

RULEMAKING ISSUE AFFIRMATION

April 3, 2007

SECY-07-0062

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: FINAL RULE: REQUIREMENTS FOR EXPANDED DEFINITION OF
BYPRODUCT MATERIAL (RIN: 3150-AH84)

PURPOSE:

To request Commission approval to publish a final rule in the *Federal Register* that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171.

SUMMARY:

The staff has developed a final rule establishing the regulatory framework for certain radium sources, accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material (hereafter referred to as NARM). This rulemaking is required by Section 651(e) of the Energy Policy Act of 2005 (EPAAct), which expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954 (AEA). The final rule revises the definition of "byproduct material," adds a definition for "discrete source," and amends existing regulations and adds certain provisions in order to provide the regulatory framework for the newly added byproduct material.

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BACKGROUND:

The EPAct was promulgated on August 8, 2005. Section 651(e) of the EPAct expanded the definition of byproduct material, as defined in Section 11e. of the AEA, to include certain discrete sources of radium, certain accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material, thereby placing these materials under U.S. Nuclear Regulatory Commission (NRC) jurisdiction. Specifically, Section 651(e)(1) of the EPAct expanded the definition of byproduct material by:

- (1) Adding as Section 11e.(3)(A) of the AEA--any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity;
- (2) Adding as Section 11e.(3)(B) of the AEA--any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity; and
- (3) Adding as Section 11e.(4) of the AEA--any discrete source of naturally occurring radioactive material, other than source material, that (a) the Commission, in consultation with other Federal officials named in the EPAct, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (b) is extracted or converted after extraction, before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity.

The NRC is also required by the EPAct to include a definition of “discrete source” in the regulation for the newly added byproduct material.

The NRC is required under Section 651(e) of the EPAct to develop a regulatory framework for licensing and regulating this newly added byproduct material. The EPAct requires NRC to consult with the States and other stakeholders in establishing requirements, and, to the maximum extent practicable, to cooperate with the States and to use model State standards in developing regulations for the newly added byproduct material. To enhance cooperation with the States and to improve efficiency in rulemaking, the staff has coordinated with both the Organization of Agreement States, Inc. (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD) since the beginning of this rulemaking process. OAS and CRCPD representatives have participated in the NARM Rulemaking Working Group and the Steering Committee in developing and finalizing this rule. The staff also has engaged the States, other Federal agencies, and other stakeholders by working closely with their representatives and by making information on this rulemaking readily available to the public. To the maximum extent practicable, the staff used the Suggested State Regulations for the Control of Radiation (SSRs) developed by the CRCPD as the model State standards in formulating regulatory requirements for the newly added byproduct material.

The EPA Act requires NRC to issue final regulations within 18 months from the date of enactment (by February 7, 2007). However, in order to ensure that the rule has a sound technical basis, and in order to provide the appropriate time for stakeholder input, the staff required additional time to develop the regulations and with the Commission approval extended the date. Appropriate members of Congress were then notified of the change in the expected publication date of the final rule.

DISCUSSION:

On July 28, 2006, the proposed rule was published in the *Federal Register* (71 FR 42952) for a 45-day public comment period. The staff held a public meeting in Las Vegas on August 22, 2006, during the public comment period, to solicit comments and to enhance stakeholder involvement. Several individuals provided written statements and oral comments during the public meeting. In addition, the NRC received a total of 39 comment letters on the proposed rule from States, other Federal agencies, professional organizations, universities, medical communities, industries, and individuals.

Comments from OAS and the States were primarily centered around implementation of the requirements for the Compatibility Category of Health and Safety designation for several definitions, especially the definition of "byproduct material." The basic concern was the need to amend definitions in State statutes and regulations. OAS and the States suggested that the Statements of Consideration for the final rule could indicate that the NRC's initial determination of the adequacy of definitions would rely on the Governor's certification that the State's program is adequate and that no changes to the State's definitions would be required. In response, the staff did modify the Statements of Consideration to indicate that States may continue to use the existing definitions including "radioactive material" in State statutes and regulations, although States may need to revise their regulations to adopt certain requirements of this rule.

