reference to part 63 in requirements for submission of an environmental impact statement by DOE.

10 CFR Part 61

Section 61.1, Purpose and scope, is amended to state that the regulations of part 61 do not apply to disposal of HLW as provided for in part 63.

In § 61.2, Definitions, the definition of ''land disposal facility'' is amended to clarify that a geologic repository as defined in part 63 is not considered a land disposal facility.

Section 61.55, Waste classification, is amended to add a reference to part 63 in the definition of a geologic repository.

10 CFR Part 70

Section 70.17—A reference to part 63 is added to the section on specific exemptions to exempt DOE activities that are subject to part 63 or part 60 from the requirements of part 70.

10 CFR Part 72

Section 72.44—A reference to part 63 is added to the section on license conditions. Part 72 already contains a provision limiting the quantity of spent fuel at the site of a monitored retrievable storage facility until a repository authorized under NWPA and part 60 begins operations. This change allows for a repository authorized under part 63 as well.

10 CFR Part 73

Section 73.1—A reference to part 63 is added to the section on purpose and scope. This makes certain requirements for the establishment and maintenance of a physical protection system applicable to a repository licensed under part 63 in addition to part 60.

Section 73.51—A reference to part 63 is added to the section on requirements for physical protection of spent fuel and HLW. Applicability of these requirements is extended to the GROA licensed under part 63.

10 CFR Part 75

Section 75.4—A reference to part 63 is added to the definition of ''Installation'' in the definitions section. This identifies locations where possession of more than 1 effective kilogram of nuclear material requires certain safeguards requirements.

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is publishing licensing criteria for the disposal of spent nuclear fuel and high-level radioactive waste in the proposed geologic repository at Yucca Mountain, Nevada. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VIII. Finding of No Significant Environmental Impact: Availability

Pursuant to section 121(c) of the Nuclear Waste Policy Act, this rule does not require the preparation of an environmental impact statement under section 102(2)(c) of the National Environmental Policy Act of 1969 or any environmental review under subparagraph (E) or (F) of section 102(2) of such act.

IX. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget, approval number 3150–0199.

The public reporting burden for this information collection is estimated to average 121 hours per response, including the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for reducing the burden, to the Records Management Branch (T–6E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0199), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

X. Regulatory Analysis

The NRC has prepared a regulatory analysis for this regulation. The analysis examines the alternatives considered by NRC. The analysis is available for inspection in the NRC's Public Electronic Reading Room at *http://www.nrc.gov/NRC/ADAMS/index.html.*

Single copies of the analysis may be obtained from Clark Prichard, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6203, e-mail *CWP@nrc.gov.*

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this final rule does not have a significant economic impact on a substantial number of small entities. This final rule relates to the licensing of only one entity, the Department of Energy, which does not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act.

XII. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule and, therefore, a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

XIII. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 2

Administrative procedure and practice, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalties, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 60

Criminal penalties, High-level waste, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 61

Criminal penalties, Low-level waste, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 63

Criminal penalties, High-level waste, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 70

Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 72

Administrative practice and procedure, Criminal Penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 75

Criminal penalties, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 2, 19, 20, 21, 30, 40, 51, 60, 61, 70, 72, 73, and 75, and adding the new 10 CFR part 63.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

1. The authority citation for part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87–615, 76 Stat. 409

(42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97–425, 96 Stat. 2213, as amended (42 U.S.C. 10134(f)); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183i, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200–2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948–951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Section 2.205(j) also issued under Pub. L. 101–410, 104 Stat. 90, as amended by section 3100(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2461 note). Sections 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.764 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart M also issued under sec. 184 (42 U.S.C. 2234) and sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91–560, 84 Stat. 1473 (42 U.S.C. 2135).

2. Section 2.101 is amended by revising paragraphs (f)(1) and (f)(5) to read as follows:

§ 2.101 Filing of applications.

* * * * *

(f)(1) Each application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, and any environmental impact statement required in connection therewith pursuant to subpart A of part 51 of this chapter, shall be processed in accordance with the provisions of this paragraph.

* * * * *

(5) If a tendered document is acceptable for docketing, the applicant will be requested to submit to the Director of Nuclear Material Safety and Safeguards such additional copies of the application and environmental impact statement as the regulations in part 60 or 63 and subpart A of part 51 of this chapter require; serve a copy of such application and environmental impact statement on the chief executive of the municipality in which the geologic repository operations area is to be located, or if the geologic repository operations area is not to be located within a municipality, on the chief executive of the county (or to the Tribal organization, if it is to be located within an Indian reservation); and make direct distribution of additional copies to Federal, State, Indian Tribe, and local officials in accordance with the requirements of this chapter, and written instructions from the Director of Nuclear Material Safety and Safeguards. All such copies shall be completely assembled documents, identified by docket number. Subsequently distributed amendments to the application, however, may include revised pages to previous submittals and, in such cases, the recipients are responsible for inserting the revised pages.

* * * * *

3. Section 2.103 is amended by revising paragraph (a) to read as follows:

§ 2.103 Action on applications for byproduct, source, special nuclear material, and operator licenses.

(a) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, finds that an application for a byproduct, source, special nuclear material, or operator license complies with the requirements of the Act, the Energy Reorganization Act, and this chapter, he will issue a license. If the license is for a facility, or for the receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, or if it is to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the State, Tribal, and local officials specified in § 2.104(e) of the issuance of the license. For notice of issuance requirements for licenses issued pursuant to part 61 of this chapter, see § 2.106(d).

* * * * *

4. Section 2.104 is amended by revising paragraph (e) to read as follows:

§ 2.104 Notice of hearing.

* * * * *

(e) The Secretary will give timely notice of the hearing to all parties and to other persons, if any, entitled by law to notice. The Secretary will transmit a notice of the hearing on an application for a license for a production or utilization facility, for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, for a license under part 61 of this chapter, for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, and for a license under part 72 of this chapter to acquire, receive or possess spent fuel for the purpose of storage in an independent spent fuel storage installation (ISFSI) to the governor or other appropriate official of the State and to the chief executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization, if it is to be so located or conducted within an Indian reservation). The Secretary will transmit a notice of hearing on an application for a license under part 72 of this chapter to acquire, receive or possess spent fuel, high-level radioactive waste or radioactive material associated with high-level radioactive waste for the purpose of storage in a monitored retrievable storage installation (MRS) to the same persons who received notice of docketing under § 72.16(e) of this chapter.

5. Section 2.105 is amended by revising paragraph (a)(5) to read as follows:

§ 2.105 Notice of proposed action.

(a) * * *

(5) A license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter.

* * * * *

6. Section 2.106 is amended by revising paragraph (c) to read as follows:

§ 2.106 Notice of issuance.

* * * * *

(c) The Director of Nuclear Material Safety and Safeguards will also cause to be published in the **Federal Register** notice of, and will inform the State, local, and Tribal officials specified in § 2.104(e) of any action with respect to, an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, or for the amendment to such license for which a notice of proposed action has been previously published.

* * * * *

7. Section 2.714 is amended by revising paragraph (d) to read as follows:

§ 2.714 Intervention.

* * * * *

(d) The Commission, the presiding officer, or the Atomic Safety and Licensing Board designated to rule on petitions to intervene and/or requests for hearing shall permit intervention, in any hearing on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area, by the State in which such area is located and by any affected Indian Tribe as defined in part 60 or 63 of this chapter.

* * * * *

8. In § 2.1001, the definitions of *Documentary material, Interested governmental participation, Licensing Support Network,* and *Party* are revised to read as follows:

§ 2.1001 Definitions.

* * * * *

Documentary material means any information upon which a party, potential party, or interested governmental participant intends to rely and/or to cite in support of its position in the proceeding for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter; any information that is known to, and in the possession of, or developed by the party that is relevant to, but does not support, that information or that party's position; and all reports and studies, prepared by or on behalf of the potential party, interested governmental participant, or party, including all related ''circulated drafts,'' relevant to both the license application and the issues set forth in the Topical Guidelines in Regulatory Guide 3.69, regardless of whether they will be relied upon and/or cited by a party. The scope of documentary material shall be guided by the topical guidelines in the applicable NRC Regulatory Guide.

* * * * *

Interested governmental participant means any person admitted under § 2.715(c) of this part to the proceeding on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter.

Licensing Support Network means the combined system that makes documentary material available electronically to parties, potential parties, and interested governmental participants to the proceeding for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, as part of the electronic docket or electronic access to documentary material, beginning in the pre-license application phase.

* * * * *

Party for the purpose of this subpart means the DOE, the NRC staff, the host State, any affected unit of local government as defined in section 2 of the Nuclear Waste Policy Act of 1982, as amended (42 U.S.C. 10101), any affected Indian Tribe as defined in section 2 of the Nuclear Waste Policy Act of 1982, as amended (42 U.S.C. 10101), and a person admitted under § 2.1014 to the proceeding on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area under part 60 or 63 of this chapter, provided that a host State, affected unit of local government, or affected Indian Tribe shall file a list of contentions in accordance with the provisions of § 2.1014(a)(2)(ii) and (iii).

* * * * *

9. Section 2.1013 is amended by revising paragraphs (a)(2) and (c)(1) to read as follows:

§ 2.1013 Use of the electronic docket during the proceeding.

(a) * * *

(2) Commencing with the docketing in an electronic form of the license application to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, the Secretary of the Commission, upon determining that the application can be properly accessed under the Commission's electronic docket rules, will establish an electronic docket to contain the official record materials of the high-level radioactive waste licensing proceeding in searchable full text, or, for material that is not suitable for entry in searchable full text, by header and image, as appropriate.

* * * * *

(c)(1) All filings in the adjudicatory proceeding on the license application to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter shall be transmitted electronically by the submitter to the Presiding Officer, parties, and the Secretary of the Commission, according to established format requirements. Parties and interested governmental participants will be required to use a password security code for the electronic transmission of these documents.

* * * * *

10. Section 2.1014 is amended by revising the introductory text of paragraph (a)(1) and paragraph (a)(4) to read as follows:

§ 2.1014 Intervention.

(a)(1) Any person whose interest may be affected by a proceeding on the application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, and who desires to participate as a party, shall file a written petition for leave to intervene. In a proceeding noticed pursuant to § 2.105, any person whose interest may be affected may also request a hearing. The petition and/or request, and any request to participate under § 2.715(c), shall be filed within thirty days after the publication of the notice of hearing in the **Federal Register**. Nontimely filings will not be entertained absent a determination by the Commission, or the Presiding Officer designated to rule on the petition and/or request, that the petition and/or request should be granted based upon a balancing of the following factors, in addition to satisfying those set out in paragraphs (a)(2) and (c) of this section:

* * * * *

(4) Any party may amend its contentions specified in paragraph (a)(2)(ii) of this section. The Presiding Officer shall rule on any petition to amend such contentions based on the balancing of the factors specified in paragraph (a)(1) of this section and a showing that a significant safety or environmental issue is involved or that the amended contention raises a material issue related to the performance evaluation anticipated by §§ 60.112 and 60.113 or §§ 63.112 and 63.113 of this chapter.

* * * * *

11. Section 2.1021 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 2.1021 First prehearing conference.

(a) In any proceeding involving an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, the Commission or the Presiding Officer will direct the parties, interested governmental participants, and any petitioners for intervention, or their counsel, to appear at a specified time and place, within seventy days after the notice of hearing is published, or such

other time as the Commission or the Presiding Officer may deem appropriate, for a conference to:

* * * * *

12. Section 2.1023 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 2.1023 Immediate effectiveness.

(a) Pending review and final decision by the Commission, an initial decision resolving all issues before the Presiding Officer in favor of issuance or amendment of a construction authorization pursuant to § 60.31 or 63.31 of this chapter or a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to § 60.41 or 63.41 of this chapter, will be immediately effective upon issuance except—

* * * * *

PART 19—NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTION AND INVESTIGATIONS

13. The authority citation for part 19 continues to read as follows:

Authority: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282 2297f); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

14. Section 19.2 is revised to read as follows:

§ 19.2 Scope.

The regulations in this part apply to all persons who receive, possess, use, or transfer material licensed by the Nuclear Regulatory Commission pursuant to the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, including persons licensed to operate a production or utilization facility under part 50 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The regulations regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the Nuclear Regulatory Commission other than those involving NRC employees or NRC contractors. The regulations in this part do not apply to subpoenas issued pursuant to 10 CFR 2.720.

15. Section 19.3 is amended by revising the definition of *License* to read as follows:

§ 19.3 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to operate a production or utilization facility pursuant to part 50 of this chapter.

* * * * *

16. Section 19.20 is revised to read as follows:

§ 19.20 Employee protection.

Employment discrimination by a licensee (or a holder of a certificate of compliance issued pursuant to part 76) or a contractor or subcontractor of a licensee (or a holder of a certificate of compliance issued pursuant to part 76) against an employee for engaging in protected activities under this part or parts 30, 40, 50, 60, 61, 63, 70, 72, 76, or 150 of this chapter is prohibited.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

17. The authority citation for part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

18. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material, or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with § 35.75, or to exposure from voluntary participation in medical research programs.

19. Section 20.1003 is amended by revising the definition of License to read as follows:

§ 20.1003 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 50, 60, 61, 63, 70, or 72 of this chapter.

* * * * *

20. Section 20.1401 is amended by revising paragraph (a) to read as follows:

§ 20.1401 General provisions and scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 50, 60, 61, 63, 70, and 72 of this chapter, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. For high-level and low-level waste disposal facilities (10 CFR parts 60, 61, and 63), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to Appendix A to 10 CFR part 40 or to uranium solution extraction facilities.

* * * * *

21. Section 20.2001 is amended by revising paragraphs (a)(1) and (b)(5) to read as follows:

§ 20.2001 General requirements.

(a) * * *

(1) By transfer to an authorized recipient as provided in § 20.2006 or in the regulations in parts 30, 40, 60, 61, 63, 70, and 72 of this chapter;

* * * * *

(b) * * *

(5) Disposal at a geologic repository under part 60 or part 63 of this chapter.

22. Section 20.2206 is amended by revising paragraph (a)(4) to read as follows:

§ 20.2206 Reports of individual monitoring.

(a) * * *

(4) Possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter; or

* * * * *

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

23. The authority citation for part 21 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 234, 83, Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C.

2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended 1246 (42 U.S.C. 5841, 5846).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

24. Section 21.2 is amended by revising paragraph (a) to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and to each director and responsible officer of such a licensee. The regulations in this part apply also to each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs a production or utilization facility licensed for the manufacture, construction, or operation pursuant to part 50 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste pursuant to part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 or 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 60, 61, 63, 70, 71, or part 72 of this chapter.

* * * * *

§ 21.3 [Amended]

25. In § 21.3, the definitions of Basic component, Commercial grade item, and Dedication are amended by adding the number 63 after ''10 CFR parts 30, 40, 50 (other than nuclear power plants), 60'' and the definition of Substantial safety hazard is amended by adding the number 63 between ''61'' and ''70.''

26. Section 21.21 is amended by revising paragraphs (d)(1)(i) and (d)(1)(ii) to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

* * * * *

(d)(1) * * *

(i) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

27. The authority citation for part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 69 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

28. Section 30.11 is amended by revising paragraph (c) to read as follows:

§ 30.11 Specific exemptions.

* * * * *

(c) The Department of Energy is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 60 or 63 of this chapter.

* * * * *

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

29. The authority citation for part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97–415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243).

Section 40.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

30. Section 40.14 is amended by revising paragraph (c) to read as follows:

§ 40.14 Specific exemptions.

* * * * *

(c) The Department of Energy is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 60 or 63 of this chapter.

* * * * *

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

31. The authority citation for part 51 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953, (42 U.S.C. 2201, 2297f); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842). Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853–854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95–604, Title II, 92 Stat. 3033–3041; and sec. 193, Pub. L. 101–575, 104 Stat. 2835 (42 U.S.C. 2243). Sections 51.20, 51.30 51.60, 51.61, 51.80, and 51.97 also issued under secs 135, 141, Pub. L. 97–425, 96 Stat, 2232, 2241, and sec. 148, Pub. L. 100–203, 101 Stat. 1330–223 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036–3038 (42 U.S.C. 2021) and under Nuclear Waste Policy Act of 1982, sec. 121, 96 Stat. 2228 (42 U.S.C. 10141). Sections 51.43, 51.67, and 51.109 also issued under Nuclear Waste Policy Act of 1982, sec 114(f), 96 Stat. 2216, as amended (42 U.S.C. 10134 (f)).

32. Section 51.20 is amended by revising paragraph (b)(13) to read as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

* * * * *

(b) * * *

(13) Issuance of a construction authorization and license pursuant to part 60 or part 63 of this chapter.

* * * * *

33. Section 51.22 is amended by revising the introductory text of paragraph (c)(3) and paragraphs (c)(10), (c)(12), and (d) to read as follows:

§ 51.22 Criteria for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c) * * *

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 39, 40, 50, 51, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to—

* * * * *

(10) Issuance of an amendment to a permit or license under parts 30, 31, 32, 33, 34, 35, 36, 39, 40, 50, 60, 61, 63, 70, or part 72 of this chapter which —

(i) Changes surety, insurance and/or indemnity requirements; or

(ii) Changes recordkeeping, reporting, or administrative procedures or requirements.

* * * * *

(12) Issuance of an amendment to a license pursuant to parts 50, 60, 61, 63, 70, 72, or 75 of this chapter relating solely to safeguards matters (i.e., protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted pursuant to parts 50, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction impacts. These amendments and approvals are confined to—

(i) Organizational and procedural matters;

(ii) Modifications to systems used for security and/or materials accountability;

(iii) Administrative changes; and

(iv) Review and approval of transportation routes pursuant to 10 CFR 73.37.

* * * * *

(d) In accordance with section 121 of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10141), the promulgation of technical requirements and criteria that the Commission will apply in approving or disapproving applications under part 60 or 63 of this chapter shall not require an environmental impact statement, an environmental assessment, or any environmental review under subparagraph (E) or (F) of section 102(2) of NEPA.

34. Section 51.26 is amended by revising paragraph (c) to read as follows:

§ 51.26 Requirement to publish notice of intent and conduct scoping process.

* * * * *

(c) Upon receipt of an application and accompanying environmental impact statement under § 60.22 or § 63.22 of this chapter (pertaining to geologic repositories for high-level radioactive waste), the appropriate NRC staff director will include in the notice of docketing required to be published by § 2.101(f)(8) of this chapter a statement of Commission intention to adopt the environmental impact statement to the extent practicable. However, if the appropriate NRC staff director determines, at the time of such publication or at any time thereafter, that NRC should prepare a supplemental environmental impact statement in connection with the Commission's action on the license application, the NRC shall follow the procedures set out in paragraph (a) of this section.

35. Section 51.67 is amended by revising paragraphs (a) and (b) to read as follows:

§ 51.67 Environmental information concerning geologic repositories.

(a) In lieu of an environmental report, the Department of Energy, as an applicant for a license or license amendment pursuant to part 60 or 63 of this chapter, shall submit to the Commission any final environmental impact statement which the Department prepares in connection with any geologic repository developed under Subtitle A of Title I, or under Title IV, of the Nuclear Waste Policy Act of 1982, as amended. (See § 60.22 or § 63.22 of this chapter as to the required time and manner of submission.) The statement shall include, among the alternatives under consideration, denial of a license or construction authorization by the Commission.

(b) Under applicable provisions of law, the Department of Energy may be required to supplement its final environmental impact statement if it makes a substantial change in its proposed action that is relevant to environmental concerns or determines that there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts. The Department shall submit any supplement to its final environmental impact statement to the Commission. (See § 60.22 or § 63.22 of this chapter as to the required time and manner of submission.)

* * * * *

PART 60—DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

36. The authority citation for part 60 continues to read as follows:

Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95–601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 114, 121, Pub. L. 97–425, 96 Stat. 2213g, 2238, as amended (42 U.S.C. 10134, 10141), and Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851).

37. Section 60.1 is revised to read as follows:

§ 60.1 Purpose and scope.

This part prescribes rules governing the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated in accordance with the Nuclear Waste Policy Act of 1982. This part does not apply to any activity licensed under another part of this chapter. This part does not apply to the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada, in accordance with the Nuclear Waste Policy Act of 1982, as amended, and the Energy Policy Act of 1992, subject to part 63 of this chapter. This part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 60.11.

PART 61—LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

38. The authority citation for part 61 continues to read as follows:

Authority: Secs. 53, 57, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246, (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95–601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851) and Pub. L. 102–486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851).

39. Section 61.1 is amended by revising paragraph (b) to read as follows:

§ 61.1 Purpose and scope.

* * * * *

(b) Except as provided in part 150 of this chapter, which addresses assumption of certain regulatory authority by Agreement States, and § 61.6 ''Exemptions,'' the regulations in this part apply to all persons in the United States. The regulations in this part do not apply to—

(1) Disposal of high-level waste as provided for in part 60 or 63 of this chapter;

(2) Disposal of uranium or thorium tailings or wastes (byproduct material as defined in § 40.4 (a-1) as provided for in part 40 of this chapter in quantities greater than 10,000 kilograms and containing more than 5 millicuries of radium-226; or

(3) Disposal of licensed material as provided for in part 20 of this chapter.

* * * * *

40. In § 61.2, the definition of Land disposal facility is revised to read as follows:

§ 61.2 Definitions.

* * * * *

Land disposal facility means the land, building, and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this chapter, a ''geologic repository'' as defined in part 60 or 63 is not considered a land disposal facility.

* * * * *

41. Section 61.55 is amended by revising paragraph (a)(2)(iv) to read as follows:

§ 61.55 Waste classification.

(a) * * *

(2) * * *

(iv) Waste that is not generally acceptable for near-surface disposal is waste for which form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this part, such waste must be disposed of in a geologic repository as defined in part 60 or 63 of this chapter unless proposals for disposal of such waste in a disposal site licensed pursuant to this part are approved by the Commission.

* * * * *

42. Part 63 is added to read as follows:

PART 63—DISPOSAL OF HIGH–LEVEL RADIOACTIVE WASTES IN A GEOLOGIC REPOSITORY AT YUCCA MOUNTAIN, NEVADA

Subpart A—General Provisions

Sec.
63.1 Purpose and scope.
63.2 Definitions.
63.3 License required.
63.4 Communications and records.
63.5 Interpretations.
63.6 Exemptions.
63.7 License not required for certain preliminary activities.
63.8 Information collection requirements: OMB Approval.
63.9 Employee protection.
63.10 Completeness and accuracy of information.
63.11 Deliberate misconduct.

Subpart B—Licenses

Preapplication Review

63.15 Site characterization.

63.1 Review of site characterization activities.

License Application

63.21 Content of application.
63.22 Filing and distribution of application.
63.23 Elimination of repetition.
63.24 Updating of application and environmental impact statement.

Construction Authorization

63.31 Construction authorization.
63.32 Conditions of construction authorization.
63.33 Amendment of construction authorization.

License Issuance and Amendment

63.41 Standards for issuance of a license.
63.42 Conditions of license.
63.43 License specification.
63.44 Changes, tests, and experiments.
63.45 Amendment of license.
63.46 Particular activities requiring license amendment.

Permanent Closure

63.51 License amendment for permanent closure.
63.52 Termination of license.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

63.61 Provision of information.
63.62 Site review.
63.63 Participation in license reviews.
63.64 Notice to State.
63.65 Representation.

Subpart D—Records, Reports, Tests, and Inspections

63.71 Records and reports.
63.72 Construction records.
63.73 Reports of deficiencies.
63.74 Tests.
63.75 Inspections.
63.78 Material control and accounting records and reports.

Subpart E—Technical Criteria

63.101 Purpose and nature of findings.
63.102 Concepts.

Preclosure Performance Objectives

63.111 Performance objectives for the geologic repository operations area through permanent closure.

Preclosure Safety Analysis

63.112 Requirements for preclosure safety analysis of the geologic repository operations area.

Postclosure Performance Objectives

63.113 Performance objectives for the geologic repository after permanent closure.

Postclosure Performance Assessment

63.114 Requirements for performance assessment.
63.115 Requirements for multiple barriers.

Land Ownership and Control

63.121 Requirements for ownership and control of interests in land.

Subpart F—Performance Confirmation Program

63.131 General requirements.
63.132 Confirmation of geotechnical and design parameters.
63.133 Design testing.
63.134 Monitoring and testing waste packages.

Subpart G—Quality Assurance

63.141 Scope.
63.142 Quality assurance criteria.
63.143 Implementation.
63.144 Quality assurance program change.

Subpart H—Training and Certification of Personnel

63.151 General requirements.
63.152 Training and certification program.
63.153 Physical requirements.

Subpart I—Emergency Planning Criteria

63.161 Emergency plan for the geologic repository operations area through permanent closure.

Subpart J—Violations

63.171 Violations.
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Subpart K—Preclosure Public Health and Environmental Standards

63.201 Purpose and scope.
63.202 Definitions for Subpart K.
63.203 Implementation of Subpart K.
63.204 Preclosure standard. ;

Subpart L—Postclosure Public Health and Environmental Standards

63.301 Purpose and scope.
63.302 Definitions for Subpart L.
63.303 Implementation of Subpart L.
63.304 Reasonable expectation.
63.305 Required characteristics of the reference biosphere.

Postclosure Individual Protection Standard

63.311 Individual protection standard after permanent closure.
63.312 Required characteristics of the reasonably maximally exposed individual.

Human-Intrusion Standard

63.321 Individual protection standard for human intrusion.
63.322 Human intrusion scenario.

Ground–Water Protection Standards

63.331 Separate standards for protection of ground water.
63.332 Representative volume.

ADDITIONAL PROVISIONS

63.341 Projections of peak dose.
63.342 Limits on performance assessments.
63.343 Severability of individual protection and ground-water protection standards.

Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95–601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 114, 121, Pub. L. 97–425, 96 Stat. 2213g, 2238, as amended (42 U.S.C. 10134, 10141), and Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851).

Subpart A—General Provisions

§ 63.1 Purpose and scope.

This part prescribes rules governing the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada, in accordance with the Nuclear Waste Policy Act of 1982, as amended, and the Energy Policy Act of 1992. As provided in 10 CFR 60.1, the regulations in part 60 of this chapter do not apply to any activity that is subject to licensing under this part. This part does not apply to any activity licensed under another part of this chapter. This part also gives notice to all persons who knowingly provide, to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 63.11.

§ 63.2 Definitions.

As used in this part:

Affected Indian Tribe means any Indian Tribe within whose reservation boundaries a repository for high-level radioactive waste or spent fuel is proposed to be located; or whose Federally-defined possessory or usage rights to other lands outside of the reservation's boundaries arising out of Congressionally-ratified treaties or other Federal law may be substantially and adversely affected by the location of the facility if the Secretary of the Interior finds, on the petition of the appropriate governmental officials of the Tribe, that the effects are both substantial and adverse to the Tribe.

Barrier means any material, structure, or feature that, for a period to be determined by NRC, prevents or substantially reduces the rate of movement of water or radionuclides from the Yucca Mountain repository to the accessible environment, or prevents the release or substantially reduces the release rate of radionuclides from the waste. For example, a barrier may be a geologic feature, an engineered structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around the waste, provided that the material substantially delays movement of water or radionuclides.

Commencement of construction means clearing of land, surface or subsurface excavation, or other substantial action that would adversely affect the environment of a site. It does not include changes desirable for the temporary use of the land for public recreational uses, site characterization activities, other preconstruction monitoring and investigation necessary to establish background information related to the suitability of the Yucca Mountain site or to the protection of environmental values, or procurement or manufacture of components of the geologic repository operations area.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Containment means the confinement of radioactive waste within a designated boundary.

Design bases means that information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be constraints derived from generally accepted ''state-of-the-art'' practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which a structure, system, or component must meet its functional goals. The values for controlling parameters for external events include:

(1) Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved; and

(2) Estimates of severe external human-induced events to be used for deriving design bases, that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.

Director means the Director of the Nuclear Regulatory Commission's Office of Nuclear Material Safety and Safeguards.

Disposal means the emplacement of radioactive waste in a geologic repository with the intent of leaving it there permanently.

DOE means the U.S. Department of Energy or its duly authorized representatives.

Engineered barrier system means the waste packages, including engineered components and systems other than the waste package (e.g., drip shields), and the underground facility.

Event sequence means a series of actions and/or occurrences within the natural and engineered components of a geologic repository operations area that could potentially lead to exposure of individuals to radiation. An event sequence includes one or more initiating events and associated combinations of repository system component failures, including those produced by the action or inaction of operating personnel. Those event sequences that are expected to occur one or more times before permanent closure of the geologic repository operations area are referred to as Category 1 event sequences. Other event sequences that have at least one chance in 10,000 of occurring before permanent closure are referred to as Category 2 event sequences.

Geologic repository means a system that is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. A geologic repository includes the engineered barrier system and the portion of the geologic setting that provides isolation of the radioactive waste.

Geologic repository operations area means a high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, where waste handling activities are conducted.

Geologic setting means the geologic, hydrologic, and geochemical systems of the region in which a geologic repository is or may be located.

High-level radioactive waste or *HLW* means:

(1) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations;

(2) Irradiated reactor fuel; and

(3) Other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation.

HLW facility means a facility subject to the licensing and related regulatory authority of the Commission pursuant to sections 202(3) and 202(4) of the Energy

Reorganization Act of 1974 (88 Stat. 1244).[1]

Host rock means the geologic medium in which the waste is emplaced.

Important to safety, with reference to structures, systems, and components, means those engineered features of the geologic repository operations area whose function is:

(1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of § 63.111(b)(1) for Category 1 event sequences; or

(2) To prevent or mitigate Category 2 event sequences that could result in radiological exposures exceeding the values specified at § 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site.

Important to waste isolation, with reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide a reasonable expectation that high-level waste can be disposed of without exceeding the requirements of § 63.113(b) and (c).

Initiating event means a natural or human induced event that causes an event sequence.

Isolation means inhibiting the transport of radioactive material to:

(1) The location of the reasonably maximally exposed individual so that radiological exposures will not exceed the requirements of § 63.113(b); and

(2) The accessible environment so that releases of radionuclides into the accessible environment will not exceed the requirements of § 63.113(c).

Performance assessment means an analysis that:

(1) Identifies the features, events, processes (except human intrusion), and sequences of events and processes (except human intrusion) that might affect the Yucca Mountain disposal system and their probabilities of occurring during 10,000 years after disposal;

(2) Examines the effects of those features, events, processes, and sequences of events and processes upon the performance of the Yucca Mountain disposal system; and

(3) Estimates the dose incurred by the reasonably maximally exposed individual, including the associated uncertainties, as a result of releases caused by all significant features, events, processes, and sequences of events and processes, weighted by their probability of occurrence.

Performance confirmation means the program of tests, experiments, and analyses that is conducted to evaluate the adequacy of the information used to demonstrate compliance with the performance objectives in subpart E of this part.

Permanent closure means final backfilling of the underground facility, if appropriate, and the sealing of shafts, ramps, and boreholes.

Preclosure safety analysis means a systematic examination of the site; the design; and the potential hazards, initiating events and event sequences and their consequences (e.g., radiological exposures to workers and the public). The analysis identifies structures, systems, and components important to safety.

Public Document Room means the place at One White Flint North, 11555 Rockville Pike, Room O–1F13, Rockville, MD, at which records of the Commission will ordinarily be made available for public inspection and any other place, the location of which has been published in the **Federal Register**, at which public records of the Commission pertaining to a geologic repository at the Yucca Mountain site are made available for public inspection.

Radioactive waste or *waste* means HLW and radioactive materials other than HLW that are received for emplacement in a geologic repository.

Reasonably maximally exposed individual means the hypothetical person meeting the criteria specified at § 63.312.

Reference biosphere means the description of the environment inhabited by the reasonably maximally exposed individual. The reference biosphere comprises the set of specific biotic and abiotic characteristics of the environment, including, but not necessarily limited to, climate, topography, soils, flora, fauna, and human activities.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set aside as a restricted area.

Retrieval means the act of permanently removing radioactive waste from the underground location at which the waste had been previously emplaced for disposal.

Saturated zone means that part of the earth's crust beneath the regional water table in which statistically all voids, large and small, are filled with water under pressure greater than atmospheric.

Site means that area surrounding the geologic repository operations area for which DOE exercises authority over its use in accordance with the provisions of this part.

Site characterization means the program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of the Yucca Mountain site, and the surrounding region to the extent necessary, relevant to the procedures under this part. Site characterization includes borings, surface excavations, excavation of exploratory shafts and/or ramps, limited subsurface lateral excavations and borings, and in situ testing at depth needed to determine the suitability of the site for a geologic repository.

Total effective dose equivalent (TEDE) means, for purposes of assessing doses to workers, the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). For purposes of assessing doses to members of the public (including the RMEI), TEDE means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Underground facility means the underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts, and boreholes, including their seals).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Unsaturated zone means the zone between the land surface and the regional water table. Generally, fluid pressure in this zone is less than atmospheric pressure, and some of the voids may contain air or other gases at atmospheric pressure. Beneath flooded areas or in perched water bodies, the fluid pressure locally may be greater than atmospheric.

Waste form means the radioactive waste materials and any encapsulating or stabilizing matrix.

Waste package means the waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

[1] These are DOE ''facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from activities licensed under such Act (the Atomic Energy Act)'' and ''Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive wastes generated by (DOE), which are not used for, or are part of, research and development activities.''

Water table means that surface in a ground-water body, separating the unsaturated zone from the saturated zone, at which the water pressure is atmospheric.

§ 63.3 License required.

(a) DOE may not receive nor possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site except as authorized by a license issued by the Commission under this part.

(b) DOE may not begin construction of a geologic repository operations area at the Yucca Mountain site unless it has filed an application with the Commission and has obtained construction authorization as provided in this part. Failure to comply with this requirement is grounds for denial of a license.

§ 63.4 Communications and records.

(a) Except where otherwise specified, all communications and reports concerning the regulations in this part and applications filed under them should be addressed to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Communications, reports, and applications may be delivered in person at the Commission's offices at 11555 Rockville Pike, Rockville, MD.

(b) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 63.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel is binding on the Commission.

§ 63.6 Exemptions.

The Commission may, upon application by DOE, any interested person, or upon its own initiative, grant an exemption from the requirements of this part if it determines that the exemption is authorized by law, does not endanger life nor property nor the common defense and security, and is otherwise in the public interest.

§ 63.7 License not required for certain preliminary activities.

The requirement for a license set forth in § 63.3(a) is not applicable to the extent that DOE receives and possesses source, special nuclear, and byproduct material at a geologic repository at the Yucca Mountain site:

(a) For purposes of site characterization; or

(b) For use, during site characterization or construction, as components of radiographic, radiation monitoring, or similar equipment or instrumentation.

§ 63.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150–0199.

(b) The approved information collection requirements contained in this part appear in §§ 63.62, 63.63, and 63.65.

§ 63.9 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant, against an employee, for engaging in certain protected activities, is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission, or his or her employer, information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those aforementioned statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section, or under these requirements, if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section;

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section does not apply to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for—

(1) Denial, revocation, or suspension of the license;

(2) Imposition of a civil penalty on the licensee or applicant; or

(3) Other enforcement action.

(d) Actions taken by an employer, or others, that adversely affect an

employee, may be predicated on nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each licensee and each applicant for a license shall prominently post the revision of NRC Form 3, ''Notice to Employees,'' referenced in § 19.11(c) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D to part 20 of this chapter or by accessing the NRC Web site *www.nrc.gov/NRC/FORMS/forms3.html.*

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision that would prohibit, restrict, or otherwise discourage an employee from participating in a protected activity as defined in paragraph (a)(1) of this section, including, but not limited to, providing information to NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

§ 63.10 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee, or information required by statute, or required by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(b) The applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having, for the regulated activity, a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, within 2 working days of identifying the information. This requirement is not applicable to information that is already required to be provided to the Commission by other reporting or updating requirements.

§ 63.11 Deliberate misconduct.

(a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

Subpart B—Licenses

Preapplication Review

§ 63.15 Site characterization.

(a) DOE shall conduct a program of site characterization with respect to the Yucca Mountain site before it submits an application for a license to be issued under this part.

(b) DOE shall conduct the investigations to obtain the required information in a manner that limits adverse effects on the long-term performance of the geologic repository at Yucca Mountain to the extent practical.

§ 63.16 Review of site characterization activities.[2]

(a) If DOE's planned site characterization activities include onsite testing with radioactive material, including radioactive tracers, the Commission shall determine whether the proposed use of such radioactive material is necessary to provide data for the preparation of the environmental reports required by law and for an application to be submitted under § 63.22.

(b) During the conduct of site characterization activities at the Yucca Mountain site, DOE shall report the nature and extent of the activities, the information that has been developed, and the progress of waste form and waste package research and development to the Commission not less than once every 6 months. The semiannual reports must include the results of site characterization studies, the identification of new issues, plans for additional studies to resolve new issues, elimination of planned studies no longer necessary, identification of decision points reached, and modifications to schedules, where appropriate. DOE shall also report its progress in developing the design of a geologic repository operations area appropriate for the area being characterized, noting when key design parameters or features that depend on the results of site characterization will be established. Other topics related to site characterization must also be covered if requested by the Director.

(c) During the conduct of site characterization activities at the Yucca Mountain site, NRC staff shall be permitted to visit and inspect the locations at which such activities are

[2] In addition to the review of site characterization activities specified in this section, the Commission contemplates an ongoing review of other information on site investigation and site characterization, to allow early identification of potential licensing issues for timely resolution at the staff level.

carried out and to observe excavations, borings, and in situ tests, as they are done.

(d) The Director may comment at any time in writing to DOE, expressing current views on any aspect of site characterization or performance assessment at the Yucca Mountain site. In particular, the Director shall comment whenever he or she determines that there are substantial grounds for making recommendations or stating objections to DOE's site characterization program. The Director shall invite public comment on any comments that the Director makes to DOE on review of the DOE semiannual reports or on any other comments that the Director makes to DOE on site characterization and performance assessment by placing the comments in a public forum to allow the public to comment on them after the Director's comments are sent to DOE.

(e) The Director shall transmit copies of all comments to DOE made by the Director under this section to the Governor and legislature of the State of Nevada and to the governing body of any affected Indian Tribe.

(f) All correspondence between DOE and NRC resulting from the requirements of this section, including the reports described in paragraph (b) of this section, must be placed in the Public Document Room.

(g) The activities described in paragraphs (a) through (f) of this section constitute informal conference between a prospective applicant and the NRC staff, as described in § 2.101(a)(1) of this chapter, and are not part of a proceeding under the Atomic Energy Act of 1954, as amended. Accordingly, the issuance of the Director's comments made under this section does not constitute a commitment to issue any authorization or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board, other presiding officers, or the Director, in any such proceeding.

License Application

§ 63.21 Content of application.

(a) An application consists of general information and a Safety Analysis Report. An environmental impact statement must be prepared in accordance with the Nuclear Waste Policy Act of 1982, as amended, and must accompany the application. Any Restricted Data or National Security Information must be separated from unclassified information. The application must be as complete as possible in the light of information that is reasonably available at the time of docketing.

(b) The general information must include:

(1) A general description of the proposed geologic repository at the Yucca Mountain site, identifying the location of the geologic repository operations area, the general character of the proposed activities, and the basis for the exercise of the Commission's licensing authority.

(2) Proposed schedules for construction, receipt of waste, and emplacement of wastes at the proposed geologic repository operations area.

(3) A description of the detailed security measures for physical protection of high-level radioactive waste in accordance with § 73.51 of this chapter. This plan must include the design for physical protection, the licensee's safeguards contingency plan, and security organization personnel training and qualification plan. The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with such requirements.

(4) A description of the material control and accounting program to meet the requirements of § 63.78.

(5) A description of work conducted to characterize the Yucca Mountain site.

(c) The Safety Analysis Report must include:

(1) A description of the Yucca Mountain site, with appropriate attention to those features, events, and processes of the site that might affect design of the geologic repository operations area and performance of the geologic repository. The description of the site must include information regarding features, events, and processes outside of the site to the extent the information is relevant and material to safety or performance of the geologic repository. The information referred to in this paragraph must include:

(i) The location of the geologic repository operations area with respect to the boundary of the site;

(ii) Information regarding the geology, hydrology, and geochemistry of the site, including geomechanical properties and conditions of the host rock;

(iii) Information regarding surface water hydrology, climatology, and meteorology of the site; and

(iv) Information regarding the location of the reasonably maximally exposed individual, and regarding local human behaviors and characteristics, as needed to support selection of conceptual models and parameters used for the reference biosphere and reasonably maximally exposed individual.

(2) Information relative to materials of construction of the geologic repository operations area (including geologic media, general arrangement, and approximate dimensions), and codes and standards that DOE proposes to apply to the design and construction of the geologic repository operations area.

(3) A description and discussion of the design of the various components of the geologic repository operations area and the engineered barrier system including:

(i) Dimensions, material properties, specifications, analytical and design methods used along with any applicable codes and standards;

(ii) The design criteria used and their relationships to the preclosure and postclosure performance objectives specified at § 63.111(b), § 63.113(b), and § 63.113(c); and

(iii) The design bases and their relation to the design criteria.

(4) A description of the kind, amount, and specifications of the radioactive material proposed to be received and possessed at the geologic repository operations area at the Yucca Mountain site.

(5) A preclosure safety analysis of the geologic repository operations area, for the period before permanent closure, to ensure compliance with § 63.111(a), as required by § 63.111(c). For the purposes of this analysis, it is assumed that operations at the geologic repository operations area will be carried out at the maximum capacity and rate of receipt of radioactive waste stated in the application.

(6) A description of the program for control and monitoring of radioactive effluents and occupational radiological exposures to maintain such effluents and exposures in accordance with the requirements of § 63.111.

(7) A description of plans for retrieval and alternate storage of the radioactive wastes, should retrieval be necessary.

(8) A description of design considerations that are intended to facilitate permanent closure and decontamination or decontamination and dismantlement of surface facilities.

