RULEMAKING ISSUE
NOTATION VOTE

November 20, 2007 SECY-07-0203

FOR: The Commissioners

FROM: Margaret Doane, Director
Office of International Programs

SUBJECT: RULEMAKING PLAN: 10 CFR PART 110, "EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL; UPDATES AND CLARIFICATIONS"

PURPOSE:

To obtain Commission approval to initiate a rulemaking to update, clarify, and correct 10 CFR Part 110 (Part 110) to improve NRC's regulatory framework for the import and export of nuclear equipment, material, and radioactive waste.

BACKGROUND:

The NRC staff is proposing to amend Part 110, "Export and Import of Nuclear Equipment and Material." In Staff Requirements Memorandum (SRM) SECY-06-0171, dated September 21, 2006, the Commission approved the staff's recommendation to amend Part 110 to allow export licensees for Category 2 quantities of radioactive material to verify that the recipient of the material has the necessary authorization (usually in the form of a license) under the laws and regulations of the importing country to receive and possess the material. In a memorandum to the Commission dated February 2, 2007 (ADAMS Accession No. ML070370079), OIP stated that the most effective and efficient manner to amend Part 110 to allow export licensees of Category 2 quantities of radioactive material to verify the authorizations from the importing country is as part of a larger rulemaking to update, clarify, and correct several provisions of Part 110. This memorandum also informed the Commission that staff planned to amend Part 110 to allow imports of Category 1 and 2 quantities of materials under an NRC general license.

DISCUSSION:

As discussed in the "Background" above, the staff proposes to make the changes related to the import and export of Category 1 and 2 quantities of material listed in Appendix P to Part 110 as part of a larger rulemaking to update, clarify, and correct several provisions of Part 110 pertaining to the import and export of nuclear equipment and material. Further, due to the

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ongoing large number of inquiries received by the OIP staff regarding NRC's import and export requirements for radioactive waste, the OIP staff determined that the current radioactive waste regulations need to be amended. Those proposed changes are discussed below and in more detail in the enclosed Rulemaking Plan.

Determinations concerning licensing requirements for imports and exports of radioactive waste are performed on a case-by-case basis. A substantial amount of time is spent evaluating questions and consulting with the Office of Nuclear Material Safety and Safeguards, the Office of Federal and State Materials and Environmental Management Programs, and the Office of the General Counsel staff to determine whether a specific license is required or the general license can be used for potential imports and exports of waste that contains or is contaminated with very small quantities of radioactive material. The regulations in Part 110 provide no flexibility and require issuance of specific licenses for all imports and exports of any waste that contains or is contaminated with source, special nuclear, or byproduct materials including extremely small quantities of such material. This is inconsistent with international practice which allows a competent authority to permit non-licensed transfers of exempt quantities of radioactive materials including waste. It also is inconsistent with the domestic treatment of radioactive waste. Consequently, the staff proposes to amend the regulations in Part 110 to facilitate the licensing process for imports and exports of radioactive waste and improve the efficiency and consistency of licensing actions.

OIP staff has identified several sections in 10 CFR Part 110 that require updates, clarifications, and corrections. For example, the staff proposes to rewrite 10 CFR 110.23 to clarify and correct the requirements for the export of byproduct material. For example, section 110.23(a)(3) includes incorrect activity threshold levels of the export of americium-241. OIP staff regularly receives questions regarding the application of section 110.23 from the regulated community and from NRC staff. OIP staff also proposes to amend section 110.40, "Commission review," to explicitly require Commission review of export applications of radioactive material listed in Appendix P involving exceptional circumstances or Category 1 quantities of materials to any country on the restricted or embargoed destination lists. Further, the staff proposes to revise section 110.40 to reduce the number of mandatory Commission reviews of exports and focus on Commission review of license applications for export that raise significant policy issues.

These and other proposed changes are discussed in detail in the enclosed Rulemaking Plan.

RECOMMENDATION:

That the Commissioners approve the plan to proceed with the proposed rulemaking to amend Part 110 in accordance with Option 2 in the enclosed rulemaking plan.

RESOURCES:

The resources to conduct the rulemaking are estimated to be 2.5 NRC FTE for the period FY 2008-2009. These resources are included in the current budget.

COORDINATION:

The Office of General Counsel has no legal objection to this rulemaking plan. The following offices concur on this rulemaking plan: Offices of Federal State Materials and Environmental Management Programs, Nuclear Material Safety and Safeguards, Nuclear Security and Incident Response, Nuclear Regulatory Research, Enforcement, and Administration. The Office of the Chief Financial Officer has reviewed the rulemaking plan for resource implications and has no objections. The Office of Information Services has reviewed this rulemaking plan for information technology and information management implications and concurs in the plan.