In addressing the public comments, changes were made in finalizing the rule. The changes between the proposed and final rule are highlighted in the following paragraphs.

Definition of Discrete Source

Section 651(e)(4) of the EPA Act requires NRC to include in its regulations a definition for "discrete source." This definition of "discrete source" will apply to radium-226 and other naturally occurring radioactive material, other than source material, that are now defined as byproduct material. The term "discrete source" does not apply to accelerator-produced radioactive material. The staff notes that this new NRC authority over radium-226 and other naturally occurring radioactive material does not extend to all naturally occurring radioactive material found in nature in its original form, concentration, and location.

The proposed rule included the following definition of discrete source: "*a source with physical boundaries, which is separate and distinct from the radiation present in nature, and in which the radionuclide concentration has been increased by human processes, with the intent that the concentrated radioactive material will be used for its radiological properties.*" Some commenters on the proposed rule expressed concern about the clarity of the definition. Several commenters believed that such provisions as the requirement that the source have physical boundaries and that the materials have been concentrated for their radiological properties were

ambiguous and could lead to uneven regulation. As a result of public comments, the staff changed the wording of the definition. The changes are for clarification purposes only and do not alter the original intent or the scope of the definition as presented in the proposed rule. In the final rule, discrete source is defined as: *“a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.”* This definition continues to exclude NRC jurisdiction over inadvertent movement or concentration of naturally occurring radioactive material, such as scale from pipes used in the fossil fuel industry, fly ash from coal power plant, phosphate fertilizers, or residuals from treatment of water. NRC’s authority over source material is not changed.

Regulatory Approach for Old Timepieces Containing Radium-226

In the proposed rule, the NRC specifically requested comments regarding the proposed exemption and licensing approach for radium-226 and requested technical, health, and safety information in support of an exemption of old radium-226 sources but did not receive any substantive information. In order to obtain a sound technical basis for its proposed regulatory approach, the staff conducted a scoping study for estimating potential doses to individuals associated with use, storage, and repair of radium-226 timepieces. The staff used widely accepted methods and employed conservative assumptions for various scenarios. In order to evaluate the potential doses associated with the proposed exemption of radium-226 timepieces, 1 microcurie (μCi) [37 kilobecquerels (kBq)] of radium-226 per timepiece was used in the scoping study instead of the typical average activities for timepieces, which provided additional conservatism. The average activities for wristwatches, pocket watches, and clocks are 5.6 kBq (0.15 μCi), 13 kBq (0.35 μCi), and 18 kBq (0.5 μCi), respectively. Radon-222 is a decay product in radium-226 and may be emitted from the timepiece resulting in exposure to an individual in proximity to the timepiece. Although it is believed that most of the radon-222 would be trapped within the timepiece, the scoping study assumed that the entire inventory of decay products instantly escaped from the timepiece because there is no established method for quantifying the trapping behavior. As a result, the estimated inhalation doses associated with radon-222 are extremely conservative. The scoping study found that the estimated doses for radium-226 exposures and radon-222 inhalation of a collector for repair, storage, and use of one radium-226 timepiece range from a fraction of 0.01 millisievert/year (mSv/yr) [1 millirem/year (mrem/yr)] to a few 0.01 mSv/yr (1 mrem/yr) to over 1 mSv/yr (100 mrem/yr).

It is important to note that the manufacturing of timepieces containing radium-226 discontinued in 1968 for watches and in 1978 for clocks. To date, a large number of radium-226 timepieces are still owned by individuals as heirlooms or collectors’ items or are on display in museums. Since collectors and museums normally collect a wide range of timepieces, only a portion of their collections may contain radium-226 timepieces. Collections of pocket watches and clocks are rare when compared to wristwatches. At one time, there were repair facilities refurbishing radium timepieces on a regular basis by replacing radium-226 paint with tritium paint, which may have resulted in contamination from scraping off radium-226 paint. The staff is not aware of any current operations in which individuals are still routinely handling radium watches in such a way that may create a contamination problem.