(9) An assessment to determine the degree to which those features, events, and processes of the site that are expected to materially affect compliance with § 63.113—whether beneficial or potentially adverse to performance of the geologic repository—have been characterized, and the extent to which they affect waste isolation. Investigations must extend from the surface to a depth sufficient to determine principal pathways for radionuclide migration from the underground facility. Specific features,

events, and processes of the geologic setting must be investigated outside of the site if they affect performance of the geologic repository.

(10) An assessment of the anticipated response of the geomechanical, hydrogeologic, and geochemical systems to the range of design thermal loadings under consideration, given the pattern of fractures and other discontinuities and the heat transfer properties of the rock mass and water.

(11) An assessment of the ability of the proposed geologic repository to limit radiological exposures to the reasonably maximally exposed individual for the period after permanent closure, as required by § 63.113(b).

(12) An assessment of the ability of the proposed geologic repository to limit releases of radionuclides into the accessible environment as required by § 63.113(c).

(13) An assessment of the ability of the proposed geologic repository to limit radiological exposures to the reasonably maximally exposed individual for the period after permanent closure in the event of human intrusion into the engineered barrier system as required by § 63.113(d).

(14) An evaluation of the natural features of the geologic setting and design features of the engineered barrier system that are considered barriers important to waste isolation as required by § 63.115.

(15) An explanation of measures used to support the models used to provide the information required in paragraphs (c)(9) through (c)(14) of this section. Analyses and models that will be used to assess performance of the geologic repository must be supported by using an appropriate combination of such methods as field tests, in situ tests, laboratory tests that are representative of field conditions, monitoring data, and natural analog studies.

(16) An identification of those structures, systems, and components of the geologic repository, both surface and subsurface, that require research and development to confirm the adequacy of design. For structures, systems, and components important to safety and for the engineered and natural barriers important to waste isolation, DOE shall provide a detailed description of the programs designed to resolve safety questions, including a schedule indicating when these questions would be resolved.

(17) A description of the performance confirmation program that meets the requirements of subpart F of this part.

(18) An identification and justification for the selection of those variables, conditions, or other items that are determined to be probable subjects of license specifications. Special attention must be given to those items that may significantly influence the final design.

(19) An explanation of how expert elicitation was used.

(20) A description of the quality assurance program to be applied to the structures, systems, and components important to safety and to the engineered and natural barriers important to waste isolation. The description of the quality assurance program must include a discussion of how the applicable requirements of § 63.142 will be satisfied.

(21) A description of the plan for responding to, and recovering from, radiological emergencies that may occur at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities, as required by § 63.161.

(22) The following information concerning activities at the geologic repository operations area:

(i) The organizational structure of DOE as it pertains to construction and operation of the geologic repository operations area, including a description of any delegations of authority and assignments of responsibilities, whether in the form of regulations, administrative directives, contract provisions, or otherwise.

(ii) Identification of key positions that are assigned responsibility for safety at and operation of the geologic repository operations area.

(iii) Personnel qualifications and training requirements.

(iv) Plans for startup activities and startup testing.

(v) Plans for conduct of normal activities, including maintenance, surveillance, and periodic testing of structures, systems, and components of the geologic repository operations area.

(vi) Plans for permanent closure and plans for the decontamination or decontamination and dismantlement of surface facilities.

(vii) Plans for any uses of the geologic repository operations area at the Yucca Mountain site for purposes other than disposal of radioactive wastes, with an analysis of the effects, if any, that such uses may have on the operation of the structures, systems, and components important to safety and the engineered and natural barriers important to waste isolation.

(23) A description of the program to be used to maintain the records described in §§ 63.71 and 63.72.

(24) A description of the controls that DOE will apply to restrict access and to regulate land use at the Yucca Mountain site and adjacent areas, including a conceptual design of monuments that would be used to identify the site after permanent closure.

§ 63.22 Filing and distribution of application.

(a) An application for a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site that has been characterized, any amendments to the application, and an accompanying environmental impact statement and any supplements, must be signed by the Secretary of Energy or the Secretary's authorized representative and must be filed in triplicate with the Director.

(b) DOE shall submit 30 additional copies of each portion of the application and any amendments, and each environmental impact statement and any supplements. DOE shall retain another 120 copies for distribution in accordance with written instructions from the Director or the Director's designee.

(c) On notification of the appointment of an Atomic Safety and Licensing Board, DOE shall update the application, eliminating all superseded information, and supplement the environmental impact statement if necessary, and serve the updated application and environmental impact statement (as it may have been supplemented) as directed by the Board. Any subsequent amendments to the application or supplements to the environmental impact statement must be served in the same manner.

(d) When an application, and any amendment to it is filed, copies must be made available in appropriate locations near the proposed geologic repository operations area at the Yucca Mountain site for inspection by the public. These copies must be updated as amendments to the application are made. The environmental impact statement and any supplements to it must be made available in the same manner. An updated copy of the application, and the environmental impact statement and supplements, must be produced at any public hearing held by the Commission on the application for use by any party to the proceeding.

(e) DOE shall certify that the updated copies of the application, and the environmental impact statement as it may have been supplemented, as referred to in paragraphs (c) and (d) of this section, contain the current contents of these documents submitted as required by this part.

§ 63.23 Elimination of repetition.

In its application or environmental impact statement, DOE may incorporate, by reference, information contained in previous applications, statements, or reports filed with the Commission, if the references are clear and specific and copies of the information incorporated are made available to the public locations near the site of the proposed geologic repository, as specified in § 63.22(d).

§ 63.24 Updating of application and environmental impact statement.

(a) The application must be as complete as possible in light of the information that is reasonably available at the time of docketing.

(b) DOE shall update its application in a timely manner so as to permit the Commission to review, before issuance of a license—

(1) Additional geologic, geophysical, geochemical, hydrologic, meteorologic, materials, design, and other data obtained during construction;

(2) Conformance of construction of structures, systems, and components with the design;

(3) Results of research programs carried out to confirm the adequacy of designs, conceptual models, parameter values, and estimates of performance of the geologic repository.

(4) Other information bearing on the Commission's issuance of a license that was not available at the time a construction authorization was issued.

(c) DOE shall supplement its environmental impact statement in a timely manner so as to take into account the environmental impacts of any substantial changes in its proposed actions or any significant new circumstances or information relevant to environmental concerns bearing on the proposed action or its impacts.

Construction Authorization

§ 63.31 Construction authorization.

On review and consideration of an application and environmental impact statement submitted under this part, the Commission may authorize construction of a geologic repository operations area at the Yucca Mountain site if it determines:

(a) Safety.

(1) That there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received and possessed in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public; and

(2) That there is reasonable expectation that the materials can be disposed of without unreasonable risk to the health and safety of the public.

(3) In arriving at these determinations, the Commission shall consider whether—

(i) DOE has described the proposed geologic repository as specified at § 63.21;

(ii) The site and design comply with the performance objectives and requirements contained in subpart E of this part;

(iii) DOE's quality assurance program complies with the requirements of subpart G of this part;

(iv) DOE's personnel training program complies with the criteria contained in subpart H of this part;

(v) DOE's emergency plan complies with the criteria contained in subpart I of this part; and

(vi) DOE's proposed operating procedures to protect health and to minimize danger to life or property are adequate.

(b) Common defense and security. That there is reasonable assurance that the activities proposed in the application will not be inimical to the common defense and security.

(c) Environmental. That, after weighing the environmental, economic, technical, and other benefits against environmental costs, and considering available alternatives, the action called for is the issuance of the construction authorization, with any appropriate conditions to protect environmental values.

§ 63.32 Conditions of construction authorization.

(a) In a construction authorization for a geologic repository operations area at the Yucca Mountain site, the Commission shall include any conditions it considers necessary to protect the health and safety of the public, the common defense and security, or environmental values.

(b) The Commission shall incorporate provisions in the construction authorization requiring DOE to furnish periodic or special reports regarding:

(1) Progress of construction;

(2) Any data about the site, obtained during construction, that are not within the predicted limits on which the facility design was based;

(3) Any deficiencies, in design and construction, that, if uncorrected, could adversely affect safety at any future time; and

(4) Results of research and development programs being conducted to resolve safety questions.

(c) The construction authorization for a geologic repository operations area at the Yucca Mountain site will include restrictions on subsequent changes to the features of the geologic repository and the procedures authorized. The restrictions that may be imposed under this paragraph can include measures to prevent adverse effects on the geologic setting as well as measures related to the design and construction of the geologic repository operations area. These restrictions will fall into three categories of descending importance to public health and safety, as follows:

(1) Those features and procedures that may not be changed without—

(i) 60 days prior notice to the Commission;

(ii) 30 days notice of opportunity for a prior hearing; and

(iii) Prior Commission approval;

(2) Those features and procedures that may not be changed without—

(i) 60 days prior notice to the Commission; and

(ii) Prior Commission approval; and

(3) Those features and procedures that may not be changed without 60 days notice to the Commission. Features and procedures falling in this paragraph section may not be changed without prior Commission approval if the Commission, after having received the required notice, so orders.

(d) A construction authorization must be subject to the limitation that a license to receive and possess source, special nuclear, or byproduct material at the Yucca Mountain site geologic repository operations area may not be issued by the Commission until;

(1) DOE has updated its application, as specified at § 63.24; and

(2) The Commission has made the findings stated in § 63.41.

§ 63.33 Amendment of construction authorization.

(a) An application for amendment of a construction authorization must be filed with the Commission that fully describes any desired changes and follows, as far as applicable, the content requirements prescribed in § 63.21.

(b) In determining whether an amendment of a construction authorization will be approved, the Commission will be guided by the considerations that govern the issuance of the initial construction authorization, to the extent applicable.

License Issuance and Amendment

§ 63.41 Standards for issuance of a license.

A license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site may be issued by the Commission on finding that—

(a) Construction of the geologic repository operations area has been substantially completed in conformity with the application as amended, the provisions of the Atomic Energy Act, and the rules and regulations of the Commission. Construction may be considered substantially complete for the purposes of this paragraph if the construction of—

(1) Surface and interconnecting structures, systems, and components; and

(2) Any underground storage space required for initial operation, are substantially complete.

(b) The activities to be conducted at the geologic repository operations area will be in conformity with the application as amended, the provisions of the Atomic Energy Act and the Energy Reorganization Act, and the rules and regulations of the Commission.

(c) The issuance of the license will not be inimical to the common defense and security and will not constitute an unreasonable risk to the health and safety of the public.

(d) Adequate protective measures can and will be taken in the event of a radiological emergency at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities.

(e) All applicable requirements of part 51 of this chapter have been satisfied.

§ 63.42 Conditions of license.

(a) The Commission shall include any conditions, including license specifications, it considers necessary to protect the health and safety of the public, the common defense and security, and environmental values in a license issued under this part.

(b) Whether stated in the license or not, the following are considered to be conditions in every license issued:

(1) The license is subject to revocation, suspension, modification, or amendment for cause, as provided by the Atomic Energy Act and the Commission's regulations.

(2) DOE shall, at any time while the license is in effect, on written request of the Commission, submit written statements to enable the Commission to determine whether or not the license should be modified, suspended, or revoked.

(3) The license is subject to the provisions of the Atomic Energy Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to or by reason of rules, regulations, and orders issued in accordance with the terms of the Atomic Energy Act.

(c) Each license includes the provisions set forth in section 183 b–d, inclusive, of the Atomic Energy Act, whether or not these provisions are expressly set forth in the license.

(d) A license issued under this part includes the provisions set forth in section 114(d) of the Nuclear Waste Policy Act, as amended, defining the quantity of solidified high-level radioactive waste and spent nuclear fuel, until such time as a second repository is in operation, whether or not these provisions are expressly set forth in the license.

§ 63.43 License specification.

(a) A license issued under this part includes license conditions derived from the analyses and evaluations included in the application, including amendments made before a license is issued, together with any additional conditions the Commission finds appropriate.

(b) License conditions include items in the following categories:

(1) Restrictions as to the physical and chemical form and radioisotopic content of radioactive waste.

(2) Restrictions as to size, shape, and materials and methods of construction of radioactive waste packaging.

(3) Restrictions as to the amount of waste permitted per unit volume of storage space, considering the physical characteristics of both the waste and the host rock.

(4) Requirements relating to test, calibration, or inspection, to assure that the foregoing restrictions are observed.

(5) Controls to be applied to restrict access and to avoid disturbance to the site and to areas outside the site where conditions may affect compliance with §§ 63.111 and 63.113.

(6) Administrative controls, which are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure that activities at the facility are conducted in a safe manner and in conformity with the other license specifications.

§ 63.44 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the geologic repository operations area design or procedures that affects a design function, event sequence, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the Safety Analysis Report (SAR) (as updated) used in establishing the preclosure safety analyses or performance assessment* means:

(i) Changing any of the elements of the method described in the SAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the SAR to another method unless that method has been approved by NRC for the intended application, addition or removal.

(3) *Safety Analysis Report (SAR) (as updated)* means the Safety Analysis Report for the geologic repository, submitted in accordance with § 63.21, as updated in accordance with § 63.24.

(4) *Geologic repository operations area as described in the SAR (as updated)* means:

(i) The structures, systems, and components important to safety or barriers important to waste isolation that are described in the SAR (as updated); and

(ii) The design and performance requirements for such structures, systems, and components described in the SAR (as updated).

(5) *Procedures as described in the SAR (as updated)* means those procedures that contain information described in the SAR (as updated) such as how structures, systems, and components important to safety, or important to waste isolation, are operated or controlled.

(6) *Tests or experiments not described in the SAR (as updated)* means any condition where the geologic repository operations area or any of its structures, systems, and components important to safety, or important to waste isolation, are utilized, controlled, or altered in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the SAR (as updated); or

(ii) Inconsistent with the analyses or descriptions in the SAR (as updated).

(b)(1) DOE may make changes in the geologic repository operations area as described in the SAR (as updated), make changes in the procedures as described in the SAR (as updated), and conduct tests or experiments not described in the SAR (as updated), without obtaining either an amendment of construction authorization under § 63.33 or a license amendment under § 63.45, if:

(i) A change in the conditions incorporated in the construction authorization or license is not required; and

(ii) The change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section.

(2) DOE shall obtain an amendment of construction authorization under § 63.33 or a license amendment under § 63.45, before implementing a change, test, or experiment if it would:

(i) Result in more than a minimal increase in the frequency of occurrence of an event sequence previously evaluated in the SAR (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of structures, systems, components important to safety, or important to waste isolation, which were previously evaluated in the SAR (as updated);

(iii) Result in more than a minimal increase in the consequences of an event sequence previously evaluated in the SAR (as updated);

(iv) Result in more than a minimal increase in the consequences of malfunction of structures, systems, components important to safety, or important to waste isolation, which were previously evaluated in the SAR (as updated);

(v) Create the possibility for an event sequence, or of a pathway for release of radionuclides, of a different type than any evaluated previously in the SAR (as updated);

(vi) Create the possibility for a malfunction of structures, systems, and components important to safety, or important to waste isolation, with a different result than any evaluated previously in the SAR (as updated);

(vii) Result in a departure from a method of evaluation described in the SAR (as updated) used in establishing the preclosure safety analysis or the performance assessment.

(3) In implementing this paragraph, the SAR (as updated) is considered to include SAR changes resulting from evaluations performed pursuant to this section and from safety analyses performed under § 63.33 or § 63.45, as applicable, after the last Safety Analysis Report was updated under § 63.24.

(4) The provisions in this section do not apply to changes to the geologic repository operations area or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(c)(1) DOE shall maintain records of changes in the geologic repository operations area at the Yucca Mountain site, of changes in procedures, and of tests and experiments made under paragraph (b) of this section. These records must include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require an amendment of construction authorization or license amendment under paragraph (b) of this section.

(2) No less frequently than every 24 months, DOE shall prepare a report containing a brief description of such changes, tests, and experiments, including a summary of the evaluation of each. DOE shall furnish the report to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Any report submitted under this paragraph must be made a part of the public record of the licensing proceedings.

(d) Changes to the quality assurance program description required by § 63.21(c)(20) must be processed in accordance with § 63.144.

§ 63.45 Amendment of license.

(a) An application for amendment of a license may be filed with the Commission fully describing the changes desired and following as far as applicable the format prescribed for license applications.

(b) In determining whether an amendment of a license will be approved, the Commission will be guided by the considerations that govern the issuance of the initial license, to the extent applicable.

§ 63.46 Particular activities requiring license amendment.

(a) Unless expressly authorized in the license, a license amendment is required for any of the following activities:

(1) Any action that would make emplaced high-level radioactive waste irretrievable or that would substantially increase the difficulty of retrieving the emplaced waste;

(2) Dismantling of structures;

(3) Removal or reduction of controls applied to restrict access to or avoid disturbance of the site and to areas outside the site where conditions may affect compliance with §§ 63.111 and 63.113;

(4) Destruction or disposal of records required to be maintained under the provisions of this part;

(5) Any substantial change to the design or operating procedures from that specified in the license, except as authorized in § 63.44; and

(6) Permanent closure.

(b) An application for an amendment must be filed, and will be reviewed, as specified in § 63.45.

Permanent Closure

§ 63.51 License amendment for permanent closure.

(a) DOE shall submit an application to amend the license before permanent closure of a geologic repository at the Yucca Mountain site. The submission must consist of an update of the license application submitted under §§ 63.21 and 63.22, including:

(1) An update of the assessment of the performance of the geologic repository for the period after permanent closure. The updated assessment must include any performance confirmation data collected under the program required by subpart F, and pertinent to compliance with § 63.113.

(2) A description of the program for post-permanent closure monitoring of the geologic repository.

(3) A detailed description of the measures to be employed—such as land use controls, construction of monuments, and preservation of records—to regulate or prevent activities that could impair the long-term isolation of emplaced waste within the geologic repository and to assure that relevant information will be preserved for the use of future generations. As a minimum, these measures must include:

(i) Identification of the site and geologic repository operations area by monuments that have been designed, fabricated, and emplaced to be as permanent as is practicable;

(ii) Placement of records in the archives and land record systems of local, State, and Federal government agencies, and archives elsewhere in the world, that would be likely to be consulted by potential human intruders—such records to identify the location of the geologic repository operations area, including the underground facility, boreholes, shafts and ramps, and the boundaries of the site, and the nature and hazard of the waste; and

(iii) A program for continued oversight, to prevent any activity at the site that poses an unreasonable risk of breaching the geologic repository's engineered barriers; or increasing the exposure of individual members of the public to radiation beyond allowable limits.

(4) Geologic, geophysical, geochemical, hydrologic, and other site data that are obtained during the operational period, pertinent to compliance with § 63.113.

(5) The results of tests, experiments, and any other analyses relating to backfill of excavated areas, shaft, borehole, or ramp sealing, drip shields, waste packages, interactions between

natural and engineered systems, and any other tests, experiments, or analyses pertinent to compliance with § 63.113.

(6) Any substantial revision of plans for permanent closure.

(7) Other information bearing on permanent closure that was not available at the time a license was issued.

(b) If necessary, to take into account the environmental impact of any substantial changes in the permanent closure activities proposed to be carried out or any significant new information regarding the environmental impacts of permanent closure, DOE shall also supplement its environmental impact statement and submit this statement, as supplemented, with the application for license amendment.

§ 63.52 Termination of license.

(a) Following permanent closure and the decontamination or decontamination and dismantlement of surface facilities at the Yucca Mountain site, DOE may apply for an amendment to terminate the license.

(b) The application must be filed and will be reviewed in accordance with the provisions of § 63.45 and this section.

(c) A license may be terminated only when the Commission finds with respect to the geologic repository:

(1) That the final disposition of radioactive wastes has been made in conformance with DOE's plan, as amended and approved as part of the license.

(2) That the final state of the geologic repository operations area conforms to DOE's plans for permanent closure and DOE's plans for the decontamination or decontamination and dismantlement of surface facilities, as amended and approved as part of the license.

(3) That the termination of the license is authorized by law, including sections 57, 62, and 81 of the Atomic Energy Act, as amended.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

§ 63.61 Provision of information.

(a) The Director shall provide the Governor and the Nevada State legislature, affected units of local government, and the governing body of any affected Indian Tribe, with timely and complete information regarding determinations or plans made by the Commission with respect to the Yucca Mountain site. Information must be provided concerning the site characterization, siting, development, design, licensing, construction, operation, regulation, permanent closure, or decontamination and dismantlement of surface facilities of the geologic repository operations area at the site.

(b) Notwithstanding paragraph (a) of this section, the Director is not required to distribute any document to any entity if, with respect to the document, that entity or its counsel is included on a service list prepared under part 2 of this chapter.

(c) Copies of all communications by the Director under this section must be placed in the Public Document Room and furnished to DOE.

§ 63.62 Site review.

(a) The Director shall make the NRC staff available to consult with representatives of the State of Nevada, affected units of local government, and affected Indian Tribes regarding the status of site characterization at the Yucca Mountain site.

(b) Requests for consultation must be made in writing to the Director.

(c) Consultation under this section may include:

(1) Keeping the parties informed of the Director's views on the progress of site characterization.

(2) Review of applicable NRC regulations, licensing procedures, schedules, and opportunities for State, affected units of local government, and Tribe participation in the Commission's regulatory activities.

(3) Cooperation in development of proposals for State, affected units of local government, and Tribal participation in license reviews.

§ 63.63 Participation in license reviews.

(a) The State, affected units of local government, and affected Indian Tribes may participate in license reviews as provided in subpart J of part 2 of this chapter.

(b) In addition, a State, or an affected unit of local government, or an affected Indian Tribe may submit a proposal to the Director to facilitate its participation in the review of the license application. The proposal may be submitted at any time and must contain a description and schedule of how the State, or affected unit of local government, or affected Indian Tribe wishes to participate in the review, or what services or activities the State, or affected unit of local government, or affected Indian Tribe wishes the NRC to carry out, and how the services or activities proposed to be carried out by the NRC would contribute to this participation. The proposal may include educational or information services (seminars, public meetings) or other actions on the part of NRC, such as establishing additional public document rooms or employment or exchange of State personnel under the Intergovernmental Personnel Act.

(c) The Director shall arrange for a meeting between the representatives of the State, or affected unit of local government, or affected Indian Tribe and the NRC staff, to discuss any proposal submitted under paragraph (b) of this section, with a view to identifying any modifications that may contribute to the effective participation by such State, or affected unit of local government, or Tribe.

(d) Subject to the availability of funds, the Director shall approve all or any part of a proposal, as it may be modified through the meeting described in paragraph (c) of this section, if it is determined that:

(1) The proposed activities are suitable in light of the type and magnitude of impacts that the State, or affected unit of local government, or affected Indian Tribe may bear;

(2) The proposed activities—

(i) Will enhance communications between NRC and the State, or affected unit of local government, or affected Indian Tribe;

(ii) Will make a productive and timely contribution to the review; and

(iii) Are authorized by law.

(e) The Director shall advise the State, or affected unit of local government, or affected Indian Tribe whether its proposal has been accepted or denied. If all or any part of a proposal is denied, the Director shall state the reason for the denial.

(f) Proposals submitted under this section, and responses to them, must be made available at the Public Document Room.

§ 63.64 Notice to State.

If the Governor and legislature of the State of Nevada have jointly designated, on their behalf, a single person or entity to receive notice and information from the Commission under this part, the Commission will provide the notice and information to the jointly designated person or entity instead of the Governor and legislature separately.

§ 63.65 Representation.

Any person who acts under this subpart as a representative for the State of Nevada (or for the Governor or legislature of Nevada), for an affected unit of local government, or for an affected Indian Tribe shall include in the request or other submission, or at the request of the Commission, a statement of the basis of his or her authority to act in this capacity.

Subpart D—Records, Reports, Tests, and Inspections

§ 63.71 Records and reports.

(a) DOE shall maintain records and make reports in connection with the licensed activity that are required by the conditions of the license or by rules, regulations, and orders of the Commission, as authorized by the Atomic Energy Act and the Energy Reorganization Act.

(b) Records of the receipt, handling, and disposition of radioactive waste at a geologic repository operations area at the Yucca Mountain site must contain sufficient information to provide a complete history of the movement of the waste from the shipper through all phases of storage and disposal. DOE shall retain these records in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

§ 63.72 Construction records.

(a) DOE shall maintain records of construction of the geologic repository operations area at the Yucca Mountain site in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

(b) The records required under paragraph (a) of this section must include at least the following—

(1) Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to readily identifiable surface features or monuments;

(2) A description of the materials encountered;

(3) Geologic maps and geologic cross-sections;

(4) Locations and amount of seepage;

(5) Details of equipment, methods, progress, and sequence of work;

(6) Construction problems;

(7) Anomalous conditions encountered;

(8) Instrument locations, readings, and analysis;

(9) Location and description of structural support systems;

(10) Location and description of dewatering systems;

(11) Details, methods of emplacement, and location of seals used; and

(12) Facility design records (e.g, design specifications and ''as built'' drawings).

§ 63.73 Reports of deficiencies.

(a) DOE shall promptly notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site, and design, and construction of the geologic repository operations area that, were it to remain uncorrected, could—

(1) Adversely affect safety at any future time;

(2) Represent a significant deviation from the design criteria and design basis stated in the design application; or

(3) Represent a deviation from the conditions stated in the terms of a construction authorization or the license, including license specifications.

(b) DOE shall implement a program for evaluating and reporting deviations and failures to comply, to identify defects and failures to comply associated with substantial safety hazards, based on the applicable requirements in 10 CFR 50.55(e) as it applies to the construction authorization and design of the geologic repository operations area at the Yucca Mountain site.

(c) DOE shall implement a program of reporting specific events and conditions that is the same as that specified in 10 CFR 72.75.

(d) The requisite notification must be as specified in the applicable regulation. Copies of the written report must be sent to the NRC Operations Center, Document Control Desk, U.S. NRC, to the Director of NMSS, U.S. NRC, and to the NRC onsite representative.

§ 63.74 Tests.

(a) DOE shall perform, or permit the Commission to perform, those tests the Commission considers appropriate or necessary for the administration of the regulations in this part. This may include tests of—

(1) Radioactive waste,

(2) The geologic repository, including portions of the geologic setting and the structures, systems, and components constructed or placed therein,

(3) Radiation detection and monitoring instruments, and

(4) Other equipment and devices used in connection with the receipt, handling, or storage of radioactive waste.

(b) The tests required under this section must include a performance confirmation program carried out in accordance with subpart F of this part.

§ 63.75 Inspections.

(a) DOE shall allow the Commission to inspect the premises of the geologic repository operations area at the Yucca Mountain site and adjacent areas to which DOE has rights of access.

(b) DOE shall make available to the Commission for inspection, on reasonable notice, records kept by DOE pertaining to activities under this part.

(c)(1) DOE shall, on requests by the Director, Office of Nuclear Material Safety and Safeguards, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air-conditioning, light, electrical outlets, and janitorial services must be furnished by DOE. The office must be convenient to and have full access to the facility and must provide the inspector both visual and acoustic privacy.

(2) The space provided must be adequate to accommodate two full-time inspectors, and other transient NRC personnel and will be generally commensurate with other office facilities at the Yucca Mountain site geologic repository operations area. A space of 250 square feet either within the geologic repository operations area's office complex or in an office trailer or other onsite space at the geologic repository operations area is suggested as a guide. For locations at which activities are carried out under licenses issued under other parts of this chapter, additional space may be requested to accommodate additional full-time inspectors. The office space provided is subject to the approval of the Director, Office of Nuclear Material Safety and Safeguards. All furniture, supplies, and communication equipment will be furnished by the Commission.

(3) DOE shall afford any NRC resident inspector assigned to the Yucca Mountain site or other NRC inspectors identified by the Regional Administrator as likely to inspect the Yucca Mountain facility, immediate unfettered access, equivalent to access provided regular employees, after proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

§ 63.78 Material control and accounting records and reports.

DOE shall implement a program of material control and accounting (and accidental criticality reporting) that is the same as that specified in §§ 72.72, 72.74, 72.76, and 72.78 of this chapter.

Subpart E—Technical Criteria

§ 63.101 Purpose and nature of findings.

(a)(1) Subpart B prescribes the standards for issuance of a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site. In particular, § 63.41(c) requires a finding that the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. The purpose of this subpart is to set out the performance objectives for postclosure performance of the geologic repository and other criteria that, if satisfied, support a finding of no unreasonable risk.

Postclosure performance objectives for the geologic repository include a requirement to limit radiological exposures to the reasonably maximally exposed individual, a requirement to limit releases of radionuclides to the accessible environment to protect ground water, and a requirement to limit radiological exposures to the reasonably maximally exposed individual in the event of human intrusion (see § 63.113(b), (c), and (d), respectively).

(2) Although the postclosure performance objectives specified at § 63.113 are generally stated in unqualified terms, it is not expected that complete assurance that the requirements will be met can be presented. A reasonable expectation, on the basis of the record before the Commission, that the postclosure performance objectives will be met, is the general standard required. Proof that the geologic repository will conform with the objectives for postclosure performance is not to be had in the ordinary sense of the word because of the uncertainties inherent in the understanding of the evolution of the geologic setting, biosphere, and engineered barrier system. For such long-term performance, what is required is reasonable expectation, making allowance for the time period, hazards, and uncertainties involved, that the outcome will conform with the objectives for postclosure performance for the geologic repository. Demonstrating compliance will involve the use of complex predictive models that are supported by limited data from field and laboratory tests, site-specific monitoring, and natural analog studies that may be supplemented with prevalent expert judgment. Compliance demonstrations should not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence. The performance assessments and analyses should focus upon the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values. Further, in reaching a determination of reasonable expectation, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity among the multiple barriers as a measure of the resiliency of the geologic repository.

(b) Subpart B lists findings that must be made in support of an authorization to construct a geologic repository operations area at the Yucca Mountain site. Prior to closure, § 63.31(a)(1) requires a finding that there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and stored in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. After permanent closure, § 63.31(a)(2) requires the Commission to consider whether there is a reasonable expectation the site and design comply with the postclosure performance objectives. Once again, although the criteria may be written in unqualified terms, the demonstration of compliance must take uncertainties and gaps in knowledge into account so that the Commission can make the specified finding with respect to paragraph (a)(2) of § 63.31.

§ 63.102 Concepts.

This section provides a functional overview of this Subpart E. In the event of any inconsistency, the definitions in § 63.2 prevail.

(a) *The HLW facility at the Yucca Mountain site.* NRC exercises licensing and related regulatory authority over those facilities described in section 202 (3) and (4) of the Energy Reorganization Act of 1974, including the site at Yucca Mountain, as designated by the Energy Policy Act of 1992.

(b) *The geologic repository operations area.*

(1) These regulations deal with the exercise of authority with respect to a particular class of HLW facility—namely, a geologic repository operations area at Yucca Mountain.

(2) *A geologic repository operations area* consists of those surface and subsurface areas of the site that are part of a geologic repository where radioactive waste handling activities are conducted. The underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts and boreholes, including their seals), are designated the *underground facility.*

(3) The exercise of Commission authority requires that the geologic repository operations area be used for storage (which includes disposal) of *high-level radioactive wastes* (HLW).

(4) HLW includes irradiated reactor fuel as well as reprocessing wastes. However, if DOE proposes to use the geologic repository operations area for storage of radioactive waste other than HLW, the storage of this radioactive waste is subject to the requirements of this part.

(c) *Stages in the licensing process.* There are several stages in the licensing process. The *site characterization* stage, when the performance confirmation program is started, begins before submission of a license application, and may result in consequences requiring evaluation in the license review. The construction stage would follow after the issuance of a construction authorization. A period of operations follows the Commission's issuance of a license. The period of operations includes the time during which *emplacement* of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are *retrievable*; and *permanent closure,* which includes sealing openings to the repository. Permanent closure represents the end of the performance confirmation program; final backfilling of the underground facility, if appropriate; and the sealing of shafts, ramps, and boreholes.

(d) *Areas related to isolation.* Although the activities subject to regulation under this part are those to be carried out at the geologic repository operations area, the licensing process also considers characteristics of adjacent areas that are defined in other ways. There must be an area surrounding the geologic repository operations area, that could include either a portion or all of the site, within which DOE shall exercise specified controls to prevent adverse human actions after permanent closure. There is an area, designated the geologic setting, which includes the geologic, hydrologic, and geochemical systems of the region in which the site and geologic repository operations area are located. The geologic repository operations area, plus the portion of the geologic setting that provides isolation of the radioactive waste, make up the geologic repository.

(e) *Performance objectives through permanent closure.* Before permanent closure, the geologic repository operations area is required to limit radiation levels and radiological exposures, in both restricted and unrestricted areas, and releases of radioactive materials to unrestricted areas, as specified at § 63.111(a).

(f) *Preclosure safety analysis.* Section 63.111 includes performance objectives for the geologic repository operations area for the period before permanent closure and decontamination or permanent closure, decontamination, and dismantlement of surface facilities. The preclosure safety analysis is a systematic examination of the site; the design; and the potential hazards, initiating events and their resulting event sequences and potential radiological exposures to workers and the public. Initiating events are to be considered for inclusion in the

preclosure safety analysis for determining event sequences only if they are reasonable (i.e., based on the characteristics of the geologic setting and the human environment, and consistent with precedents adopted for nuclear facilities with comparable or higher risks to workers and the public). The analysis identifies structures, systems, and components important to safety.

(g) *Performance objectives after permanent closure.* After permanent closure, the geologic repository is required to:

(1) Limit radiological exposures to the reasonably maximally exposed individual, as specified at § 63.113(b);

(2) Limit releases of radionuclides to the accessible environment to protect ground water, as specified at § 63.113(c); and

(3) Limit radiological exposures to the reasonably maximally exposed individual in the event of human intrusion, as specified at § 63.113(d).

(h) *Multiple barriers.* Section 63.113(a) requires that the geologic repository include multiple barriers, both natural and engineered. Geologic disposal of HLW is predicated on the expectation that one or more aspects of the geologic setting will be capable of contributing to the isolation of radioactive waste and thus be a barrier important to waste isolation. Although there is an extensive geologic record ranging from thousands to millions of years, this record is subject to interpretation and includes many uncertainties. In addition, there are uncertainties in the isolation capability and performance of engineered barriers. Although the composition and configuration of engineered structures (barriers) can be defined with a degree of precision not possible for natural barriers, it is recognized that except for a few archaeologic and natural analogs, there is a limited experience base for the performance of complex, engineered structures over periods longer than a few hundred years, considering the uncertainty in characterizing and modeling individual barriers. These uncertainties are addressed by requiring the use of a multiple barrier approach; specifically, an engineered barrier system is required in addition to the natural barriers provided by the geologic setting. The performance assessment provides an evaluation of the repository performance based on credible models and parameters including the consideration of uncertainty in the behavior of the repository system. Thus the performance assessment results reflect the capability of each of the barriers to cope with a variety of challenges (e.g., combinations of parameters leading to less favorable performance for individual barriers and combinations of barriers). A description of each barrier's capability (e.g., retardation of radionuclides in the saturated zone, waste package lifetime, matrix diffusion in the unsaturated zone), as reflected in the performance assessment, provides an understanding of how the natural barriers and the engineered barrier system work in combination to enhance the resiliency of the geologic repository. The Commission believes that this understanding can increase confidence that the postclosure performance objectives specified at § 63.113(b) and (c) will be achieved and that DOE's design includes a system of multiple barriers.

(i) *Reference biosphere and reasonably maximally exposed individual.* The performance assessment will estimate the amount of radioactive material released to water or air at various locations and times in the future. To estimate the potential for future human exposures resulting from release of radioactive material from a geologic repository at Yucca Mountain, it is necessary to make certain assumptions about the location and characteristics of the reasonably maximally exposed individual. The environment inhabited by the reasonably maximally exposed individual, along with associated human exposure pathways and parameters, make up the reference biosphere, as described in § 63.305. The reasonably maximally exposed individual, as a hypothetical person living in a community with characteristics of the Town of Amargosa Valley, is a representative person using water with average concentrations of radionuclides as described at § 63.312. The reasonably maximally exposed individual is selected to represent those persons in the vicinity of Yucca Mountain who are reasonably expected to receive the greatest exposure to radioactive material released from a geologic repository at Yucca Mountain. Characteristics of the reference biosphere and the reasonably maximally exposed individual are to be based on current human behavior and biospheric conditions in the region, as described in § 63.305 and § 63.312.

(j) *Performance assessment.* Demonstrating compliance with the postclosure performance objective specified at § 63.113(b) requires a performance assessment to quantitatively estimate radiological exposures to the reasonably maximally exposed individual at any time during the compliance period. The performance assessment is a systematic analysis that identifies the features, events, and processes (i.e., specific conditions or attributes of the geologic setting, degradation, deterioration, or alteration processes of engineered barriers, and interactions between the natural and engineered barriers) that might affect performance of the geologic repository; examines their effects on performance; and estimates the radiological exposures to the reasonably maximally exposed individual. The features, events, and processes considered in the performance assessment should represent a wide range of both beneficial and potentially adverse effects on performance (e.g., beneficial effects of radionuclide sorption; potentially adverse effects of fracture flow or a criticality event). Those features, events, and processes expected to materially affect compliance with § 63.113(b) or be potentially adverse to performance are included, while events (event classes or scenario classes) that are very unlikely (less than one chance in 10,000 over 10,000 years) can be excluded from the analysis. An event class consists of all possible specific initiating events that are caused by a common natural process (e.g., the event class for seismicity includes the range of credible earthquakes for the Yucca Mountain site). Radiological exposures to the reasonably maximally exposed individual are estimated using the selected features, events, and processes, and incorporating the probability that the estimated exposures will occur. Additionally, performance assessment methods are appropriate for use in demonstrating compliance with the postclosure performance objectives for ground-water protection and human intrusion, and are subject to the requirements for performance assessments specified at § 63.114 and applicable criteria in Subpart L (e.g., criteria for evaluating compliance with ground-water protection and individual protection standards).

(k) *Institutional controls.* Active and passive institutional controls will be maintained over the Yucca Mountain site, and are expected to reduce significantly, but not eliminate, the potential for human activity that could inadvertently cause or accelerate the release of radioactive material. However, because it is not possible to make scientifically sound forecasts of the long-term reliability of institutional controls, it is not appropriate to include consideration of human intrusion into a fully risk-based performance assessment for purposes of evaluating the ability of

the geologic repository to achieve the performance objective at § 63.113(b). Hence, human intrusion is addressed in a stylized manner as described in paragraph (l) of this section.

(l) *Human intrusion.* In contrast to events unrelated to human activity, the probability and characteristics of human intrusion occurring many hundreds or thousands of years into the future cannot be estimated by examining either the historic or geologic record. Rather than speculating on the nature and probability of future intrusion, it is more useful to assess how resilient the geologic repository would be against a human intrusion event. Although the consequences of an assumed intrusion event would be a separate analysis, the analysis is similar to the performance assessment required by § 63.113(b) but subject to specific requirements for evaluation of human intrusion specified at §§ 63.321, 63.322 and 63.342 of subpart L of this part.

(m) *Performance confirmation.* A performance confirmation program will be conducted to evaluate the adequacy of assumptions, data, and analyses that led to the findings that permitted construction of the repository and subsequent emplacement of the wastes. Key geotechnical and design parameters, including any interactions between natural and engineered systems and components, will be monitored throughout site characterization, construction, emplacement, and operation to identify any significant changes in the conditions assumed in the license application that may affect compliance with the performance objectives specified at § 63.113(b) and (c).

(n) *Ground-Water Protection.* Separate ground-water protection standards are designed to protect the ground water resources in the vicinity of Yucca Mountain. These standards, specified at § 63.331, require the estimation of ground water concentrations in the representative volume of water. Depending on the radionuclide, the estimated concentrations must either be below a specified concentration or result in an annual, drinking water dose to the whole body or any organ of no greater than 0.04 mSv (4 mrem). Although the estimation of radionuclide concentrations in the representative volume would be a separate analysis, the analysis is similar to the performance assessment required by § 63.113(b) but subject to specific requirements for evaluation of ground-water protection specified at §§ 63.331, 63.332 and 63.342 of subpart L of this part.

Preclosure Performance Objectives

§ 63.111 Performance objectives for the geologic repository operations area through permanent closure.

(a) *Protection against radiation exposures and releases of radioactive material.*

(1) The geologic repository operations area must meet the requirements of part 20 of this chapter.

(2) During normal operations, and for Category 1 event sequences, the annual TEDE (hereafter referred to as ''dose'') to any real member of the public located beyond the boundary of the site may not exceed the preclosure standard specified at § 63.204.

(b) *Numerical guides for design objectives.*

(1) The geologic repository operations area must be designed so that, taking into consideration Category 1 event sequences and until permanent closure has been completed, the aggregate radiation exposures and the aggregate radiation levels in both restricted and unrestricted areas, and the aggregate releases of radioactive materials to unrestricted areas, will be maintained within the limits specified in paragraph (a) of this section.

(2) The geologic repository operations area must be designed so that, taking into consideration any single Category 2 event sequence and until permanent closure has been completed, no individual located on, or beyond, any point on the boundary of the site will receive, as a result of the single Category 2 event sequence, the more limiting of a TEDE of 0.05 Sv (5 rem), or the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The lens dose equivalent may not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin may not exceed 0.5 Sv (50 rem).

(c) *Preclosure safety analysis.* A preclosure safety analysis of the geologic repository operations area that meets the requirements specified at § 63.112 must be performed. This analysis must demonstrate that:

(1) The requirements of § 63.111(a) will be met; and

(2) The design meets the requirements of § 63.111(b).

(d) *Performance confirmation.* The geologic repository operations area must be designed so as to permit implementation of a performance confirmation program that meets the requirements of subpart F of this part.

(e) *Retrievability of waste.*

(1) The geologic repository operations area must be designed to preserve the option of waste retrieval throughout the period during which wastes are being emplaced and thereafter, until the completion of a performance confirmation program and Commission review of the information obtained from such a program. To satisfy this objective, the geologic repository operations area must be designed so that any or all of the emplaced waste could be retrieved on a reasonable schedule starting at any time up to 50 years after waste emplacement operations are initiated, unless a different time period is approved or specified by the Commission. This different time period may be established on a case-by-case basis consistent with the emplacement schedule and the planned performance confirmation program.

(2) This requirement may not preclude decisions by the Commission to allow backfilling part, or all of, or permanent closure of the geologic repository operations area, before the end of the period of design for retrievability.