/RA/

Margaret Doane, Director
Office of International Programs

Enclosure: Rulemaking Plan – 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material; Updates and Clarifications"

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Enclosure: Rulemaking Plan – 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material; Updates and Clarifications"

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**via email

*previously concurred

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OFFICIAL RECORD COPY

Rulemaking Plan
Export and Import of Nuclear Equipment and Material; Updates and Clarifications
10 CFR Part 110

REGULATORY PROBLEM

Import and Export of Category 1 and Category 2 Radioactive Sources (Appendix P)

On July 1, 2005 (70 FR 37985), the Nuclear Regulatory Commission (NRC) published regulations that amended 10 CFR Part 110 (Part 110). Those amendments, which became effective on December 28, 2005, take into account provisions of the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) and the supplemental IAEA Guidance on the Import and Export of Radioactive Sources (Guidance). The amendments provided for enhanced security for the import and export of Category 1 and 2 quantities of radioactive materials listed in Appendix P to 10 CFR Part 110. The rule provided new specific export and import licensing requirements, advance notification procedures prior to shipment, verification of the recipient facility's licensing status, and review of the adequacy of the receiving country's controls on radioactive sources.

On August 1, 2006, the Office of International Programs (OIP) submitted SECY-06-0171, "Analysis of 10 CFR Part 110, Appendix P Implementation Issues," for the Commission's consideration of several issues related to implementation of Part 110, Appendix P. In Staff Requirements Memorandum (SRM) SECY-06-0171 dated September 21, 2006, the Commission approved the staff's recommendation to amend Part 110 to allow export licensees for Category 2 quantities of radioactive material to verify that the recipient of the material has the necessary authorization (usually in the form of a license) under the laws and regulations of the importing country to receive and possess the material. The SRM also directed OIP to closely monitor other countries implementation of the Code of Conduct to ensure that domestic licensees are on a "level playing field" with foreign competitors.

In a memorandum to the Commission dated February 2, 2007 (ADAMS Accession No. ML070370079), OIP stated that the most effective and efficient manner to amend Part 110 to allow export licensees for Category 2 quantities of material to verify the authorizations from the importing country is as part of a larger rulemaking to update, clarify, and correct many provisions of Part 110. In this memorandum, OIP also informed the Commission that it planned to amend Part 110 to allow imports of Category 1 and 2 materials under an NRC general license. This change would align NRC regulations with the direction our international counterparts are taking and would create a more "level playing field" for U.S. licensees. Further, this approach is consistent with the Radiation Source Protection and Security Task Force Report (August 15, 2006; ADAMS Accession Nos. ML062080375, ML062190299, ML062080392, ML062080395, and ML062190349) recommendation that the NRC consider reevaluating the need for a specific import license to allow the import of Category 1 and 2 radioactive sources to a U.S.-licensed user. OIP consulted with the Department of State (DOS) on this proposal. The effective date for the change to allow imports of Category 1 and 2

ENCLOSURE

material under a general license would be delayed until the National Source Tracking System is fully operational. Such a delay would be consistent with the current Canadian approach and would address some of the concerns raised in response to the recent Government Accountability Office investigation. (*See* SECY-07-0147, "Response to U.S. Government Accountability Office Recommendations and Other Recommendations to Address Security Issues in the U.S. Nuclear Regulatory Commissions Materials Program, dated August 25, 2007.")

Import and Export of Radioactive Waste

Due to the ongoing large number of inquiries received by the OIP staff regarding NRC's import and export requirements for radioactive waste, the OIP staff determined that the current regulations need to be amended. Determinations concerning licensing requirements for imports and exports of radioactive waste by OIP staff are performed on a case-by-case basis. A substantial amount of time is spent evaluating questions and consulting with Office of Nuclear Material Safety and Safeguards (NMSS), Office of Federal and State Materials and Environmental Management Programs (FSME) and Office of the General Counsel (OGC) staff to determine whether a specific license is required or the general license can be used for potential imports and exports of waste that contains or is contaminated with very small quantities of radioactive material. The regulations in Part 110 provide no flexibility and require issuance of specific licenses for all imports and exports of any waste that contains or is contaminated with source, special nuclear, or byproduct materials including extremely small quantities of such material. This is inconsistent with international practice which allows a competent authority to permit non-licensed transfers of exempt quantities of radioactive materials including waste. It also is inconsistent with the domestic treatment of radioactive waste.