In finalizing the rule, the staff considered a number of factors such as that: (1) These timepieces were manufactured before the NRC assumed regulatory authority over radium-226;

(2) These timepieces are already in public possession; (3) These timepieces are mostly kept as collectors' items or museum pieces; (4) The scoping study indicates no significant risk to public health and safety and the environment; and (5) Most Agreement States have managed these items as if they were exempt. As a result of its review, the staff has determined that no change is needed from the proposed rule to exempt previously manufactured, intact timepieces containing no more than 37 kBq (1 μ Ci) of radium-226. However, a change was made to regulate the repair of timepieces and the possession of nonintact timepieces, hands and dials, and timepieces containing 37 kBq (1 μ Ci) or more of radium-226, under a general license, to be consistent with the SSRs and to provide regulatory flexibility for the Agreement States. The combination of the exemption and general license provisions should cover most of the current practices involving timepieces containing radium-226 and minimize impacts to individual collectors and small businesses. A general license is automatically granted by NRC regulations to any persons meeting the general license criteria. No action is required from these persons to obtain a general license, and license or annual fees are normally not applicable to these persons operating under this general license.

Regulating Other Radium-226 Sources

In response to public comments, the general license provisions for luminous gauges and other luminous products containing radium-226 were changed. Specifically, the provision for luminous items installed in aircraft was expanded to include those installed in air, marine, and land vehicles. Two subparagraphs in 10 CFR 31.12 for the general license were revised and simplified in the final rule. One subparagraph that allowed no more than 50 luminous products, including timepiece hands and dials, now covers only timepieces and timepiece hands and dials, and the number limitation was eliminated because it was determined to be unnecessary based on the scoping study. The other subparagraph that allowed no more than 100 luminous items no longer installed in aircraft, is simplified to allow all other luminous products, and the number of luminous items remains unchanged at 100 items. In addition, a provision was added to exempt individuals operating under a general license from reporting and recordkeeping requirements to further reduce the regulatory burden on stakeholders.

Regulating Accelerator-Produced Radioactive Material

Through reviewing the public comments, it became clear that the discussion in the proposed rule on the distinction between radionuclide production licensing and radioactive drug production licensing was confusing. The regulations were restructured and the Statements of Consideration expanded to give a clearer overview of the regulatory framework. The production of radionuclides by accelerators (including Positron Emission Tomography (PET) radionuclides from cyclotrons), as well as the subsequent possession and use of these radionuclides, will be licensed under existing requirements in 10 CFR Part 30. The producer of the accelerator-produced radionuclides (including PET radionuclides) can transfer these radionuclides to manufacturers and other specific licensees under the provisions of 10 CFR 30.41. This includes both commercial and noncommercial distribution of accelerator-produced radionuclides (including PET radionuclides) to specifically licensed universities and research laboratories, for basic research, but not for use on human beings which is specifically excluded in the definition of research and development in 10 CFR 30.4.

There is a distinction between the “production of radionuclides” and “preparation of radioactive drugs.” Production of radionuclides (including production of PET radionuclides using a cyclotron) is regulated under 10 CFR Part 30. Preparation of radioactive drugs (including PET radioactive drugs) from radionuclides is regulated under 10 CFR 32.72 and 10 CFR Part 35; preparation of radioactive drugs may occur at locations other than the production facility. In the proposed rule, a provision was included in 10 CFR 32.72 to authorize commercial nuclear pharmacies that were not registered with the Food and Drug Administration, or registered with a State as a PET drug production facility, to produce PET radionuclides if their radiation safety programs meet the criteria in 10 CFR 30.33. Since the purpose of 10 CFR 32.72 is to address the criteria and requirements for the production and commercial distribution of radioactive drugs, and not the production of radionuclides, this particular provision was removed from the rule. Activities related to production of radionuclides are governed under 10 CFR Part 30 regulations.