(3) For purposes of paragraph (e) of this section, a reasonable schedule for retrieval is one that would permit retrieval in about the same time as that required to construct the geologic repository operations area and emplace waste.

Preclosure Safety Analysis

§ 63.112 Requirements for preclosure safety analysis of the geologic repository operations area.

The preclosure safety analysis of the geologic repository operations area must include:

(a) A general description of the structures, systems, components, equipment, and process activities at the geologic repository operations area;

(b) An identification and systematic analysis of naturally occurring and human-induced hazards at the geologic repository operations area, including a comprehensive identification of potential event sequences;

(c) Data pertaining to the Yucca Mountain site, and the surrounding region to the extent necessary, used to identify naturally occurring and human-induced hazards at the geologic repository operations area;

(d) The technical basis for either inclusion or exclusion of specific, naturally occurring and human-induced hazards in the safety analysis;

(e) An analysis of the performance of the structures, systems, and components to identify those that are important to safety. This analysis identifies and describes the controls that are relied on to limit or prevent potential event sequences or mitigate their

consequences. This analysis also identifies measures taken to ensure the availability of safety systems. The analysis required in this paragraph must include, but not necessarily be limited to, consideration of—

(1) Means to limit concentration of radioactive material in air;

(2) Means to limit the time required to perform work in the vicinity of radioactive materials;

(3) Suitable shielding;

(4) Means to monitor and control the dispersal of radioactive contamination;

(5) Means to control access to high radiation areas or airborne radioactivity areas;

(6) Means to prevent and control criticality;

(7) Radiation alarm system to warn of significant increases of radiation levels, concentrations of radioactive material in air, and increased radioactivity in effluents;

(8) Ability of structures, systems, and components to perform their intended safety functions, assuming the occurrence of event sequences;

(9) Explosion and fire detection systems and appropriate suppression systems;

(10) Means to control radioactive waste and radioactive effluents, and permit prompt termination of operations and evacuation of personnel during an emergency;

(11) Means to provide reliable and timely emergency power to instruments, utility service systems, and operating systems important to safety if there is a loss of primary electric power;

(12) Means to provide redundant systems necessary to maintain, with adequate capacity, the ability of utility services important to safety; and

(13) Means to inspect, test, and maintain structures, systems, and components important to safety, as necessary, to ensure their continued functioning and readiness.

(f) A description and discussion of the design, both surface and subsurface, of the geologic repository operations area, including—

(1) The relationship between design criteria and the requirements specified at § 63.111(a) and (b); and

(2) The design bases and their relation to the design criteria.

Postclosure Performance Objectives

§ 63.113 Performance objectives for the geologic repository after permanent closure.

(a) The geologic repository must include multiple barriers, consisting of both natural barriers and an engineered barrier system.

(b) The engineered barrier system must be designed so that, working in combination with natural barriers, radiological exposures to the reasonably maximally exposed individual are within the limits specified at § 63.311 of subpart L of this part. Compliance with this paragraph must be demonstrated through a performance assessment that meets the requirements specified at § 63.114 of this subpart, and §§ 63.303, 63.305, 63.312 and 63.342 of Subpart L of this part.

(c) The engineered barrier system must be designed so that, working in combination with natural barriers, releases of radionuclides into the accessible environment are within the limits specified at § 63.331 of subpart L of this part. Compliance with this paragraph must be demonstrated through a performance assessment that meets the requirements specified at § 63.114 of this subpart and §§ 63.303, 63.332 and 63.342 of subpart L of this part.

(d) The ability of the geologic repository to limit radiological exposures to the reasonably maximally exposed individual, in the event of human intrusion into the engineered barrier system, must be demonstrated through an analysis that meets the requirements at §§ 63.321 and 63.322 of subpart L of this part. Estimating radiological exposures to the reasonably maximally exposed individual requires a performance assessment that meets the requirements specified at § 63.114 of this subpart, and §§ 63.303, 63.305, 63.312 and 63.342 of subpart L of this part.

Postclosure Performance Assessment

§ 63.114 Requirements for performance assessment.

Any performance assessment used to demonstrate compliance with § 63.113 must:

(a) Include data related to the geology, hydrology, and geochemistry (including disruptive processes and events) of the Yucca Mountain site, and the surrounding region to the extent necessary, and information on the design of the engineered barrier system used to define parameters and conceptual models used in the assessment.

(b) Account for uncertainties and variabilities in parameter values and provide for the technical basis for parameter ranges, probability distributions, or bounding values used in the performance assessment.

(c) Consider alternative conceptual models of features and processes that are consistent with available data and current scientific understanding and evaluate the effects that alternative conceptual models have on the performance of the geologic repository.

(d) Consider only events that have at least one chance in 10,000 of occurring over 10,000 years.

(e) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment. Specific features, events, and processes must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(f) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers in the performance assessment, including those processes that would adversely affect the performance of natural barriers. Degradation, deterioration, or alteration processes of engineered barriers must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(g) Provide the technical basis for models used in the performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs).

§ 63.115 Requirements for multiple barriers.

Demonstration of compliance with § 63.113(a) must:

(a) Identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation.

(b) Describe the capability of barriers, identified as important to waste isolation, to isolate waste, taking into account uncertainties in characterizing and modeling the behavior of the barriers.

(c) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste. The technical basis for each barrier's capability shall be based on and consistent with the technical basis for the performance assessments used to demonstrate compliance with § 63.113(b) and (c).

Land Ownership and Control

§ 63.121 Requirements for ownership and control of interests in land.

(a) *Ownership of land.*

(1) The geologic repository operations area must be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use.

(2) These lands must be held free and clear of all encumbrances, if significant, such as:

(i) Rights arising under the general mining laws;

(ii) Easements for right-of-way; and

(iii) All other rights arising under lease, rights of entry, deed, patent, mortgage, appropriation, prescription, or otherwise.

(b) *Additional controls for permanent closure.* Appropriate controls must be established outside of the geologic repository operations area. DOE shall exercise any jurisdiction and control over surface and subsurface estates necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation. The rights of DOE may take the form of appropriate possessory interests, servitudes, or withdrawals from location or patent under the general mining laws.

(c) *Additional controls through permanent closure.* Appropriate controls must be established outside the geologic repository operations area. DOE shall exercise any jurisdiction or control of activities necessary to ensure the requirements at § 63.111(a) and (b) are met. Control includes the authority to exclude members of the public, if necessary.

(d) *Water rights.*

(1) DOE shall also have obtained such water rights as may be needed to accomplish the purpose of the geologic repository operations area.

(2) Water rights are included in the additional controls to be established under paragraph (b) of this section.

Subpart F—Performance Confirmation Program

§ 63.131 General requirements.

(a) The performance confirmation program must provide data that indicate, where practicable, whether:

(1) Actual subsurface conditions encountered and changes in those conditions during construction and waste emplacement operations are within the limits assumed in the licensing review; and

(2) Natural and engineered systems and components required for repository operation, and that are designed or assumed to operate as barriers after permanent closure, are functioning as intended and anticipated.

(b) The program must have been started during site characterization, and it will continue until permanent closure.

(c) The program must include in situ monitoring, laboratory and field testing, and in situ experiments, as may be appropriate to provide the data required by paragraph (a) of this section.

(d) The program must be implemented so that:

(1) It does not adversely affect the ability of the geologic and engineered elements of the geologic repository to meet the performance objectives.

(2) It provides baseline information and analysis of that information on those parameters and natural processes pertaining to the geologic setting that may be changed by site characterization, construction, and operational activities.

(3) It monitors and analyzes changes from the baseline condition of parameters that could affect the performance of a geologic repository.

§ 63.132 Confirmation of geotechnical and design parameters.

(a) During repository construction and operation, a continuing program of surveillance, measurement, testing, and geologic mapping must be conducted to ensure that geotechnical and design parameters are confirmed and to ensure that appropriate action is taken to inform the Commission of design changes needed to accommodate actual field conditions encountered.

(b) Subsurface conditions must be monitored and evaluated against design assumptions.

(c) Specific geotechnical and design parameters to be measured or observed, including any interactions between natural and engineered systems and components, must be identified in the performance confirmation plan.

(d) These measurements and observations must be compared with the original design bases and assumptions. If significant differences exist between the measurements and observations and the original design bases and assumptions, the need for modifications to the design or in construction methods must be determined and these differences, their significance to repository performance, and the recommended changes reported to the Commission.

(e) In situ monitoring of the thermomechanical response of the underground facility must be conducted until permanent closure, to ensure that the performance of the geologic and engineering features is within design limits.

§ 63.133 Design testing.

(a) During the early or developmental stages of construction, a program for testing of engineered systems and components used in the design, such as, for example, borehole and shaft seals, backfill, and drip shields, as well as the thermal interaction effects of the waste packages, backfill, drip shields, rock, and unsaturated zone and saturated zone water, must be conducted.

(b) The testing must be initiated as early as practicable.

(c) If backfill is included in the repository design, a test must be conducted to evaluate the effectiveness of backfill placement and compaction procedures against design requirements before permanent backfill placement is begun.

(d) Tests must be conducted to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale operation proceeds to seal boreholes, shafts, and ramps.

§ 63.134 Monitoring and testing waste packages.

(a) A program must be established at the geologic repository operations area for monitoring the condition of the waste packages. Waste packages chosen for the program must be representative of those to be emplaced in the underground facility.

(b) Consistent with safe operation at the geologic repository operations area, the environment of the waste packages selected for the waste package monitoring program must be representative of the environment in which the wastes are to be emplaced.

(c) The waste package monitoring program must include laboratory experiments that focus on the internal condition of the waste packages. To the extent practical, the environment experienced by the emplaced waste packages within the underground facility during the waste package monitoring program must be duplicated in the laboratory experiments.

(d) The waste package monitoring program must continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

§ 63.141 Scope.

As used in this part, *quality assurance* comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, or components will perform satisfactorily in service. Quality assurance includes

quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 63.142 Quality assurance criteria.

(a) *Introduction and Applicability.* DOE is required by § 63.21(c)(20) to include in its safety analysis report a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities. The description must indicate how the applicable quality assurance requirements will be satisfied. DOE shall include information pertaining to the managerial and administrative controls to be used to ensure safe operation in its safety analysis report. High-level waste repositories include structures, systems, and components that prevent or mitigate the consequences of postulated event sequences or that are important to waste isolation capabilities that could cause undue risk to the health and safety of the public. The pertinent requirements of this subpart apply to all activities that are important to waste isolation and important to safety functions of those structures, systems, and components. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, site characterization, performance confirmation, permanent closure, decontamination, and dismantling of surface facilities.

(b) *Organization.* DOE shall establish and execute a quality assurance program. DOE may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of it, but DOE retains responsibility for it.

(1) The authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to waste isolation and important to safety must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of:

(i) Assuring that an appropriate quality assurance program is established and effectively executed; and

(ii) Verifying that activities important to waste isolation and important to safety functions have been correctly performed by checking, auditing, and inspection of structures, systems, and components.

(2) The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

(3) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to 10 CFR part 63 are being performed must have direct access to the levels of management as may be necessary to perform this function.

(c) *Quality assurance program.* DOE shall establish a quality assurance program that complies with the requirements of this subpart at the earliest practicable time, consistent with the schedule for accomplishing the activities. This program must be documented by written policies, procedures, or instructions and must be carried out throughout facility life in accordance with those policies, procedures, or instructions.

(1) DOE shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program must control activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety.

(2) Activities affecting quality must be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.

(3) The program must take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program must provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

(4) DOE shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

(d) *Design control.* (1) DOE shall establish measures to assure that applicable regulatory requirements and the design basis, as defined in § 63.2 and as specified in the license application, for those structures, systems, and components to which this subpart applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are important to waste isolation and important to safety functions of the structures, systems and components.

(2) DOE shall establish measures to identify and control design interfaces and for coordination among participating design organizations. These measures must include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

(i) The design control measures must provide for verifying or checking the adequacy of design, such as by the

performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process must be performed by individuals or groups other than those who performed the original design. These individuals may be from the same organization. If a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it must include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures must be applied to items such as: criticality physics, stress, thermal, hydraulic, and preclosure and postclosure analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; and delineation of acceptance criteria for inspections and tests.

(ii) Design changes, including field changes, must be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

(e) *Procurement document control.* DOE shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee or applicant or by its contractors or subcontractors. To the extent necessary, procurement documents must require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this section.

(f) *Instructions, procedures, and drawings.* Activities affecting quality must be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and must be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

(g) *Document control.* DOE shall establish measures to control the issuance of documents, such as instructions, procedures, and drawings, including changes to them that prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents must be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

(h) *Control of purchased material, equipment, and services.* DOE shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.

(1) These measures must include appropriate provisions for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(2) Documentary evidence that material and equipment conform to the procurement requirements must be available at the high-level waste repository site before the material and equipment are installed or used. This documentary evidence must be retained at the high-level waste repository site and be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.

(3) The effectiveness of the control of quality by contractors and subcontractors must be assessed by the licensee or applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

(i) *Identification and control of materials, parts, and components.* Measures must be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures must assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective material, parts, and components.

(j) *Control of special processes.* DOE shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

(k) *Inspection.* DOE shall establish and execute a program for inspection of activities affecting quality to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected.

(1) Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when control is inadequate without both.

(2) If mandatory inspection hold points that require witnessing or inspecting by the applicant's designated representative and beyond which work may not proceed without the consent of its designated representative are required, the specific hold points must be indicated in appropriate documents.

(l) *Test control.* DOE shall establish a test program to assure that all testing required to demonstrate that structures, systems, and components important to safety will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents.

(1) The test program must include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during repository operation, of structures, systems, and components.

(2) Test procedures must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

(3) Test results must be documented and evaluated to assure that test requirements have been satisfied.

(m) *Control of measuring and test equipment.* DOE shall establish measures to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

(n) *Handling, storage, and shipping.* DOE shall establish measures to control the handling, storage, shipping, cleaning

and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, must be specified and provided.

(o) *Inspection, test, and operating status.* DOE shall establish measures to indicate the status of inspections and tests performed on individual items of the high-level waste repository by markings such as stamps, tags, labels, routing cards, or other suitable means. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures must also be established for indicating the operating status of structures, systems, and components of the high-level waste repository, such as by tagging valves and switches, to prevent inadvertent operation.

(p) *Nonconforming materials, parts, or components.* DOE shall establish measures to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(q) *Corrective action.* DOE shall establish measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. If significant conditions are adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(r) *Quality assurance records.* DOE shall maintain sufficient records to furnish evidence of activities affecting quality.

(1) The records must include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.

(2) The records must also include closely-related data such as qualifications of personnel, procedures, and equipment.

(3) Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

(4) Records must be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

(s) *Audits.* DOE shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

§ 63.143 Implementation.

DOE shall implement a quality assurance program based on the criteria required by § 63.142.

§ 63.144 Quality assurance program change.

Changes to DOE's NRC-approved Safety Analysis Report quality assurance program description are processed as follows:

(a) DOE may change a previously accepted quality assurance program description included or referenced in the Safety Analysis Report without prior NRC approval, if the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted every 24 months, in accordance with paragraph (b)(1) of this section. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered reductions in commitment:

(1) The use of a quality assurance standard approved by the NRC which is more recent than the quality assurance standard in DOE's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(b) DOE shall submit changes made to the NRC-accepted Safety Analysis Report quality assurance program description that do reduce the commitments to the NRC and receive NRC approval prior to implementation, as follows:

(1) The signed original must be submitted to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, one copy to the Director, Office of Nuclear Material and Safeguards, U. S. Nuclear Regulatory Commission, Washington, DC 20555, and one copy to the appropriate NRC Resident Inspector if one has been assigned to the site or facility.

(2) The submittal of a change to the Safety Analysis Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to describe how the requirements of § 63.142 will be satisfied and continues to satisfy the criteria of § 63.142 and the Safety Analysis Report quality assurance program description previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(3) DOE shall maintain records of quality assurance program changes that do reduce commitments.

Subpart H—Training and Certification of Personnel

§ 63.151 General requirements.

Operations of systems and components that have been identified as

important to safety in the Safety Analysis Report and in the license must be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operation. Supervisory personnel who direct operations that are important to safety must also be certified in such operations.

§ 63.152 Training and certification program.

DOE shall establish a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel.

§ 63.153 Physical requirements.

The physical condition and the general health of personnel certified for operations that are important to safety may not be such as might cause operational errors that could endanger the public health and safety. Any condition that might cause impaired judgment or motor coordination must be considered in the selection of personnel for activities that are important to safety. These conditions need not categorically disqualify a person, so long as appropriate provisions are made to accommodate the conditions.

Subpart I—Emergency Planning Criteria

§ 63.161 Emergency plan for the geologic repository operations area through permanent closure.

DOE shall develop and be prepared to implement a plan to cope with radiological accidents that may occur at the geologic repository operations area, at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities. The emergency plan must be based on the criteria of § 72.32(b) of this chapter.

Subpart J—Violations

§ 63.171 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 63.172 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in this part 63 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in this part 63 that are not issued under sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 63.1, 63.2, 63.5, 63.6, 63.7, 63.8, 63.15, 63.16, 63.21, 63.22, 63.23, 63.24, 63.31, 63.32, 63.33, 63.41, 63.42, 63.43, 63.45, 63.46, 63.51, 63.52, 63.61, 63.62, 63.63, 63.64, 63.65, 63.101, 63.102, 63.111, 63.112, 63.113, 63.114, 63.115, 63.121, 63.131, 63.132, 63.133, 63.134, 63.141, 63.142, 63.143, 63.153, 63.161, 63.171, 63.172, 63.201, 63.202, 63.203, 63.204, 63.301, 63.302, 63.303, 63.304, 63.305, 63.311, 63.312, 63.321, 63.322, 63.331, 63.332, 63.341, and 63.342.

Subpart K—Preclosure Public Health and Environmental Standards

§ 63.201 Purpose and scope.

This subpart covers the storage of radioactive material by DOE in the Yucca Mountain repository and on the Yucca Mountain site. For the purposes of demonstrating compliance with this subpart, to the extent there may be any conflict with the requirements specified in this subpart and the requirements contained in Subparts A–J of this regulation, including definitions, the requirements in this subpart shall take precedence.

§ 63.202 Definitions for Subpart K.

General environment means everywhere outside the Yucca Mountain site, the Nellis Air Force Range, and the Nevada Test Site.

Member of the public means anyone who is not a radiation worker for purposes of worker protection.

Radioactive material means matter composed of or containing radionuclides subject to the Atomic Energy Act of 1954, as amended (42 U.S.C. sec. 2014 et seq.). Radioactive material includes, but is not limited to, high-level radioactive waste and spent nuclear fuel.

Spent nuclear fuel means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing.

Storage means retention (and any associated activity, operation, or process necessary to carry out successful retention) of radioactive material with the intent or capability to readily access or retrieve such material.

Yucca Mountain repository means the excavated portion of the facility constructed underground within the Yucca Mountain site.

Yucca Mountain site means:

(1) The site recommended by the Secretary of DOE to the President under section 112(b)(1)(B) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10132(b)(1)(B)) on May 27, 1986; or

(2) The area under the control of DOE for the use of Yucca Mountain activities at the time of licensing, if the site designated under the Nuclear Waste Policy Act is amended by Congress prior to the time of licensing.

§ 63.203 Implementation of Subpart K.

DOE must demonstrate that normal operations at the Yucca Mountain site will and do occur in compliance with this subpart before the Commission grants or continues a license for DOE to receive and possess radioactive material within the Yucca Mountain site.

§ 63.204 Preclosure standard.

DOE must ensure that no member of the public in the general environment receives more than an annual dose of 0.15 mSv (15 mrem) from the combination of:

(a) Management and storage (as defined in 40 CFR 191.2) of radioactive material that:

(1) Is subject to 40 CFR 191.3(a); and

(2) Occurs outside of the Yucca Mountain repository but within the Yucca Mountain site; and

(b) Storage (as defined in § 63.202) of radioactive material inside the Yucca Mountain repository.

Subpart L—Postclosure Public Health and Environmental Standards

§ 63.301 Purpose and scope.

This subpart covers the disposal of radioactive material in the Yucca Mountain repository by DOE. For the purposes of demonstrating compliance with this subpart, to the extent that there may be any conflict with the requirements specified in this subpart and the requirements contained in Subparts A–J of this part, including definitions, the requirements in this subpart shall take precedence.

§ 63.302 Definitions for Subpart L.

All definitions in subpart K of this part, and the following:

Accessible environment means any point outside of the controlled area, including:

(1) The atmosphere (including the atmosphere above the surface area of the controlled area);

(2) Land surfaces;

(3) Surface waters;

(4) Oceans; and

(5) The lithosphere.

Aquifer means a water-bearing underground geological formation, group of formations, or part of a formation (excluding perched water bodies) that can yield a significant amount of ground water to a well or spring.

Controlled area means:

(1) The surface area, identified by passive institutional controls, that encompasses no more than 300 square kilometers. It must not extend farther:

(i) South than 36°40′13.6661″ North latitude, in the predominant direction of ground-water flow; and

(ii) Than five kilometers from the repository footprint in any other direction; and

(2) The subsurface underlying the surface area.

Disposal means the emplacement of radioactive material into the Yucca Mountain disposal system with the intent of isolating it for as long as reasonably possible and with no intent of recovery, whether or not the design of the disposal system permits the ready recovery of the material. Disposal of radioactive material in the Yucca Mountain disposal system begins when all of the ramps and other openings into the Yucca Mountain repository are sealed.

Ground water means water that is below the land surface and in a saturated zone.

Human intrusion means breaching of any portion of the Yucca Mountain disposal system, within the repository footprint, by any human activity.

Passive institutional controls means:

(1) Markers, as permanent as practicable, placed on the Earth's surface;

(2) Public records and archives;

(3) Government ownership and regulations regarding land or resource use; and

(4) Other reasonable methods of preserving knowledge about the location, design, and contents of the Yucca Mountain disposal system.

Peak dose means the highest annual dose projected to be received by the reasonably maximally exposed individual.

Period of geologic stability means the time during which the variability of geologic characteristics and their future behavior in and around the Yucca Mountain site can be bounded, that is, they can be projected within a reasonable range of possibilities.

Plume of contamination means that volume of ground water in the predominant direction of ground-water flow that contains radioactive contamination from releases from the Yucca Mountain repository. It does not include releases from any other potential sources on or near the Nevada Test Site.

Repository footprint means the outline of the outermost locations of where the waste is emplaced in the Yucca Mountain repository.

Slice of the plume means a cross-section of the plume of contamination with sufficient thickness parallel to the prevalent direction of flow of the plume that it contains the representative volume.

Total dissolved solids means the total dissolved (filterable) solids in water as determined by use of the method specified in 40 CFR part 136.

Undisturbed performance means that human intrusion or the occurrence of unlikely natural features, events, and processes do not disturb the disposal system.

Undisturbed Yucca Mountain disposal system means that the Yucca Mountain disposal system is not affected by human intrusion.

Waste means any radioactive material emplaced for disposal into the Yucca Mountain repository.

Well-capture zone means the volume from which a well pumping at a defined rate is withdrawing water from an aquifer. The dimensions of the well-capture zone are determined by the pumping rate in combination with aquifer characteristics assumed for calculations, such as hydraulic conductivity, gradient, and the screened interval.

Yucca Mountain disposal system means the combination of underground engineered and natural barriers within the controlled area that prevents or substantially reduces releases from the waste.

§ 63.303 Implementation of Subpart L.

DOE must demonstrate that there is a reasonable expectation of compliance with this subpart before a license may be issued. In the case of the specific numerical requirements in § 63.311 of this subpart, and if performance assessment is used to demonstrate compliance with the specific numerical requirements in §§ 63.321 and 63.331 of this subpart, compliance is based upon the mean of the distribution of projected doses of DOE's performance assessments which project the performance of the Yucca Mountain disposal system for 10,000 years after disposal.

§ 63.304 Reasonable expectation.

Reasonable expectation means that the Commission is satisfied that compliance will be achieved based upon the full record before it. Characteristics of reasonable expectation include that it:

(1) Requires less than absolute proof because absolute proof is impossible to attain for disposal due to the uncertainty of projecting long-term performance;

(2) Accounts for the inherently greater uncertainties in making long-term projections of the performance of the Yucca Mountain disposal system;

(3) Does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence; and

(4) Focuses performance assessments and analyses on the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values.

§ 63.305 Required characteristics of the reference biosphere.

(a) Features, events, and processes that describe the reference biosphere must be consistent with present knowledge of the conditions in the region surrounding the Yucca Mountain site.

(b) DOE should not project changes in society, the biosphere (other than climate), human biology, or increases or decreases of human knowledge or technology. In all analyses done to demonstrate compliance with this part, DOE must assume that all of those factors remain constant as they are at

the time of submission of the license application.

(c) DOE must vary factors related to the geology, hydrology, and climate based upon cautious, but reasonable assumptions consistent with present knowledge of factors that could affect the Yucca Mountain disposal system over the next 10,000 years.

(d) Biosphere pathways must be consistent with arid or semi-arid conditions.

Postclosure Individual Protection Standard

§ 63.311 Individual protection standard after permanent closure.

DOE must demonstrate, using performance assessment, that there is a reasonable expectation that, for 10,000 years following disposal, the reasonably maximally exposed individual receives no more than an annual dose of 0.15 mSv (15 mrem) from releases from the undisturbed Yucca Mountain disposal system. DOE's analysis must include all potential pathways of radionuclide transport and exposure.

§ 63.312 Required characteristics of the reasonably maximally exposed individual.

The reasonably maximally exposed individual is a hypothetical person who meets the following criteria:

(a) Lives in the accessible environment above the highest concentration of radionuclides in the plume of contamination;

(b) Has a diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada. DOE must use projections based upon surveys of the people residing in the Town of Amargosa Valley, Nevada, to determine their current diets and living styles and use the mean values of these factors in the assessments conducted for §§ 63.311 and 63.321;

(c) Uses well water with average concentrations of radionuclides based on an annual water demand of 3000 acre-feet;

(d) Drinks 2 liters of water per day from wells drilled into the ground water at the location specified in paragraph (a) of this section; and

(e) Is an adult with metabolic and physiological considerations consistent with present knowledge of adults.

Human Intrusion Standard

§ 63.321 Individual protection standard for human intrusion.

DOE must determine the earliest time after disposal that the waste package would degrade sufficiently that a human intrusion could occur without recognition by the drillers. DOE must:

(a) Provide the analyses and its technical bases used to determine the time of occurrence of human intrusion (see § 63.322) without recognition by the drillers.

(b) If complete waste package penetration is projected to occur at or before 10,000 years after disposal:

(1) Demonstrate that there is a reasonable expectation that the reasonably maximally exposed individual receives no more than an annual dose of 0.15 mSv (15 mrem) as a result of a human intrusion, at or before 10,000 years after disposal. The analysis must include all potential environmental pathways of radionuclide transport and exposure subject to the requirements at § 63.322; and

(2) If exposures to the reasonably maximally exposed individual occur more than 10,000 years after disposal, include the results of the analysis and its bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance.

(c) Include the results of the analysis and its bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance, if the intrusion is not projected to occur before 10,000 years after disposal.

§ 63.322 Human intrusion scenario.

For the purposes of the analysis of human intrusion, DOE must make the following assumptions:

(a) There is a single human intrusion as a result of exploratory drilling for ground water;

(b) The intruders drill a borehole directly through a degraded waste package into the uppermost aquifer underlying the Yucca Mountain repository;

(c) The drillers use the common techniques and practices that are currently employed in exploratory drilling for ground water in the region surrounding Yucca Mountain;

(d) Careful sealing of the borehole does not occur, instead natural degradation processes gradually modify the borehole;

(e) No particulate waste material falls into the borehole;

(f) The exposure scenario includes only those radionuclides transported to the saturated zone by water (e.g., water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone); and

(g) No releases are included which are caused by unlikely natural processes and events.

Ground-Water Protection Standards

§ 63.331 Separate standards for protection of ground water.

DOE must demonstrate that there is a reasonable expectation that, for 10,000 years of undisturbed performance after disposal, releases of radionuclides from waste in the Yucca Mountain disposal system into the accessible environment will not cause the level of radioactivity in the representative volume of ground water to exceed the limits in the following Table 1:

TABLE 1.—LIMITS ON RADIONUCLIDES IN THE REPRESENTATIVE VOLUME

Radionuclide or type of radiation emitted	Limit	Is natural background included?
Combined radium-226 and radium-228	5 picocuries per liter	Yes.
Gross alpha activity (including radium-226 but excluding radon and uranium).	15 picocuries per liter	Yes.
Combined beta and photon emitting radionuclides	0.04 mSv (4 mrem) per year to the whole body or any organ, based on drinking 2 liters of water per day from the representative volume.	No.

§ 63.332 Representative volume.

(a) The representative volume is the volume of ground water that would be withdrawn annually from an aquifer containing less than 10,000 milligrams of total dissolved solids per liter of water to supply a given water demand. DOE must project the concentration of radionuclides released from the Yucca Mountain disposal system that will be in the representative volume. DOE must use the projected concentrations to

demonstrate a reasonable expectation that the Yucca Mountain disposal system complies with § 63.331. The DOE must make the following assumptions concerning the representative volume:

(1) It includes the highest concentration level in the plume of contamination in the accessible environment;

(2) Its position and dimensions in the aquifer are determined using average hydrologic characteristics which have cautious, but reasonable, values representative of the aquifers along the radionuclide migration path from the Yucca Mountain repository to the accessible environment as determined by site characterization; and

(3) It contains 3,000 acre-feet of water (about 3,714,450,000 liters or 977,486,000 gallons).

(b) DOE must use one of two alternative methods for determining the dimensions of the representative volume. The DOE must propose its chosen method, and any underlying assumptions, to NRC for approval.

(1) DOE may calculate the dimensions as a well-capture zone. If DOE uses this approach, it must assume that the:

(i) Water supply well(s) has (have) characteristics consistent with public water supply wells in the Town of Amargosa Valley, Nevada, for example, well-bore size and length of the screened intervals;

(ii) Screened interval(s) include(s) the highest concentration in the plume of contamination in the accessible environment; and

(iii) Pumping rates and the placement of the well(s) must be set to produce an annual withdrawal equal to the representative volume and to tap the highest concentration within the plume of contamination.

(2) DOE may calculate the dimensions as a slice of the plume. If DOE uses this approach, it must:

(i) Propose, for approval, where the location of the edge of the plume of contamination occurs. For example, the place where the concentration of radionuclides reaches 0.1% of the level of the highest concentration in the accessible environment;

(ii) Assume that the slice of the plume is perpendicular to the prevalent direction of flow of the aquifer; and

(iii) Assume that the volume of ground water contained within the slice of the plume equals the representative volume.

Additional Provisions

§ 63.341 Projections of peak dose.

To complement the results of § 63.311, DOE must calculate the peak dose of the reasonably maximally exposed individual that would occur after 10,000 years following disposal but within the period of geologic stability. No regulatory standard applies to the results of this analysis; however, DOE must include the results and their bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance.

§ 63.342 Limits on performance assessments.

DOE's performance assessments should not include consideration of very unlikely features, events, or processes, i.e., those that are estimated to have less than one chance in 10,000 of occurring within 10,000 years of disposal. Unlikely features, events, and processes, or sequences of events and processes shall be excluded from the assessments for the human intrusion and ground water protection standards upon prior Commission approval for the probability limit used for unlikely features, events, and processes. In addition, DOE's performance assessments need not evaluate the impacts resulting from any features, events, and processes or sequences of events and processes with a higher chance of occurrence if the results of the performance assessments would not be changed significantly.

§ 63.343 Severability of individual protection and ground-water protection standards.

The individual protection and ground-water protection standards are severable.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

43. The authority citation for part 70 continues to read:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246, (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

44. Section 70.17 is amended by revising paragraph (c) to read as follows:

§ 70.17 Specific exemptions.

* * * * *

(c) The DOE is exempt from the requirements of the regulations in this part to the extent that its activities are subject to the requirements of part 60 or part 63 of this chapter.

* * * * *

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

45. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224, (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

46. Section 72.44 is amended by revising paragraphs (g)(1) and (g)(3) to read as follows:

§ 72.44 License conditions.

* * * * *

(g) * * *

(1) Construction of the MRS may not begin until the Commission has authorized the construction of a repository under section 114(d) of NWPA (96 Stat. 2215, as amended by 101 Stat. 1330–230, 42 U.S.C. 10134 (d)) and part 60 or 63 of this chapter;

* * * * *

(3) The quantity of spent nuclear fuel or high-level radioactive waste at the site of the MRS at any one time may not

exceed 10,000 metric tons of heavy metal until a repository authorized under NWPA and part 60 or 63 of this chapter first accepts spent nuclear fuel or solidified high-level radioactive waste; and

* * * * *

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

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

Authority: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C, 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99–399, 100 Stat. 876 (42 U.S.C. 2169).

48. In § 73.1, paragraph (b)(6) is revised to read as follows:

§ 73.1 Purpose and scope.

* * * * *

(b) * * *

(6) This part prescribes requirements for the physical protection of spent nuclear fuel and high-level radioactive waste stored in either an independent spent fuel storage installation (ISFSI) or a monitored retrievable storage (MRS) installation licensed under part 72 of this chapter, or stored at the geologic repository operations area licensed under part 60 or part 63 of this chapter.

* * * * *

49. Section 73.51 is amended by revising paragraph (a) to read as follows:

§ 73.51 Requirements for the physical protection of stored spent nuclear fuel and high-level radioactive waste.

(a) *Applicability.* Notwithstanding the provisions of §§ 73.20, 73.50, or 73.67, the physical protection requirements of this section apply to each licensee that stores spent nuclear fuel and high-level radioactive waste pursuant to paragraphs (a)(1)(i), (ii), and (2) of this section. This includes—

(1) Spent nuclear fuel and high-level radioactive waste stored under a specific license issued pursuant to part 72 of this chapter:

(i) At an independent spent fuel storage installation (ISFSI) or

(ii) At a monitored retrievable storage (MRS) installation; or

(2) Spent nuclear fuel and high-level radioactive waste at a geologic repository operations area (GROA) licensed pursuant to part 60 or 63 of this chapter;

* * * * *

PART 75—SAFEGUARDS ON NUCLEAR MATERIAL—IMPLEMENTATION OF US/IAEA AGREEMENT

50. The authority citation for part 75 continues to read as follows:

Authority: Secs. 53, 63, 103, 104, 122, 161, 68 Stat. 930, 932, 936, 937, 939, 948, as amended (42 U.S.C. 2073, 2093, 2133, 2134, 2152, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 75.4 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

51. Section 75.4 is amended by revising paragraph (k)(5) to read as follows:

§ 75.4 Definitions.

* * * * *

(k) * * *

(5) Any location where the possession of more than 1 effective kilogram of nuclear material is licensed pursuant to parts 40, 60, 63, or 70 of this chapter or an Agreement State license.

* * * * *

Dated at Rockville, Maryland, this 23rd day of October, 2001.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 01–27157 Filed 11–1–01; 8:45 am]

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Part III

Securities and Exchange Commission

17 CFR Parts 240 and 242

Books and Records Requirements for Brokers and Dealers Under the Securities Exchange Act of 1934; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240 and 242

[Release No. 34–44992; File No. S7–26–98]

RIN 3235–AH04

Books and Records Requirements for Brokers and Dealers Under the Securities Exchange Act of 1934

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; request for comments on Paperwork Reduction Act burden estimate.

SUMMARY: The Securities and Exchange Commission today is adopting amendments to its broker-dealer books and records rules. The amendments clarify and expand recordkeeping requirements with respect to purchase and sale documents, customer records, associated person records, customer complaints, and certain other matters. In addition, the amendments expand the types of records that broker-dealers must maintain and require broker-dealers to maintain or promptly produce certain records at each office to which those records relate. These amendments are specifically designed to assist securities regulators when conducting sales practice examinations of broker-dealers, particularly examinations of local offices.

EFFECTIVE DATE: May 2, 2003.

FOR FURTHER INFORMATION CONTACT: Michael A. Macchiaroli, Associate Director, at (202) 942–0131; Thomas K. McGowan, Assistant Director, at (202) 942–4886; or Bonnie L. Gauch, Attorney, at (202) 942–0765; Office of Risk Management and Control, Division of Market Regulation, United States Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–1001.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Securities and Exchange Commission's (the ''Commission'') books and records rules, Rule 17a–3[1] and Rule 17a–4[2] under the Securities Exchange Act of 1934 (''Exchange Act'')(hereinafter the ''Books and Records Rules''), specify minimum requirements with respect to the records that broker-dealers must make, and how long those records and other documents relating to a broker-dealer's business must be kept. The Commission has required that broker-dealers create and maintain certain records so that, among other things, the Commission, self-regulatory organizations (''SROs''), and State Securities Regulators[3] (collectively ''securities regulatory authorities'') may conduct effective examinations of broker-dealers.

The Commission originally proposed amending the Books and Records Rules in 1996 in response to concerns raised by members of the North American Securities Administrator's Association (''NASAA'') regarding the adequacy of those Rules.[4] On October 11, 1996, the National Securities Market Improvement Act of 1996 (''NSMIA'') was enacted.[5] NSMIA prohibits States from establishing books and records rules that differ from, or are in addition to, the Commission's rules. Prior to NSMIA many States had laws or rules that required broker-dealers to make and keep certain books and records that allowed the State Securities Regulators to conduct examinations and investigations to review for, among other things, sales practice violations.[6] NSMIA also provides that the Commission must consult periodically with the States concerning the adequacy of the Commission's Books and Records Rules,[7] particularly relating to the need by State Securities Regulators to have records readily accessible for their examinations.[8]

The Commission, recognizing the vital role that State regulators play in providing for customer protection, issued the Proposing Release, in part, to enhance the ability of the State Securities Regulators to conduct effective and efficient sales practice examinations of activities within their respective States, including those involving smaller broker-dealer offices. By adopting these rules, the Commission enables the State regulators to adopt and enforce similar rules on a State level, to support their examination responsibilities, and investigatory and enforcement requirements. An important aspect of the amendments is that broker-dealers are required to produce records at offices within a State. Moreover, many of these amendments require broker-dealers to make or keep records currently kept by broker-dealers as a matter of business practice or to comply with SRO rules. However, unless these requirements are adopted as Commission rules, the State regulators are unable to apply or enforce them at the State level.

II. Proposing and Reproposing Releases

In response to the comments received on the Proposing Release, the Commission substantially modified the amendments, and reproposed them to allow for public comment on the modifications.[9] In response to the reproposal, the Commission received approximately 115 comment letters from various groups, including broker-dealers, law firms representing broker-dealers, industry associations, and State Securities Regulators. Generally, State Securities Regulators supported the rules as reproposed, but suggested some minor changes. While broker-dealers generally supported the Commission's efforts to adopt uniform books and records rules, they opposed various sections of the reproposed rules. In particular, firms were opposed to the requirements to periodically update the customer account record and to maintain records at local offices. As discussed in the respective sections throughout this release, the Commission has substantially modified the content of the re-proposed amendments and incorporated many of the suggested changes into the final rules.

To a significant degree, the amendments to Rules 17a–3 and 17a–4 adopted by the Commission track existing SRO requirements and certain State regulations that were in place prior to NSMIA. In addition, they largely represent a codification of prudent recordkeeping practices of many broker-dealers. Accordingly, many portions of the Books and Records Rule amendments should not present additional burdens for most broker-dealers.

[1] 17 CFR 240.17a–3.

[2] 17 CFR 240.17a–4.

[3] For purposes of this release, ''State Securities Regulators'' include, as described in Section 15(h) of the Exchange Act, ''the securities commissions (or any agency or office performing like functions) of the States.'' 15 U.S.C. 78*o*(h).

[4] *See* Exchange Act Release No. 37850 (October 22, 1996), 61 FR 55593 (Oct. 28, 1996) (''Proposing Release'' and/or ''Proposal'') (File No. S7–27–96).

[5] Pub. L. No. 104–290, 110 Stat. 3416 (1996).

[6] *E.g.*, violations of State suitability and fraud laws, or federal regulations.

[7] 15 U.S.C. 78*o*(h).

[8] 142 Cong.Rec.S. 12093, S12094 (October 1, 1996) (statement of Sen. Dodd) (''It is the intent of the conferees that the SEC work closely with the States to determine what records should be maintained at branch offices and to establish a mechanism so that States could require such records be kept in the branch office, rather than at a back office halfway across the Nation.'').

[9] Exchange Act Release No. 40518 (Oct. 2, 1998), 63 FR 54404 (Oct. 9, 1998) (the ''Reproposing Release'' and/or ''Reproposal''). The staff of the Division of Market Regulation has prepared a summary of the comment letters received on the reproposed rules and rule amendments (hereinafter referred to as ''Comment Summary''). Copies of the comment letters and the Comment Summary have been placed in Public Reference File No. S7–26–98 and are available for inspection in the Commission's Public Reference Room.

III. Amendments to Rule 17a–3

In brief, the amendments to present Rule 17a–3 include revisions to the information that must be recorded on order tickets, and new requirements to: create certain records relating to associated persons; collect certain account record information and verify that information with customers periodically; create a record of customer complaints; create a record indicating compliance with applicable advertising rules; and create records identifying persons responsible for establishing procedures and persons able to explain the broker-dealer's records to a regulator.

A. Memoranda of Brokerage Orders and Dealer Transactions

Rule 17a–3 has been amended to require that a brokerage order ticket contain the identity of the associated person, if any, responsible for the account and any other person who entered or accepted the order on behalf of the customer, and whether it was entered subject to discretionary authority. In addition, a brokerage order ticket must include the time at which the broker-dealer received a customer order, even if the order is subsequently transmitted for execution.[10] A dealer ticket must include information regarding any modifications to the order.[11] This will allow securities regulators to better focus their examinations and investigations because they will be able to identify certain types of violative activities and the individuals responsible for those activities more easily.