For example, the staff recently engaged in extensive deliberations concerning an import of contaminated laundry, both launderable and polyvinyl alcohol (PVA)-based (e.g. dissolvable), from a Mexican nuclear power plant. After much deliberation the staff concluded that although Part 110 authorizes the import and export of launderable clothing under a general license, a specific license is required for imports of the PVA-based protective clothing. The reason is that the PVA-based dissolvable clothing is designed for one-time use and the launderable clothing is recycled and reused. Based on the definition of "radioactive waste" in Part 110, the dissolvable clothing designed for one-time use is waste under the definition in 10 CFR 110.2, and requires issuance of a specific license. Although this distinction between the launderable, reusable clothing from the single-use, dissolvable clothing is consistent with the guidelines of the IAEA Code of Practice on the International Transboundary Movement of Radioactive Waste (Code of Practice) that includes the concept of foreseeable use in the definition of radioactive waste, it is inconsistent with the Code of Practice to the extent that the Code of Practice permits imports and exports of exempt quantities of radioactive materials without a license. Further, this outcome is inconsistent with U.S. domestic licensing, which does not consider such PVA-based items to be waste; rather, the treatment of this type of material is licensed as a decontamination process. (See Letter to Michael R. Fuller, UniTech Services Group, Inc. from Paul H. Lohaus, Director, Office of State and Tribal Programs, dated October 23, 2003 (ADAMS Accession No. ML022960614.)

Based on our evaluation of the definition of and licensing requirements for “radioactive waste” in Part 110 and the regulatory history of the Final Rule, Import and Export of Radioactive Waste, 60 FR 37555 (July 21, 1995), it became clear that the definition of waste is confusing and different from how the term is used domestically. Similarly, the concept of incidental radioactive material (IRM) as defined in Part 110 causes a great deal of confusion with regard to its scope, applicability, and relationship to radioactive waste. Specifically, the meaning of the phrase “recycling or resource recovery” in the definition of IRM is unclear and difficult to apply because IRM is limited to Part 110. A potential solution to this confusion would be to simply remove the definition of and all references to IRM from Part 110. Currently, the confusion about these terms delays regulatory action and consumes agency resources.

Consequently, the staff proposes to amend the regulations in Part 110 to facilitate the licensing process for imports and exports of radioactive waste and improve the efficiency and consistency of licensing actions.

Updates, Clarifications and Corrections to 10 CFR Part 110

The OIP staff has identified several sections in Part 110 that require updates, clarifications, and corrections. For example, the staff proposes to amend 10 CFR 110.23, “General license for the export of byproduct material,” to clarify and correct the requirements for the export of byproduct material. This section has been amended several times over the past twenty years resulting in several errors. For example, section 110.23(a)(3) includes incorrect activity threshold levels of the export of americium-241. The OIP staff regularly receives questions regarding the application of section 110.23 from the regulated community and from the NRC staff. The OIP staff also proposes to amend section 110.40, “Commission review,” to explicitly require Commission review of export applications of radioactive material listed in Appendix P involving exceptional circumstances or Category 1 quantities of materials to any country on the restricted or embargoed destination lists. Further, the staff proposes to revise 10 CFR 110.40 to reduce the number of mandatory Commission reviews of exports and focus on Commission review of license applications for export that raise significant policy issues. This approach is consistent with the new approach taken with regard to approval of routine 10 CFR Part 810 authorizations. (See Staff Requirements - SECY-06-0157, “Proposed 10 CFR Part 810 Authorization for USEC Inc. to Transfer Business Proprietary Information Related to the Design of Feed and Withdrawal Stations Gas Centrifuge Enrichment Technology to Metaflex Isosystems B.V.” dated August 15, 2006).

Updates, clarifications and corrections, many of which are purely administrative, are also needed for sections 110.2, “Definitions”; 110.26, “General license for the export of nuclear reactor components”; 110.27, “General License for imports”; 110.30, “Members of the Nuclear Suppliers Group”; 110.31, “Application for a specific license”; 110.43, “Import licensing criteria”; 110.50, “Terms”; and 110.51, “Amendment and renewal of licenses.” As the staff continues review of 10 CFR Part 110, additional revisions may be identified and included in a proposed rule that will be submitted to the Commission for review and approval.

Options for Resolution

Two principal options were considered to resolve the regulatory issues.

Option 1: Maintain the current regulatory framework and limit rulemaking to one issue.

Option 2: Revise 10 CFR Part 110 to address all inefficiencies and inconsistencies.