Noncommercial Distribution of PET Radioactive Drug

Because of the extremely short half-life of PET radionuclides for medical use, a PET radionuclide production facility is generally located near the medical use facility. Therefore, there is a need for noncommercial distribution of PET radioactive drugs, and provisions were included in the proposed rule to allow noncommercial distribution of PET radioactive drugs. Public comments indicated that there was some confusion about these provisions. As a result of public comments, the provisions for noncommercial distribution were restructured for clarification purposes. Specifically, provisions were moved from 10 CFR Part 35 to 10 CFR Part 30 to provide for the licensing of a radionuclide production facility and for noncommercial transfers of PET radioactive drugs to licensees within the same consortium. The provisions were moved because a PET radionuclide facility is regulated under 10 CFR Part 30 requirements, and it may not also have a medical use license under 10 CFR Part 35. In addition, a definition of consortium has been added.

Derived Air Concentrations for Nitrogen-13 and Oxygen-15

During the development of the proposed rule, the staff performed a preliminary calculation and found that the calculated values for nitrogen-13 and oxygen-15 are larger than the default values in Appendix B of 10 CFR Part 20 for Derived Air Concentration (DAC) and effluent concentration only by a factor of about 40 and 20, respectively. Because the approach used to calculate values for these radionuclides is different from that used for other radionuclides included in 10 CFR Part 20, Appendix B, due to lack of certain dose conversion factors and because the SSRs do not include DAC values for nitrogen-13 and oxygen-15, the NRC did not add specific values for these radionuclides in the proposed rule. In response to comments from the medical community, the staff conducted a study to develop scientifically sound inhalation dose coefficients for occupational and public exposures for nitrogen-13 and oxygen-15. Based on the results of the study, a specific DAC value of 1.48×10^{-2} becquerels per milliliter (Bq/ml) (4×10^{-6} μ Ci/ml) and a corresponding effluent concentration of 7.4×10^{-4} Bq/ml (2×10^{-8} μ Ci/ml) for both nitrogen-13 and oxygen-15 are added to 10 CFR Part 20, Appendix B, in the final rule.

Implementation Strategy

In the proposed rule, one aspect of the implementation approach provided that, in order for persons to continue to use NARM after the expiration or termination of the waiver, requests for licensing actions (e.g., amendments or new applications) would need to be received by the NRC on or before August 7, 2009 (the date that the waiver expires) or earlier, if the waiver was terminated earlier. This would essentially mean that all waivers would need to be terminated in August 2008, in order to provide all affected persons the same amount of time to submit licensing actions to the NRC. Public comments were received requesting that the NRC allow sufficient time for users to prepare for regulatory change, by terminating the waiver in conjunction with the waiver expiration date. In response to public comments, minor changes have been made to the final rule to provide for a limited number of waivers in certain States (including States expressing interest in becoming Agreement States) to be terminated in conjunction with the expiration date of the waiver on August 7, 2009. These minor implementation changes also compensate for the delay in the schedule for this rulemaking and provide sufficient time to transition regulatory authority to the NRC Regional offices, while closely coordinating with the impacted States and licensees. When these waivers are terminated, the final rule allows for persons to submit requests for a license amendment within 6 months from the waiver expiration date of August 7, 2009, and requests for a license within 12 months from the waiver expiration date. These minor changes have been coordinated with the States and are being communicated to licensees in a broad status update on the implementation of NRC's regulatory authority for NARM. Finally, consistent with the approach described in SECY-06-0195, the staff plans to publish the final transition plan after the final rule is published in the *Federal Register*, and prior to the effective date of the final rule.