The Commission clarified that the identity of the associated person responsible for the account must be included only if the broker-dealer assigns to an associated person responsibility for certain accounts. This modification was made in response to broker-dealer comment letters that noted some firms do not assign a particular associated person to each account, and some firms allow customers to enter orders directly into a broker-dealer's systems, such as through an on-line trading account. Further, this modification addresses the concerns of some commenters that without a qualifying phrase, such as ''if any,'' the rule may be interpreted erroneously as placing on firms an affirmative obligation to assign an associated person to each account.

If a firm has assigned identification numbers or codes to the persons entering customer orders to comply with the requirement to record the identity of the person entering customer orders, a broker-dealer may record the identification number or code on the order ticket instead of the associated person's name. Further, if the person entering a customer order has been assigned to a computer terminal but does not have a specific identification number or code, it is acceptable for the broker-dealer to identify the number or code of a computer terminal at which an order was entered. In either case, upon request by a representative of a securities regulatory authority, the firm must provide the actual identity of the person who entered the order. Either of these alternatives may be satisfied by using a companion record to the order tickets.[12]

With these amendments, paragraphs (a)(6) and (a)(7) require that broker-dealers record the identity of ''any [person other than the associated person responsible for the account] who entered or accepted the order on behalf of the customer.'' In response to comments by the online brokerage community, the Commission included, after this requirement, the phrase, ''if a customer entered the order on an electronic system, a notation of such entry.'' Because most firms that accept orders through an electronic system already identify, for supervisory purposes, which orders were entered directly by a customer, this requirement will not create much additional burden on the firms. Further, it will assist them in identifying for securities regulatory authorities why certain tickets do not identify the associated person who received the order from the customer.

One commenter argued that firms that primarily accept ''unsolicited'' orders and do not pay transaction-based commissions should not be required to include on the order ticket information regarding associated persons because no sales practice concerns would be implicated in these types of transactions. However, the Commission believes that recording the identity of the associated person on a broker-dealer's order tickets is essential for adequate surveillance of, and accountability for, transactions.

One commenter wrote that for some transactions the time of entry frequently is simultaneous or nearly simultaneous with the time the order is received, and suggested that under these conditions, the firm should not have to make a separate entry for each time. In those situations, it must be clear from the order ticket that the time of receipt was the same as the time of entry. However, the time recorded must be accurate and this should not be construed as an exception to allow firms to use an approximate time for one or both entries.[13]

Finally, the Commission recognizes that for some types of transactions, such as purchases of mutual funds or variable annuities, the customer may simply fill out an application or a subscription agreement that the broker-dealer then forwards directly to the issuer.[14] These documents would include the information that is important for and specific to the particular type of transaction. Hence, the Commission has added paragraph (a)(6)(ii) under Rule 17a–3 to allow firms to keep a copy of the application or subscription document instead of making a separate record as to transactions described in the exemption. This paragraph would also exempt transactions such as automatic dividend reinvestments. The Commission views this additional paragraph as a codification of current industry practice, and it is limited to these types of transactions.

B. Associated Person Records

1. New Records Concerning Associated Persons

Rule 17a–3(a)(12) requires a firm to make records relating to associated persons of the firm, including information regarding the associated person's employment and disciplinary history. The amendments require a record listing all of a firm's associated

[10] 17 CFR 240.17a–3(a)(6). Most broker-dealers are currently required to record the time the order was received from a customer under the National Association of Securities Dealers' (''NASD'') Order Audit Trail System (''OATS'') rules (NASD rules 6950 through 6957 and 3110) (hereinafter ''OATS rules'') (*See* specifically NASD rules 6954(b)(16) and 3110(h)), and New York Stock Exchange (''NYSE'') rules 123 and 410A.

[11] 7 CFR 240.17a–3(a)(7).

[12] *E.g.*, a firm may satisfy this requirement by using the record listing any internal identification number or code assigned to associated persons which is required under new Rule 17a–3(a)(12)(ii) (17 CFR 240.17a–3(a)(12)(ii)). Additionally, the Commission believes this requirement is consistent with the NASD's OATS rules.

[13] A number of firms have asked for guidance on the meaning of the term ''to the extent feasible.'' The time of execution should be included on the order ticket except for situations in which it may be impossible to determine the precise time when the transaction was executed; however, in that case the broker-dealer must note the approximate time of execution. Exchange Act Release No. 3040 (Oct. 13, 1941), 11 FR 10984. The Commission has stated that the ''phrase ''to the extent feasible'' was intended to be applicable only in exceptional circumstances where it might be actually impossible to determine the exact time of execution.'' Exchange Act Release No. 13508 (May 5, 1977) 42 FR 25318. However, in that case the broker-dealer must note the approximate time of execution.

[14] This is referred to elsewhere in the rules as a ''subscription-way basis'' transaction. *See* 17 CFR.15c3–1(a)(2)(v).

persons showing every office where each associated person regularly conducts business, and listing all internal identification numbers and the CRD number assigned to each associated person.[15] This will allow securities regulators to identify where associated persons work, and to read various records which may identify the associated persons solely through the use of identification numbers. Also, three technical changes were made from the rule as reproposed.[16]

2. The Definition of Associated Person

The Commission had proposed to eliminate from Rule 17a–3 a definition of ''associated person'' and instead use the definition of ''associated person'' as defined in sections 3(a)(18) and 3(a)(21) of the Exchange Act. However, the statutory definition of ''associated person of a broker or dealer'' in section 3(a)(18) specifically excludes those persons whose functions are clerical or ministerial from the definition solely for purposes of section 15(b) of the Exchange Act. Current Rule 17a–3 excludes those persons from the recordkeeping requirements. The Commission has determined that those persons should continue to be exempt from the recordkeeping requirements of Rules 17a–3 and 17a–4. Therefore, the Commission believes it is appropriate to retain a definition of the term ''associated person'' in the rule. This definition has been moved to paragraph (g), however, and has been modified for the sake of uniformity to incorporate the definitions of ''associated person of a member'' and ''associated person of a broker or dealer'' as set forth in sections 3(a)(21) and 3(a)(18) of the Exchange Act.[17] In addition, for purposes of Rules 17a–3 and 17a–4, the Commission has excluded from the definition persons whose functions are solely clerical or ministerial. In order to avoid redundancy and achieve greater consistency in interpretation, this phrase shall be interpreted in the same manner as the phrase ''solely clerical and ministerial'' is interpreted under section 3(a)(18) of the Exchange Act.

The Exchange Act provisions define an associated person to include any partner, officer, director, or branch manager of a broker-dealer (any person occupying a similar status or performing similar functions), any person directly or indirectly controlling, controlled by, or under common control with a broker-dealer, or any employee of a broker-dealer. This includes order-takers. The Commission interprets the term associated person to include any independent contractor, consultant, franchisee, or other person providing services to a broker-dealer equivalent to those services provided by the persons specifically referenced in the statute.[18]

C. Customer Account Record

The Commission is adopting new Rule 17a–3(a)(17)[19] under the Exchange Act, which requires broker-dealers to create a record containing certain minimum information as to each customer. The primary purpose of Rule 17a–3(a)(17) is to provide regulators, particularly State Securities Regulators, with access to books and records which enable them to review for compliance with suitability rules.[20] Rule 17a–3(a)(17) also requires broker-dealers to furnish that information to each customer on a periodic basis. The rule should not be construed to affect or supersede any Federal, State, or SRO requirement, including those relating to ''know your customer,'' suitability, or supervisory obligations.

1. Account Record Information

The information required under new Rule 17a–3(a)(17)(i)(A) for each account with a natural person as a customer includes the customer's name, tax identification number, address, telephone number, date of birth, employment status (including occupation and whether the customer is an associated person of a member, broker or dealer), annual income, net worth (excluding value of primary residence), and investment objectives. Most broker-dealers already collect this information to assist them in assessing customers' suitability or to comply with other rules. For accounts with more than one owner, the record should include personal information for each owner of the account; however, the record should reflect the investment objectives for the account and not the individual investment objectives for each ''joint'' owner named on the account. Further, financial information for the owners can be combined. For discretionary accounts, firms also must include as part of the account record the dated signature of each customer granting the discretionary authority and the dated signature of each natural person[21] to whom discretionary authority was granted. In response to comments received, the Commission did not adopt the reproposed requirement that the account record include information regarding a customer's marital status and number of dependents.[22]

Under the final rule, the account record must indicate whether it has been signed by the associated person responsible for the account, and approved or accepted by a principal of the firm.[23] This will identify for regulators the persons responsible for accepting a particular account on behalf of the firm. Similar to the comments made regarding order tickets, some commenters stated that they do not always assign an associated person to each account. Therefore, the Commission has added the phrase ''if any'' to the requirement that the account record indicate whether it has been approved by an associated person. The account record still must indicate

[15] 17 CFR 240.17a–3(a)(12)(ii).

[16] First, reproposed paragraphs (a)(12)(ii) and (a)(12)(iii) have been moved to paragraph (a)(19) of Rule 17a–3 to keep all requirements relating to compensation records in the same section (most agreements between associated persons and broker-dealers relate to compensation in some manner). Second, reproposed paragraphs (a)(12)(iv) and (a)(12)(v) have been combined into new paragraph (a)(12)(ii). And finally, the Commission has deleted the references to local offices and state record depositories to make this paragraph consistent with the changes to the definition of ''office'' in paragraph (g)(1) of Rule 17a–3.

[17] 15 U.S.C. 78*c*(a)(21) and 15 U.S.C. 78*c*(a)(18).

[18] The Commission has consistently taken the position that independent contractors (who are not themselves registered as broker-dealers) involved in the sale of securities on behalf of a broker-dealer are ''controlled by'' the broker-dealer, and, therefore, are associated persons of the broker-dealer. *See, e.g., In the Matter of William V. Giordano,* 61 S.E.C. Dkt. 345, Exchange Act Release No. 36742 (Jan. 19, 1996) (in finding that an officer of a broker-dealer firm failed reasonably to supervise an independent contractor, the Commission found that the independent contractor was an ''associated person'' of the firm within the meaning of Section 3(a)(18) of the Exchange Act). *See, also,* Letter from Douglas Scarff, Director, Division of Market Regulation, to Gordon S. Macklin, NASD; Charles J. Henry, Chicago Board Options Exchange; Robert J. Birnbaum, American Stock Exchange; and John J. Phelan, NYSE, [1982–1983 Transfer Binder] Fed. Sec. L. Rep. (CCH) P77,303 at P77,116 (Jun. 18, 1982); *Hollinger* v. *Titan Capital Corp.,* 974 F.2d 1564, 1572–76 (9th Cir. 1990), *cert. denied,* 111 S. Ct. 1621 (1991). A similar analysis would be applicable to other persons, such as consultants and franchisees, performing securities activities with or for the broker-dealer.

[19] This provision was reproposed as Rule 17a–3(a)(16).

[20] Generally, suitability rules require that broker-dealers and their associated persons refrain from recommending transactions or investment strategies to a customer that would be ''unsuitable'' for that customer based upon the customer's situation. Factors that may be considered in assessing a customer's situation include the customer's age, financial situation, and investment experience or knowledge of the industry.

[21] *See* NYSE Rule 408 and NASD Rule 2510(b).

[22] *See, e.g.,* Comment Letters from Raymond James, p. 4; Investment Management and Research, p. 3, and Mayer, Brown & Platt, pp. 6–7.

[23] 17 CFR 240.17a–3(a)(17)(i)(A). This requirement is consistent with SRO rules regarding the signatures of associated persons and principals when opening customer accounts. *See* NYSE Rule 405(3) and NASD Rule 3110(c)(1)(C).

whether it has been approved by a principal.[24]

In the Reproposal, the Commission specifically sought comment on whether, for joint accounts, the firm should obtain the account record information for each individual. Most commenters that addressed this issue did not object to maintaining personal information for each owner of joint accounts. However, some commenters pointed out that it would be unnecessary and redundant to obtain individual information for certain types of joint accounts, such as a joint account of two spouses with similar information regarding income and net worth. These commenters also contended that the investment objectives should reflect the objectives for the account and not the objectives of the individual owners. In those cases, it is sufficient under paragraph (a)(17) of Rule 17a–3 [25] that the account record reflect that portions of the account record information are the same for each owner of the account. It is acceptable for firms to combine joint owners' financial information as opposed to obtaining and maintaining that information separately for each of the joint owners. Lastly, the investment objectives recorded should be those for the account, and not those of the individual owners.

Some commenters requested clarification as to how this information must be maintained and whether all the information and signatures must be included on the same form.[26] Although a broker-dealer must create a single record for each account, that record may consist of more than one document, such as two or more account applications.

A broker-dealer is not required to furnish a copy of a customer's account record to the customer within thirty days when obtaining new information to complete the initial account record, required under Rule 17a–3(a)(17)(i)(A),[27] for an account in existence on the effective date of the rule amendments. However, as stated in Rule 17a–3(a)(17)(i)(B)(*1*),[28] broker-dealers must create a record indicating that the broker-dealer furnished these customers with a copy of the account record information within three years of the effective date of the rule.

2. Furnishing the Account Record Information

Rule 17a–3(a)(17) requires that the firm periodically furnish account record information to the customer.[29] The new requirement allows the customer to review the information regarding the account that the firm has on file and from which the associated person or the firm is making investment recommendations or suitability determinations for the account. The requirement to furnish this record to customers is designed to reduce the number of misunderstandings between customers and broker-dealers regarding the customer's situation or investment objectives. Firms may, of course, elect to provide this information to customers more frequently in order to coincide with other mailings.

Paragraph (a)(17) of the rule identifies four provisions that trigger the requirement that a broker-dealer furnish to a customer a copy of information contained in the account record.[30] Those provisions include (i) the opening of a new account;[31] (ii) the periodic updating of an account that must occur at least once every 36 months;[32] (iii) a change of customer name or address;[33] and (iv) a change of other customer information.[34]

Although paragraph (a)(17)(i) of Rule 17a–3 requires broker-dealers to periodically update customer records, the rule does not affect a broker-dealer's obligations under any SRO ''know your customer'' rules. It may be appropriate in certain circumstances for broker-dealers to obtain updated information from customers more often than once every 36 months.

Because different terms ascribed to categories of investment objectives may vary among firms, the firms must describe these terms when furnishing the account record to customers. When opening an account, the customer has the opportunity to question the meaning of the investment objective terms, but when the customer receives a copy of the account record at home, that customer may have forgotten or misunderstood the meaning of those terms. This requirement to describe investment objective terminology should help ensure that the customer and the firm have a mutual understanding of the meaning of each term.

Paragraph (a)(17) of Rule 17a–3 also provides that a broker-dealer is not required to include the customer's tax identification number and date of birth with the information provided to the customer. Several commenters suggested that unauthorized access to such information could facilitate the perpetration of fraud against the customer.[35]

The Commission did not adopt the portion of the rule as reproposed that would have required firms to send a notification of change of address to both the old and new addresses. This change was in response to comments that prudent business practice requires that this notification be sent only to the old address to prevent misdirection of account information. Therefore, as adopted, firms are required to send a notification of a change of address only to the old address.

Some commenters sought clarification as to whether the amendment required a separate mailing of the customer account record information. This rule does not require a separate mailing, and the Commission anticipates that firms will combine this mailing with other mailings. Further, the account record information may be printed on a customer's account statement. Finally, a firm may mail the customer a copy of the customer's complete account record reflecting any change of other account record information [36] on or before the 30th day after the date the member, broker or dealer received notice of any change, or it may choose to send this notification with the next statement scheduled to be mailed to the customer.

3. Explanation of the Neglect, Refusal, or Inability of a Customer To Provide Required Information

As adopted, Rule 17a–3(a)(17)(i)(C) does not require broker-dealers to include an explanation of the customer's neglect, refusal, or inability to provide the required information. However, a broker-dealer is required to make a good faith effort to collect this information. If the account record does not include the required information, the broker-dealer would bear the burden of explaining why this information is not available. Rule 17a–3(a)(17)(i)(C) is

[24] The Commission believes that this requirement is consistent with SRO requirements regarding customer accounts such as those discussed above in footnote 23.

[25] 17 CFR 240.17a–3(a)(17).

[26] *See* Comment Letters from Donaldson, Lufkin and Jenrette, p. 9, and the International Association for Financial Planning, pp. 2–3.

[27] 17 CFR 240.17a–3(a)(17)(i)(A).

[28] 17 CFR 240.17a–3(a)(17)(i)(B)(*1*).

[29] Certain SRO rules already require that customer account records be sent to customers who open options accounts. *See* NASD Rule 2860(b)(16)(C) and IM–2860–2, and NYSE Rule 721(c) and Supplemental Material at .30 regarding options accounts.

[30] 17 CFR 240.17a–3(a)(17)(i)(B)(*1*) through (B)(*3*).

[31] 17 CFR 240.17a–3(a)(17)(i)(B)(*1*).

[32] *Id.*

[33] 17 CFR 240.17a–3(a)(17)(i)(B)(*2*).

[34] 17 CFR 240.17a–3(a)(17)(i)(B)(*3*).

[35] *See* Comment Letters from Fidelity Investments, p. 5, Benefits Communication Corporation, p. 1, American Express Financial Advisors, Inc., p. 4, and Comerica Securities, p. 3.

[36] 17 CFR 240.17a–3(a)(17)(i)(B)(*4*).

specifically limited in application to paragraph (a)(17), and does not apply to any other Federal or SRO rules regarding collections of information (*e.g.,* Rule 17a–3(a)(9)).

4. Exemption From Account Record Information Requirements

A number of broker-dealer firms argued that the Commission should create an exemption from the account record information requirements of Rule 17a–3(a)(17)(i), contending that this record is intended to allow examiners to review for suitability, but broker-dealers are not subject to SRO suitability requirements for all of their accounts.[37] Therefore, they argue, where they have no suitability obligation, they should not be required to obtain account record information. The Commission is adopting the account record requirements with an exemption for certain accounts,[38] such that a broker-dealer is not required to create an account record for an account if the firm is not required (under any Federal or SRO rules) to make a suitability determination as to the account. However, the obligation to collect and record information of the type enumerated in Rule 17a–3(a)(17)(i)(A) may arise under SRO rules and interpretations. If, after the account is opened, the firm or its associated person engage in conduct that would subject the firm to any requirement to make a suitability determination, the firm must obtain the information before making such a recommendation. The firm would have to comply thereafter with the requirement to furnish customers with a copy of their account record for verification, under paragraph (a)(17)(i)(B)(*1*) of Rule 17a–3, but the account could re-qualify for the exemption.

For accounts existing on the effective date of these amendments, a broker-dealer will not be required to create or update the account record if, within the 36-month period beginning on the effective date of this rule, the firm has not been required to make a suitability determination as to that account.

For the purposes of paragraph (a)(17)(i)(D) of Rule 17a–3, the term ''suitability determination'' should be interpreted broadly. A broker-dealer may have an obligation to perform a suitability determination under the Exchange Act,[39] Commission rules,[40] SRO rules,[41] or common law.[42] Rule 17a–3(a)(17) does not change or limit a broker-dealer's obligation to make a suitability determination.

It is important to note that even if a broker-dealer is not required to create an account record under Rule 17a–3(a)(17) for an account, the firm must still comply with federal laws and regulations and SRO rules requiring collections of information regarding customer accounts, including paragraph (a)(9) of Rule 17a–3,[43] NYSE Rule 405, and MSRB Rule G–8(a)(xi).

5. Applicability of Account Record Requirements and 36-Month Grace Period

The requirement to create an account record applies to both new and existing accounts. For accounts opened on or after the effective date of these amendments (''new accounts''), the firm must obtain the account record information required under Rule 17a–3(a)(17)(i)(A) when the account is opened.

As originally proposed, the grace period to obtain the customer account record information for accounts existing on the effective date of these amendments would have been one year. However, many commenters[44] stated that with a large number of accounts it would be unduly burdensome to obtain the account record information within one year. Therefore, the Commission has provided broker-dealers with a 36-month grace period. Specifically, under paragraph (B)(*1*) of Rule 17a–3(a)(17)(i), for accounts existing on the effective date of these amendments, a firm will have 36 months to obtain the information required on the account record under paragraph (a)(17)(i)(A) of Rule 17a–3. The new 36-month furnishing cycle under paragraph (a)(17)(i)(B) of Rule 17a–3 will begin when the firm obtains the account record information within the initial 36-month grace period.

6. Written Customer Agreements

New paragraph (a)(17)(iii) of Rule 17a–3 requires each broker-dealer to create a record for each account indicating that each customer was furnished with a copy of any written agreement entered into on or after the effective date of this paragraph pertaining to that account. This will allow customers to review the terms of agreements to which they are subject, and to better understand their rights and responsibilities (and those of the broker-dealer) under these agreements. In addition, if any customer specifically requests a copy of an agreement relating to their account, this paragraph would require that the broker-dealer maintain a record that it was provided to the customer.

D. Complaints

New paragraph (a)(18)(i) of Rule 17a–3[45] requires firms to make a record as to each associated person that includes every written customer complaint received by the firm concerning that associated person.[46] This will allow securities regulators to quickly identify any trends, and focus examinations. This record must include complaints received electronically from customers. The rule requires that the record include the complainant's name, address, and account number; the date the complaint was received; the name of each associated person identified in the complaint; a description of the nature of the complaint; and the disposition of the complaint. However, because firms already are required to keep originals of incoming written complaints,[47] rather than make a separate record, firms have the option under this rule to keep the original complaint along with a record of the disposition of the complaint, if kept by name of associated person. This rule does not limit a broker-dealer's

[37] *See, e.g.,* NASD Rules 2310 and 2860(b)(16)(B), NYSE Rule 723, Chicago Board Options Exchange Rule 9.9, and Municipal Securities Rulemaking Board Rule G–19.

[37] 17 CFR 240.17a–3(a)(17)(i)(D).

[39] Sections 10(b) and 15(c) (15 U.S.C. 78*j*(b) and 15 U.S.C. 78*o*(c)). *See e.g., Hanley* v. *SEC,* 415 F.2d 589, 596 (2d Cir. 1969); *F.J. Kaufman and Co.,* 50 S.E.C. 164 (1989); *O'Connor* v. *R.F.Lafferty & Co.,* 965 F.2d 893 (10th Cir. 1992).

[40] 17 CFR 240.10b–5 and 17 CFR 240.15c1–2.

[41] *See supra* note 37.

[42] If a recommendation is made, a suitability obligation arises irrespective of the medium used to deliver that recommendation. For example, a broker-dealer can make a recommendation in person, on a website, via telephone, mail, or email. A broker-dealer also can recommend a security online regardless of whether that recommendation is attributable to a specific registered representative. Whether a broker-dealer has made a recommendation is a question that can only be answered by considering all of the facts and circumstances. (*See* ''Suitability Hypotheticals,'' Report of Commissioner Laura S. Unger, Online Brokerage: Keeping Apace of Cyberspace, pp. 32–4. (Nov. 1999))

[43] 17 CFR 240.17a–3(a)(9).

[44] *See, e.g.,* Comment Letter of Salomon Smith Barney, pp. 3–4.

[45] This paragraph was proposed as paragraph (a)(17) of Rule 17a–3.

[46] This requirement is in addition to other recordkeeping requirements such as Rule 17a–4(b)(4), which requires firms to keep originals of all correspondence received. For example, if a broker-dealer firm received a written complaint regarding the firm itself, the firm would be required to keep that complaint under Rule 17a–4(b)(4). If the complaint related to a particular associated person, the firm would also be required to make a record of the complaint as to that associated person under Rule 17a–3(a)(18); however, the firm may keep one copy of the complaint to satisfy both Rules 17a–3(a)(18)(i) and 17a–4(b)(4).

[47] *See* 17 CFR 240.17a–4(b)(4), and NASD Rule 3110(d).

responsibilities under SRO and other regulations that may require creation and maintenance of records regarding, or reporting of, oral complaints.

Paragraph (ii) of Rule 17a–3(a)(18) requires firms to make a record indicating that each customer has been provided with a notice of the address and telephone number of the department of the firm to which any complaints may be directed.[48] This will assist both customers and broker-dealers to ensure that complaints reach the proper person or department so they can be recorded, reported (if necessary), and answered. Some commenters requested clarification of whether, in an introducing/clearing relationship,[49] the contact information should be that of the introducing firm, the clearing firm, or both. To the extent not otherwise required, this should be a matter of negotiation between the introducing firm and the clearing firm.[50] If contact information is provided for both firms, the notification should clearly indicate which firm the customer should contact and for what purposes. Two other commenters requested clarification as to whether this notification could take the form of a notice on customer statements.[51] The Commission believes that firms should have flexibility as to how they may deliver this notice to customers, and inserting the notice on a customer statement is one acceptable alternative.

E. Compensation

Paragraph (a)(19)(i) of Rule 17a–3 requires firms to make a record as to each associated person listing each purchase and sale of a security[52] attributable, for compensation purposes, to that associated person. Again, the purpose for this requirement is to allow securities regulators to quickly identify compensation trends and focus examinations. The record must include the amount of compensation (if monetary) and a description of the compensation (if non-monetary). Under this requirement, firms must make records of all commissions, concessions, overrides, and other compensation to the extent they are earned or accrued for transactions. In addition, if the compensation is non-monetary, that description should include an estimate of its value.

The term ''non-monetary compensation'' includes compensation such as sales incentives, gifts, or trips that would be provided to associated persons if certain sales goals were achieved. Such non-monetary compensation should be recorded if directly related to sales. If sales would be counted toward achieving these goals, then a notation of the sales should be made regardless of whether that goal is actually achieved. Non-monetary compensation does not include items of little value distributed by the firm.

Paragraph (ii) of new Rule 17a–3(a)(19)[53] requires that firms maintain a record of all agreements pertaining to the relationship between each associated person and the broker-dealer, including a summary of each associated person's compensation arrangement or plan. Further, to the extent that compensation is based on factors other than remuneration on a per trade basis, the firm must make a record that describes the method by which compensation is to be determined.

It should be noted that the requirement under paragraph (ii) that a broker-dealer maintain a record of all agreements between itself and each associated person includes verbal agreements and records, such as commission schedules, which may change on a periodic basis.

The term ''relationship,'' as used in paragraph (a)(19) of Rule 17a–3, solely refers to the employment or contractual relationship between the associated person and the broker-dealer. It would not relate to personal relationships unrelated to the firm's business.

F. Compliance With Requirements for Communications With the Public

New paragraph (a)(20) of Rule 17a–3[54] requires each firm to make a record documenting that the firm has complied with, or adopted policies and procedures reasonably designed to establish compliance with, applicable federal regulations and SRO rules which require that a principal approve any advertisements, sales literature, or other communications with the public.[55] This paragraph would apply to marketing materials, sales scripts, and other paper or electronic material, such as audio or video tapes, used by broker-dealers in communicating with the public. This paragraph, which is designed to allow State Securities Regulators to examine broker-dealers for compliance with SRO rules relating to communications with the public, does not establish a new source of supervisory responsibility. In addition, a broker-dealer has many options as to how it may create this record.[56]

The Commission did not adopt the portion of this rule as reproposed that referenced specific types of advertisements or sales literature. Instead, the Commission will defer to SRO rules as to which communications with the public must be approved by a principal of the firm.

G. Persons To Explain Records and Their Content

Paragraph (a)(21) of Rule 17a-3 requires a record listing, by name or title, all personnel at an office who, without delay, can explain the types of records the firm maintains at that office, and the information contained in those records. Commenters, particularly the States, indicated that this requirement is important because recordkeeping practices typically vary from firm to firm in ways ranging from format and presentation to the name of a record. Therefore, each firm must be able to promptly explain how it makes, keeps, and titles its records. To comply with this rule, a firm may identify more than one person and list which records each person is able to explain.

Because it may be burdensome for firms to keep this record current if it lists each person by name, a firm may satisfy this requirement by recording the

[48] This requirement expands on an existing interpretation of the Commission's financial responsibility rules and the Securities Investor Protection Act of 1970, which states that, for purposes of custody of securities, for a firm to qualify as an introducing firm with a lesser net capital requirement than a clearing firm, its customers must be treated as customers of the clearing firm. In addition, under that interpretation, the clearing firm must issue account statements directly to customers, and each account statement must contain the name, address, and telephone number of a responsible individual at the clearing firm whom a customer can contact with inquiries and complaints regarding the customer's account.

[49] *See, e.g.,* Comment Letter from Lawrence M. Lowman, p. 1.

[50] *See supra* note 48; Exchange Act Release No. 31511 at note 21 and accompanying text, (Nov. 24, 1992), 57 FR 56973 (Dec. 2, 1992).

[51] *See* Comment Letters from the Discount Brokers, p. 7, and Donaldson, Lufkin & Jenrette, p. 10.

[52] The phrase ''and the specific security,'' which appeared in the Reproposing Release, was not included in the Rule as adopted because it is redundant. The record ''listing all purchases and sales of securities for which the associated person was compensated'' must provide enough information to identify that purchase or sale to which the compensation was attributable.

[53] This Rule was reproposed as Rule 17a–3(a)(12)(ii) and Rule 17a–3(a)(12)(iii).

[54] This paragraph was reproposed as paragraph (a)(19) of Rule 17a–3.

[55] *See e.g.,* NASD Rule 2210(b) and NYSE Rule 472.

[56] *E.g.,* the record may consist of a principal's signature or initials on the communication, or a signed memo from the principal granting permission for use of the communication. Further, a firm may have policies and procedures designed to establish compliance with applicable federal regulations and SRO rules which require that a principal approve any advertisements, sales literature, or other communications with the public. Thus, records presently used to evidence compliance with SRO rules may also be used to fulfill this requirement.

persons capable of explaining the firm's records by either name or title.

H. Record Listing Principals of the Firm

New paragraph (a)(22) of Rule 17a–3 requires firms to make a record listing each principal of the firm responsible for establishing policies and procedures reasonably designed to ensure compliance with any applicable securities regulatory authority requirements that require acceptance or approval of a record by a principal. This requirement is unchanged from the reproposal, and is intended to assist securities regulators by identifying individuals responsible for designing a broker-dealer's compliance procedures and managing the firm.

I. Definition of Principal

Paragraph 17a–3(g)(2) defines the term ''principal'' to include any individual registered with a registered national securities association as a principal or branch manager of a member, broker or dealer, or any other person who has been delegated supervisory responsibility for the firm or its associated persons. By including any person who has been delegated supervisory responsibility in the definition of the term ''principal,'' the rule has been modified from the reproposal to include the definitions of ''principal'' used by other securities regulatory authorities.

J. Definition of Securities Regulatory Authority

The definition of ''securities regulatory authority'' in paragraph (g)(3) of Rule 17a–3 is substantially similar to that in the Reproposing Release, except that State Securities Regulators are identified as ''the securities commissions (or any agency or office performing like functions) of the States * * *''[57] mirroring the language that Congress used in NSMIA.

K. Miscellaneous

The Commission has not adopted reproposed paragraph (a)(20) of Rule 17a–3, which would have required firms to make a record as to each associated person listing chronologically all customer purchase or sale transactions for which the associated person entered the order or was primarily responsible. Commenters stated that the information required in this record would already be maintained in other records, although not necessarily in the chronological format that this paragraph would have required. The Commission also has not adopted reproposed paragraph (a)(23) of Rule 17a–3, which would have required a firm to make a record listing each office of the firm and whether that office had been designated as a State record depository, since firms need no longer designate a State record depository for any purpose. This proposed record also would have required firms to list each associated person working out of or storing records at each office. The Commission has not adopted this requirement because firms are required to make a record of similar information under new paragraph (ii) of Rule 17a–3(a)(12).[58]

IV. Office Records

The Reproposing Release would have required that broker-dealers make certain records for each local office and maintain copies of those records at the office to which the records relate. These requirements were designed to assist securities regulators when conducting sales practice examinations at particular offices. The Commission has adopted the requirements regarding the creation of these records substantially as reproposed, but has materially altered the alternatives for maintenance of those records.

Generally, State Securities Regulators supported a requirement that records as to a particular office be maintained at that office, even if only electronically. The State Securities Regulators stated, in their comment letters, that they had encountered excessive and costly delays when conducting examinations when records were kept at another office. In sum, they stated that although firms generally had the records available in local offices, the firms preferred to funnel all records requested by examiners through their centralized compliance departments in order to assure accuracy, anticipate any potential violations, review material for applicable privileges, and make a record of documents reviewed by regulators.[59] While the State regulators have the power to impose fines and penalties on firms that fail to timely produce records, the delays still result in unnecessary, wasted examination time at firms waiting for the records production. The delay is costly for regulators, particularly when they travel to remote areas to conduct surprise examinations at an office where they may spend numerous days awaiting the records.[60]

The broker-dealer commenters were strongly opposed to this requirement for two main reasons. First, they stated that the requirement to maintain copies of documents at all local offices would be costly and burdensome because they would need to create and maintain two sets of records. They stated that even with the flexibility of being able to maintain the records electronically, this requirement would be costly because many firms do not currently have computer systems capable of retaining and producing all the required records. Second, firms stated that maintaining records at all local offices would force them to decentralize their recordkeeping, which would potentially compromise their controls on recordkeeping and supervisory practices.

Requiring records to be maintained at each local office was the requirement most seriously disputed by the firms. The reproposal has been altered to allow a firm, rather than to maintain records at an office, to produce the records promptly at the request of a representative of a securities regulatory authority at the office to which the records relate or at such other place as is agreed to by the representative. These alternative methods for complying with paragraph (k) of Rule 17a–4 were added in response to comments that the requirement, as reproposed, would have forced firms to decentralize their recordkeeping systems and would have compromised their internal controls and supervisory practices.[61]

The Commission believes that the amendments to Rules 17a–3 and 17a–4 adopted today, which set forth, (i) the definition of ''office,'' (ii) what records must be created as to each office,[62] and (iii) what records must be maintained at each office,[63] address the concerns of both regulators and broker-dealers.

[57] *Supra* note 7.

[58] New paragraph (a)(12)(ii) of Rule 17a–3 requires firms to make a record showing, for each associated person, every office where the associated person regularly conducts a securities business and certain other information.

[59] *See* Comment Letter from Citicorp, p. 3, ''RRs in all local offices would have to be trained to do a function outside their current job responsibilities, namely to review material for applicable privileges and make records of documents reviewed by regulators.''

[60] *See, e.g.,* Comment Letters from Arkansas Securities Department, pp. 1–3; Department of Financial Institutions, Commonwealth of Kentucky, p. 6; and Securities Division, State of Rhode Island and Providence Plantations, p. 1.

[61] This does not relieve broker-dealers from any other Federal or SRO requirements to maintain records at office locations. *See, e.g.,* NASD Rule 3110(d) which requires firms to keep at each Office of Supervisory Jurisdiction (defined at NASD Rule 3010(g)(1)), either a separate file of all written complaints of customers and action taken by the firm, or a separate record of such complaints and a clear reference to the files containing the correspondence connected with such complaint maintained in such office.

[62] 17 CFR 240.17a–3(f).

[63] 17 CFR 240.17a–4(k).

A. Definition of Office

For both creation and maintenance of records, the definition of ''office'' adopted by the Commission includes any location where an associated person regularly conducts business.[64] However, an office would not include a customer's office that an associated person may visit on a regular basis.

The Commission has also addressed concerns that arise when an associated person's residence is an office. Rule 17a–4(k) states that a broker-dealer is not required to produce records at an office that is a private residence, provided that (i) only one associated person, or multiple associated persons who reside at that location and are members of the same immediate family,[65] regularly conduct business at the office; (ii) the office is not held out to the public as an office; and (iii) neither customer funds nor securities are handled at that office. Instead, Rule 17a–4(k) allows a broker-dealer to either maintain those records at some other location within the same State as that office as the broker-dealer chooses, or to promptly produce those records at an agreed upon location.

For purposes of paragraph (f) of Rule 17a–3 [66] and paragraph (k) of Rule 17a–4,[67] in circumstances where an associated person works out of multiple offices, such as bank circuit riders, a firm may treat all the locations where the associated person regularly works as a single office.[68]

B. Records ''As To'' Each Office

New paragraph (f) of Rule 17a–3 requires firms to make and keep current, separately for each office, certain books and records that reflect the activities of the office.[69] It should be noted that 75% of broker-dealers have reported that they have no branch locations.[70] The definition of ''office'' may be broader and more inclusive than the definition of ''branch,'' however.

The Commission removed the sentence, ''This requirement may be satisfied by demonstrating that the data is maintained in a system which is capable of promptly generating records for each office upon request'', because the requirement to either maintain the specified records at each location or produce them on the same day a request is made has been changed to allow firms to produce these records promptly.

C. Records To Be Maintained at Office Locations

There have been two major changes to new paragraph (k) of Rule 17a–4 from the reproposal. First, the requirement to maintain certain records at the office locations has been expanded from one year to two years. This was done to establish parity with the retention requirements for the separate sections as provided under paragraph (b) of Rule 17a–4.

Second, under paragraph (k) of Rule 17a–4, if a broker-dealer does not maintain records at an office, but instead chooses to produce the records upon request, the broker-dealer must produce the records ''promptly.''[71] The word ''promptly'' has deliberately not been defined in the rule. Generally, requests for records which are readily available at the office (either on-site or electronically) should be filled on the day the request is made. If a request is unusually large or complex, then the firm should discuss with the regulator a mutually agreeable time-frame for production.[72]

Based on the foregoing, the Commission has not adopted the reproposed provision of Rule 17a–4(k) that would have allowed firms to maintain records at a State records depository in lieu of maintaining the records at the office to which the records relate.

One commenter requested guidance on how this paragraph relates to a foreign office of a U.S. registered broker-dealer.[73] Under paragraph (f) of Rule17a–3, a broker-dealer must make certain records for a foreign office; however, a broker-dealer is not required to maintain or produce those records at the foreign office under paragraph (k). Instead, those records would be maintained at the broker-dealer's main office.

V. Rule 17a–4

A. General Record Retention Requirements

Paragraphs (a) and (b)(1) of Rule 17a–4 list certain records required under Rule 17a–3 that must be kept for six and three years, respectively. The amendments to these two paragraphs have been modified from the reproposal to remain consistent with the modifications to Rule 17a–3.

B. Retention of Communications

Paragraph (b)(4) of Rule 17a–4 previously required that each broker-dealer keep originals of all communications received and copies of all communications sent by the firm relating to its business as a broker-dealer, including inter-office memoranda and communications. With respect to memoranda, including e-mail messages, the Commission has stated that the content and audience of the message determine whether a copy must be preserved, regardless of whether the message was sent on paper or sent electronically.[74] The amendments to this paragraph adopted today will require firms to retain communications that are subject to SRO rules regarding ''communications with the public'' (such as advertising) as well, a requirement reproposed separately as paragraph (b)(10) of Rule 17a–4. This requirement is designed to provide State Securities Regulators with the ability to access these public communications records so they can enforce their laws relating to the form and use of public communications.

It should be noted that a written advertisement that is never released to the public would not be covered by this rule; however, a sales script that is used by an associated person when communicating with the public would be covered even if the script itself is not delivered to the public.

The requirement, as reproposed, that ''any written procedures [a broker-dealer] uses for reviewing the communications received or sent'' has been moved to new paragraph (e)(7) of Rule 17a–4, which requires firms to keep all compliance, supervisory, and procedures manuals, including any written procedures for reviewing communications.

[64] 17 CFR 240.17a–3(g)(1).

[65] The term ''immediate family,'' as used in paragraph (k), should be interpreted to have the same meaning as it does in NASD IM–2110–1(*l*)(2).

[66] New paragraph (f) of Rule 17a–3 requires firms to make and keep current separately as to each office, the books and records required under various paragraphs in Rule 17a–3.

[67] New paragraph (k) of Rule 17a–4 requires firms to either keep certain records at each office or produce them at that office or at another agreeable location.

[68] Firms need not apply to or notify securities regulators as to which office it selects as the associated person's ''office.'' However, pursuant to paragraph (a)(12)(iii) of Rule 17a–3, the firm must identify the office as such.

[69] The specific paragraphs of Rule 17a–3 that are included in this requirement are (a)(1), (a)(6), (a)(7), (a)(12), (a)(16), (a)(17), (a)(18), (a)(19), (a)(20), (a)(21), and (a)(22).

[70] Per *Schedule 1* data filed by broker-dealers as of year-ending December 31, 1998. Pursuant to 17 CFR 240.17a–10, Broker-dealers are required to file *Schedule 1,* which requires the reporting of general information designed to measure certain economic and financial characteristics.

[71] *Supra* note.

[72] Valid reasons for delays in producing the requested records do not include the need to send the records to the firm's compliance office for review prior to providing the records.

[73] *See* Comment Letter from A.G. Edwards & Sons, Inc., p. 8.

[74] Exchange Act Release No. 38245 (Jan. 31, 1997), 62 FR 6469 (Feb. 12, 1997).

C. Organizational Documents

The Commission has modified paragraph (d) of Rule 17a–4, which require a broker-dealer to maintain certain organizational records. Specifically, the Commission has added language to clarify that organizational records of legal entities not specifically delineated in the present rule [75] are still required to be preserved under this rule. Various State statutes use different terms to describe the legal entities that may be created under their rules and the organizational documents necessary to create those entities; accordingly, the Commission has included in this paragraph generic terms to describe the types of records that firms must keep. The Commission believes that generally broker-dealers that are not formed as corporations or partnerships are already keeping these types of records and that this amendment codifies current business practices. Similar to the amendment to paragraph (g)(3) of Rule 17a–3 noted above, the Commission has replaced the phrase ''state securities jurisdictions and self-regulatory organizations'' in the Reproposing Release with the term ''securities regulatory authorities.''

Under this paragraph, every broker-dealer is also required to maintain copies of its Form BD and all amendments thereto. To comply with this requirement with respect to amendments to Form BD, a broker-dealer is required to retain a copy of only those portions of the Form that were amended. The Commission believes that generally broker-dealers are already keeping these records and that this amendment codifies current business practices.

D. Account Record Information

New paragraph (e)(5) of Rule 17a–4 requires broker-dealers to retain account record information for six years. The six-year period begins either at the time the account is closed or when the information is replaced or updated. This provision will allow regulators to review account record information for at least the six years immediately prior to the examination or investigation. Broker-dealers generally maintain account record information for at least the life of the account to facilitate a number of business purposes, including suitability determinations and supervision of accounts and representatives.