Option 1: Maintain current regulatory framework

Option 1 is to maintain the current regulatory framework. The only advantage of this option is that no resources would be expended on rulemaking activities. However, on balance, any resource savings from maintaining the status quo would not be realized because the inefficiencies and inconsistencies in Part 110 delay regulatory action and consume agency resources.

Under this option, the NRC would continue to move forward with a proposed rule to amend Part 110 to allow Category 2 export licensees to verify the authorizations from the importing country consistent with Commission direction in the SRM from SECY-06-0171. Further, the NRC may still propose individual, specific amendments to Part 110.

Option 2: Revise 10 CFR Part 110

This option would amend Part 110 to reflect agency experience implementing the import and export regulations. This proposed rule would make several substantive changes that would improve the regulatory framework in the area of import and export by increasing efficiencies and reducing burden on licensees and NRC staff. It would also update, clarify, and correct several provisions in Part 110. The only disadvantage of this option is that agency resources would be necessary to complete the rulemaking. However, the proposed rule would result in significant savings to the agency. The proposed changes would increase effectiveness and eliminate inefficiencies and inconsistencies in NRC's current regulatory framework for import and export by accomplishing three goals. First, it would revise requirements related to the import and export of Category 1 and Category 2 radioactive sources. Second, it would clarify licensing requirements for the import and export of radioactive waste to facilitate the licensing process and improve efficiency and consistency of licensing actions. Third, this proposed rule would update, clarify, and correct a number of provisions in the import and export regulations.

RECOMMENDED APPROACH

The NRC staff recommends Option 2 because it: (1) improves effectiveness and eliminates inefficiencies and inconsistencies; (2) enhances NRC's strategic goals of effective, efficient, realistic, and timely regulatory actions; and (3) enhances the implementation of NRC's import and export regulations.

THE OFFICE OF GENERAL COUNSEL (OGC) LEGAL ANALYSIS

The proposed rulemaking plan is consistent with current NRC regulations. OGC has no legal objections to implementing the recommendations of this rulemaking plan.

BACKFIT CONSIDERATIONS

The rulemaking does not involve any provision that constitutes a backfit as defined in 10 CFR 50.109(a)(1). Thus, the backfit rule does not apply and a backfit analysis is not required.

PAPERWORK REDUCTION ACT

The Office of Information Services (OIS) has reviewed this rulemaking plan for information technology and information management implications and concurs in it. The OIS will aid rulemaking staff in their development of the Office of Management and Budget (OMB) clearance package and in formulating an appropriate Paperwork Reduction Act Statement for the proposed rule. The OMB clearance package will be submitted to OMB before the proposed rule is forwarded to the *Federal Register* for publication.

REGULATORY ANALYSIS

A regulatory analysis will be prepared during the preparation of the proposed rule and will form the basis of specific recommendations for regulatory amendments.

AGREEMENT STATE IMPLEMENTATION ISSUES

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" (September 3, 1997; 62 FR 46517), the proposed revisions are designated a Compatibility Category NRC. Compatibility category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended, or provisions of 10 CFR. These program elements should not be adopted by the Agreement States.

MAJOR RULE

This is not a major rule as defined by the Congressional Review Act of 1996, and the staff will verify this determination with the Office of Information and Regulatory Affairs of OMB prior to the effective date of the eventual final rule.

SUPPORTING DOCUMENTS

If the Commission directs the NRC staff to proceed with the rulemaking, additional supporting documents are not likely to be necessary. An environmental assessment is not needed for amendments to 10 CFR Part 110, per 10 CFR 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review." A regulatory flexibility analysis, in accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 606(b)), is not likely to be needed because this rule will not have significant economic impact on a substantial number of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

RESOURCES

An estimated 2.5 FTE will be required to complete and implement the preferred option over the next two fiscal years. These resources are included in the current budget.

OIP - 1.30 FTE
OGC - 0.20 FTE
Other - 1.00 FTE

LEAD OFFICE AND STAFF FROM SUPPORTING OFFICES	CONCURRING OFFICIAL
Brooke G. Smith, OIP/ECIO Supporting Staff TBD	Margaret Doane, OIP

INTEROFFICE MANAGEMENT STEERING GROUP

No interoffice management group is necessary for this rulemaking.

PUBLIC PARTICIPATION

The proposed rulemaking will be provided for public comment.

SCHEDULE

- Proposed rule to Commission (12 months after approval of rulemaking plan)
- Public comment period (75 days after publication in the *Federal Register*)
- Final rule to the Commission (6 months after public comment period ends unless significant public comments are received)