The transition to the NRC regulation of these materials could present some challenges in the inspection and enforcement arenas. During the time between the termination of the waiver and the user's application for an NRC license or amendment (up to a year), users in Government agencies, Federally recognized Indian Tribes, and non-Agreement States will be under the NRC jurisdiction but will either not have an NRC license or not have one that has been amended to recognize the use of the newly regulated byproduct material. In such circumstances, the NRC will have authority to issue Orders and Notices of Violation; however, the use of civil penalties may be problematic. Further, the staff estimates that there will be a very small group of users of the newly regulated byproduct material who will be unaware of the need to seek a license from the NRC. The size of this group of users is estimated to be very small because in many applications such as medical and industrial uses, both NRC regulated and the previously unregulated materials are used within the same organization. Since these entities are licensed for other NRC regulated materials, these users will be informed of the need to add the newly regulated byproduct material to their license through NRC communications issued to licensees. The production of gauges and other devices using materials such as radium ceased years ago. The likelihood that there are significant numbers of such devices in use at companies not already possessing a license is very small. During the transition, the staff intends to handle enforcement cases involving the use of the newly regulated byproduct material on a case-by-case basis. However, should the number of cases involving these materials be larger than anticipated, the staff will prepare additional enforcement guidance to ensure consistency in handling such issues.

NRC Strategic and Performance Goals

The rule is consistent with NRC's strategic objectives and performance goals. Because the rule is based on NRC's statutory authority to ensure protection of the public health and safety and the environment and to ensure the secure use and management of radioactive material, the rule establishes the regulatory structure to ensure proper management and safe use of the newly added byproduct material. Regulating the newly added byproduct material in conjunction with the existing byproduct material would result in an overall improvement of public health and safety and the environment in the non-Agreement States because the regulatory structure varies from State to State. Furthermore, using the general license approach to regulate certain discrete sources of radium-226 would support NRC's risk-informed regulatory approach. Regulating the newly added byproduct material within the NRC's existing regulatory structure will make the NRC's actions more effective and efficient. To ensure openness in the regulatory process, the staff held a public meeting on this rulemaking in early November 2005 and again in August 2006 to solicit public input. In addition, the proposed rule was published for public comment, and a NARM Rulemaking Web Page was created to keep the stakeholders informed. The staff plans to post the draft final rule on the NARM Rulemaking Web Page once this Commission Paper is publicly released.

State Coordination

Since the beginning of the rulemaking process, the staff has coordinated closely with both OAS and CRCPD to enhance State involvement and to improve efficiency and effectiveness of rulemaking. The NRC has received continued support through State participation in the NARM Rulemaking Working Group and the Steering Committee. The State representatives who participated in these various groups have played a key role in the development of the rule and have provided valuable input to the rulemaking process.

During the public comment period, comments were received from OAS and from other individual States in support of the OAS comments as well as providing additional comments of their own on the proposed rule. State comments were addressed in finalizing the rule. On February 26, 2007, a copy of the draft final rule was posted on NRC's Technical Conference Forum so the States (both Agreement States and non-Agreement States) could have an early opportunity to review and comment on the draft final rule. Comments were received from the OAS and 5 Agreement States (Idaho, Illinois, Michigan, New Jersey, Washington, and Wisconsin). OAS was particularly concerned with the Compatibility Category designation of "B" for the revised definition of "Authorized User" and "Authorized Nuclear Pharmacist" to recognize those individuals who have used NARM. To address the OAS concern, the staff determined that it was not necessary to revise the existing definitions of these two terms and that individuals who use NARM may be recognized through the other grandfather provisions in the rule. The grandfather provisions have a Compatibility Category designation of "D" since Agreement States have regulated NARM and have included NARM users as "Authorized Users" and "Authorized Nuclear Pharmacists."

For definitions and sections with a Compatibility Category designation of "B," OAS stated that the definitions should be designated as "H&S." In the final rule, all definitions are designated as Compatibility Category (H&S) with the exception for the definition of "Waste," which still has the Compatibility Category designation of "B." Since the EPA Act allows for disposal of the newly

added byproduct material at a disposal facility in accordance with any Federal or State solid or hazardous waste law, it is necessary for both the NRC and the Agreement States to include the same allowance in their regulations. Because categorization of waste and waste disposal have direct transboundary implications, the definition of "Waste" is assigned a Compatibility Category designation of "B."