[75] For instance, limited liability companies (''LLCs'') would be covered.

E. Special Reports

New paragraph (e)(6) of Rule 17a–4 requires a firm to keep for three years a copy of all reports that a securities regulatory authority has requested or required a specific firm to create. Such special reports would include those reports that are requested or required under an order or settlement that requires the firm to produce the report as part of the terms of the order or settlement. The purpose of this paragraph is to clarify that these records must be kept and to provide guidance as to how long firms are expected to maintain these records.

This requirement is not designed to limit the ability of securities regulatory authorities to obtain records that are otherwise required to be created and maintained, such as records of internal communications required to be maintained under paragraph (b)(4) of Rule 17a–4.

F. Compliance, Supervisory and Procedure Manuals

The Commission is also adopting, as reproposed, new paragraph (e)(7) of Rule 17a–4. This paragraph requires firms to retain a copy of all compliance, supervisory, and procedures manuals describing the firm's policies and practices with respect to compliance and supervision, as currently in use and for three years after the termination of the use of each manual, including any updates, modifications, and revisions to the manuals. This will ensure that securities regulators are able to obtain information as to what policies and procedures were in place at a given time.

G. Exception Reports

New paragraph (e)(8)(ii) of Rule 17a–4 requires firms to maintain copies of reports produced to review for unusual activity in customer accounts (commonly referred to as ''exception reports''). This paragraph does not obligate broker-dealers to create exception reports. Exception reports would include reports that identify exceptional numerical occurrences, such as frequent trading in customer accounts, unusually high commissions, or an unusually high number of trade corrections or cancelled transactions. These reports will help securities regulators discover sales practice problems such as churning, unauthorized trading, or other indications of micro-cap fraud, and will also provide securities regulators with information as to what type of data may have been available to the broker-dealer.

In lieu of retaining copies of the reports, a member, broker or dealer may choose to promptly re-create the reports upon request by a securities regulatory authority. If the broker-dealer elects to re-create exception reports instead of maintaining a copy of the report, but the firm has changed its systems so that it cannot re-create the same report, the broker-dealer may provide a copy of the report in the format presently available using historical data,[76] but must also provide a record explaining each system change that affected each report.[77] Lastly, if the firm is unable to re-create the report in any format for the most recent 18 months, due to changes, for example, in a database, software, or physical system, the rule provides that the broker-dealer may instead provide a record of the parameters that were used to generate the report for the time period specified by the representative of the securities regulatory authority. The Commission provided these alternatives in order to make this rule less burdensome on broker-dealers.

Many firms commented that this requirement would be potentially counter-productive because, if firms are required to retain copies of all reports that they create, they would create fewer reports. However, the Commission believes that broker-dealers will continue to create those exception reports that are necessary to adequately supervise their business, and that retaining these reports will increase the efficiency of examinations by regulators and may reduce the examination burden on broker-dealers.

VI. Effective Date

The final rules adopted today shall become effective May 2, 2003.

VII. Technical Amendments

A. Electronic Storage Media

On February 5, 1997, the Commission amended Rule 17a–4 to allow broker-dealers to employ, under certain conditions, electronic storage media to maintain its records.[78] The Commission proposed and is now adopting technical amendments to that rule.[79] The

[76] For example, if the original report includes customer name, account number, social security number, and transactional information, however the report that can be re-created at a later date does not include social security numbers, the firm should provide the re-created report to the regulator with an explanation that although social security numbers appeared on the original report, the firm is unable to re-create the report including that information.

[77] This includes changes to hardware, software, or changes to the database used to produce the exception reports.

[78] Exchange Act Release No. 38245 (Feb. 5, 1997), 62 FR 6469 (Feb. 12, 1997) (''Electronic Storage Media Release'').

[79] 17 CFR 240.17a–4(f).

Electronic Storage Media Release requires a broker-dealer that employs micrographic or electronic storage media to be ready at all times to immediately provide a facsimile enlargement upon request by the Commission or its representatives.[80] It also requires a broker-dealer that exclusively uses electronic storage media to fulfill some or all of its record preservation requirements to contract with a third party download provider that will file undertakings with the broker-dealer's designated examining authority indicating that the download provider will furnish promptly to the Commission, its designees or representatives, the information necessary to download information kept on the broker-dealer's electronic storage media.[81] Because SROs and State Securities Regulators are neither representatives nor designees of the Commission but, to the extent that they have jurisdiction over the broker-dealer serviced by the third party download provider, are organizations that should have access to facsimile enlargements and download information, the Commission is adopting these technical amendments to provide them with access to these records. The Commission is also adopting these technical amendments so that when broker-dealers use the undertaking option under Regulation ATS, SROs and State Securities Regulators will have access to those records.[82]

B. Other Technical Amendments

The Commission is adopting amendments to Rule 17a-3(a)(12)(i) to update the list of stock exchanges for which an associated person's application for registration or approval may be used to satisfy the requirements under that paragraph. This amendment is a codification of current practices. The Commission is also adopting amendments to the language throughout Rules 17a-3 and 17a-4 that eliminate masculine references, and replace them with gender neutral references.

VIII. Costs and Benefits of the Amendments

In the Reproposing Release, the Commission requested comment on the costs and benefits associated with the reproposed rules and rule amendments.[83] Of the comments received by the Commission, fifty-seven commenters discussed the benefits and costs associated with the reproposal. Of those commenters, thirty were broker-dealers,[84] twenty-two were States,[85] two were consumer groups,[86] two were other groups,[87] and one was an individual.[88] Most of the commenters (including all of the broker-dealer commenters) argued that the costs outweighed the benefits of the reproposed amendments and that the cost estimates provided in the Reproposing Release were too low. Although most of those arguments were general in nature, twenty-three commenters specifically referenced paragraph (a)(17)(i) of Rule 17a–3,[89] and fifteen commenters specifically referenced paragraph (k) of Rule 17a–4.[90] All the States and the consumer groups that commented argued that most broker-dealers presently maintained most, if not all, the records required under the reproposed amendments, and that the benefits, although difficult to quantify, justified any costs which might be incurred.

One commenter stated that well-organized firms are less likely to experience the potentially catastrophic losses that result from serious securities violations.[91] Many State Securities Regulators indicated in their comment letters that their agencies generally found that firms with inadequate books and records were more likely to have other problems, such as inadequate supervisory systems and selling-away issues. According to the NASD's Office of Dispute Resolution, $126 million and $76 million were awarded by NASD arbitrators in 1999 and 2000 respectively in customer claimant cases, of which $48 million and $21 million respectively constituted punitive damages.[92] The vast majority of claims filed for arbitration with the NASD's Office of Dispute Resolution during this time period related to sales practice issues. In addition, two industry participants estimated that they presently pay outside counsel approximately $50 million and $25 million respectively each year to deal with sales practice complaints.[93]

Many States indicated that they believed the amendments would impose only minimal additional costs to broker-dealers because, in their experience, many broker-dealers already maintain the records required by the amendments in order to comply with SRO rules, State laws that applied prior to NSMIA, or simply to properly manage costs and supervise offices. Further, some States indicated that they believed that broker-dealers were exaggerating the potential costs of the reproposed amendments.[94]

In fact, the States of Connecticut[95] and Florida[96] conducted special reviews, in conjunction with their examination programs, to determine the extent to which broker-dealers already maintained the records required under the Reproposal at office locations. The State of Connecticut concluded that its review "overwhelmingly indicate[d] that all the books and records that would be required by the re-proposed

[80] *See* 17 CFR 240.17a–4(f)(3)(i).

[81] *See* 17 CFR 240.17a–4(f)(3)(vii).

[82] Exchange Act Release No. 40760 (Dec. 8, 1998), 63 FR 70844 (Dec. 22, 1998).

[83] *See supra* note 9, at p. 54411.

[84] *See* Comment Letters from Mutual Service Corporation, p. 6; Titan Value Equities Group, Inc., pp. 2 and 4; USAA, pp. 2 and 6; MetLife, p. 4; A.G. Edwards and Sons, Inc., p. 6; MONY, p. 4; Capital West, p. 2; Comerica Securities, p. 2; Nationwide Investment Services Corporation, p. 2; Edward Jones, pp. 1 and 3; Advest, p. 1; Salomon Smith Barney, pp. 1 to 2; NyLife Securities, pp. 6 to 7; HD Vest, p. 2; American Express Financial Advisors, pp. 2 to 5; First Union, pp. 3 to 4; Charles Schwab, pp. 3 to 4; MML Investors Services, Inc., pp. 2 to 4; National Planning Corporation, p. 1; Pumphrey Securities, p. 2; Citicorp Investment Services, pp. 2 to 3; Discount Brokers, pp. 4 to 5; M & T Securities, pp. 1 and 2; Donaldson, Lufkin & Jenrette, p. 6; Investment Management & Research, Inc., p. 4; John Hancock Distributors, Inc., pp. 3 to 4; Southwest Securities, p. 2; the Securities Industry Association, p. 10; Merrill Lynch, pp. 1, 6 to 7, and 11; and Raymond James, p. 5.

[85] *See* Comment Letters from Michigan, pp. 1 to 2; Idaho, pp. 1 and 4; Kansas, pp. 1 to 2; Delaware, pp. 1 to 2; Colorado, p. 2; North Dakota, p. 1; Ohio, p. 1; Texas, pp. 1, 2 to 3, and 6; Hawaii, pp. 1 to 2; Rhode Island, pp. 1 to 2; New Hampshire, pp. 1 and 2; Nebraska, p. 1; Utah, pp. 1 and 3; NASAA, pp. 3 to 5 and 22; New York, pp. 1 and 3; Virginia, pp. 1 to 3; New Jersey, pp. 2 to 7; Washington, pp. 2 and 6; Arkansas, pp. 1, 3, and 5; New Mexico, p. 1; North Carolina, pp. 1 to 2; and Montana, pp. 1, and 3 to 5.

[86] *See* Comment Letters from AARP, p. 2; and the Consumer Federation of America, pp. 2 to 3.

[87] *See* Comment Letters from American Council of Life Insurance, pp. 12 to 13; and International Association of Financial Planning, p. 6.

[88] *See* Comment Letter from Thomas Koutris, p. 1.

[89] This paragraph provides that broker-dealers must obtain certain information relating to the accounts of natural customers, and that customer account records must be updated regularly.

[90] In the reproposed rule this paragraph provided that certain records had to be maintained at the local office, or that they had to be produced at the local office to which they related on the same day a request for those records was made by a representative of a securities regulatory authority.

[91] *See* Comment Letter from State of Virginia, pp. 1 to 3.

[92] Per NASD Dispute Resolution, Inc. website: www.nasdradr.com/statistics.asp.

[93] It should be noted that these estimates do not include any internal compliance, operational, and/or legal costs incurred by these firms in dealing with these complaints.

[94] *See, e.g.*, Comment Letter from the State of New Jersey, p. 5.

[95] *See* Second Comment Letter from State of Connecticut. The State of Connecticut performed examinations of forty-nine office locations of twenty-three broker-dealers in five States. Seventeen of these offices had two or less associated persons working there. In addition, the State reviewed the most recent 100 examinations it had performed, and as well as investigatory materials from the prior two years wherein subpoenas were issued to obtain broker-dealer records.

[96] *See* Second Comment Letter from NASAA. The State of Florida performed examinations on 19 broker-dealers.

rule proposal are, at the present time, being maintained in offices within Connecticut and similarly outside the state.'' Further, Connecticut stated, ''During this review process the records were immediately available for inspection upon request,'' and ''the types of records required by the reproposed rule would not be burdensome in that the firms retained substantially more records than required.'' Connecticut also stated, ''[t]he retention schedules listed in the firms' compliance [manuals] were consistent with the requirements under the reproposed rule.'' Florida stated, ''[t]he reviews indicated that based on records maintained most branch offices met or exceeded the records requirement for the [re-]proposed rule, and ''[a] vast majority of the branch offices maintained the records on-site for periods of at least 2 years (and in some cases up to 6 years).'' Further, Connecticut stated, ''[t]he firms' recordkeeping requirements did not vary from location to location or even state to state because they were required by the firms' own compliance manuals,'' and ''[i]n certain instances, the firms' compliance manuals indicated that these additional records were necessary to adequately supervise its branch operations.'' Similarly, Florida stated, ''[m]anagement of several firms visited reported that record creation and retention is a nationwide requirement; the same for all offices in all states, not specific to the state of Florida * * * [t]his information was verified by the firms' Operational/Supervisory Compliance Manuals.''

A number of the States contend that investors are defrauded of millions and millions of dollars every year as a result of sales practice violations by broker-dealers.[97] Further, Commission staff found through ''The Large Firm Project'' [98] ''25% of the branch office examinations conducted in this project resulted in referrals for enforcement investigation and possible disciplinary action,'' and ''[t]he examinations also revealed that some branch office managers were not implementing firm procedures adequately,'' and recommended that ''the Commission should develop better means of identifying sales practice problems.'' [99] The enhanced recordkeeping requirements would help make available critical information necessary for securities regulatory authorities to discover and take appropriate action for various securities violations, particularly sales practice violations. The cost to securities regulatory authorities to obtain the same information and evidence that otherwise would be available by these rules from other methods would be high. In addition, the possibility exists that government regulatory authorities would be unable to obtain certain information by any other means if the information is not required to be kept. Investigatory delays often lead to additional investor losses. The State of New Jersey contended that these delays could lead to an erosion of public confidence in the industry, which can be exacerbated by the public's belief that securities regulatory authorities lack the ability to properly oversee broker-dealers and enforce securities regulations.[100] NASAA commented that lack of public confidence in the marketplace can lead to an inability of issuers to raise capital.[101]

Most broker-dealer commenters indicated that two of the reproposed amendments would cause them to incur substantial additional costs. These two amendments were paragraph (k) of Rule 17a–4, which required that records be maintained at local offices or that firms produce those records at the local office on the same day a request for records was made by a regulator at that local office, and paragraph (a)(17)(i) of Rule 17a–3, which required that a broker-dealer provide customers with a copy of their account record at specified times. As a result of comments received in response to the Reproposing Release, the Commission substantially modified those two amendments as described above.

The only other paragraphs broker-dealers specifically identified as resulting in increased costs were (a)(6) and (a)(7) of Rule 17a–3, which require that brokerage order tickets include the time of receipt, and that dealer order tickets include a notation of any modifications to an order. The Commission addressed some of these comments by modifying paragraph (a)(6) to provide an exemption for mutual fund and variable contract orders processed on a subscription-way basis. Further, for certain securities, the receipt time and notation of modification are already required under SRO rules.[102] The only cost to firms resulting from these paragraphs relate to assuring that processes for recording this information will record the information for all orders that are not exempt and not just those orders covered by SRO rules.

A few commenters attempted to provide alternative cost estimates for use in calculating the costs of the amendments. Some firms provided specific numbers, but provided no explanation as to the source of their estimates or their reason for believing that they would be more accurate than the Commission's estimates. In addition, certain costs are no longer relevant because the Commission substantially modified the amendments in response to comments. Accordingly, after consideration of all of the circumstances, the Commission has altered its cost estimates to reflect the fact that changes were made to the amendments in response to the comments received. Further, where the amendments were not altered significantly, the Commission has substantially increased estimates of costs that commenters argued were significantly underestimated.

The Commission estimates that the aggregate cost of these amendments will be approximately between $78.2 million and $84.3 million in the first year, and between $52.5 and $58.6 million per year thereafter (depending on what estimated postage cost is included in the calculations). Dollar costs relating to specific amendments are detailed below.

For purposes of this cost-benefit analysis, the amendments to Rules 17a–3 and 17a–4 are divided into three groups: (i) Those pertaining to the maintenance of office records and alternatives to these requirements; (ii) those pertaining to the periodic updating of customer information; and (iii) all other new requirements covered by the amendments.

A. Changes To Rule 17a–4, Including Maintenance of Office Records and Alternatives To These Requirements

As amended, Rule 17a–4 requires broker-dealers to maintain certain

[97] Four States provided specific information regarding investor losses. Illinois indicated (in its Comment Letter, p. 2) that over the past 8 years, 29 enforcement cases were brought in which Illinois investors lost over $38.9 million dollars. Kansas indicated (in the attachment to its Comment Letter) that, with respect to cases they have brought over the past ten years, Kansas customers have lost over $6.4 million dollars. Ohio indicated (in its Comment Letter, p. 3) that in one particular case Ohio investors lost over $60 million dollars. Lastly, Connecticut indicated (in its Comment letter, p. 2) that, with respect to cases they have brought where the investors' relationship was established through small offices, Connecticut investors have lost over $12 million.

[98] Report by the Division of Market Regulation and the Division of Enforcement, U.S. Securities and Exchange Commission, *The Large Firm Project: A Review of Hiring, Retention and Supervisory Practices* (May 1994).

[99] *Id.*, at pp. 5 and 7.

[100] *See*, Comment Letter from the State of New Jersey, p. 3.

[101] *See*, Comment Letter from NASAA, pp. 7–8.

[102] *E.g.*, the NASD's OATS rules, and NYSE rules 123 and 410A.

records at each office. As discussed above, new Rule 17a–4(k) was modified from the reproposal to provide broker-dealers with the alternative of ''promptly'' producing certain records pertaining to a particular office at that office or at a mutually agreeable alternative location. This modification should significantly reduce the compliance costs associated with the amendments.

The amendments standardize the amount of time broker-dealers must maintain certain records, and may thereby increase the amount of time these records are kept by certain firms. Broker-dealers generally maintain these records already to comply with Federal laws or regulations, SRO rules, or in the normal course of business. These records include, (i) information relating to the principals responsible for reviewing and updating policies and procedures, (ii) copies of Forms BD, BDW and amendments thereto, (iii) copies of compliance, supervisory, and procedures manuals, (iv) customer account records, (v) order ticket information, (vi) records relating to compensation of associated persons, (vii) evidence of compliance with SRO advertising and sales literature rules, (viii) exception reports, and (ix) specialized reports produced pursuant to an order or settlement.

The amendments will also standardize the type of records that must be kept by broker-dealers and the manner in which those records must be produced during examinations. Before NSMIA, States had various books and records requirements. Although these requirements were similar to Commission and SRO requirements, differences existed that broker-dealers had to track and comply with. As one commenter stated, ''the cost savings to industry of moving from compliance in the pre-NSMIA days with a variety of State laws to a new uniform should be equally substantial and should more than make up for any [additional] burden imposed by the [amendments].'' [103] The uniformity provided by NSMIA and these amendments to Rules 17a–3 and 17a–4 should result in significant cost savings to broker-dealers that operate in multiple jurisdictions.

1. Benefits

The amendments should result in increased efficiency and effectiveness of broker-dealer examinations, especially with respect to small offices. Increasing the efficiency of examinations tends to decrease the costs incurred by both regulators, whose staff spends time conducting examinations, and broker-dealers, whose personnel may be inconvenienced for the period the examiners are present in their offices. One State estimated that the average cost for them to perform an office examination was $1,300 to $1,500 per day.[104] Another State suggested that a local office with well organized records normally takes 2 to 3 days to complete, but that an office with incomplete records takes an additional 2 or more days.[105] While average costs and time periods may vary from State to State, their operations tend to be similar and the Commission expects the amendments to reduce the time and costs of State securities examinations. This will also allow regulators to identify abusive practices earlier during inspections and perform more targeted examinations. In addition, broker-dealers should benefit by having their operations interrupted for shorter time periods. Costs of examinations may also be further reduced due to the uniformity of the recordkeeping provided by the amendments, because regulators and broker-dealers will know what records the firms should have on hand.

2. Costs

The amendments were drafted to permit flexible methods for the creation and maintenance of records in order to reduce the burdens on broker-dealers. This gives broker-dealers the flexibility to choose the least costly method to comply with the rules based upon their present processes and systems capabilities.

The Commission believes that the amendments to Rule 17a–4 will not impose significant cost burdens because, in order to comply with federal laws or regulations, SRO rules, or in the normal course of business, broker-dealers already maintain most of the records specified in the amended rule. Similarly, broker-dealers already are required to provide regulators with books and records on demand. The Commission estimates that the amendments to Rule 17a–4 could result in additional costs for some broker-dealers who do not presently maintain certain items for the prescribed periods of time or in a manner where they can be easily segregated by office. On average, the Commission estimates these additional costs incurred by each broker-dealer to ensure compliance with the amendments to Rule 17a–4 to be approximately $405.00 [106] per year, resulting in an overall cost to the industry of about $2.9 million per year.[107]

Also, as mentioned previously, the State of Connecticut concluded in its study that, ''the types of records required by the re-proposed rule would not be burdensome in that the firms retained substantially more records than required.'' [108]

B. Periodic Updating of Customer Account Record Information

Paragraph (a)(17) of Rule 17a–3 requires broker-dealers to obtain additional account record information. Present federal and SRO rules require that firms obtain and maintain that same information in many circumstances,[109] and many broker-dealers presently obtain and maintain this information as a prudent business practice to avoid disputes with customers, or for other business reasons.

The amendments also require that broker-dealers send account record information [110] to customers for verification within thirty days of account opening and at least every thirty-six months thereafter [111] and to require that broker-dealers provide customers with certain account record information when changes are made.[112]

[103] *See,* Comment Letter from the Consumer Federation of America, p. 3, note 4.

[104] *See* Comment Letter from State of Michigan Department of Consumer & Industry Services, p. 1.

[105] *See* Comment Letter from State of Texas' State Securities Board, pp. 2–3.

[106] The Commission estimates that these amendments to Rule 17a–4 will take broker-dealers an additional four hours each per year. In the Reproposal the Commission estimated that these amendments would take an additional eight hours. Since the amendments being adopted today allow broker-dealers the option of not maintaining records at each office or producing records to the office to which they relate on the same day they are requested, the original estimate was reduced by one-half. The Commission believes that firms will have senior compliance personnel ensure compliance with these amended rules. According to the Securities Industry Association (''SIA'') *Management and Professional Earnings 2000* report, Table 051, the hourly cost of a Compliance Manager + 35% overhead is $101.25. ($101.25 × 4)=approximately $405.00 for each respondent, per year.

[107] ($405.00 per respondent × (7,217 broker-dealers)=approximately $2.9 million per year.

[108] *Supra* at note 95 .

[109] 17 CFR 240.17a–3(a)(9), NASD Rules 2310(b), 3110(c) and IM–2860–2, and NYSE Rules 405, 407, 408, 410A, and 721.10.

[110] Including customer name, address, telephone number, employment status, annual income, net worth, and the investment objectives for the account.

[111] The Commission originally proposed that broker-dealers verify customer account information at least once each year (*See* Proposing Release), however this was modified and reproposed as once every thirty-six months in the Reproposal based upon comments received from broker-dealers who contended that it would be too costly to send account information to customers yearly.

[112] Broker-dealers must furnish notification of a change in the name or address information to the

Continued

Many broker-dealers already send customers notification of address changes,[113] and some also send a copy of a customer's new account form to the customer when an account is opened.[114] While there is presently no requirement to send a copy of the customer account record at least once every 36 months to verify the information, broker-dealers are required to keep their records current.[115]

1. Benefits

The amendments should benefit broker-dealers by assuring that they have up-to-date information when making investment recommendations and reviewing suitability of certain transactions or investment strategies. Further, both broker-dealers and their customers will benefit by assuring that there is mutual understanding of the customer's financial position and objectives for the account. Indeed, requiring broker-dealers to update customer account records may assist less well managed firms in better supervising their operations to identify potential problems before they lead to regulatory or legal exposure and monetary losses.

Moreover, the amendments have been modified to exempt corporate accounts, inactive accounts, and accounts not requiring a determination of suitability. These changes reduce the total number of accounts covered by the updating requirements by over 25,000,000.[116]

2. Costs

The requirement to send account record information to customers will cause firms to incur costs to update their processes, and, with respect to the individual mailings, will add preparation expenses and additional postage charges. Further, firms will incur additional costs to update account information when customers notify the firm that their account record information has changed. Because broker-dealer processes, systems capabilities, and customer bases vary so widely, it is difficult to provide an estimated cost with which all parties will agree; however, the Commission estimates that for each of the 23,500,000 accounts to which a copy of the account record must be sent each year,[117] broker-dealers will spend an average of approximately 3.28 minutes [118] (including time for processing and any updating) costing between $1.36 and $1.62 per piece,[119] including postage. Thus the aggregate cost of Rule 17a–3(a)(17) is estimated to be between $32 million and $38.1 million (depending on what estimated postage cost is included in the calculations). In addition, the Commission estimates that all broker-dealers will, on average, incur a one-time cost of approximately $312.00 each [120] to update their forms, resulting in an aggregate cost of approximately $2.25 million.

As described more fully below, the Commission estimates that large broker-dealers (broker-dealers having over 100,000 accounts) will, on average, incur startup costs and ongoing costs to purchase and maintain additional equipment and develop systems of $.31 per account and $.25 per account respectively. Based upon the comment letters,[121] the Commission believes that the additional costs for smaller broker-dealers is included in the hourly burden costs delineated above.

Two large broker-dealers estimated the start-up costs of purchasing equipment and modifying systems to range from $1,000,000 [122] to $1,300,000.[123] These two firms had a total of approximately 7,500,000 accounts which appeared to be subject

customer's old address, and must furnish a copy of new account record information to the customer if some other information component is changed.

[113] *See e.g.,* Comment Letter from Raymond James Financial, Inc., p. 4.

[114] *See e.g.,* Comment Letter from Investment Management & Research, Inc., p. 4.

[115] *Supra* note 1.

[116] *See infra* note 117.

[117] Broker-dealers reported, in their 12/31/00 *Schedule 1* filings (required to be filed pursuant to 17 CFR 240.17a–10), that they maintained a total of 97,600,000 customer accounts. The Commission estimates that at least 27,100,000 of these accounts are excluded from the provisions of Rule 17a–3(a)(17) because they are either not accounts of natural persons, inactive, or accounts for which the broker-dealer does not have a suitability requirement (the Commission arrived at this number using estimates provided by the firms, in their comment letters and otherwise, as to how many of their accounts would fit into one or more of these categories. *See* Rule 17 CFR 240.17a–3(a)(17)(i)(D)). Accordingly, the total number of accounts which would need to be contacted for updating is 70,500,000 every three years. 70,500,000/3 = 23,500,000 per year.

[118] Of the 23,500,000 accounts to which a copy of the account agreement must be sent each year, 22,975,000 (or 97%) of those accounts are attributable to 70 large broker-dealers which maintain over 100,000 customer accounts. Based upon the comment letters and other communications, large broker-dealers are more automated and small broker-dealers have more manual processes. The estimated additional time to send out customer account information is 1½ minutes per account for large broker-dealers and 7 minutes per account for small broker-dealers. The estimated number of customers who will provide updated account record information is 4,700,000 (or 20% of customers to which notification is sent—this estimate is based on a comment letter sent by Merrill Lynch) (4,559,000 the 4,700,000 are estimated to be maintained at large broker-dealers). The estimated time to update these account records is 5 minutes per account record for large broker-dealers and 10 minutes per account for small broker-dealers, and the estimated time to send updated account record to customer to notify of change is 1½ minutes for large broker-dealers and 7 minutes for small broker-dealers. The estimated number of customers who will change their account record without being prompted by a mailing is 3,525,000 (3,419,250 of which are maintained at large broker-dealers), and the estimated time to send updated account record information to those customers is 1½ minutes per account for large broker-dealers and 7 minutes per account for small broker-dealers. Thus it would take approximately 2.25 minutes per account contacted each year to send account records (((22,795,000 × 1½) + (705,000 × 7)) + ((4,559,000 × 1½) + (141,000 × 7)) + ((3,419,250 × 1½) + (105,750 × 7)))/23,500,000 accounts contacted yearly. In addition, it would take approximately 1.03 minutes per account contacted each year to update the account records (((4,559,000 × 5) + (141,000 × 10))/23,500,000 accounts contacted yearly. In total, the Staff estimates that it would take 3.28 minutes per account contacted each year for processing and any updating.

[119] The estimated total additional hours to provide customers with account record information is 880,369 hours ((((22,795,000 × 1½) + (705,000 × 7)) + ((4,559,000 × 1½) + (141,000 × 7)) + ((3,419,250 × 1½) + (105,750 × 7)))/60 minutes). The estimated total additional hours to update customers accounts is 403,417 hours (((4,559,000 × 5) + (141,000 × 10))/60 minutes in an hour). The hourly wage of the average person who would be providing customers with account record information is $22.70 per hour (per the SIA *Report on Office Salaries In the Securities Industry 2000,* Table 082 (Retail Sales Assistant, Registered) and including 35% in overhead charges). The hourly wage of the average person who would be updating account record information is $25.90 per hour (per the SIA *Report on Office Salaries In the Securities Industry 2000,* Table 086 (Data Entry Clerk, Senior) and including 35% in overhead charges). Thus the aggregate cost of these hours is about $30.4 million ((880,369 hours × $22.70) + (403,417 hours × $25.90)). The estimated additional cost of paper, printing, and postage to provide this information to customers is between $.05 and $.244 per record sent, or between $1.6 million and $7.7 million (($.05 or $.244) × (23,500,000 + 4,700,000 + 3,525,000)). Yielding a total cost per record sent of between $1.36 and $1.62 (($30.4 million + ($1.6 million or $7.7 million))/23,500,000 records sent per year).

[120] It is estimated that it will take firms 2 hours each, on average, to update their forms to include information regarding the meaning of investment objective terms. The Commission believes that firms will have an attorney perform this task. According to the SIA *Management and Professional Earnings 2000* report, Tables 107 (Attorney) and 108 (Compliance Attorney), the hourly cost of an attorney + 35% overhead is $156.00 per hour. ($156.00 × 2) = approximately $312.00 per broker-dealer.

[121] One small broker-dealer stated, ''smaller firms lack the automation to do this type of action* * * without additional personnel,'' (*See* Comment Letter from Titan Value Equities Group, Inc., p. 2) another stated, ''[w]e do not have electronic account records,'' (*See* Comment Letter from Capital West Securities, Inc., p. 2) and another stated, ''for most firms [the] initial identification process would be manual'' and ''compiling the account record to send would require* * * pulling out a paper file for the account and making photo copies of the documents or pulling up the account on a computer system and printing out the required account information screens.'' (*See* Comment Letter from Comerica Securities, p. 2.) No smaller broker-dealer provided information regarding any increased equipment or systems development costs.

[122] *See* Comment Letter from Morgan Stanley Dean Witter, p. 4.

[123] *See* Comment Letter from Merrill Lynch, p. 7 ($630,000 + $370,000 + $300,000).

to the updating requirement. The start-up costs per account, based upon these figures, is approximately $0.31 (($1,000,000 + $1,300,000)/7,500,000 accounts). It is important to note that the firms' estimates were based upon the assumption that they would have to update all of their accounts. Since the amendments adopted today provide an exemption for corporate accounts, inactive accounts, and accounts for which no suitability determination must be made, the actual costs will probably be much lower. These two firms further estimate that ongoing costs for equipment and systems development would range from $300,000 [124] to about $1,600,000 [125] per year. The ongoing costs per account would be $0.25 per account (($300,000 + $1,600,000)/7,500,000 accounts). Therefore, the total additional start-up and ongoing costs to obtain equipment and develop systems for these two large firms would be $0.56 per account ($0.31 + $0.25).

Of the 70,500,000 accounts, 68,385,000 (97%) belong to large broker-dealers that have more than 100,000 accounts, therefore the total start-up costs for large broker-dealers to purchase equipment and develop their systems is about $21.2 million (68,385,000 × $0.31). Similarly, the ongoing equipment and systems development costs for large broker-dealers would be about $17.1 million per year (68,385,000 × $0.25).

C. Other New Requirements Covered by the Amendments

Paragraphs (a)(12) and (a)(19) of Rule 17a–3 require broker-dealers to keep certain records regarding each associated person, including all agreements pertaining to the associated person's relationship with the broker-dealer and a summary of each associated person's compensation arrangement,[126] a record delineating all identification numbers relating to each associated person,[127] a record of the office at which each associated person regularly conducts business,[128] and a record as to each associated person listing transactions for which that person will be compensated.[129] The Commission believes that broker-dealers generally create and maintain these records already under prudent recordkeeping procedures.[130] The list of transactions for which each associated person will be compensated can be created at the time of an examination.

Paragraph (a)(18) of Rule 17a–3 requires broker-dealers to keep a record relating to written customer complaints and maintain a record of whether customers were provided with an address where they should direct complaints. Firms may, instead of creating a separate record of complaints, simply maintain a copy of each complaint, along with a record of the disposition of the complaint.

Paragraphs (a)(6) and (a)(7) of Rule 17a–3 have been amended to require that broker-dealers also record the identity of the associated person responsible for an account and the identity of the person who accepted the order, and whether the order was entered pursuant to discretionary authority. In addition, the amendment to paragraph (a)(6) requires that firms record the time an order was received from a customer, and the amendments to paragraph (a)(7) require that firms make a record of any modifications to an order. Paragraph (a)(6) now contains an exception providing that, for transactions done on a ''subscription-way'' basis, where an application or subscription agreement is sent to the issuer in place of an order ticket, broker-dealers may keep the application or subscription agreement in place of the order ticket. In addition, SRO rules already require that firms record and maintain certain of this information,[131] and firms, to assist in their supervision of the activities of their associated persons and to assure that commissions are properly paid, already record the identity of persons as required under the amendments.

The amendments also require broker-dealers to make records indicating that they have complied with applicable regulations of certain securities regulatory authorities,[132] listing persons who can explain the information in the broker-dealer's records,[133] and listing principals who are responsible for establishing compliance policies and procedures.[134] The Commission believes that these amendments will cause broker-dealers to incur only minimal additional costs. Firms presently maintain records to evidence compliance with SRO and other rules, they presently maintain lists of principals or branch managers responsible for supervising each of their offices under other SRO rules, and they maintain lists of associated persons operating out of each office location. Firms must, as part of their supervisory system, identify principals responsible for reviewing the firm's procedures and taking action to achieve compliance with applicable securities laws, regulations and rules.[135]

1. Benefits

The records required by these sections are either presently required under other federal laws or rules or SRO rules or currently maintained by many firms as a prudent business practice. These amendments codify current recordkeeping practices and make clear what records broker-dealers may be required to provide to State and other regulators. These records are expected to assist firms in better supervising their operations and identifying potential problems before they lead to regulatory or legal exposure and monetary losses.

2. Costs

The Commission has endeavored to codify present broker-dealer business practices in these amendments and has adjusted the amendments based upon comments received in response to the Proposal and Reproposal, as discussed above. Thus, these amendments are not expected to change market or industry behavior significantly. For example, firms are presently required to maintain copies of all communications under Exchange Act Rule 17a–4(b)(4), and certain SRO rules require that members maintain copies of all written complaints and a record of the actions taken by the broker-dealer with respect to each complaint.[136] Therefore, the Commission believes that amending Rule 17a–3 to require this information will not cause broker-dealers to incur any additional costs. Similarly, the Commission does not believe that the amendments to Rules 17a–3(a)(6) and 17a–3(a)(7) will cause any additional cost.

Nevertheless, broker-dealers may incur costs in assuring that their present practices comply with the amendments. For example, the Commission believes that the requirement to provide customers with an address where they can send complaints will cause firms to incur a one-time cost of approximately

[124] *See* Comment Letter from Dean Witter, p. 4.

[125] *See* Comment Letter from Merrill Lynch, p. 7. Merrill Lynch's estimate that they would spend $3.8 million for ongoing costs was reduced to account for the fact that the Commission has included costs to send account records to customers, costs to update customer account records, costs to send notification of updates to customers, and postage costs, which are included in Merrill's $3.8 million figure, elsewhere.

[126] 17 CFR 240.17a–3(a)(19)(ii).

[127] 17 CFR 240.17a–3(a)(12)(ii).

[128] 17 CFR 240.17a–3(a)(12)(iii).

[129] 17 CFR 240.17a–3(a)(19)(i).

[130] *See supra* text accompanying notes 95 and 96.

[131] *See supra* 102 note.

[132] 17 CFR 240.17a–3(a)(17)(ii) and 17 CFR 240.17a–4(b)(4).

[133] 17 CFR 240.17a–3(a)(21).

[134] 17 CFR 240.17a–3(a)(22).

[135] *See e.g.,* NASD Rule 3010.

[136] *See e.g.,* NASD Rule 3110(d), and for options complaints NASD Rule 2860(b)(17).

$312.00[137] each, resulting in an aggregate cost of approximately $2.25 million. In addition, the Commission estimates that it will cost each firm an average of $50.83 per year to ensure compliance with paragraphs (a)(12) and (a)(19) of Rule 17a–3 (regarding associated person records),[138] resulting in an aggregate cost of approximately $0.4 million per year. Finally, the Commission estimates that each firm will spend an average of approximately $16.88 per year to ensure compliance with other requirements,[139] resulting in an aggregate cost of approximately $0.1 million per year.

IX. Effects on Efficiency, Competition, and Capital Formation

Section 23(a)(2) of the Exchange Act[140] requires the Commission, in adopting Exchange Act rules, to consider the impact any such rule would have on competition and to not adopt a rule that would impose a burden on competition not necessary or appropriate in furthering the purposes of the Exchange Act. Section 3(f) of the Exchange Act[141] provides that whenever the Commission is engaged in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, the Commission shall consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. The Commission has considered the amendments to Rules 17a–3 and 17a–4 in light of the standards in Sections 23(a)(2) and 3(f) of the Exchange Act.

In the Reproposing Release, the Commission requested comment on the effect of the reproposed rule amendments on competition, efficiency, and capital formation.[142] The Commission received 115 substantive comment letters[143] in response to the Reproposal. Approximately 44% were from broker-dealers opposing particular amendments and approximately 37% were from State Securities Regulators supporting the amendments. Few commenters provided any information on how these amendments would affect competition, efficiency, or capital formation. One commenter argued that, ''[c]ompetition among broker-dealers is facilitated by the amendments to the [Books and Records Rules]'' because they ''[allow] firms to create and maintain records by alternative means * * *.''[144] Conversely, a few of commenters argued that; (i) the requirement to maintain records at local offices would place an unfair competitive burden upon smaller broker-dealers who do not have the resources to utilize imaging technology,[145] and (ii) the amendments would have a disparate impact on non-traditionally organized broker-dealers with limited businesses.[146] In addition, a number of commenters, while not specifically addressing this issue, did argue that it would be duplicative to maintain records at a local office while also maintaining the same documents at a main office. In response to these concerns and others, the Commission has modified the amendments to allow firms the flexibility to promptly produce records at the offices to which they relate instead of maintaining those records at the offices,[147] and has added exemptions in recognition of present business practices.[148]

The Commission believes that any burden imposed by the amendments is justified by the enhanced investor protections described above. Further, as NASAA pointed out in its comment letter, when addressing Section 23(a) concerns, ''the [amendments] to Rules 17a–3 and 17a–4, pursuant to a directive by Congress, must also reflect the needs of the State Securities Regulators as well as federal regulators.''[149] In addition, by improving examination capabilities of all securities regulatory authorities, the amendments should improve investor confidence in broker-dealer firms and help to maintain fair and orderly markets.

Broker-dealers with larger customer bases would have correspondingly greater obligations under the amendments than smaller broker-dealers. Accordingly, any burden on competition should be slight, especially in light of the significant regulatory benefits discussed above.

X. Summary of Final Regulatory Flexibility Analysis

A Final Regulatory Flexibility Analysis (''FRFA'') regarding the amendments to Rules 17a–3 and 17a–4 under the Exchange Act,[150] which require broker-dealers to maintain certain additional records, specify that certain books and records must be maintained at each office, and set forth the length of time these records must be kept, has been prepared in accordance with the provisions of the Regulatory Flexibility Act (5 U.S.C. 604).

A. Need for the Rules and Rule Amendments

As discussed more fully in the FRFA, these amendments are intended to provide the Commission, SROs, and State Securities Regulators with timely access to broker-dealers' books and records to conduct effective examinations, investigations and enforcement actions. NSMIA prohibits States from establishing books and records rules that differ from, or are in addition to, the Commission's rules, and provides that the Commission must consult periodically with the States concerning the adequacy of the Commission's books and records rules,[151] particularly with regard to whether the Commission's rules satisfy State Securities Regulators' need to have

[137] The Commission estimates that it will take each broker-dealer, on average, two hours to update its forms to include the address to which complaints should be sent. This is a very conservative estimate, since it will probably take much less than 2 hours to write down the broker-dealer's address and where it should be placed on the form, but additional time was added to account for supervisory review. The Commission believes broker-dealers would have an attorney perform this task. According to the SIA *Management and Professional Earnings 2000* report, Tables 107 (Attorney) and 108 (Compliance Attorney), the hourly cost of an attorney + 35% overhead is $156.00 per hour. ($156.00 × 2) = approximately $312.00 per broker-dealer.

[138] The Commission estimated in its Reproposal that, on average, this requirement will obligate a broker-dealer to spend approximately 30 minutes each year to ensure that the records are in compliance with these amendments. The Commission received no specific comments relating to this estimate. The Commission believes firms may have senior compliance personnel perform this task. According to the SIA *Management and Professional Earnings 2000* report, Table 051, the hourly cost of a Compliance Manager + 35% overhead is $101.25. ($101.25 × ½ hour) = approximately $50.63 per broker-dealer.

[139] The Commission estimated in its Reproposal that it will take each firm 10 additional minutes each year to assure compliance with the amendments, and it received no specific comments relating to this estimate. The Commission believes that firms will have senior compliance personnel perform this task. According to the SIA *Management and Professional Earnings 2000* report, Table 051, the hourly cost of a Compliance Manager + 35% overhead is $101.25. ($101.25 × 10 minutes/60 minutes in an hour) = approximately $16.88 per broker-dealer.

[140] 15 U.S.C. 78*w*(a)(2).

[141] 15 U.S.C. 78*c*(f).

[142] *Supra* note 9, at 54411.

[143] Of the 144 total ''comment letters'' on file, seventeen are memos by the staff of the Commission relating to meetings with various industry groups, and twelve simply request that the comment period be extended.

[144] *See,* Comment Letter from NASAA, p. 7.

[145] *See,* Comment Letters from Titan Value Equities Groups, Inc., p. 3; BenefitsCorp Equities, Inc., p. 2; and One Orchard Equities, Inc. p. 2.

[146] *See,* Comment Letter from MML Investor Services, Inc., pp. 5 to 6.

[147] Paragraph (k) of Rule 17a–4.

[148] *See* paragraphs (a)(6)(ii) and (a)(17)(i)(D) of Rule 17a–3. In addition, paragraph (a)(17) of Rule 17a–3 was modified to limit the requirement to accounts with a natural person as the customer.

[149] *See* Comment Letter from NASAA, p. 4.

[150] 15 U.S.C. 78*a et. seq.,* adopted on October 11, 1996.

[151] 15 U.S.C. 78*o*(h).

records readily accessible for their examinations.[152]

If these amendments are not adopted, the Commission believes that the Commission staff and State Securities Regulators will be hampered in their efforts to obtain documentation, because the books and records that broker-dealers maintain may not always be sufficient or in such order as to enable regulators to conduct thorough and effective examinations, investigations, and enforcement proceedings. The Commission further believes that a failure to re-establish certain customer protection safeguards present in the marketplace prior to the enactment of NSMIA would reduce the regulatory oversight of broker-dealers. In addition, the Commission believes that this may also reduce customer confidence in the marketplace, which would be detrimental to market integrity and capital formation.

B. Small Entities Subject to the Rule

It is expected that these amendments will affect the approximately 1,000 broker-dealers that fall within the category of ''small business'' [153] (''Small Business Broker-Dealers''). The amendments would affect these Small Business' Broker-Dealers because they, like other broker-dealers, would have to create and maintain certain additional books and records and would have to provide access to specific books and records at each office. An OTC Derivatives Dealer would not be considered a small entity because of the minimum net capital requirement.

A summary of the Initial Regulatory Flexibility Analysis (''IRFA'') appeared in the Reproposing Release,[154] where the Commission specifically requested comment with respect to the IRFA. In response to the Reproposing Release, the Commission received only one comment letter specifically concerning the IRFA.[155] In addition, three other commenters addressed aspects of the reproposed rules and rule amendments that could potentially affect small businesses.[156]

The commenter that did specifically discuss the IRFA stated, ''The Initial Regulatory Flexibility Analysis does not give careful consideration to the economic impact on [broker-dealers that limit their business in certain ways[157]] of the new account cards, blotter records, and signatures of principals on account cards.'' However, the Commission has carefully considered the economic impact of these rules on various types of broker-dealers. Furthermore, the Commission notes that the commenter does not take into account the fact that, even with respect to broker-dealers that limit their business, existing NASD rules[158] require that broker-dealers maintain certain customer account information, including the signature of a principal accepting the account, and that Rule 17a–3(a)(1) [159] presently requires that broker-dealers retain blotter records. The Commission has amended new paragraph 17a–3(a)(17) to provide an exemption from obtaining certain information where broker-dealers have no Federal or SRO suitability requirement and are therefore not otherwise required to obtain that information.

Of the three commenters that addressed aspects of the reproposed rules and rule amendments that could potentially affect small businesses, one stated, ''[t]he proposal to require blotters in local offices may cause an initial financial burden to firms which have * * * three or less broker offices.'' [160] Another argued that the requirement to maintain records at local offices ''place[s] an unfair competitive burden on smaller broker-dealers who do not have the resources to image the required documents and place them upon a network that is available to both the firm's principal office and the local branch.'' [161] While the amendments as reproposed would require that firms maintain certain records in each local office or produce those records within the same business day that they are requested, the amendments have been changed in order to give firms the flexibility to produce those records promptly when they are requested by a representative of a securities regulatory authority. This change significantly reduces the cost of the amendments for most firms. In addition, recognizing that broker-dealers may not be required to maintain those records under SRO rules or other regulations, the Commission has attempted to reduce the impact of these amendments on firms that engage in certain specialized types of businesses by changing the amendments to allow those broker-dealers to utilize records they presently create and maintain in compliance with SRO or other rules and prudent business practices.

Another firm contended that the requirement to update account records is unduly burdensome on smaller firms because such firms lack the automation to perform that task quickly and without additional personnel.[162] The Commission has attempted to make these amendments sufficiently flexible to accommodate different types of operational systems, and broker-dealers may choose the operational methods that best suit their business in order to comply with the amendments.

Lastly, another firm disagreed with the Commission's statement in the Reproposing Release that, ''[l]arger broker-dealers would have correspondingly greater obligations under the amendments,'' [163] stating, ''the 'wire house' firms will be virtually unaffected by this proposal,'' because ''wire houses * * * have very few small offices.'' [164] To the extent that Small Business Broker-Dealers service fewer customer accounts, employ fewer associated persons, and operate fewer offices than larger broker-dealers, they will be affected by the rule in proportion to their size.

C. Projected Reporting, Recordkeeping, and Other Compliance Requirements

Most broker-dealers, including Small Business Broker-Dealers, already maintain many of the records specified in the amendments in the ordinary course of business. The Commission's intent has been to minimize the impact of the amendments on all broker-dealers by limiting, consistent with the objectives of the amendments, the number of instances in which broker-dealers would be obligated to create or

[152] *See supra* note 8.

[153] Pursuant to 17 CFR 240.0–10, the term ''small business'' or ''small organization'' when used with reference to a broker or dealer means a broker or dealer that: (i) had total capital (net worth plus subordinated liabilities) of less than $500,000 on the date its audited financial statements for the prior fiscal year were prepared pursuant to 17 CFR 240.17–5(d) or, if not required to file such statements, a broker-dealer that had total net capital (net worth plus subordinated liabilities) of less than $500,000 on the last business day of the preceding fiscal year (or in the time that it has been in business, if shorter); and (ii) is not affiliated with any person (other than a natural person) that is not a small business or small organization as defined in 17 CFR 240.0–10. In addition, Exchange Act Release No. 40122 (June 24, 1998) 63 FR 35508 (June 30, 1998) recently amended standard that defines what it means to be ''affiliated'' with any person that is not a small business.

[154] *See supra* note 9.

[155] *See* Comment Letter from American Council of Life Insurance, p. 16.

[156] *See* Comment Letters from Titan Value Equities Group, Inc., pp. 2–3; Lawrence Lowman, p. 1; and John Hancock Distributors, Inc., p. 3.

[157] *E.g.,* broker-dealers which only facilitate transactions in certain types of products or broker-dealers which do not make recommendations.

[158] *See e.g.,* NASD Rule 3110(c).

[159] 17 CFR 240.17a–4(a)(1).

[160] *See* Comment Letter from Lawrence Lowman, p. 1.

[161] *See* Comment Letter from Titan Value Equities, p. 3.

[162] *Id.,* p. 2.

[163] *See* Comment Letter from John Hancock Distributors, Inc., p. 3.

[164] *Id.*

maintain records that they do not already maintain in the ordinary course of business. In addition, the amendments were designed to be sufficiently flexible to accommodate different types of recordkeeping systems, and broker-dealers may choose the format in which they wish to maintain those records.

D. Agency Action To Minimize Effect on Small Entities

As discussed further in the FRFA, the Commission has attempted to minimize the economic impact these amendments might have on broker-dealers, including Small Business Broker-Dealers, while still achieving the overall objective of assuring that regulators have the ability to perform effective examinations, including examinations for sales practice issues. In response to comments elicited by the Reproposing Release, many significant changes were made to the amendments to reduce the burdens associated with these amendments.

The Regulatory Flexibility Act directs the Commission to consider significant alternatives that would accomplish the stated objective, while minimizing any significant adverse impact on small entities. The Commission considered the following alternatives: (i) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (ii) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for small entities; (iii) the use of performance rather than design standards; and (iv) an exemption from coverage of the rule, or any part thereof, for small entities. The Commission also considered whether these alternatives to the reproposed rules and rule amendments would accomplish the stated objectives of improving the effectiveness of the Commission's and State regulatory agencies' ability to perform investigations, examinations and enforcement actions.

The additional burdens placed on Small Business Broker-Dealers will vary depending upon the number of customer accounts at the firm, the number of associated persons employed by the firm, and the number of offices that the firm operates. Further, the rule provides substantial flexibility in the manner in which firms may comply with the amendments. Additionally, the Commission believes that obtaining essential information regarding the sales practices of all broker-dealers, including Small Business Broker-Dealers, is necessary to permit securities regulators to effectively oversee the securities markets and protect investors; therefore, the Commission does not believe that establishing differing compliance or reporting requirements for Small Business Broker-Dealers would be appropriate.

The Commission believes that the proposal could not be formulated differently for Small Business Broker-Dealers and still achieve the stated objectives. The Commission has considered Small Business Broker-Dealers in developing the amendments and has determined that all types of broker-dealers, including Small Business Broker-Dealers, engage in sales practice abuses; therefore, the Commission does not believe that further clarification, consolidation, or simplification of the proposed amendments would be appropriate. As stated previously, however, the Commission has made every effort to assure that, to the extent possible, the amendments require broker-dealers to maintain the same types of records required under other federal and SRO rules or that firms usually maintain as part of their present business practices, and has highlighted instances where records that broker-dealers presently maintain may serve to fulfill the requirements under these amendments.

The Commission does not believe that it would be appropriate to use performance standards, rather than design standards, with relation to these amendments. Because information must be collected and maintained in a uniform manner to be useful, design standards are necessary to achieve the objectives of the proposal. Any additional burden placed on broker-dealers by these amendments is dependent on the number of accounts serviced, the number of associated persons employed, and the number of offices operated. Thus, although the use of performance standards would be an inappropriate measure with relation to these amendments, the standards used do take into account the size of each firm. The Commission also notes that the recordkeeping requirements permit broker-dealers to keep records in different formats or systems as long as specified information can be sorted and produced upon request.

Lastly, customers may be exposed to fraud and sales practice violations by Small Business Broker-Dealers as well as other firms. Exempting Small Business Broker-Dealers from coverage of the rules, or any part thereof, would create a gap in industry oversight, where regulatory authorities may be unable to obtain documentation necessary to conduct comprehensive examinations of Small Business Broker-Dealers. Therefore, the Commission believes that it should not exempt Small Business Broker-Dealers from the requirements of the amendments.

The Commission believes that enacting the amendments in their present form is the best way to assure that regulators have the ability to perform effective examinations, including examinations for sales practice issues, and that no less burdensome alternatives are available to accomplish the objectives of the amendments. As stated previously, after NSMIA, States were constrained from ''establishing books and records rules that differ from, or are in addition to the Commission's rules.'' [165] The States play an integral role in achieving customer protection by performing examinations on broker-dealers within their jurisdiction and reviewing for sales practice violations. Without these amendments, the States may be unable to obtain those books and records necessary to conduct comprehensive examinations. Finally, the Commission believes that most Small Business Broker-Dealers currently maintain certain of the additional records specified in the amendments.

A copy of the FRFA may be obtained by contacting Bonnie L. Gauch, Attorney, United States Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–1001.

XI. Paperwork Reduction Act

Certain provisions of the amendments contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995.[166] The Commission has submitted the amendments to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11 under the title ''Books and Records Rule Amendments.'' The rules being amended contain currently approved collections of information under OMB control numbers 3235–0033 and 3235–0279 respectively. The collections and maintenance of information, and the reports made to the SEC and others that are required pursuant to Rules 17a-3 and 17a-4 are mandatory. 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 control number.

[165] 15 U.S.C. 78*o*(h).

[166] 44 U.S.C. 3502 *et seq.*

A. Collection of Information Under the Amendments

As discussed previously in this release, the Books and Records Rule Amendments would require registered broker-dealers to maintain additional records with respect to purchase and sale documents, customer information, associated person information, customer complaints and certain other matters.

B. Proposed Use of Information

The information collected pursuant to the Books and Records Rule Amendments would be used by the Commission, SROs, and other securities regulatory authorities for examinations, investigations, and enforcement proceedings regarding broker-dealers and associated persons. No governmental agency would regularly receive any of the information described above. Instead, the information would be stored by the registered broker-dealer and made available to the various securities regulatory authorities as required to facilitate examinations, investigations, and enforcement proceedings. To comply with the amendments that require broker-dealers to update customer account records at least once every 36 months, broker-dealers would have to furnish the customers with copies of their account records. This requirement and the estimated burden associated with it are discussed in detail below.

C. Respondents

The Books and Records Rule Amendments would apply to all of the approximately 7,217 active broker-dealers that are registered with the Commission.[167]

D. Total Annual Reporting and Recordkeeping Burden

The hour burden of the Books and Records Rule Amendments is difficult to ascertain, because any additional burdens would vary widely due to differences in broker-dealer activity levels and current recordkeeping systems employed by the broker-dealers. Therefore, the estimates in this section are based on averages among the various types and sizes of broker-dealers. Recognizing that large broker-dealers maintaining over 100,000 customer accounts are generally more automated than small broker-dealers maintaining less than 100,000 customer accounts with relation to certain of the amendments, the Commission has attempted to provide for these differences in its calculations.

Most of the requirements of the Books and Records Rule Amendments involve collections of information that broker-dealers already maintain pursuant to prudent business practices or to comply with existing SRO regulations. While some of the comment letters argued that the Commission's estimates set forth in the Reproposing Release were low, few contained actual alternative cost estimates, and none contained estimates which could be applied generally to broker-dealer firms. The Commission has increased its estimation of the expected burden of the amendments where, in general, commenters felt that the estimates were too low, and has provided a more detailed explanation of its estimates where it believes the amendments will impose little or no additional burden on broker-dealers. In addition, in response to the comments received relating to the Reproposing Release, the Commission modified its proposal and adopted amendments that reduce the amount of additional records that firms will be required to create and maintain.

1. Rule 17a–3

The amendments modify Rule 17a–3 by, among other things, requiring broker-dealers to send account information to customers for verification within 30 days of account opening and at least once every 36 months thereafter. As stated above, the total number of accounts that would need to be contacted for updating is 70,500,000.[168] Approximately 70 of the 7,217 active, registered broker-dealers maintain over 100,000 accounts, and the remaining broker-dealers (7,147) maintain less than 100,000 accounts each. Of the 70,500,000 accounts which may be affected by these amendments, approximately 68,385,000 (or 97%) are maintained at these large broker-dealers, and 2,115,000 (or 3%) are maintained at broker-dealers with less than 100,000 accounts each.

The Commission estimates that, as their processes are more automated, it will take large broker-dealers an average of 1½ additional minutes per account every three years,[169] thus requiring large broker-dealers to spend an additional 569,875 hours per year (68,385,000 account records/3 years × 1.5 minutes / 60 minutes) to send account information to customers. As small broker-dealers utilize processes which are more manual in nature,[170] the Commission estimates that it will take small broker-dealers an average of 7 minutes per account[171] every three years, thus requiring small broker-dealers to spend an additional 82,250 hours per year (2,115,000 account records/3 years × 7 minutes/60 minutes) to send account records to customers. Thus the total additional burden on the industry to send account records to customers is 652,125 hours.

The Commission estimates that approximately 20%[172] of the customers from whom information is requested will update their account record resulting in 4,700,000 updated account records each year (70,500,000/3 years × 20%). The Commission estimates that it would take, on average, 5 minutes for large broker-dealers to update each account and 10 minutes[173] for small broker-dealers to update each account, resulting in an additional burden of 403,417 hours per year ((4,559,000 account records × 5 minutes/60 minutes) + (141,000 account records × 10 minutes/60 minutes)). This estimate takes into account the amount of time it would take to receive the returned data and input any changes into the account record. While it is acknowledged that some customers will provide broker-dealers with changes to their account information outside of this update process, as those are changes broker-dealers must contend with in the present environment, the amendments create no additional burden in this regard. Broker-dealers presently maintain current account records in the ordinary course of their business because existing SRO rules require them to maintain current information about their customers.

If a customer has provided the broker-dealer with updated account record information, under paragraphs (a)(17)(i)(B) (*2*) and (*3*) of Rule 17a–3 the broker-dealer must send a copy of the revised account record to the customer within 30 days after it received notification of the change or, under paragraph (a)(17)(i)(B)(*3*), the broker-

[167] Of approximately 7,739 broker-dealers registered with the Commission, approximately 341 are not yet active because their registration is pending SRO approval and approximately 181 are inactive because they have ceased doing a securities business and have filed a Form BDW with the Commission. Of these 7,217 active, registered broker-dealers, three are registered OTC Derivatives Dealers. OTC Derivatives Dealers are a special class of broker-dealers that limit their business to dealer activities in eligible over-the-counter derivative instruments and that meet certain financial responsibility and other requirements.

[168] *Supra* note 117.

[169] The Commission, in its Reproposal, estimated that it would take broker-dealers 10 seconds to furnish the account record to customers. Because many commenters contended that this estimate was too low, the Commission raised its estimates.

[170] *Supra* note 121.

[171] *See* Comment Letter from Comerica Securities, p. 2.

[172] *See* Comment Letter from Merrill Lynch, p. 7.

[173] *See* Comment Letter from Titan Value Equities, Inc., p. 2.

dealer may send the notification with the next statement mailed to the customer. The Commission estimates that, in addition to the 70,500,000 updated account records discussed above, 3,525,000 customers (5% of the 70,500,000 accounts for which firms will be required to make the account record) will initiate changes to their account records on a yearly basis, just as they do now, with no prompting from any account record mailing. The Commission estimates, as stated above, that it will take large broker-dealers 1½ minutes and smaller broker-dealers 7 minutes to send out account information to each customer who updated their account. The Commission estimates that 8,225,000 (4,700,000 + 3,525,000) customers will update their account record, and that broker-dealers will spend an additional 228,244 hours each year ((7,978,250 account records x 1.5 minutes / 60 minutes) + (246,750 account records x 7 minutes / 60 minutes)) sending the updated account records to customers.

The amendments also impose a requirement that broker-dealers obtain the following additional information for each account with a natural person as the customer: the customer name, tax identification number, address, telephone number, date of birth, employment status, annual income, net worth, investment objectives, and the signature of the associated person and a principal. Present Rule 17a–3(a)(9) already requires that a firm maintain a record of a customer's name and address. Further, SRO rules require that firms obtain and maintain records of: whether a customer is of legal age (firms usually obtain a customer's date of birth to satisfy this requirement), the signature of the registered representative and principal, a customer's tax identification number, the customer's occupation, and whether or not the customer is associated with another broker-dealer.[174] In addition, certain SRO rules require that before making any recommendations to customers, broker-dealers obtain information, regarding the customer's annual income, net worth, and the investment objectives for the account in question in order to formulate a basis for any recommendation.[175]

In addition, the amendments require that, if the account is a discretionary account, the firm must obtain (i) The signature of the customer granting discretion, (ii) the date discretion was granted, and (iii) the signature of the person to whom discretion was granted. Certain SRO rules require that for discretionary accounts, broker-dealers must obtain the signature of the person who was granted discretion, and the date discretion was granted,[176] while other SRO rules require that firms obtain written authorization of the customer before exercising discretion in an account.[177] Further, the Commission believes that obtaining these records is a prudent business practice followed by most broker-dealers to avoid disputes with customers.

In addition to the account record requirements, the amendments require broker-dealers to keep certain records regarding their associated persons, including all agreements pertaining to the associated persons relationship with the broker-dealer and a summary of each associated person's compensation arrangement,[178] a record delineating all identification numbers relating to each associated person,[179] a record of the office at which each associated person regularly conducts business,[180] and a record as to each associated person listing transactions for which that person will be compensated.[181] The Commission believes that broker-dealers generally create and maintain these records under prudent recordkeeping procedures. Therefore, the Commission estimates that, on average, these records would require each broker-dealer to spend approximately 30 minutes each year to ensure that it is in compliance with these amendments, a total of about 3,609 hours ((7,217 broker-dealers x 30 minutes/60 minutes).

The amendments also require broker-dealers to keep a record relating to written customer complaints that includes: the complainant's name, address, and account number; the date the complaint was received; the name of any associated person identified in the complaint; a description of the nature of the complaint; and, the disposition of the complaint. In order to account for differing broker-dealer practices, the Commission has provided broker-dealers with an alternative; instead of creating what may be a new record, broker-dealers can simply maintain a copy of each complaint, along with a record of the disposition of the complaint.[182] Firms are presently required to maintain copies of all communications under Rule 17a–4(b)(4), and certain SRO rules require that members maintain copies of all written complaints and a record of the actions taken by the broker-dealer in specified offices, and that copies of options-related complaints be maintained in both the main office and in the branch office to which they relate.[183] Most firms maintain copies of all complaints and related information and documents at their headquarters, and some already maintain both option and non-option complaints at all offices as well. While the Reproposal would have required that complaints relating to an office be maintained in that office or be produced on the business day they are requested, the amendments as adopted require only that records of complaints for an office be produced promptly at the office to which the complaints relate.

The amendments also require broker-dealers to make records which indicate that they have complied with applicable regulations of certain securities regulatory authorities,[184] which list persons who can explain the information in the broker-dealer's records,[185] and that list principals responsible for establishing compliance policies and procedures.[186] Firms presently maintain records to evidence compliance with SRO and other rules; therefore, no additional burden is created by this amendment. The Commission believes that broker-dealers presently maintain lists of principals or branch managers responsible for supervising each of their offices under applicable SRO rules, and that they also have lists of associated persons operating out of each office location. Under certain SRO rules, broker-dealers must presently have supervisory systems in place that include identification of principals responsible for reviewing the firm's procedures and taking action to achieve compliance with applicable securities laws, regulations and rules.[187] The Commission estimates, therefore, that on average each broker-dealer would spend 10 minutes each year to ensure compliance with these requirements, yielding a total additional burden of about 1,203 hours ((7,217 broker-dealers x 10 minutes/60 minutes).

The amendments relating to order tickets require that broker-dealers note, in addition to information already required, the identity of the associated

[174] *See* NASD Rules 3110(c) and IM–2860–2, and NYSE Rules 405, 407, 410A, and 721.10.

[175] *See e.g.,* NASD Rule 2310(b) and IM–2860–2.

[176] Supra note 158.

[177] *See e.g.,* NYSE Rule 408.

[178] *Supra* note 126.

[179] *Supra* note 127.

[180] *Supra* note 128.

[181] *Supra* note 129.

[182] 17 CFR 240.17a–3(a)(18)(i).

[183] *Supra* note 136.

[184] 17 CFR 240.17a–3(a)(17)(ii) and 17 CFR 240.17a–3(a)(20).

[185] *Supra* note 133.

[186] *Supra* note 134.

[187] *Supra* note 135.

person responsible for an account and the identity of the person who accepted the order, and whether the order was entered pursuant to discretionary authority. In addition, the amendments to Rule 17a–3(a)(6) require that firms record the time an order was received from a customer, and the amendments to Rule 17a–3(a)(7) require that firms make a record of any modifications to an order. SRO rules already require that firms record, maintain, and in some cases report, the time an order was received, and information regarding modification and cancellation including instructions and the time.[188] Further, firms who assign associated persons to particular accounts usually refer the customer to that person to initiate transactions. The identity of the person who accepted the order from the customer, whether or not it was the person assigned to the account, is generally recorded and maintained at the present time by firms as a prudent business practice that assists the firm in properly supervising the activities of their associated persons and assuring that commissions are properly paid. In addition, the amendment to Rule 17a–3(a)(6) contains an exception for transactions done on a ''subscription-way'' basis, where an application or subscription agreement is sent to the issuer in place of an order ticket. For these types of transactions, broker-dealers may keep the application or subscription agreement in the place of the order ticket. Thus the Commission does not believe that the amendments to Rules 17a–3(a)(6) and 17a–3(a)(7) will cause any additional burden.

In total, the Commission estimates that compliance with the amendments to Rule 17a–3 will require an additional 1,288,598 hours (1,283,786 [189] + 3,609 [190] + 1,203 [191]).

2. Rule 17a–4

The amendments modify Rule 17a–4 by requiring broker-dealers to maintain certain additional books and records, including a record listing all persons who are qualified to explain a broker-dealer's books and records. The amendments also require broker-dealers to make available certain records at each office. As discussed above, new Rule 17a–4(k) was modified to provide that, instead of requiring that firms either maintain copies of records in the office to which they pertain, broker-dealers now have the option of producing certain records which relate to a particular office ''promptly.'' This significantly reduces the additional burden caused by the amendments to Rule 17a–4.

The amendments also increase the amount of time broker-dealers must maintain certain records. Broker-dealers generally maintain these records to comply with other federal or SRO Rules or in the normal course of business. These records include, (i) information relating to the principals responsible for reviewing and updating policies and procedures, (ii) copies of Forms BD, BDW and amendments thereto, (iii) copies of compliance, supervisory, and procedures manuals, (iv) customer account records, (v) order ticket information, (vi) records relating to compensation of associated persons, (vii) evidence of compliance with SRO advertising and sales literature rules, (viii) exception reports, and (ix) specialized reports produced pursuant to an order or settlement.

Based upon the information above, and due to the fact that the amendments to Rule 17a–4 require only that information be kept for prescribed periods of time, the Commission estimates that, on average, each broker-dealer would spend four hours each year to ensure that it is in compliance with the amendments to Rule 17a–4 and to produce required records promptly at an office when so required. Therefore, the Commission estimates that compliance with the amendments for Rule 17a–4 would require an additional 28,868 hours each year ((7,217 broker-dealers x 4 hours).

E. Request for Comment

Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments to—(i) Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collections of information; (iii) Enhance the quality, utility, and clarity of the information to be collected; (iv) Minimize the burden of the collections of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology. The Commission encourages commenters to identify and supply any relevant data, analysis and estimates concerning the burden of the proposed rules, especially where any commenter believes the Commission's estimates to be inaccurate.

Persons desiring to submit comments on the collection of information requirements proposed above should direct them to the following persons: (1) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503; and (2) Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609 with reference to File No. S7–26–98. OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication, so a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. The Commission has submitted the proposed collections of information to OMB for approval. Requests for the materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–26–98, and be submitted to the Securities and Exchange Commission, Records Management, Office of Filings and Information Services, 450 Fifth Street, NW., Washington, DC 20549.

XII. Statutory Basis

The amendments are adopted pursuant to the authority conferred on the Commission by the Exchange Act, including Sections 17(a) and 23(a).

List of Subjects in 17 CFR Parts 240 and 242

Brokers, Reporting and recordkeeping requirements, Securities.

For the reasons set forth in the preamble, Title 17 Chapter II of the Code of Federal Regulation is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for Part 240 is amended by adding the following citation:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78*o*, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*, 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

Section 240.17a–4 also issued under secs. 2, 17, 23(a), 48 Stat. 897, as amended; 15 U.S.C. 78a, 78d–1, 78d–2; sec. 14, Pub. L. 94–29, 89 Stat. 137 (15 U.S.C. 78a); sec. 18, Pub. L. 94–29, 89 Stat. 155 (15 U.S.C. 78w);

* * * * *

[188] *Supra* note 102.

[189] 17 CFR 240.17a–3(a)(17).

[190] 17 CFR 240.17a–3(12) and (19).

[191] 17 CFR 240.17a–3(a)(20) to (22).

2. The authority citations following §§ 240.17a–3 and 240.17a–4 are removed.

3. Section 240.17a–3 is amended by:

a. Revising paragraphs (a)(6) and (a)(7);

b. Revising the introductory text of paragraph (a)(12)(i);

c. Revising paragraph (a)(12)(ii);

d. Redesignating paragraphs (a)(12)(i)(*a*) through (a)(12)(i)(*h*) as paragraphs (a)(12)(i)(A) through (a)(12)(i)(H); and

e. Adding paragraphs (a)(17), (a)(18), (a)(19), (a)(20), (a)(21), (a)(22), (f) and (g).

The revisions and additions read as follows:

§ 240.17a–3 Records to be made by certain exchange members, brokers and dealers.

(a) * * *

(6)(i) A memorandum of each brokerage order, and of any other instruction, given or received for the purchase or sale of securities, whether executed or unexecuted. The memorandum shall show the terms and conditions of the order or instructions and of any modification or cancellation thereof; the account for which entered; the time the order was received; the time of entry; the price at which executed; the identity of each associated person, if any, responsible for the account; the identity of any other person who entered or accepted the order on behalf of the customer or, if a customer entered the order on an electronic system, a notation of that entry; and, to the extent feasible, the time of execution or cancellation. The memorandum need not show the identity of any person, other than the associated person responsible for the account, who may have entered or accepted the order if the order is entered into an electronic system that generates the memorandum and if that system is not capable of receiving an entry of the identity of any person other than the responsible associated person; in that circumstance, the member, broker or dealer shall produce upon request by a representative of a securities regulatory authority a separate record which identifies each other person. An order entered pursuant to the exercise of discretionary authority by the member, broker or dealer, or associated person thereof, shall be so designated. The term *instruction* shall include instructions between partners and employees of a member, broker or dealer. The term *time of entry* shall mean the time when the member, broker or dealer transmits the order or instruction for execution.

* * * * *

(ii) This memorandum need not be made as to a purchase, sale or redemption of a security on a subscription way basis directly from or to the issuer, if the member, broker or dealer maintains a copy of the customer's subscription agreement regarding a purchase, or a copy of any other document required by the issuer regarding a sale or redemption.

(7) A memorandum of each purchase and sale for the account of the member, broker, or dealer showing the price and, to the extent feasible, the time of execution; and, in addition, where the purchase or sale is with a customer other than a broker or dealer, a memorandum of each order received, showing the time of receipt; the terms and conditions of the order and of any modification thereof; the account for which it was entered; the identity of each associated person, if any, responsible for the account; the identity of any other person who entered or accepted the order on behalf of the customer or, if a customer entered the order on an electronic system, a notation of that entry. The memorandum need not show the identity of any person other than the associated person responsible for the account who may have entered the order if the order is entered into an electronic system that generates the memorandum and if that system is not capable of receiving an entry of the identity of any person other than the responsible associated person: in that circumstance, the member, broker or dealer shall produce upon request by a representative of a securities regulatory authority a separate record which identifies each other person. An order with a customer other than a member, broker or dealer entered pursuant to the exercise of discretionary authority by the member, broker or dealer, or associated person thereof, shall be so designated.

* * * * *

(12)(i) A questionnaire or application for employment executed by each ''associated person'' (as defined in paragraph (g)(4) of this section) of the member, broker or dealer, which questionnaire or application shall be approved in writing by an authorized representative of the member, broker or dealer and shall contain at least the following information with respect to the associated person:

* * * * *

(ii) A record listing every associated person of the member, broker or dealer which shows, for each associated person, every office of the member, broker or dealer where the associated person regularly conducts the business of handling funds or securities or effecting any transactions in, or inducing or attempting to induce the purchase or sale of any security for the member, broker or dealer, and the Central Registration Depository number, if any, and every internal identification number or code assigned to that person by the member, broker or dealer.

* * * * *

(17) For each account with a natural person as a customer or owner:

(i)(A) An account record including the customer's or owner's name, tax identification number, address, telephone number, date of birth, employment status (including occupation and whether the customer is an associated person of a member, broker or dealer), annual income, net worth (excluding value of primary residence), and the account's investment objectives. In the case of a joint account, the account record must include personal information for each joint owner who is a natural person; however, financial information for the individual joint owners may be combined. The account record shall indicate whether it has been signed by the associated person responsible for the account, if any, and approved or accepted by a principal of the member, broker or dealer. For accounts in existence on the effective date of this section, the member, broker or dealer must obtain this information within three years of the effective date of the section.

(B) A record indicating that:

(*1*) The member, broker or dealer has furnished to each customer or owner within three years of the effective date of this section, and to each customer or owner who opened an account after the effective date of this section within thirty days of the opening of the account, and thereafter at intervals no greater than thirty-six months, a copy of the account record or an alternate document with all information required by paragraph (a)(17)(i)(A) of this section. The member, broker or dealer may elect to send this notification with the next statement mailed to the customer or owner after the opening of the account. The member, broker or dealer may choose to exclude any tax identification number and date of birth from the account record or alternative document furnished to the customer or owner. The member, broker or dealer shall include with the account record or alternative document provided to each customer or owner an explanation of any terms regarding investment objectives. The account record or alternate document

furnished to the customer or owner shall include or be accompanied by prominent statements that the customer or owner should mark any corrections and return the account record or alternate document to the member, broker or dealer, and that the customer or owner should notify the member, broker or dealer of any future changes to information contained in the account record.

(*2*) For each account record updated to reflect a change in the name or address of the customer or owner, the member, broker or dealer furnished a notification of that change to the customer's old address, or to each joint owner, and the associated person, if any, responsible for that account, on or before the 30th day after the date the member, broker or dealer received notice of the change.

(*3*) For each change in the account's investment objectives the member, broker or dealer has furnished to each customer or owner, and the associated person, if any, responsible for that account a copy of the updated customer account record or alternative document with all information required to be furnished by paragraph (a)(17)(i)(B)(*1*) of this section, on or before the 30th day after the date the member, broker or dealer received notice of any change, or, if the account was updated for some reason other than the firm receiving notice of a change, after the date the account record was updated. The member, broker or dealer may elect to send this notification with the next statement scheduled to be mailed to the customer or owner.

(C) For purposes of this paragraph (a)(17), the neglect, refusal, or inability of a customer or owner to provide or update any account record information required under paragraph (a)(17)(i)(A) of this section shall excuse the member, broker or dealer from obtaining that required information.

(D) The account record requirements in paragraph (a)(17)(i)(A) of this section shall only apply to accounts for which the member, broker or dealer is, or has within the past 36 months been, required to make a suitability determination under the federal securities laws or under the requirements of a self-regulatory organization of which it is a member. Additionally, the furnishing requirement in paragraph (a)(17)(i)(B)(*1*) of this section shall not be applicable to an account for which, within the last 36 months, the member, broker or dealer has not been required to make a suitability determination under the federal securities laws or under the requirements of a self-regulatory organization of which it is a member. This paragraph (a)(17)(i)(D) does not relieve a member, broker or dealer from any obligation arising from the rules of a self-regulatory organization of which it is a member regarding the collection of information from a customer or owner.

(ii) If an account is a discretionary account, a record containing the dated signature of each customer or owner granting the authority and the dated signature of each natural person to whom discretionary authority was granted.

(iii) A record for each account indicating that each customer or owner was furnished with a copy of each written agreement entered into on or after the effective date of this paragraph pertaining to that account and that, if requested by the customer or owner, the customer or owner was furnished with a fully executed copy of each agreement.

(18) A record:

(i) As to each associated person of each written customer complaint received by the member, broker or dealer concerning that associated person. The record shall include the complainant's name, address, and account number; the date the complaint was received; the name of any other associated person identified in the complaint; a description of the nature of the complaint; and the disposition of the complaint. Instead of the record, a member, broker or dealer may maintain a copy of each original complaint in a separate file by the associated person named in the complaint along with a record of the disposition of the complaint.

(ii) Indicating that each customer of the member, broker or dealer has been provided with a notice containing the address and telephone number of the department of the member, broker or dealer to which any complaints as to the account may be directed.

(19) A record:

(i) As to each associated person listing each purchase and sale of a security attributable, for compensation purposes, to that associated person. The record shall include the amount of compensation if monetary and a description of the compensation if non-monetary. In lieu of making this record, a member, broker or dealer may elect to produce the required information promptly upon request of a representative of a securities regulatory authority.

(ii) Of all agreements pertaining to the relationship between each associated person and the member, broker or dealer including a summary of each associated person's compensation arrangement or plan with the member, broker or dealer, including commission and concession schedules and, to the extent that compensation is based on factors other than remuneration per trade, the method by which the compensation is determined.

(20) A record, which need not be separate from the advertisements, sales literature, or communications, documenting that the member, broker or dealer has complied with, or adopted policies and procedures reasonably designed to establish compliance with, applicable federal requirements and rules of a self-regulatory organization of which the member, broker or dealer is a member which require that advertisements, sales literature, or any other communications with the public by a member, broker or dealer or its associated persons be approved by a principal.

(21) A record for each office listing, by name or title, each person at that office who, without delay, can explain the types of records the firm maintains at that office and the information contained in those records.

(22) A record listing each principal of a member, broker or dealer responsible for establishing policies and procedures that are reasonably designed to ensure compliance with any applicable federal requirements or rules of a self-regulatory organization of which the member, broker or dealer is a member that require acceptance or approval of a record by a principal.

* * * * *

(f) Every member, broker or dealer shall make and keep current, as to each office, the books and records described in paragraphs (a)(1), (a)(6), (a)(7), (a)(12), (a)(17), (a)(18)(i), (a)(19), (a)(20), (a)(21), and (a)(22) of this section.

(g) When used in this section:

(1) The term *office* means any location where one or more associated persons regularly conduct the business of handling funds or securities or effecting any transactions in, or inducing or attempting to induce the purchase or sale of, any security.

(2) The term *principal* means any individual registered with a registered national securities association as a principal or branch manager of a member, broker or dealer or any other person who has been delegated supervisory responsibility over associated persons by the member, broker or dealer.

(3) The term *securities regulatory authority* means the Commission, any self-regulatory organization, or any securities commission (or any agency or office performing like functions) of the States.

(4) The term *associated person* means an ''associated person of a member'' or ''associated person of a broker or dealer'' as defined in sections 3(a)(21) and 3(a)(18) of the Act (15 U.S.C. 78c(a)(21) and (a)(18)) respectively, but shall not include persons whose functions are solely clerical or ministerial.

§ 240.17a–3 [Amended]

4. Section 240.17a–3 is amended by:

a. Removing from the introductory text of paragraph (a) and paragraph (a)(5) the word ''his'' and in its place adding ''it'';

b. Removing from paragraph (a)(11)(ii) the word ''he'' and in its place adding ''it'';

c. Removing from redesignated paragraphs (a)(12)(i)(A) and (a)(12)(i)(B) the word ''His'' and in its place adding ''The associated person's'';

d. Removing from redesignated paragraphs (a)(12)(i)(A), (a)(12)(i)(C), and (a)(12)(i)(H) the word ''his'' and in its place adding ''the associated person's'';

e. Removing from redesignated paragraphs (a)(12)(i)(D) and (a)(12)(i)(F) the word ''him'' and in its place adding ''the associated person'';

f. Removing from redesignated paragraphs (a)(12)(i)(D), (a)(12)(i)(E), (a)(12)(i)(F) and (a)(12)(i)(H) the word ''he'' and in its place adding ''the associated person'' and

g. Removing from redesignated paragraph (a)(12)(i)(H) the phrase ''or the American Stock Exchange, the Boston Stock Exchange, the Midwest Stock Exchange, the New York Stock Exchange, the Pacific Coast Stock Exchange, or the Philadelphia-Baltimore Stock Exchange'' and in its place adding ''the American Stock Exchange LLC, the Boston Stock Exchange, Inc., the Chicago Stock Exchange, Inc., the New York Stock Exchange, Inc., the Pacific Exchange, Inc., the Philadelphia Stock Exchange, Inc., the Chicago Board Options Exchange, Inc., the Cincinnati Stock Exchange, Inc. or the International Securities Exchange''.

5. Section 240.17a–4 is amended by:

a. Revising paragraph (a);

b. Revising the introductory text of paragraph (b);

c. Revising paragraphs (b)(1), (b)(4), (c) and (d);

d. Revising the introductory text of paragraph (e);

e. Adding paragraphs (e)(5), (e)(6), (e)(7), (e)(8);

f. Revising paragraph (j); and

g. Adding paragraphs (k) and (l).

The revisions and additions read as follows:

§ 240.17a–4 Records to be preserved by certain exchange members, brokers and dealers.

(a) Every member, broker and dealer subject to § 240.17a–3 shall preserve for a period of not less than six years, the first two years in an easily accessible place, all records required to be made pursuant to paragraphs § 240.17a–3(a)(1), (a)(2), (a)(3), (a)(5), (a)(21), (a)(22), and analogous records created pursuant to paragraph § 240.17a–3(f).

(b) Every member, broker and dealer subject to § 240.17a–3 shall preserve for a period of not less than three years, the first two years in an easily accessible place:

(1) All records required to be made pursuant to § 240.17a–3(a)(4), (a)(6), (a)(7), (a)(8), (a)(9), (a)(10), (a)(16), (a)(18), (a)(19), (a)(20), and analogous records created pursuant to § 240.17a–3(f).

* * * * *

(4) Originals of all communications received and copies of all communications sent (and any approvals thereof) by the member, broker or dealer (including inter-office memoranda and communications) relating to its business as such, including all communications which are subject to rules of a self-regulatory organization of which the member, broker or dealer is a member regarding communications with the public. As used in this paragraph (b)(4), the term communications includes sales scripts.

* * * * *

(c) Every member, broker and dealer subject to § 240.17a–3 shall preserve for a period of not less than six years after the closing of any customer's account any account cards or records which relate to the terms and conditions with respect to the opening and maintenance of the account.

(d) Every member, broker and dealer subject to § 240.17a–3 shall preserve during the life of the enterprise and of any successor enterprise all partnership articles or, in the case of a corporation, all articles of incorporation or charter, minute books and stock certificate books (or, in the case of any other form of legal entity, all records such as articles of organization or formation, and minute books used for a purpose similar to those records required for corporations or partnerships), all Forms BD (§ 249.501 of this chapter), all Forms BDW (§ 249.501a of this chapter), all amendments to these forms, all licenses or other documentation showing the registration of the member, broker or dealer with any securities regulatory authority.

(e) Every member, broker and dealer subject to § 240.17a–3 shall maintain and preserve in an easily accessible place:

* * * * *

(5) All account record information required pursuant to § 240.17a–3(a)(17) until at least six years after the earlier of the date the account was closed or the date on which the information was replaced or updated.

(6) Each report which a securities regulatory authority has requested or required the member, broker or dealer to make and furnish to it pursuant to an order or settlement, and each securities regulatory authority examination report until three years after the date of the report.

(7) Each compliance, supervisory, and procedures manual, including any updates, modifications, and revisions to the manual, describing the policies and practices of the member, broker or dealer with respect to compliance with applicable laws and rules, and supervision of the activities of each natural person associated with the member, broker or dealer until three years after the termination of the use of the manual.