The State of Michigan expressed concern for allowing disposal of the newly added byproduct material, especially those large radiation sources, at solid and hazardous waste landfills and suggested a change to the rule allowing disposal only for discrete source of naturally occurring radioactive material meeting certain general license provisions. Since the suggested change would be in direct conflict with the statutory requirements of the EAct, the staff did not make any change as a result of this comment.

The State of New Jersey had two concerns, both related to those previously expressed during the public comment period. These concerns were: (1) NRC's continued support of the exemption under 10 CFR 30.20 for smoke detectors containing up to 74 kBq (2 uCi) of radium-226. In this connection, the State took issue with the statement in the draft Federal Register notice that such smoke detectors are already being exempted by the States, because the State of New Jersey does not exempt such quantity of material and (2) the difficulties in proving whether old radium-226 sources were used for commercial, medical, or research activities. To address the first concern, a minor clarification in the response to public comments was made to correct the statement that all states exempt these smoke detectors. As for the second concern, the staff recognizes the difficulties associated with making this determination. However, the EAct only gives the NRC authority to regulate any discrete sources of radium-226 that is produced, extracted, or converted after extraction for use for commercial, medical, or research activity. Inclusion of such phrase in the definition of "discrete source" is consistent with the EAct. A discussion of these concerns is already included in Section III, "Summary and Analysis of Public Comments on the Proposed Rule," of the Federal Register notice.

Other State comments are mostly editorial or suggestions for clarification of the rule and some of the comments are not directly related to the rule. All comments were considered, and changes were made, where appropriate, to the *Federal Register* notice for the final rule.

Coordination with the Advisory Committee on the Medical Uses of Isotopes (ACMUI)

A copy of the draft final rule was sent to the ACMUI for comment at the same time that it was sent to the States, and comments were received from the ACMUI on March 13, 2007. ACMUI comments were primarily related to NRC's licensing practice and not directly related to the rule. ACMUI comments also included some editorial suggestions to clarify statements in the discussion section of the *Federal Register* notice. ACMUI comments were considered, and appropriate changes were made.

COMMITMENTS:

Listed below are the actions or activities committed to by the staff in this paper.

1. The staff will post the draft final rule on the NRC Web site once the Commission paper is publicly released.
2. The staff plans to publish the final transition plan after the final rule is published in the *Federal Register* and prior to the effective date of the rule.
3. The staff plans to notice separately in the *Federal Register* the draft guidance associated with this rule, which is currently being finalized, for public comment in Spring of 2007.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the final amendments to 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (Enclosure 1).
2. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule if promulgated will not have significant impact on a substantial number of small entities. This certification is included in the enclosed *Federal Register* notice.
3. Note:
 - a. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b);
 - b. A final Environmental Assessment has been prepared for this rulemaking (Enclosure 2);
 - c. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 3);
 - d. The staff has determined that this action is not a "major rule," as defined in the Congressional Review Act (CRA) of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the OMB. The appropriate Congressional and Government Accountability Office contacts will be informed (Enclosure 4);
 - e. The appropriate Congressional committees will be informed;
 - f. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register; and

- g. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

Less than 0.3 full-time equivalent (FTE) in FY 2007 is needed to complete this rulemaking. These resources are included within the FY 2007 total budget for this rulemaking of 1.8 FTE for FSME. The information on resources and schedule reflects the current environment. If a significant amount of time (greater than 30 days) passes, or the Commission provides the staff direction that differs from, or adds to, the staff's recommended actions, the resources may need to be revisited after issuance of the draft Staff Requirements Memorandum.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rule. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. Information collection requirements for the rule must be submitted to OMB for approval prior to publication in the *Federal Register*.

/RA Martin J. Virgilio Acting For/

Luis A. Reyes,
Executive Director
for Operations

Enclosures:

1. *Federal Register* Notice
2. Environmental Assessment
3. Regulatory Analysis
4. CRA forms

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