(8) All reports produced to review for unusual activity in customer accounts until eighteen months after the date the report was generated. In lieu of maintaining the reports, a member, broker or dealer may produce promptly the reports upon request by a representative of a securities regulatory authority. If a report was generated in a computer system that has been changed in the most recent eighteen month period in a manner such that the report cannot be reproduced using historical data in the same format as it was originally generated, the report may be produced by using the historical data in the current system, but must be accompanied by a record explaining each system change which affected the reports. If a report is generated in a computer system that has been changed in the most recent eighteen month period in a manner such that the report cannot be reproduced in any format using historical data, the member, broker or dealer shall promptly produce upon request a record of the parameters that were used to generate the report at the time specified by a representative of a securities regulatory authority, including a record of the frequency with which the reports were generated.

* * * * *

(j) Every member, broker and dealer subject to this section shall furnish promptly to a representative of the Commission legible, true, complete, and current copies of those records of the member, broker or dealer that are

required to be preserved under this section, or any other records of the member, broker or dealer subject to examination under section 17(b) of the Act (15 U.S.C. 78*q*(b)) that are requested by the representative of the Commission.

(k) Records for the most recent two year period required to be made pursuant to § 240.17a–3(f) and paragraphs (b)(4) and (e)(7) of this section which relate to an office shall be maintained at the office to which they relate. If an office is a private residence where only one associated person (or multiple associated persons who reside at that location and are members of the same immediate family) regularly conducts business, and it is not held out to the public as an office nor are funds or securities of any customer of the member, broker or dealer handled there, the member, broker or dealer need not maintain records at that office, but the records must be maintained at another location within the same State as the member, broker or dealer may select. Rather than maintain the records at each office, the member, broker or dealer may choose to produce the records promptly at the request of a representative of a securities regulatory authority at the office to which they relate or at another location agreed to by the representative.

(l) When used in this section:

(1) The term *office* shall have the meaning set forth in § 240.17a–3(g)(1).

(2) The term *principal* shall have the meaning set forth in § 240.17a–3(g)(2).

(3) The term *securities regulatory authority* shall have the meaning set forth in § 240.17a–3(g)(3).

(4) The term *associated person* shall have the meaning set forth in § 240.17a–3(g)(4).

§ 240.17a–4 [Amended]

6. Section 240.17a–4 is amended by:

a. Removing from paragraph (b)(7) the word ''his'' and in its place adding ''its'; and

b. Removing from paragraph (e)(1) the phrase ''the ''associated person'' has terminated his employment and any other connection with the member, broker or dealer.'' and in its place adding ''the associated person's employment and any other connection with the member, broker or dealer has terminated.''.

c. Removing from paragraph (f)(3)(ii) the phrase ''the Commission or its representatives'' and in its place adding ''the staffs of the Commission, any self-regulatory organization of which it is a member, or any State securities regulator having jurisdiction over the member, broker or dealer''.

d. Removing from paragraph (f)(3)(vii):

i. The phrase ''the U.S. Securities and Exchange Commission (''Commission''), its designees or representatives,'' and in its place adding ''the U.S. Securities and Exchange Commission (''Commission''), its designees or representatives, any self-regulatory organization of which it is a member, or any State securities regulator having jurisdiction over the member, broker or dealer,'';

ii. The phrase ''the Commission's or designee's staff'' and in its place adding ''the staffs of the Commission, any self-regulatory organization of which it is a member, or any State securities regulator having jurisdiction over the member, broker or dealer''; and

iii. From each place it appears, the phrase ''the Commission's staff or its designee'' and in its place adding ''the staffs of the Commission, any self-regulatory organization of which it is a member, or any State securities regulator having jurisdiction over the member, broker or dealer''.

PART 242—REGULATIONS M and ATS

7. The authority citation for part 242 continues to read as follows:

Authority: 15 U.S.C. 77g, 77q(a), 77s(a), 78b, 78c, 78i(a), 78j, 78k–1(c), 78*l*, 78m, 78mm, 78n, 78o(b), 78o(c), 78o(g), 78q(a), 78q(b), 78q(h), 78w(a), 78dd–1, 80a–23, 80a–29, and 80a–37.

8. In § 242.303, paragraph (d) is amended by removing the phrase ''representatives or designees of the Securities and Exchange Commission, and to promptly furnish to the Commission or its designee'' and in its place adding ''the staff of the Securities and Exchange Commission, any self-regulatory organization of which the alternative trading system is a member, or any State securities regulator having jurisdiction over the alternative trading system, and to promptly furnish to the Commission, self-regulatory organization of which the alternative trading system is a member, or any State securities regulator having jurisdiction over the alternative trading system.''

Dated: October 26, 2001.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–27439 Filed 11–1–01; 8:45 am]

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Federal Register

Friday,
November 2, 2001

Part IV

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–7095–6]

National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; amendments.

SUMMARY: On June 29, 1999, we issued the National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards (64 FR 34854). On November 22, 1999 (64 FR 63779), we proposed minor amendments to the June 29, 1999 promulgated rule concerning the regulation of surge control vessels and bottoms receiver vessels. These final amendments are necessary to correct discrepancies between the promulgated rule and our intent.

EFFECTIVE DATE: November 2, 2001.

ADDRESSES: Docket No. A–97–17 contains supporting information used in developing these amendments to the Generic MACT rulemaking subpart (40 CFR part 63, subpart YY). The docket is located at the U.S. EPA, 401 M Street, SW., Washington, DC 20460 in Room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. David W. Markwordt, Policy, Planning, and Standards Group, Emission Standards Division (MD–13), U.S.EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0837, facsimile (919) 541–0942, electronic mail address: *markwordt.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

Docket. The docket is an organized and complete file of all the information considered by EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. See section 307(d)(7)(A) of the Clean Air Act (CAA). The regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be mailed on request from the Air Docket by calling (202) 260–7548. A reasonable fee may be charged for copying docket materials.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of today's final rule will also be available on the WWW through the EPA's Technology Transfer Network (TTN). Following signature, a copy of the rule will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules, *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

Regulated entities. Categories and entities potentially affected by this action include:

Category	SIC [a]	NAICS [b]	Regulated entities
Industry	2869	325199	Producers of homopolymers and/or copolymers of, alternating oxymethylene units. Producers of either acrylic fiber or modacrylic fiber synthetics composed of acrylonitrile (AN) units. Producers of polycarbonate.
Industry	2819	325188	Producers of, and recoverers of, HF by reacting calcium fluoride with sulfuric acid. For the purpose of implementing the rule, HF production is not a process that produces gaseous HF for direct reaction with hydrated aluminum to form aluminum fluoride (i.e., the HF is not recovered as an intermediate or final product prior to reacting with the hydrated aluminum).

[a] Standard Industrial Classification.
[b] North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility is regulated by this action, you should examine the applicability criteria in § 63.1103(a)(1), (b)(1), (c)(1), and (d)(1) of the rule.

Judicial Review. Under section 307(b) of the CAA, judicial review of these final amendments is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by January 2, 2002. Under section 307(d)(7)(B) of the CAA, only an objection to these amendments which was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by today's final action may not be challenged separately in any civil or criminal proceeding we bring to enforce these requirements.

I. What Is the Background for the Amendments?

On June 29, 1999 (64 FR 34854), we published the National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards, which promulgated standards for four major hazardous air pollutants (HAP) source categories (i.e., acetal resins (AR) production, acrylic and modacrylic fiber (AMF) production, hydrogen fluoride (HF) production, and polycarbonate (PC) production). On November 22, 1999, we proposed amendments to the June 29, 1999 promulgated rule concerning the regulation of surge control vessels and bottoms receiver vessels (64 FR 63779). The proposed amendments changed the definition of ''storage vessel'' to include bottoms receivers and surge control vessels and changed the definition of ''equipment'' to not include bottoms receivers and surge control vessels. These amendments were necessary to correct discrepancies between the promulgated rule and our intent.

We received one comment on the proposed amendments. The commenter

stated that if the proposed amendments are finalized, acetal resins production surge control vessels and bottoms receivers that are part of the front-end process of the process train (and treated as front-end process vents in the promulgated rule) would be required to install additional controls beyond those determined to be maximum achievable control technology (MACT) for these sources. The commenter explained that when determining MACT for front-end process vents, the EPA intentionally identified surge control vessels and bottoms receivers that are part of the front-end of the process train as front-end process vents.

When we proposed the amendments to the definition of ''storage vessel,'' we had no intention of changing the requirements for acetal resins production surge control vessels and bottoms receivers that are part of the front-end process of the process train. Therefore, we are finalizing amendments that maintain the requirements for acetal resins production front-end process vents (including surge control vessels and bottoms receivers that are part of the front-end process) as promulgated and intended.

For acetal resins production, we are requiring that bottoms receivers and surge control vessels that are part of the front-end process train be controlled under the acetal resins production front-end process vent provisions. The rationale for inclusion of surge control vessels and bottoms receivers as part of the MACT determination for front-end process vents can be found in a memorandum to the docket supporting these amendments (Docket No. A–97–17). These final amendments are consistent with our intent at promulgation of the original standards.

II. What Are the Impacts Associated With These Amendments?

This action consists of a clarification of our intent at the time of promulgation of 40 CFR part 63, subpart YY, and will not affect the estimated emissions reductions or the control costs for the standards promulgated for AR, AMF, HF, and PC production source categories on June 29, 1999 (64 FR 34854). This clarification makes it easier for owners and operators of affected sources, and for local and State authorities, to understand and implement the requirements of 40 CFR part 63, subpart YY.

III. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), we 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. The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that these final rule amendments do not constitute a ''significant regulatory action'' under the terms of Executive Order 12866. Consequently, this action was not submitted to OMB for review under Executive Order 12866.

B. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under Executive Order 13132, the EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the regulation.

The EPA has concluded that these final rule amendments will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of section 6 of the Executive Order do not apply to these amendments.

C. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 entitled, ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

These final rule amendments do not have tribal implications. They will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. No tribal governments own or operate facilities that will be subject to this final rule. Thus, Executive Order 13175 does not apply to these final amendments.

D. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be ''economically significant,'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that the EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of

the planned rule on children and explain why the planned rule is preferable to other potentially effective and reasonable alternatives considered by the EPA.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. These final rule amendments are not subject to Executive Order 13045 because they are based on technology performance and not on safety risks. Furthermore, these amendments have been determined not to be ''economically significant'' as defined under Executive Order 12866.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in aggregate, or by the private sector, of $100 million or more in any 1 year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows the EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation as to why that alternative was not adopted. Before the EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that these final rule amendments do not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. There is no cost associated with these amendments. Thus, today's amendments are not subject to the requirements of sections 202 and 205 of the UMRA. In addition, the EPA has determined that these final amendments do not contain regulatory requirements that might significantly or uniquely affect small governments because they do not contain requirements that apply to such governments or impose obligations upon them. Therefore, today's final amendments are not subject to the requirements of section 203 of the UMRA.

Because these final rule amendments do not include a Federal mandate and are estimated to result in expenditures less than $100 million in any 1 year by State, local, and tribal governments, the EPA has not prepared a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative. Therefore, the requirements of the UMRA do not apply to this action.

F. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with today's final rule amendments. Because there is no cost associated with these amendments, the EPA has also determined that today's final rule amendments will not have a significant economic impact on a substantial number of small entities. For purposes of assessing the impacts of today's final rule amendments on small entities, small entities are defined as: (1) A small business that has fewer than 500 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule amendments on small entities, the EPA has concluded that this action will not have a significant impact on a substantial number of small entities.

G. Paperwork Reduction Act

The OMB approved the information collection requirements under the Generic MACT rule for the AR, AMF, HF, and PC production source categories and assigned the OMB control number 2060–0420 to the ICR. This approval expires September 30, 2002.

A copy may be obtained from Sandy Farmer by mail at the Collection Strategies Division (2822), Office of Environmental Information, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, by e-mail at *farmer.sandy@epa.gov*, or by calling (202) 260–2740. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr*.

These final rule amendments will not impact the information collection estimates made previously for the Generic MACT consolidated rulemaking package. Therefore, the ICR has not been revised.

H. National Technology Transfer and Advancement Act

As noted in the proposed amendments, section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, (Public Law No. 104–113) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. These final rule amendments do not involve technical standards.

I. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing these amendments and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the

amendments in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. These final rule amendments do not constitute a ''major rule'' as defined by 5 U.S.C. 804(2). These amendments will be effective November 2, 2001.

J. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

These amendments are not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because they do not constitute a significant regulatory action under Executive Order 12866.

List of Subjects for 40 CFR Part 63

Environmental protection, Acetal resins production, Acrylic and modacrylic fiber production, Air emissions control, Administrative practice and procedures, Hazardous air pollutants, Hydrogen fluoride production, Intergovernmental relations, Polycarbonate production, Process vents, Recordkeeping and reporting requirements, Storage vessels.

Dated: October 24, 2001.

Christine Todd Whitman,

Administrator.

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

PART 63—[AMENDED]

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

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

Subpart YY—[Amended]

2. Section 63.1101 is amended by revising the definitions for ''equipment'' and ''storage vessel'' to read as follows:

§ 63.1101 Definitions.

* * * * *

Equipment means each of the following that is subject to control under this subpart: pump, compressor, agitator, pressure relief device, sampling collection system, open-ended valve or line, valve, connector, instrumentation system in organic hazardous air pollutant service as defined in § 63.1103 for the applicable process unit, whose primary product is a product produced by a source category subject to this subpart.

* * * * *

Storage vessel or *tank*, for the purposes of regulation under the storage vessel provisions of this subpart, means a stationary unit that is constructed primarily of nonearthen materials (such as wood, concrete, steel, fiberglass, or plastic) that provides structural support and is designed to hold an accumulation of liquids or other materials. Storage vessel includes surge control vessels and bottoms receiver vessels. For the purposes of regulation under the storage vessel provisions of this subpart, storage vessel does not include vessels permanently attached to motor vehicles such as trucks, railcars, barges, or ships; or wastewater storage vessels. Wastewater storage vessels are covered under the wastewater provisions of § 63.1106.

* * * * *

3. Section 63.1103 is amended by revising paragraph (a)(1)(i)(A) to read as follows:

§ 63.1103 Source category-specific applicability, definitions, and requirements.

(a) * * *

(1) * * *

(i) * * *

(A) All storage vessels that store liquids containing organic HAP. For purposes of regulation, surge control vessels and bottoms receivers that are located as part of the process train prior to the polymer reactor are to be regulated under the front-end process vent provisions.

* * * * *

[FR Doc. 01–27593 Filed 11–1–01; 8:45 am]

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Federal Register

Friday,
November 2, 2001

Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 419

Medicare Program—Prospective Payment System for Hospital Outpatient Services; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 419

[CMS–1179–IFC]

RIN 0938–AK59

Medicare Program—Prospective Payment System for Hospital Outpatient Services: Criteria for Establishing Additional Pass-Through Categories for Medical Devices

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period sets forth the criteria the Secretary will use to establish new categories of medical devices eligible for transitional pass-through payments under Medicare's hospital outpatient prospective payment system.

DATES: *Effective date*: These regulations are effective December 3, 2001.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 2, 2002.

ADDRESSES: Mail an original and 3 copies of written comments to the following address only:

Centers for Medicare & Medicaid Services Department of Health and Human Services, Attention: CMS–1179–IFC, P.O. Box 8018, Baltimore, MD 21244–8018

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–1179–IFC.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

For information on ordering copies of the **Federal Register** containing this document and electronic access, see the beginning of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Nancy Edwards, (410) 786–0378 or Barry Levi, (410) 786–4529.

SUPPLEMENTARY INFORMATION

Inspection of Public Comments

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room C5–10–04 of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD, on Monday through Friday of the week from 8:30 a.m. to 5 p.m. Please call (410) 786–7195 or (410) 786–4668 to view these comments.

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I. Background

Section 1833(t) of the Social Security Act (the Act), as added by section 4523 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105–133, provided for implementation of a prospective payment system (PPS) for hospital outpatient services furnished to Medicare beneficiaries. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Pub. L. 106–113, amended section 1833(t) of the Act to make major changes that affected the new PPS for hospital outpatient services. On April 7, 2000, we published in the **Federal Register** (65 FR 18434), a final rule with comment period to implement the new PPS for hospital outpatient services. The new system establishes payment rates for each service paid under this system using ambulatory payment classification (APC) groups. On June 30, 2000, we published a notice in the **Federal Register** (65 FR 40535) announcing a delay in the effective date of the hospital outpatient PPS (OPPS) from July 1, 2000 (as set forth in the April 7, 2000 final rule) until August 1, 2000. Therefore, OPPS became effective on August 1, 2000. The regulations implementing the payment system appear at 42 CFR part 419.

Among the provisions of the April 7, 2000 final rule with comment period are those implementing section 1833(t)(6) of the Act, which was added by section 201(b) of the BBRA. This section provided for temporary additional payments, referred to as ''transitional pass-through payments,'' for certain drugs, biologicals, and devices. The provision required the Secretary to make additional payments to hospitals for at least 2, but no more than 3, years for specific items. The items designated by the BBRA are as follows:

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act.
- Current drugs, biologicals, and brachytherapy devices used for the treatment of cancer.
- Current radiopharmaceutical drugs and biologicals.
- New medical devices, drugs, and biologicals in instances in which the item was not being paid as a hospital outpatient service as of December 31, 1996, and when the cost of the item is ''not insignificant'' in relation to the OPPS payment amount. For those drugs, biologicals, and devices referred to as ''current,'' the transitional payment begins on the first date the hospital OPPS is implemented, as required by section 1833(t)(6)(B)(i) of the Act (before enactment of the Medicare, Medicaid, and SCHIP Program Benefits Improvement and Protection Act (BIPA), Pub. L. 106–554, enacted December 21, 2000).

Section 1833(t)(6)(B) of the Act requires payment to be made on a ''pass-through'' basis for the designated items. Specifically, for devices, the payment is determined by taking the hospital's charge for the device on the individual claim submitted to Medicare, multiplying by the hospital's cost-to-charge ratio, and subtracting an amount identified by the Secretary as already included in the associated APC to reflect payment for similar devices.

In the April 7, 2000 final rule with comment period, we discussed the

criteria that we will use to determine which medical devices are eligible for transitional pass-through payments. These criteria were further discussed and several modifications were made in an interim final rule with comment period published in the **Federal Register** on August 3, 2000 (65 FR 47670). The modifications included changes in the test used to determine when the cost of the item is ''not insignificant.'' Effective August 1, 2000, we used these criteria in determining which devices were eligible for transitional pass-through payments.

From the initial implementation of the new system on August 1, 2000 through March 31, 2001, we determined eligibility for all medical devices (as well as drugs and biologicals) for transitional pass-through payment on an item-specific basis, that is, distinguishing by individual trade names (and, in some instances, model numbers) of the eligible devices. Devices that we determined eligible were listed in one of a number of Program Memoranda we published on this subject. These lists were also posted on our Web site, *www.hcfa.gov*. Other devices, even if similar to those on the published lists, were not eligible in the absence of a specific eligibility decision published in a Program Memorandum. We established a quarterly process by which interested parties could submit applications to us for eligibility determinations for particular devices. Using this process, we determined that over 1,000 devices were eligible for transitional pass-through payments.

The most significant reason for adopting an item-specific approach rather than a category approach, which was also considered, was the requirement in section 1833(t)(6)(A)(iv)(I) of the Act that, for a device to be eligible for a transitional pass-through payment, ''payment for the device * * * as an outpatient hospital service under this part was not being made as of December 31, 1996.'' We adopted an item-specific approach in order to distinguish which devices met this criterion. If we had adopted a categorical approach, any category that contained any device that Medicare had paid for before 1997 would not be eligible for transitional pass-through payments. No device included in that category, regardless of when Medicare started to pay for it, would be eligible. This approach would have severely limited the eligibility of devices for transitional pass-through payments, a result that we believed was contrary to the intent of the statute. Our reasons for adopting an item-specific approach to determining eligibility of transitional pass-through payments are further discussed in the November 13, 2000 interim final rule with comment period (65 FR 67806).

Section 402 of BIPA, which amends section 1833(t)(6) of the Act, requires us to use categories in determining the eligibility of devices for transitional pass-through payments effective April 1, 2001. Section 1833(t)(6)(B)(ii)(IV) of the Act, as added by section 402(a) of BIPA, requires us to establish a new category for a medical device when—

- The cost of the device is not insignificant in relation to the OPD fee schedule amount;
- No existing device category is appropriate for the device; and
- Payment was not being made for the device as an outpatient hospital service as of December 31, 1996. However, section 1833(t)(6)(B)(iv) of the Act, also added by section 402(a) of BIPA, provides that a medical device may be treated as meeting these requirements if either—
- The device is described by one of the initial categories established; or
- The device is described by one of the additional categories established under this rule, and—
- An application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved; or
- The device has been cleared for market under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or
- The device is exempt from the requirements of section 510(k) of the Federal Food, Drug, and Cosmetic Act under section 510(l) or section 510(m) of that Act.

Thus, otherwise covered devices that are described by a category may be eligible for transitional pass-through payments even if they were paid as part of an outpatient service as of December 31, 1996. At the same time, no categories will be created on the basis of devices that were paid on or before December 31, 1996. Under section 1833(t)(6)(B)(iv) of the Act, no further application or approval is required for a covered device that is described by a category to qualify for a transitional pass-through payment.

Section 1833(t)(6)(B)(i)(I) of the Act, as amended by BIPA, required us to establish, by April 1, 2001, an initial set of categories based on device by type in such a way that devices eligible for transitional pass-through payments under sections 1833(t)(A)(ii) and (iv) as of January 1, 2001 would be included in a category. We developed this initial set of categories in consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties, as required by section 1833(t)(6)(B)(i)(II) of the Act, as amended by BIPA. We issued the list of initial categories on March 22, 2001, in Program Memorandum (PM) No. A–01–41, which is available on our Web site, *www.hcfa.gov*.

As required by section 1833(t)(6)(B)(iii) of the Act, the period during which a category of devices is eligible for transitional pass-through payments is at least 2, but not more than 3, years. This period begins with the first date on which a transitional pass-through payment is made for any medical device that is described by the category.

Section 1833(t)(6)(B)(ii)(III) of the Act, as amended by BIPA, requires us to establish criteria by July 1, 2001 that will be used to create additional categories. This provision requires that no medical device be described by more than one category. In addition, the criteria must include a test of whether the average cost of devices that would be included in a category is ''not insignificant'' in relation to the APC payment amount for the associated service.

A conforming amendment made by section 402(b)(3) of BIPA revises section 1833(t)(12)(E) of the Act concerning the limitation on administrative or judicial review of the OPPS. As amended, that section now prohibits administrative or judicial review of the determination and deletion of initial and new categories. In addition to the requirement to use device categories for purposes of the transitional pass-through payments, BIPA made other changes to those payments. Section 406 of BIPA amends section 1833(t)(6)(A)(ii) of the Act to extend transitional pass-through payments to devices used for temperature monitored cryoablation, effective for devices furnished on or after April 1, 2001.

Section 430 of BIPA amends section 1861(t)(1) of the Act to expand the definition of ''drugs'' to include contrast agents effective for items and services furnished on or after July 1, 2001. We implemented this provision by program memorandum (Transmittal A–01–73, June 1, 2001). Thus, contrast agents have been eligible for transitional pass-through payments since that date. The amount of the pass-through payment will be determined, as for other drugs, on the basis of 95 percent of the average wholesale price less the amount determined to be already included in the payment for the associated APC.

II. Provisions of This Interim Final Rule with Comment Period

This interim final rule sets forth the criteria for establishing new categories of medical devices eligible for transitional pass-through payments under the hospital outpatient PPS as required by section 1833(t)(6)(B)(ii) of the Act, as amended by BIPA. The provisions relating to transitional pass-through payments for eligible drugs and biologicals remain unchanged and are not addressed in this rule (except for the change relating to contrast agents as provided in section 430 of BIPA). Similarly, the provisions relating to new technology ambulatory payment classification (APC) groups remain the same, as set forth in our April 7, 2000 final rule (66 FR 18476). We note, however, that in the proposed rule to update the hospital OPPS for CY 2002, published on the August 24, 2001 (66 FR 44702), we proposed certain changes to the criteria for eligibility for payment in a new technology APC.

A. Changes to the Criteria for Eligibility for Pass-Through Payment of a Medical Device

As noted above, in our April 7, 2000 final rule with comment period (65 FR 18480), we defined new or innovative devices using eight criteria, three of which were revised in our August 3, 2000 interim final rule with comment period (65 FR 47673–74). These criteria were set forth in regulations at § 419.43(e)(4). For the most part, these criteria will remain applicable when defining a new category for devices. That is, devices to be included in a category must meet all previously established applicable criteria for a device eligible for transitional pass-through payments. The definition of an eligible device, however, must change to conform to the requirements of the amended section 1833(t)(6)(B)(ii) of the Act.

In addition, we are clarifying our criterion that states that a device must be approved or cleared by the FDA. The approval or clearance criterion applies only if FDA approval or clearance is required for the device as specified at new § 419.66(b)(1). For example, a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with § 405.203 through § 405.207 and §§ 405.211 through 405.215 is exempt from this requirement. A device that has received an FDA IDE and is classified by the FDA as a Category B device is eligible for a transitional pass-through payment if all other requirements are met.

B. Criteria for Establishing Device Categories

As described above in section I of this preamble, in determining the criteria for establishing additional categories, section 1833(t)(6)(B)(ii) of the Act mandates that new categories must be established for devices that were not being paid for as an outpatient hospital service as of December 31, 1996, in such a way that no device is described by more than one category and the average cost of devices to be included in a category is not insignificant in relation to the APC payment amount for the associated service. Based on these requirements, we will use the following criteria to establish a category of devices:

- *Substantial clinical improvement.* The category describes devices that demonstrate a substantial improvement in medical benefits for Medicare beneficiaries compared to the benefits obtained by devices in previously established categories or other available treatments, as described in regulations at new § 419.66(c)(1).

This criterion ensures that no existing or previously existing category contains devices that are substantially similar to the devices to be included in the new category. This is consistent with the statutory mandate that no device is described by more than one category.

In addition, this criterion limits the number of new categories, and consequently transitional pass-through payments, to those categories containing devices that offer the prospect of substantial clinical improvement in the care of Medicare beneficiaries. Section 1833(t)(6)(E)(iii) of the Act, as redesignated by BIPA, requires that, if the Secretary estimates before the beginning of the year that the total amount of pass-through payments would exceed a specified percentage of total program payments (2.5 percent before 2004 and no more than 2 percent thereafter), we must uniformly reduce (prospectively) each pass-through payment in that year by an amount adequate to ensure that the limit is not exceeded.

We believe it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, the need for additional payments for devices that offer little or no clinical improvement over a previously existing device is less apparent. These devices can still be used by hospitals, and hospitals will be paid for them through the appropriate APC payment. To the extent these devices are used, the hospitals' charges for the associated procedures will reflect their use. We will use data on hospital charges to update the APC payment rates as part of the annual update cycle. Thus, the payment process will provide an avenue to reflect appropriate payments for devices that are not substantial improvements.

We will be evaluating a request for a new category of devices against the following criteria in order to determine if it meets the substantial clinical improvement requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:
  - Reduced mortality rate with use of the device.
  - Reduced rate of device-related complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process treated because of the use of the device.
  - Decreased pain, bleeding, or other quantifiable symptom.
  - Reduced recovery time.

As part of the application process (described below in section II.C.), we will require the requester to submit evidence that the category of devices meets one or more of these criteria. We note that the requirements set forth above will be used only for determining whether a device is eligible for a new category under section 1833(t)(6)(B) of the Act, which authorizes transitional pass through payments for categories of devices. These criteria are not intended for use in making coverage decisions

under section 1862(a)(1)(A) of the Act. We note that adoption of these criteria is consistent with the recommendation of the Medicare Payment Advisory Commission, in its March 2001 Report to Congress, that pass-through payments for specific technologies be made only when a technology is new or substantially improved.

We expect to determine which devices represent a substantial clinical improvement over existing devices by using a panel of Federal clinical and other experts, supplemented if appropriate by individual consultation with outside experts. These decisions will, in general, be based on information submitted by the requester about the clinical benefit of the devices as described in the above criteria, including, where available, evidence from clinical trials or other clinical investigations.

We believe that almost all substantial clinical improvements in technology that are appropriately paid for under the transitional pass-through provisions result in measurable improvements in care from the perspective of the beneficiary. Nevertheless, there may be some improvements in the medical technology itself that are so significant that we may wish to recognize them for separate payment even though they do not directly result in substantial clinical improvements. For example, improvements in such factors as the strength of materials, increased battery life, miniaturization, might so improve convenience, durability, ease of operation, etc., that such an improvement in medical technology might be considered as a separate factor from ''substantial clinical improvement'' in beneficiary care. We invite public comment on this issue and are particularly interested in learning of examples of medical technologies for which pass through payments might be appropriate even though they would not also pass a test based on substantial improvement in beneficiary outcomes.

We note that we welcome comments on all aspects of these criteria for substantial clinical improvement, and we will consider timely comments in developing a final rule. (Comments on all parts of this interim final rule with comment will be considered if they are received within 30 days after the publication of this rule.) We will continue to evaluate these criteria as we gain experience in applying them, and we will consider revisions and refinements to them over time as appropriate.

• *Cost.* We determine that the estimated cost to hospitals of the devices in a new category (including any candidate devices and the other devices that we believe will be included in the category) is ''not insignificant'' relative to the payment rate for the applicable procedures. The estimated cost of devices in a category will be considered ''not insignificant'' if they meet the following criteria found in regulations at new § 419.66(d):

• The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service associated with the category of devices.

• The estimated average reasonable cost of devices in the category exceeds the cost of the device-related portion of the APC payment amount for the service associated with the category of devices by at least 25 percent.

• The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment.

Of these three cost criteria, the latter two are unchanged from our current thresholds for individual devices (however, as discussed below, their effective date is revised). The first criterion, however, represents a change from the current threshold.

In the April 7, 2000 final rule, we provided that a device's expected reasonable cost must exceed 25 percent of the applicable APC payment for the associated service as the criterion for determining when the cost of a specific device is ''not insignificant'' in relation to the APC payment (65 FR 18480). In the August 3, 2000 interim final rule, we lowered the threshold to 10 percent because we believed the 25 percent limit was too restrictive based on the brand specific approach at the time (65 FR 47673; § 419.43(e)(1)(iv)(C)). However, given our payment experience over the past year using the 10 percent threshold, including our current information on the likely amount of pass-through payments in CY 2002, we believe a higher threshold is warranted. We believe that setting a higher cost threshold will ensure that new categories are created only in those instances where they are most valuable to beneficiaries and hospitals, given the overall limits on pass-through payments. That is, pass-through payments will be targeted only to those devices where cost considerations might be most likely to interfere with patient access.

We found that once we lowered the threshold to 10 percent, a very small minority (less than 10 percent) of devices that met all other criteria for the pass-through payment were rejected on the basis of this criterion. Partly as a result, the list of devices qualified for pass-through payments increased to well over 1000 devices by the end of 2000. Although the extensive number of qualified devices allowed hospitals to receive additional payment for many devices, we have estimated that the overall pass-through payment amount for calendar year 2002 exceeds the 2.5 percent cap. Therefore, for that year, a substantial reduction in the amount of each pass-through payment as required by section 1833(t)(6)(E)(iii) of the Act, will be necessary. Thus, allowing a large number of marginally costly devices to qualify for the pass-through payment would reduce the amount of additional payment a hospital would receive for any one device. We believe raising the threshold for this criterion will benefit hospitals by focusing the pass-through payments on those devices that represent a substantial loss to the hospital. We believe this change will also preserve beneficiary access to especially expensive devices.

In addition, once a category is established, devices included in the category will be eligible for pass-through payments regardless of the cost of the device. Therefore, we believe that it is reasonable to set a higher threshold than 10 percent to establish the category. While the cost of most devices described by a category may equal or exceed the threshold we use in establishing a category, the cost of individual devices could easily fall below the threshold. Therefore, we believe that it is reasonable to use a higher threshold in establishing a category than in qualifying individual devices.

The latter two criteria for determining that the estimated cost of a category of devices is not insignificant are unchanged from those currently included in § 419.66 (as related to individual devices). As we provided in the August 3, 2000 interim final rule, we intended to apply these criteria to devices for which a pass-through payment is first made on or after January 1, 2003 (65 FR 47673). We stated that the delay would allow us sufficient time to gather and analyze data needed to determine the current portion of the APC payment associated with the devices.

Based on the outpatient claims data we are currently using for analysis, we believe that we are able, in many cases, to begin using these criteria at this time. Although the 1996 data did not provide a level of information that allowed us to determine the portion of the APC payment that was related to the device

(except in a very few cases such as pacemakers), the newer data often does provide this level of detail. Therefore we will begin using the second and third criteria for the purpose of creating categories, as described in regulations at §§ 419.66(d)(2) and 419.66(d)(3), as soon after the implementation of this final rule as we have data to do so rather than on January 1, 2003. Although in some instances the lack of specific data will prevent the application of these criteria, we do not believe that should delay our use of these criteria in those situations in which the data are available.

C. Application Process for Creation of a New Device Category

Device manufacturers, hospitals, or other interested parties may apply for a new device category for transitional pass-through payments. The application process is very similar to the process that was previously used for item-specific review of devices and that is currently used for drugs and biologicals. Details regarding deadlines and other aspects of the application process will be available on our web site, *www.hcfa.gov.*

We will accept applications at any time. However, we will establish new categories only at the beginning of a calendar quarter, in deference to our computer systems needs and those of our contractors and hospitals. We must receive applications in sufficient time before the beginning of the calendar quarter in which a category would be established to allow for decision-making and programming. For now, we will require that applications be received at least 4 months before the beginning of the quarter.

We may change the details of this application process in the future to reflect experience and programmatic needs. If we revise these instructions in any way, we will submit the revisions to the Office of Management and Budget pursuant to the Paperwork Reduction Act. We will also post the revisions on our web site.

D. Announcing a New Device Category

If we determine a new category is warranted, we will issue a Program Memorandum specifying a new Healthcare Common Procedure Coding System (HCPCS, formerly known as HCFA Common Procedure Coding System) code and short and long descriptors for the category. We may also include additional clarifying or definitional information to help distinguish the new category from other existing or previously existing categories. It may be necessary to redefine, or make other changes to, existing categories to accommodate a new category and ensure that no medical device is described by more than one category, though we will attempt to keep these changes to a minimum. We will post these Program Memoranda on our web site.

We may find it necessary occasionally to correct or amend the list of (and clarifying information associated with) new categories or initial categories. We do not expect this step will be needed often, but if it is necessary, we will issue any changes in a Program Memorandum.

E. Temperature-Monitored Cryoablation Devices

Section 406 of BIPA amends section 1833(t)(6)(A)(ii) of the Act to extend transitional pass-through payments to a device of temperature-monitored cryoablation. We have implemented this provision through PM No. A–01–40, which included categories for these devices. In our regulations at new § 419.66(e)(2), we have extended the transitional pass-through payments to a device of temperature-monitored cryoablation and specify that this medical device is not subject to the cost criteria described in § 419.66(d).

F. Contrast Agents as a Drug

Section 430 of BIPA revises the definition of drugs at section 1861(t)(1) of the Act to include contrast agents, therefore making them eligible for a transitional pass-through payment. We have implemented this provision effective July 1, 2001, through PM No. A–01–73, issued on June 1, 2001. This provision does not require any changes in our regulations as we are simply including contrast agents within the definition of drugs that were not paid as hospital outpatient services before 1997.

G. Redesignations

We are redesignating and revising our regulations at § 419.43(e) relating to transitional pass-through payments for drugs, biologicals, and devices to incorporate the changes in our policy that result from this interim final rule. Paragraph (e) has been removed and redesignated as a new subpart G. (Current subpart G is redesignated as subpart H.) The new subpart G consists of the following sections:

§ 419.62 Transitional pass-through payments: General rules.

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

§ 419.66 Transitional pass-through payments: Medical devices.

We are redesignating § 419.43(f), Budget neutrality, as § 419.43(e) and revising that paragraph to limit its application only to outlier adjustments. The budget neutrality provision relating to pass-through payments is now found at § 419.62(b). We are also revising § 419.60(e), Limitations on administrative or judicial review, to conform to the changes made to section 1833(t)(12)(E) of the Act by section 402(b)(3) of BIPA.

In recodifying paragraph (e), we have made additional editorial changes to existing regulations text.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, when we proceed with a subsequent **Federal Register** document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a proposed rule in the **Federal Register** and invite public comment on the proposed rule. The proposed rule includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We believe that, in this case, prior notice and comment procedures would be impracticable because the statute requires we issue the criteria by July 1, only slightly more than 6 months after passage of the underlying statute. This deadline does not permit completion of the full cycle of notice and comment rulemaking before the criteria are published. Furthermore, section 1833(t)(6)(B)(ii)(I) of the Act, as amended by section 402(a) of BIPA, gives explicit authority to use an interim final rule with comment period. Therefore, we find good cause to waive

the notice of proposed rulemaking and to issue this final rule on an interim basis.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of the issues for the information collection requirement discussed below.

Process and Information Required To Apply for Additional Device Categories For Transitional Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System

The application itself for additional device categories may be found at *www.hcfa.gov*. The application process is very similar to the process that was previously used for item-specific review of devices and that is currently used for drugs and biologicals. Details regarding deadlines and other aspects of the application process will be available on the above web site. (See also section II. Above.)

We estimate that approximately 100 entities will file an application yearly. We believe it will take each of these entities around 16 hours to gather the necessary information and fill out the application.

We have submitted a copy of this interim final rule with comment to OMB for its review of the information collection requirement described above. The requirement is not effective until it has been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, DHES, SSG, Attn: John Burke, CMS–1179–IFC, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503 Attn: Allsion Eydt, Desk Officer.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This interim final rule is not a major rule because we have determined that the economic impact will be negligible for the revisions related to the transitional pass-through payments for new or innovative medical devices. In addition, the budget impact related to the transitional pass-through provision has already been addressed in the outpatient prospective payment system implementing rule published on April 7, 2000 (65 FR 18530). As stated in that rule, the pass-through provision is implemented in a budget-neutral manner as required by section 1833(t)(2)(E) of the Act. Section 1833(t)(6)(E) of the Act, as amended by BBRA and redesignated by BIPA, caps the projected additional payments annually at 2.5 percent of the total projected payments for hospital outpatient services each year before calendar year 2004 and no more than 2.0 percent in year 2004 and subsequent years.

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues ranging between $5 million and $25 million or less annually, depending on the particular health care industry (for details see the Small Business Administration's final rule size standards for health care at 65 FR 69432). Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that 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. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with not more than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the prospective payment system, we classify these hospitals as urban hospitals.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This interim final rule will not have a significant economic effect on these governments or the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule will not have a substantial effect on States or local governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 419

Health facilities, Hospitals, Medicare.

For the reasons set forth in the preamble, 42 CFR part 419 is amended as follows:

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

2. Section 419.43 is amended by—

A. Removing paragraph (e).

B. Redesignating paragraph (f) as paragraph (e) and revising it to read as follows.

§ 419.43 Adjustments to national program payment and beneficiary coinsurance amounts.

* * * * *

(e) *Budget neutrality.* CMS establishes payment under paragraph (d) of this section in a budget-neutral manner.

3. Section 419.60(e) is revised to read as follows:

§ 419.60 Limitations on administrative and judicial review.

* * * * *

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with subpart G of this part), the determination of initial and new categories under § 419.66, the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.62(c).

4. Redesignate Subpart G as Subpart H.

5. New Subpart G is added to read as follows:

Subpart G Transitional Pass-through Payments

Sec.

§ 419.62 Transitional pass-through payments: general rules.
§ 419.64 Transitional pass-through payments: Drugs and biologicals.
§ 419.66 Transitional pass-through payments: Medical devices.

§ 419.62 Transitional pass-through payments: General rules.

(a) *General.* CMS provides for additional payments under §§ 419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.

(b) *Budget neutrality.* CMS establishes the additional payments under §§ 419.64 and 419.66 in a budget neutral manner.

(c) *Uniform prospective reduction of pass-through payments.* (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

§ 419.64 Transitional pass-through payments: drugs and biologicals.

(a) *Eligibility for pass-through payment.* CMS makes a transitional pass-through payment for the following drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) *Orphan drugs.* A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) *Cancer therapy drugs and biologicals.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) *Radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) *Other drugs and biologicals.* A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under § 419.32(c)) as defined in paragraph (b) of this section.

(b) *Cost.* CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) *Services furnished before January 1, 2003.* The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) *Services furnished after December 31, 2002.* CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.

(iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10 percent of the APC payment amount for the related service.

(c) *Limited period of payment.* CMS limits the eligibility for a pass-through payment under this section to a period of at least 2 years, but not more than 3 years, that begins as follows:

(1) For a drug or biological described in paragraphs (a)(1) through (a)(3) of this section—August 1, 2000.

(2) For a drug or biological described in paragraph (a)(4) of this section—the date that CMS makes its first pass-through payment for the drug or biological.

(d) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological is 95 percent of the average wholesale price of the drug or biological minus the portion of the APC payment amount CMS determines is associated with the drug or biological.

§ 419.66 Transitional pass-through payments: medical devices.

(a) *General rule.* CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices

established by CMS under the criteria in paragraph (c) of this section.

(b) *Eligibility.* A medical device must meet the following requirements:

(1) If required by the FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter) or another appropriate FDA exemption.

(2) The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part (as required by section 1862(a)(1)(A) of the Act).

(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

(4) The device is not any of the following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(iii) A material that may be used to replace human skin (for example, a biological or synthetic material).

(c) *Criteria for establishing device categories.* CMS uses the following criteria to establish a category of devices under this section:

(1) CMS determines that a device to be included in the category is not described by any of the existing categories, and was not being paid for as an outpatient service as of December 31, 1996.

(2) CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) *Cost criteria.* CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) *Devices exempt from cost criteria.* The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) *Identifying a category for a device.* A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) *Limited period of payment for devices.* CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years beginning on the date that CMS establishes a category of devices.

(h) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 2, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 19, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–27658 Filed 10–31–01; 9:17 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 419

[CMS–1159–F1]

RIN 0938–AK54

Medicare Program; Announcement of the Calendar Year 2002 Conversion Factor for the Hospital Outpatient Prospective Payment System and a Pro Rata Reduction on Transitional Pass-Through Payments

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule announces the Medicare hospital outpatient prospective payment system conversion factor for calendar year (CY) 2002. In addition, it describes the Secretary's estimate of the total amount of transitional pass-through payments for CY 2002 and the implementation of a uniform reduction in each of the pass-through payments for that year.

EFFECTIVE DATE: This final rule is effective January 1, 2002 and applies to services furnished on or after January 1, 2002. This rule is a major rule as defined in 5 U.S.C. 804(2). According to 5 U.S.C. 801(a)(1)(A), we are submitting a report to the Congress on this rule on November 1, 2001.

FOR FURTHER INFORMATION CONTACT: Anne Tayloe, (410) 786–0600.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register.**

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online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

Section 1833(t) of the Social Security Act (the Act), as added by section 4523 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105–133, provided for implementation of a prospective payment system (PPS) for hospital outpatient services furnished to Medicare beneficiaries. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Pub. L. 106–113, amended section 1833(t) of the Act to make major changes that affected the new prospective payment system. On April 7, 2000, we published a final rule with comment period in the **Federal Register** (65 FR 18434) to implement the new PPS for hospital outpatient services. The new system established payment rates for each service paid under this system using ambulatory payment classification (APC) groups. On June 30, 2000, we published a notice in the **Federal Register** (65 FR 40535) announcing a delay in the effective date of the hospital outpatient PPS (OPPS) from July 1, 2000 (as set forth in the April 7, 2000 final rule) until August 1, 2000. Therefore, OPPS became effective on August 1, 2000. The regulations implementing the payment system appear at 42 CFR part 419.

On August 3, 2000, we published an interim final rule with comment period (65 FR 47670) that modified criteria that we use to determine which medical devices are eligible for transitional pass-through payments. On November 13, 2000, we published an interim final rule with comment period in the **Federal Register** (65 FR 67798) that provided for the annual update to the amounts and factors for OPPS payment rates effective for services furnished on or after January 1, 2001. We also responded to public comments on those portions of the April 7, 2000 final rule that implemented related provisions of the BBRA and public comments on the August 3, 2000 rule.

On August 24, 2001, we published a proposed rule in the **Federal Register** (66 FR 44672) that set forth proposed changes to the OPPS to implement applicable statutory requirements, including relevant provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted on December 21, 2000, as well as changes arising from our continuing experience with the system. That document described proposed changes to the amounts and factors used to determine the payment rates for services paid under the hospital OPPS for CY 2002. These amounts and factors include the updated conversion factor, APC classifications and relative weights, wage index values, copayment amounts, and the discussion of a possible pro rata reduction to be applied to the transitional pass-through payments for certain drugs, biologicals, and medical devices.

We received approximately 400 timely items of correspondence containing multiple comments on the August 24, 2001 proposed rule. In this final rule, we will respond to those comments addressing the Secretary's estimate of the total amount of pass-through payments for CY 2002 and the need for a uniform reduction to those payments in 2002 as well as the determination of the OPPS conversion factor for CY 2002.

In a subsequent final rule to be published by December 1, 2001, we will address the remainder of the comments and include the tables necessary to calculate CY 2002 payment rates and beneficiary copayment amounts.

II. Transitional Pass-Through Payments

A. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain innovative medical devices, drugs, and biologicals. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug and Cosmetic Act; current drugs, biologicals, and brachytherapy devices used for the treatment of cancer; and current radiopharmaceutical drugs and biologicals. Transitional pass-through payments are also required for new medical devices, drugs, and biologicals that were not being paid for as a hospital outpatient service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payment for the procedures or services associated with the new device, drug, or biological. Under the statute, transitional pass-through payments for any given device, drug, or biological are to be made for at least 2 years but not more than 3 years.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for drugs and biologicals eligible for a transitional pass-through payment as the amount by which the amount determined under section 1842(o) of the Act (that is, 95 percent of the applicable average wholesale price) exceeds the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the drug or biological. Section 1833(t)(6)(D)(ii) of the Act sets the transitional pass-through payment for a medical device at the amount by which the hospital's charges, adjusted to cost, exceeds the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the device.

B. Pro Rata Reductions

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for a given year to an ''applicable percentage'' of projected total payments under the hospital OPPS. For a year before 2004, the applicable percentage is 2.5 percent; for 2004 and subsequent years, the applicable percentage is a percentage specified by the Secretary up to 2.0 percent. If the Secretary estimates before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments for that year to ensure that the limit is not exceeded.

In the August 24, 2001 proposed rule setting out the proposed changes for CY 2002 in the OPPS, we described the extensive data base that we have constructed in order to prepare for making an estimate of pass-through payments for 2002. This data base includes outpatient claims data submitted by hospitals for services furnished on or after July 1, 1999 and before July 1, 2000, as well as device cost and utilization data extracted from applications for pass-through status submitted by manufacturers, hospitals, specialty societies, and other entities. In their applications for pass-through status, manufacturers have supplied information on the expected cost to hospitals of devices and the procedures with which the devices are commonly used.

In the August 24, 2001 proposed rule, we indicated that the information collected to that time suggested that a significant pro rata reduction might be required for 2002 in order to meet the statutory limit on the amount of the pass-through payments. We also announced that we were considering the appropriateness of a number of possible alternative approaches that would have the effect of minimizing the amount of any potential reduction in these

payments. Finally, we presented a discussion of the methodology that we contemplate using in the development of our estimate.

We announced in the August 24, 2001 proposed rule that we were considering a number of possible approaches to different technical aspects of estimating payments. We also indicated that, as is always the case in making these types of estimates, it would be necessary to make a number of assumptions in interpreting the data. We were tentatively contemplating using the following assumptions and techniques in developing our methodology:

1. Data and Procedures for Estimation

We planned to base the estimate of 2002 pass-through expenditures on the claims we would use to set payment rates for 2002; 2001 pass-through amounts for drugs and radiopharmaceuticals; and device cost and use data from pass-through applications submitted by manufacturers, hospitals, specialty societies, and other entities. We proposed to make projections to CY 2002 on the basis of price, volume, and service-mix inflators consistent with our baseline for OPPS spending. Estimates for drugs, radiopharmaceuticals, and devices would be made separately and combined for the final projection of pass-through spending.

2. Drug Estimate

We also proposed to identify those drugs eligible for pass-through status that have been separately billed to the Medicare program on the claims that we intend to employ for the estimate. We proposed to multiply the frequency of use for each of these drugs (that is, the number of line items multiplied by the number of units billed as shown in the claims data) by its 2001 pass-through payment amount. We would determine a reasonable adjustment to account for those drugs that do not appear in the claims data. Such an adjustment might take into account the extent to which the noncoded items were classified as orphan drugs and therefore to be used infrequently.

3. Radiopharmaceutical Estimate

As in the case of the drug estimates, we proposed to identify those radiopharmaceuticals eligible for pass-through status that were separately billed to Medicare in the claims data file. We proposed to estimate expenditures for these radiopharmaceuticals directly as described above. For radiopharmaceutical drugs, we would multiply the frequency of use for each item by the 2001 pass-through amount. We would estimate expenditures for the remaining items by using the frequency counts for all nuclear medicine procedures not billed with one of these radiopharmaceuticals.

4. Device Estimate

We proposed to estimate the transitional pass-through payments attributable to devices by linking the frequencies for all device-related procedures in the claims data file with the cost and use data supplied by the manufacturers or other entities as part of their applications for pass-through status. We proposed to match each device eligible as of January 2001 with the procedures with which it would be used. We would then calculate an average cost for each device or device package associated with a procedure.

The statute requires that we calculate transitional pass-through payments for devices by adjusting the hospital's charge for the device to cost and then subtracting an amount that reflects the device costs already included in the payment for the associated APC. As we explained in the April 7, 2000 final rule (65 FR 18481), we were not able to implement these subtractions at the time of implementation of the system. For 2001, we made these deductions for pacemakers and neurostimulators. In the August 24, 2001 proposed rule, we proposed to make these subtractions for most other devices beginning in 2002. For the purpose of doing this estimation, we proposed to deduct these amounts from each device package before multiplying that cost by the procedure frequencies.

5. Projecting to 2002

We planned to project prices and quantities in the estimates determined as above to 2002 using actuarial projections of price and enrollee volume and service increase consistent with the OPPS baseline. We then proposed to add the three separate results in an estimate of total pass-through spending.

We received over 80 comments in response to our proposal, including comments from national provider associations, hospitals, device and drug manufacturers, and their representative associations.

Comment: Many commenters expressed concern about the data and the methodology that we proposed to use in developing an estimate of pass-through spending for 2002. A number of these commenters specifically cited the lack of actual claims data under the OPPS as one major concern. Commenters doubted that claims from the period before implementation of the OPPS would contain sufficiently accurate coding or adequately reflect utilization of pass-through items to allow us to make an accurate estimate.

Response: We believe that the outpatient claims data submitted by hospitals for services furnished on or after July 1, 1999 and before July 1, 2000 provide adequate information for use in projecting pass-through spending for 2002. These claims are the most recent outpatient data available to us, and we are also using these claims for the purpose of recalibrating the APC relative weights for 2002. These data provide useful information on the frequencies of the procedures in which pass-through items are used, as well as of the utilization frequencies of some of the pass-through items themselves (especially drugs). Claims data for the period after the implementation of the prospective payment system are not at present available for analysis. Under the best of circumstances, we would only expect data from the prior calendar year to be available. Thus, only data from the first 5 months under the OPPS (August to December 2000) might be available at this point in the update cycle. However, the extent to which these data, were they available, would offer any significant improvement for these purposes is unclear. Those claims data would not contain information on most of the devices approved for pass-through payment in 2002 because those items became eligible for payment after January 1, 2001. It would still be necessary to use a crosswalk that maps devices to procedures in order to project spending for pass-through devices in 2002.

Comment: Some commenters questioned the appropriateness of using data on cost, utilization, and coding derived from applications from device manufacturers for pass-through status in developing the estimate. These commenters specifically contended that these data were not collected for the purpose of establishing payment amounts. They also contended that the cost, utilization, and coding information were not requested in a specific format on the applications, and that this information was therefore not presented in an appropriately consistent manner for the requisite level of analysis.

Response: The assertions of the commenters are incorrect. We were aware that we would have to develop estimates of pass-through costs for the purposes of applying the statutory limit on these costs when we developed the applications for pass-through status. We also knew at that time that we needed cost data in order to apply the cost significance eligibility criteria for pass-

through status. We deliberately developed the applications in order to generate reliable information on the cost, coding, and use of devices.

We specifically requested that the following information be uniformly provided: ''Current cost of the item or service to hospitals (*i.e.*, actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in-kind).'' We also specifically asked applicants to identify the Healthcare Common Procedure Coding System (HCPCS) or American Medical Association Current Procedural Terminology (CPT) service codes associated with each device application. We certainly assume that the manufacturers would be reliable sources of this information. We did not derive information on utilization frequencies solely from the manufacturers' applications for pass-through status. Rather, we calculated our projections of utilization by analyzing the claims at our disposal using a crosswalk of pass-through items to procedure codes that our clinical staff developed from the information supplied by manufacturers. The crosswalk established the CPT codes and the APCs with which the particular devices are used, while the claims data provided the frequency of use for devices in those APCs.

Comment: Many commenters questioned the validity of matching items eligible for pass-through payment with the procedures with which they would be used, citing the complexity of the CPT coding system and the variety and number of pass-through items that could be associated with particular procedure codes. The commenters asserted that a crosswalk that matched pass-through items and codes would require external review and validation. One commenter expressed concern that this crosswalk could overstate the frequencies of device use, since devices may not actually be used in every procedure where they could have been used.

Response: Using the information from the applications, our clinical staff (including physicians, nurses, and coding specialists) developed the device-to-procedure crosswalk. The staff employed a rigorous process of analysis and verification in developing this crosswalk. All members of the staff reviewed each tentative assignment of pass-through items to procedures. In order to minimize the use of individual clinical judgement, the staff made final decisions only after reaching a consensus on the assignment of pass-through items to each procedure. We are confident that the crosswalk reflects an appropriate level of analytical rigor and independent validation.

The clinical staff also followed a conservative approach in matching devices to procedures. Specifically, they assigned pass-through items only to procedures for those pass-through items that would be typically used, even if there were other procedures in which those items might occasionally be used. Moreover, the crosswalk specifically accounts for procedures where a device or devices might be used less than 100 percent of the time. We are confident that the crosswalk procedure itself has not in any way led to an overstatement of pass-through costs.

Comment: Many commenters asserted that the method described in the August 24, 2001 proposed rule is necessarily flawed because we excluded multiple service claims from the data.

Response: We use only single service claims in calibrating the APC weights because we have no way of allocating ancillary service costs among the various procedures on multiple service claims. However, for all other facets of our annual calculation of OPPS payment amounts and factors (for example, our estimate of outlier spending and resulting thresholds), we use both single and multiple service claims. Similarly, we included both single service and multiple service claims in developing our estimate of pass-through costs and the pro rata reduction. Specifically, we used both types of claims in developing the count of the procedures associated with the use of pass-through items.

Comment: Several commenters questioned whether we had provided sufficient notice of a possible pro rata reduction to comply with the requirements of the Administrative Procedure Act. These commenters contended that the description of the proposed method for calculating a pro rata reduction was too general to allow for adequate public comment and that the data supporting the need for such a reduction should have been published to allow for public review and analysis. One commenter argued that a pro rata reduction cannot be implemented legally without specifying the size of the reduction in a proposed rule with an adequate comment period. A commenter from the drug industry stated that data on utilization should be released in time for review and analysis so that the industry could have sufficient opportunity to assess the contribution of its products to pass-through spending and to develop options and recommendations for legislative and administrative action.

Response: At the time the August 24, 2001 proposed rule was published, we had assembled a data base and developed a preliminary methodology for making an estimate of pass-through spending in 2002. Our best judgment was that further review and analysis of the data and methodology were warranted before we announced a specific estimate of 2002 pass-through spending and any requisite pro rata reduction. We therefore confined our discussion in the proposed rule to the information that was then clearly known to us, namely the general methodology that we proposed to employ, and the likely magnitude of a pro rata reduction.

We believe that our description of our data sources and methodology allowed ample opportunity for substantive comment, and we did receive numerous substantive comments on both the data sources and the methodology. Furthermore, our notice that a ''significant pro rata reduction could be required for 2002'' provided interested parties sufficient opportunity to assess the situation and to develop options and recommendations for both legislative and administrative action. We received many comments with proposals and recommendations for administrative action, as well as proposals for possible legislative measures that commenters have urged us to bring to the attention of the Congress. (We respond to these comments below.) Finally, we note that section 1833(t)(12) of the Act provides that there ''shall be no administrative or judicial review * * * of the application of any pro rata reduction * * *.''

Based on the methodology described above, we estimate that the total amount of transitional pass-through payments for 2002 would exceed the limit of 2.5 percent of total spending under the OPPS. Specifically, we estimate that total transitional pass-through payments for 2002 would be about $2.26 billion, of which about $1.89 billion is attributable to devices and about $0.37 billion is attributable to drugs and radiopharmaceuticals. (Of the latter number, radiopharmaceuticals account for about $0.17 billion, and drugs account for about $0.20 billion.) Estimated total pass-through payments would thus be approximately 13 percent of the baseline projection of $17.5 billion in total payments (including both program and beneficiary payments) to hospitals in 2002 under the OPPS, and pass-through payments for devices are approximately 11 percent total of OPPS payments in 2002. Based on this estimate, a pro rata reduction of 80.7 percent would be required by the statute.

Many commenters recommended measures to delay or mitigate the effects of any pro rata reduction. These comments and our responses are set forth below.

Comment: A number of commenters requested a 1-year delay in implementing a pro rata reduction, citing their concerns about data limitations and methodological weaknesses as reasons for such a delay. Other commenters recommended that any pro rata reduction should be phased in over a period of several years in order to allow vendors and hospitals adequate time to adjust to the reduced payment.

Response: The statute specifically requires that, if the Secretary estimates before the beginning of a year that the amount of the pass-through payments for that year will exceed the limit, ''the Secretary shall reduce pro rata the amount of each of the additional payments * * * *for that year.*'' (Emphasis added.) Therefore, we can legally neither delay the reduction until a later year nor spread the reduction over the payments for several years. We now have an estimate of pass-through spending for 2002, and we have explained above why we believe that our methodology for determining it was reasonable.

Comment: Several commenters recommended that we use the amount ''reserved'' for outlier payments (up to 2.5 percent of OPPS payments) to increase the amount of money available for pass-through payments in order to reduce the need for a pro rata reduction. (As we have explained in other contexts, outlier payments are financed through a prospective reduction to PPS rates. We do not ''set aside'' money in a discrete fund to pay for outliers, and the same is true for pass-through payments.) Another commenter advocated that we fold the pass-through payments into the outlier ''pool,'' and pay for the high costs of new technology as part of our payment for high cost services of all types. Other commenters contended that the 2.5 percent limit on pass-through payments was inadequate to pay for the costs of new technologies and recommended that the limit be raised.

Response: The statute provides for both the outlier and transitional pass-through payments and establishes the 2.5 percent limits on those payments for the years before 2004 (when the limit for outliers increases to 3.0 percent and the limit for transitional pass-throughs decreases to 2.0 percent). Thus, we do not have the administrative authority to make any of the changes that these commenters have recommended. Rather, legislative action would be required to make any of these changes.

Comment: One commenter recommended that we move the procedures associated with pass-through items to the inpatient list so that they can be paid under the hospital inpatient PPS.

Response: We believe that the commenter is confused about the purpose of the inpatient list. The inpatient list identifies procedures that may not be paid under the OPPS. If medically necessary, any procedure, including those not on the inpatient list, that is performed in an inpatient setting may be paid under the hospital inpatient PPS. We decide which procedures are included on the inpatient list on the basis of clinical criteria alone. We believe that procedures should not be included on the inpatient list for payment reasons.

Comment: Several commenters asserted that a pro rata reduction will be necessary in 2002 only because we have failed to implement the transitional pass-through program as the Congress intended it. Specifically, these commenters contended that we have failed to restrict the pass-through payments to the incremental costs of new technologies by identifying the costs for predecessor technologies that are already represented in the APC payment rates and subtracting those amounts from the pass-through payments, as contemplated by the statute.

Response: Because of constraints on our data analysis before implementation of the pass-through provision, we did have difficulty initially in determining appropriate offsets for the technology costs already represented in the payment rates for many APCs. However, in the August 24, 2001 proposed rule, based on the updated claims data, we proposed appropriate offset amounts for 25 APCs that are associated with the use of pass-through devices. We will announce our final computations of the offset amounts for the affected APCs in a subsequent rule, which will be published before the beginning of the year. We will thus have substantially accounted for the technology costs that are already represented in APC payment rates, and, therefore, the magnitude of the pro rata reduction cannot be attributed to a failure to restrict pass-through payments to the incremental costs of new technology.

Comment: Many commenters expressed their concern about the prospect for a significant pro rata reduction, and the potential effect of such a reduction on access of Medicare beneficiaries to necessary treatments in the outpatient setting. These commenters therefore urged us not to implement a pro rata reduction in 2002.

Response: A significant pro rata reduction could affect the availability of improved medical technology for Medicare beneficiaries, but the possibility of such a result is inherent in the statutory scheme. The Congress has set up a scheme to limit the aggregate amount of (projected) pass-through payments in a given year, including a requirement for a pro rata reduction. The statute reflects a balance of competing considerations— providing pass-through payments for new technologies but limiting the aggregate amount of those payments so that payments for other services are not reduced significantly (if there were no limit on projected pass-through payments, then, other things being equal, we would be reducing the base payments by 13 percent rather than 2.5 percent to ensure budget neutrality). In order to promote access to new technologies, we have decided to take a significant administrative action in order to reduce the size of the reduction. That action, which incorporates a portion of the pass-through costs into the base APCs, is discussed below. We believe that there are no other feasible and prudent administrative options available to reduce the amount of a pro rata reduction.

Comment: Several commenters, including device manufacturers and the associations that represent them, recommended that we fold the costs of pass-through devices into the base APC rates. These commenters noted that such a step would limit pass-through payments to the incremental costs of new technologies, and at least reduce the size of a pro rata reduction. Some of these commenters urged us not to implement any pro rata reduction until we have revised the base rates to include these costs.

Response: The transitional pass-through payment provision was intended as an interim measure to allow for adequate payment of new, innovative technology while we collected the necessary data to incorporate the costs for these items into the base APC rates. The statute and regulations specifically limit the payment for individual pass-through items to at least 2 years but no more than 3 years, with the intention that the costs for these items should be incorporated into the APC rates for the procedures associated with these items after that period. We agree with these commenters that we have the discretion to fold some of these costs into the APC rates before the time period for

transitional payment of specific devices has expired. (We cannot fold all of the current pass-through costs into the APC rates at this time, because the statute implies that pass-through payments for devices that have been eligible for less than 2 years must continue to be made.)

We also agree with the commenters that it is reasonable and prudent to incorporate some of the pass-through costs into the APC rates now, before we are legally required to do so, in order to mitigate the effects of the significant pro rata reduction that is mandated by the statute. Prudence also dictates, however, that we take into account all the other effects of incorporating these costs into the base rates at this time in deciding how much of the costs to incorporate into the base rates for 2002.

In addition to reducing the size of the pro rata reduction, incorporating a portion of the cost of pass-through devices into the basic APC costs has an effect on the APC relative weights. This is because the costs to be incorporated are not evenly distributed among the APCs, but are rather concentrated in a relatively small number of APCs that include the procedures that use pass-through devices. The effect of incorporating pass-through costs into the APCs is thus to decrease the APC weights for services such as clinic visits, preventive care, and diagnostic tests, while the weights for the APCs into which the pass-through costs are incorporated generally increase, often by large percentages.

In addition, increases in the relative weights for some APCs can lead to increases in beneficiary copayments because, by statute, the coinsurance rate cannot be less than 20 percent of the payment rate for an APC. We note, however, that beneficiaries are protected from much of this increase on an individual APC basis because section 1833(t)(8)(C) of the Act limits the copayment for a procedure performed in a year to no more than the amount of the inpatient hospital deductible for that year. For CY 2002, that amount is $812.

Accordingly, choosing a percentage of the estimated pass-through costs for devices to fold into the APCs associated with the use of those devices requires us to balance several considerations. We must be mindful not only of the effect on transitional pass-through payments for drugs and devices, but also on the payments for other services and on beneficiary copayments. In addition, we note that, in CY 2003, almost all of the items currently receiving transitional pass-through payments will have reached the end of their eligibility for this payment status, and their costs must be folded into the APCs at that time. Changes made in CY 2002 will thus provide a transition to rates in CY 2003. After weighing these factors, and considering the potential impacts of a variety of options, we have concluded it is appropriate to incorporate 75 percent of the estimated pass-through costs for devices into the procedure APCs associated with these devices. We are incorporating 75 percent of the device pass-through payments, or approximately $1.4 billion, into the costs that are used to establish the APC relative weights for 2002.

We are not incorporating any of the current drug and biological pass-through costs into the APCs for two reasons. First, the costs for drugs and biologicals are already incorporated to a large extent into a base APC rate. As discussed more fully in the August 24, 2001 proposed rule (66 FR 44701), we assume that, for most drugs, 68 percent of the AWP is acquisition costs of the drug or biological that is already recognized in the base costs. Thus, the pass-through payment for those drugs and biologicals is 27 percent of the AWP. Second, it is generally not feasible to determine which APCs are associated with the use of drugs and biologicals from our current claims data. Unlike devices, which are used solely in the performance of certain procedures, drugs and biologicals can be provided in connection with almost any outpatient service. Thus, we are postponing the incorporation of these costs until we have data that allow us to determine the APCs with which the use of these items is associated. We note, however, that the pro rata reduction will be applied to the pass-through payment for drugs and biologicals as well as devices.

To incorporate 75 percent of the device payments, we are employing the following methodology. We use the crosswalk that we developed as part of the methodology for estimating total pass-through spending as the basis for determining the device costs that we include in setting the relative weight for each APC. As we have discussed above, this crosswalk matches devices to the typical procedures in which they are used.

In developing the total pass-through estimate, we used this crosswalk to produce a device package for each CPT code associated with device use, based on the device or devices used in each procedure included in an APC. We adjusted the costs of each package by subtracting the device costs already represented in the payment amount for the APC. (These are the costs that we deduct from each pass-through payment to ensure that the pass-through payments are limited to the incremental costs of the new technologies. The principle for making this subtraction is the same in each case: to avoid double-counting costs already represented in the APC rates.) We then add 75 percent of these adjusted costs of the package to the costs at the claim level for each device-related procedure in the APC. At this point, we determine a revised median cost for the APC. That new median cost in turn is the basis for the APC's new relative weight.

The costs folded in will affect the relative weights of the APCs. The resulting APC payment rates will not increase on a dollar-for-dollar basis with the device costs folded into the APCs. In most cases, the device costs folded into an APC will not be uniformly distributed among the procedures in that APC. This is because procedures in an APC may require different types or numbers of devices and some procedures may not require devices at all. Therefore, the increase in median cost for an affected APC is unlikely to exactly equal the amount of the cost folded in. Furthermore, the statute requires that APC recalibration and reclassification changes be made in a manner that assures that aggregate payments will be neither greater nor less than they would have been without the changes. Changes in an APC's payment rate therefore cannot be expected to vary on a dollar-for-dollar basis with changes in the costs used to determine the APC's relative weight.

Finally, we note that the initial payments under the OPPS were calculated to be budget neutral to the methodology in use before the implementation of the OPPS. The prior payment methodology paid hospitals, on average, approximately 83 percent (the actual payment-to-cost ratio under the prior system) of their costs for furnishing outpatient services. Under the pass-through payment methodology, eligible devices are paid at 100 percent of their costs. Once these costs are incorporated into the APCs, they will also be paid at rates calculated to reflect these reductions.

The increase in APC rates due to the incorporation of these pass-through costs will be offset against the estimated 2002 pass-through payments. (As discussed above, we subtract the amount of the pass-through costs represented in the rate for the associated APC from each pass-through payment.) The remaining amount of estimated pass-through spending for 2002, once we have applied these offsets, will be subject to the pro rata reduction. Because we have not completed the recalculation of the adjusted APC payments, we are unable to provide the

specific amount of the pro rata reduction at this time. We will announce the exact amount of the reduction that will be required before the beginning of 2002. In the meantime, we are announcing that we expect the required reduction will be in the range of 65 to 70 percent. As can be seen from this estimate, folding in 75 percent of the device costs into the APCs does not reduce the pro rata by 75 percent. The following is a simplified illustration of the process.

Example: Assume there is only one device eligible for a pass-through and only one associated APC. That APC has a payment rate of $3,000, of which $1,000 is associated with device costs already in the APC. If a hospital bills a device with that APC whose charge adjusted to cost is $9,000, the payment for the pass-through is $9,000 minus $1,000, or $8,000. Thus, the payment for the entire service is $3,000 for the base APC and $8,000 for the device, for a total payment of $11,000. The pro rata reduction would be applied to the $8,000. If we were to implement the 80.7 percent reduction, the total payment would be $4,544 ($3,000 + $8,000 (0.193)).

For the 75 percent fold-in, we would first adjust the $9,000 device cost to account for the $1,000 in device costs already represented in the APC rate. The remaining $8,000 represents the adjusted costs for the device. We would then incorporate $6,000 of the $8,000 in adjusted costs into the APC rate. As discussed above, the increase in the APC rate is not a dollar-for-dollar match with the amount folded in. Therefore, assume that the APC rate increases by $3,500, for a total of $6,500. The $6,500 payment rate now reflects $4,500 in device costs '' the original $1,000 plus the difference between the original APC payment ($3,000) and the APC payment rate after the fold-in ($6,500), or $3,500. The increase in the amount of device costs reflected in the APC is a dollar-for-dollar match with the increase in the payment rate. The total payment for the service is now $6,500 for the base APC and $4,500 for the device ($9,000 minus $4,500), for a total payment of $11,000. Even though 75 percent of the $8,000, or $6,000, has been folded into the APC rate, the pass-through payment (before any pro rata reduction) is reduced by only $4,500, to $4,500. Thus, folding in 75 percent of the device costs does not reduce the total pass-through estimate by that same 75 percent. However, any remaining pro rata reduction would be applied only to the $4,500. Based on an expected reduction of between 65 and 70 percent, total payment would be between $8,075 and $7,850, respectively.

Comment: Several commenters requested that we clarify how the incorporation of pass-through costs into the associated APCs would affect the APC payments. Specifically, some of these commenters requested that we clarify whether there would be a dollar-for-dollar match between the costs incorporated into an APC and the resulting increase in the APC's rate. Others asked whether there would be a dollar-for-dollar match between the increase in the APC's rate and the increase in the reduction in the pass-through payments to account for the device costs incorporated into the APC.

Response: As discussed in the response immediately preceding, there is not a dollar-for-dollar match between the costs incorporated into an APC and the resulting increase in the APC's payment rate. There is, however, a dollar-for-dollar match between the increase in an APC's rate and the increase in the reduction for the pass-through payment for devices associated with that APC. This is because the additional payment for a pass-through item equals the amount by which the hospital's cost for the item exceeds the portion of the applicable APC payment amount that is associated with the item. There is thus necessarily a dollar-for-dollar match between the increase in the APC's rate that is due to the new costs being incorporated into the APC, and the reduction applied to the pass-through payments.

Comment: Several commenters made specific requests for data files and other information related to any possible pro rata reduction. These requests included the following:

- The data files used to estimate pass-through spending, including claims data from the period July 1, 1999 and July 1, 2000.
- A comprehensive description of the methods used to identify gaps in the reporting of drugs, biologicals, and devices, and the assumptions used to estimate utilization of pass-through items.
- An estimate of projected pass-through payments for 2002, including breakdowns by category (orphan drugs, cancer drugs, devices, etc.).
- An estimate of the magnitude of any proposed reduction in pass-through payments to meet the 2.5 percent statutory cap.
- A detailed description of how any pro rata reduction would be implemented.

Response: It is our general practice to release the data we use in setting Medicare payment amounts to the public when we announce proposed payment amounts. Some of the data requested by these commenters, especially the relevant claims data for the period July 1, 1999 and July 1, 2000, were in fact released at the time of the August 24, 2001 proposed rule because these data were used in developing the proposed APC payment rates in that rule. We did publish a substantive description of the methodology that we were proposing to use in developing an estimate of pass-through costs, and we received numerous comments on that proposed methodology. To the degree that we did not release some of the other information requested by these commenters, such as an estimate of a proposed pro rata reduction and a breakdown of pass-through costs by category, it was because we were still reviewing our methodology and analyzing the data. We did, however, present the public with the likely magnitude of a reduction at that time.

In this final rule, in response to the comments, we are providing more information on the methodology that we have used to determine the pro rata reduction. We are also providing a detailed account of our calculation of 2002 pass-through costs. We plan to release additional information when we announce the exact percentage of the required pro rata reduction before the beginning of the year. The pro rata reduction will be implemented by our systems as a uniform reduction to every pass-through payment.

Comment: The Medicare Payment Assessment Commission commented that the transitional pass-through provision has three flaws:

- The use of categories to determine the eligibility of devices allows devices the costs of which had already been taken into account in setting the base rates to qualify for pass-through payments.
- The pass-through payments for drugs and biologicals are set at 95 percent of average wholesale cost, thus creating an incentive to increase Medicare payments by raising prices for these items.
- Pass-through payment rates are based on hospital-specific cost-to-charge ratios, allowing hospitals to increase their payments by raising the charges for eligible items.

The Commission recommended that the Congress enact three statutory changes to improve the transitional pass-through provision:

- Restrict the eligibility for pass-through payments to technologies that are new or substantially improved and that add substantially to the cost of care.
- Allow for the costs of pass-through items to be completely incorporated into the base APC rates more quickly than the current statutory eligibility period of 2 to 3 years allows.

• Replace the facility-specific payments for devices with national payments.

Response: We appreciate the Commission's comments about flaws in the transitional pass-through provision. We will be available to provide technical assistance to the appropriate congressional committees in developing measures to improve the provision. We do note, however, that although the use of categories allows devices whose costs had previously been included in the calculation of the APC payment rates to qualify for pass-through payments, those payments will be reduced by the amount that we have calculated to be reflected in that APC. However, this subtraction of the costs in the APC may not reduce the pass-through payment for those devices to zero.

III. Conversion Factor Update for CY 2002

Section 1833(t)(3)(C)(ii) of the Act requires us to update the conversion factor used to determine payment rates under the OPPS on an annual basis. Section 1833(t)(3)(C)(iv) of the Act, as redesignated by section 401 of the BIPA, provides that for 2002, the update is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act, reduced by one percentage point. Further, section 401 of the BIPA increased the conversion factor for 2001 to reflect an update equal to the full market basket percentage increase amount.

To set the proposed OPPS conversion factor for 2002, we increased the 2001 conversion factor of $50.080, which reflects the BIPA provision of the full market basket update, by 2.3 percent, that is, the full market basket percentage increase of 3.3 percent minus 1 percentage point.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the conversion factor for 2002 to ensure that the revisions we made to update the wage index are made on a budget-neutral basis. A proposed budget neutrality factor of 0.9924 was calculated for wage index changes by comparing total payments from our simulation model using the proposed FY 2002 hospital inpatient PPS wage index values to those payments using the current (FY 2001) wage index values.

The increase factor of 2.3 percent for 2002 and the required wage index budget neutrality adjustment of 0.9924 resulted in a proposed conversion factor for 2002 of $50.842.

Based on the 2.3 percent update factor and the final FY 2002 hospital inpatient wage index values, the final wage index budget neutrality adjustment is 0.9936, which results in a final conversion factor for 2002 of $50.904.

We received one comment on the calculation of the conversion factor.

Comment: One commenter requested clarification of the methodology used to calculate the conversion factor for CY 2002, particularly as it relates to the payment update provided by section 401 of BIPA. The commenter is concerned that we did not explain that the CY 2001 conversion factor we set forth in the August 24, 2001 proposed rule as the basis for the CY 2002 conversion factor was never used to make payment in CY 2001.

Response: Before the enactment of BIPA on December 21, 2000, section 1833(t)(3)(C)(iii) of the Act provided for a 2001 update of the market basket percentage increase reduced by 1 percentage point. This is the update that was implemented by the November 13, 2000 final rule (65 FR 67827).

Section 401(a) of BIPA amended section 1833(t)(3)(C)(iii) (redesignated by section 401(b) of BIPA as section 1833(t)(3)(C)(iv)) of the Act to provide for a full market basket percentage increase for CY 2001. However, section 401(c) of BIPA also provided a special payment rule for CY 2001 that requires the payment rate for services furnished under the OPPS on or after April 1, 2001 and before January 1, 2002 to be updated by an additional 0.32 percent to account for the timing of the implementation of the full market basket update for 2001. Thus, the conversion factor used to make payment on or after January 1 and before April 1, 2001 was based on a market basket percentage increase minus 1 percentage point, and the conversion factor used to make payment on or after April 1, 2001 was based on a full market basket percentage increase increased by 0.32 percent. Payment was never made in 2001 using a conversion factor based on a full market basket percentage increase. However, it is this last conversion factor (which is equal to $50.080) that must be used to update the conversion factor for CY 2002.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Regulatory Impact Analysis

A. General

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

The statutory effects of the provisions that are implemented by this final rule result in expenditures exceeding $100 million per year. We estimate the total impact of these changes for CY 2002 payments compared to CY 2001 payments to be approximately a $400 million increase. Therefore, this final rule is an economically significant rule under Executive Order 12866, and a major rule under 5 U.S.C. 804(2).

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 to $25 million or less annually (see 65 FR 69432). For purposes of the RFA, all providers of hospital outpatient services are considered small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us 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. With the exception of hospitals located in certain New England counties, 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 (MSA) and has fewer than 100 beds, or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New

England counties as belonging to the adjacent NECMA. Thus, for purposes of the OPPS, we classify these hospitals as urban hospitals.

It is clear that the changes in this final rule affect both a substantial number of rural hospitals as well as other classes of hospitals, and the effects on some may be significant. The discussion below, in combination with the rest of this final rule, constitutes a regulatory impact analysis.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This final rule does not mandate any requirements for State, local, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined this final rule in accordance with Executive Order 13132, Federalism, and have determined that it will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

B. Changes in This Final Rule

This final rule implements changes to the OPPS that are required by the statute. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. In addition, section 1833(t)(6)(E)(iii) of the Act requires a uniform reduction in the amount of each of the transitional pass-through payments made in a year if the Secretary estimates, before the beginning of that year, that the total pass-through payments will exceed an applicable percentage of total payments estimated to be made under OPPS in that year. For CY 2002, the applicable percentage is 2.5 percent.

The projected aggregate impact of updating the conversion factor is to increase total payments to hospitals by 2.3 percent. As described in the preamble, a budget neutrality adjustment is made to the conversion factor to assure that the revision in the wage index does not affect aggregate payments.

C. Estimated Impacts of This Final Rule

The 2.3 percent update in the conversion factor results, in the aggregate, in an increase in payments for hospitals under the OPPS of approximately $400 million.

As discussed above in section II of this preamble, we have estimated that the total amount of pass-through payments for CY 2002 would be $2.26 billion if we did not fold in costs of pass-through devices into the base APC rates. Of that amount, approximately $0.37 million represents payments for drugs and biologicals and $1.89 billion represents payments for medical devices. Total OPPS payments in CY 2002 are estimated to be $17.5 billion. Because the estimate of pass-through payments exceeds 2.5 percent of estimated total payments, which is approximately $437 million (2.5 percent of $17.5 billion), we must implement a uniform reduction of all pass-through payments. Absent any administrative action, the estimate of the reduction necessary to account for the full pass-through estimate would be 80.7 percent. That is, we would pay 19.3 percent of the otherwise applicable pass-through payment for drugs, biologicals, and devices.

As further discussed above in section II of this preamble, in order to mitigate the effects of this significant pro rata reduction, we are incorporating, into the base APC costs, 75 percent of the cost of the devices currently eligible for pass-through payment. In the proposed rule, we estimated for most APCs that involve devices, an amount that represents the cost of devices already included in the APC payments. Those amounts would be subtracted from any pass-through payments associated with those APCs (before the pro rata reduction). That policy reduced the total estimate of pass-through payments by approximately $450 million. Because we are now incorporating additional device costs into the base APC costs, those subtraction amounts will increase to reflect the additional amounts included in the device-related APC payments. Thus, the total amount of pass-through payments estimated to be made in CY 2002 will be reduced, which will, in turn, reduce the amount of the pro rata reduction necessary to meet the 2.5 percent limit. As noted above in this preamble, because we have not yet completed our analysis and computations related to the fold in, we cannot yet announce the exact size of the pro rata reduction. However, we estimate that the amount of the reduction will be between 65 and 70 percent. The incorporation of costs into the base APCs results in the pro rata reduction being applied only to the marginal costs of the pass-through devices not incorporated into the APCs.

We believe that the changes we have made in this final rule will lessen the impact on hospitals of the required pro rata reduction on pass-through payments.

We estimate that the implementation of the pro rata reduction on pass-through payments for devices will affect urban hospitals more than rural hospitals and, in urban areas, large urban and teaching hospitals will be affected more than other urban hospitals. This is due to the fact that the types of outpatient procedures that use the pass-through devices are more frequently performed in large urban hospitals, particularly teaching hospitals. We estimate that the effect of the reduction on pass-through payments for drugs and biologicals may be more uniform across types of hospitals. Use of these items is more widespread among hospitals, although hospitals that furnish chemotherapy may be affected to a greater degree than others.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR part 419 is amended as follows:

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

2. In § 419.62, paragraph (c) is republished and a new paragraph (d) is added to read as follows:

§ 419.62 Transitional pass-through payments: General rules.

* * * * *

(c) *Uniform prospective reduction of pass-through payments.* (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

(d) *CY 2002 incorporated amount.* For CY 2002, CMS incorporated 75 percent of the estimated pass-through costs (before the incorporation and any pro rata reduction) for devices into the procedure APCs associated with these devices.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 30, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 26, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–27659 Filed 10–31–01; 12 pm]

BILLING CODE 4120–01–P

Federal Register

Friday,
November 2, 2001

Part VI

The President

Notice of October 31, 2001—Continuation of Sudan Emergency

Federal Register
Vol. 66, No. 213
Friday, November 2, 2001

Presidential Documents

Title 3—

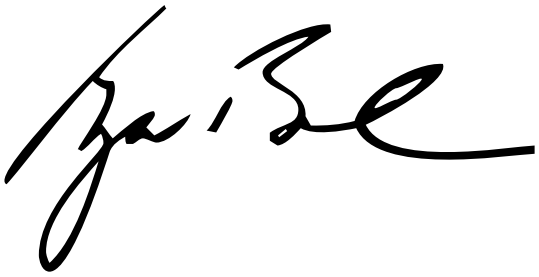
The President

Notice of October 31, 2001

Continuation of Sudan Emergency

On November 3, 1997, by Executive Order 13067, the President declared a national emergency with respect to Sudan pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701-1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions and policies of the Government of Sudan, including continuing concern about its record on terrorism and the prevalence of human rights violations, including slavery, restrictions on religious freedom, and restrictions on political freedom. Because the actions and policies of the Government of Sudan continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States, the national emergency declared on November 3, 1997, and the measures adopted on that date to deal with that emergency must continue in effect beyond November 3, 2001. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Sudan.

This notice shall be published in the **Federal Register** and transmitted to the Congress.



THE WHITE HOUSE,
October 31, 2001.

[FR Doc. 01–27777
Filed 11–1–01; 9:18 am]
Billing code 3195–01–P

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H.J. Res. 70/P.L. 107–58

Making further continuing appropriations for the fiscal year 2002, and for other purposes. (Oct. 31, 2001; 115 Stat. 406)

Last List October 31, 2001

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