RULEMAKING ISSUE
NOTATION VOTE

January 23, 2009 SECY-09-0013

FOR: The Commissioners

FROM: Margaret M. Doane, Director
Office of International Programs

SUBJECT: REVIEW OF PROPOSED RULE PACKAGE, "EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL; UPDATES AND CLARIFICATIONS (10 CFR PART 110, RIN 3150-AI16)

PURPOSE:

To request Commission approval to publish a proposed rule in the *Federal Register* that would amend 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material" (Part 110) (Enclosure 1).

SUMMARY:

This paper requests the Commission's decision to approve for publication in the *Federal Register* a proposed rule to update, clarify, and correct several provisions of Part 110 to improve the regulatory framework for the export and import of nuclear equipment and material including radioactive waste.

BACKGROUND:

In Staff Requirements Memorandum (SRM) - SECY-07-0203, dated December 17, 2007, the Commission approved the staff's recommendation to initiate a rulemaking to update, clarify, and correct Part 110 to improve the NRC's regulatory framework for the export and import of nuclear equipment and material including radioactive waste. In 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 listed in Appendix P to verify that the recipient of the material has the necessary authorization (usually in the form of a

CONTACT: Brooke G. Smith, OIP
415-2347

SECY NOTE: "PUBLICLY RELEASABLE UPON REMOVAL OF ENCLOSURE 2."

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 (ML070370079), the Office of International Programs (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 would be 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 listed in Appendix P to Part 110 under an NRC general import license.

DISCUSSION:

OIP is proposing to make changes related to the export and import of Category 1 and 2 quantities of material listed in Table 1 of Appendix P to Part 110 as part of a larger rulemaking to update, clarify, and correct several provisions of Part 110 governing the export and import of nuclear equipment, material, and waste. Further, the staff is proposing to revise the current definition of radioactive waste in 10 CFR Part 110 to facilitate the licensing process for exports and imports of radioactive waste and improve the efficiency and consistency of licensing actions.

In addition, the staff identified several sections in Part 110 that require updates, clarifications, and corrections including revisions to clarify the requirements of the general license for the export of byproduct material and to address inconsistencies inadvertently resulting from prior changes.

As discussed in SECY-07-0203, the staff proposes to amend § 110.40, "Commission review," to reduce the number of export license applications that require Commission review and, would instead, focus Commission review on the export license applications that raise significant policy issues. By focusing on policy issues, this proposed change would increase efficiency on routine NRC export applications. Any export that is subject to special limitations as determined by the staff or the Executive Branch would be considered one that raises an important policy issue and would continue to require Commission review. This approach is consistent with the 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).

In addition, the staff proposes to amend § 110.40 to mandate Commission review of import license applications that raise significant policy issues. The staff also proposes to amend this section to require Commission review of export applications of material listed in Appendix P involving exceptional circumstances, as defined in § 110.42, or Category 1 quantities of material to any country listed in § 110.28 (embargoed destinations).

The Executive Branch (Departments of State, Energy, Commerce, and Defense) has concurred, with comments, in the proposed rule change (Enclosure 2). The comments provided by the Executive Branch have been taken into consideration in the enclosed *Federal Register* notice.

Appropriate Congressional committees will be informed.

A discussion of the most significant proposed changes is found below.

1. Category 1 and 2 Quantities of Radioactive Material Listed in Appendix P to Part 110

On July 1, 2005, the NRC published a final rule that amended Part 110 to 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. The amendments provided for enhanced security for the export and import of Category 1 and Category 2 quantities of radioactive materials listed in a new Appendix P to Part 110.

Since these new requirements have been implemented, the staff has reevaluated the need for a specific license for the import of Category 1 and 2 quantities of radioactive material to a U.S.-licensed user in light of enhancements made to the NRC's domestic regulatory framework. As a result, the staff is proposing to amend Part 110 to allow imports of Category 1 and 2 quantities of materials listed in Appendix P under a general license. The proposed change would align the NRC's regulations with the practices of other countries and is responsive to the comments the NRC has received from U.S. licensees.

The most significant enhancement pertinent to these materials is the establishment of the National Source Tracking System (NSTS) that will track transactions involving Category 1 and 2 radioactive sources from "cradle to grave" (71 FR 65686; November 8, 2006). Licensees will be responsible for recording the manufacture, shipment, arrival, and disposal of all licensed and tracked Category 1 and 2 sources. For every nationally tracked source that is imported, the facility obtaining the source will be required to report the information to the NSTS by the close of the next business day after receipt of the imported source. The effective date for this proposed change to allow imports of Category 1 and 2 material under a general license would be delayed until the NSTS is fully operational; however, it is expected that the NSTS would be fully operational well before this proposed change is promulgated as a final rule. The current estimate for the launch of the NSTS is January 31, 2009. With the NSTS in place, there will be much more information about imported sources available to the staff, reducing the need for a specific license. Further, to ensure that potential security gaps are not created by the elimination of the specific license to import Category 1 and 2 quantities of material, OIP will revise the current procedures for verifying the authenticity of import documents and transactions with additional procedures that include utilizing the NSTS.

Importers of Category 1 and 2 materials under a general license would still be subject to the notification requirements *prior* to shipment as required by § 110.50. Moreover, imports of radioactive material into the United States would continue to be contingent on the consignee being authorized to receive and possess the material under a general or specific NRC or Agreement State license.

2. Import and Export of Radioactive Waste

In 1995, the NRC promulgated a final rule requiring specific licenses for exports and imports of radioactive waste (60 FR 37555; July 21, 1995). Since that time, based on the staff's extensive experience in implementing the rule, it became clear that the rule warrants revision. Specifically, the definition of radioactive waste is confusing and inconsistent with how the term is used domestically. Likewise, the term "incidental radioactive material" (IRM), as defined in Part 110, is unclear with regard to its scope, applicability, and relationship to radioactive waste. Consequently, the staff is proposing changes to the definition of radioactive waste in § 110.2 to address these concerns. Among the proposed changes is the deletion of the definition of IRM

from § 110.2 and incorporation of aspects of it in the revised definition of radioactive waste. These proposed changes to Part 110 would facilitate the licensing process for exports and imports of radioactive waste and improve the efficiency and consistency of licensing actions. The revised definition of "radioactive waste" is proposed to read as follows:

> *Radioactive waste*, for the purposes of this Part, means any material that contains or is contaminated with source, byproduct, or special nuclear material that by its possession would require a specific radioactive material license in accordance with this Chapter and is imported or exported for the purposes of (1) disposal in a land disposal facility as defined in Part 61, a disposal area as defined in Appendix A to Part 40, or an equivalent facility; or (2) recycling, waste treatment or other waste management process that generates radioactive material for disposal in a land disposal facility as defined in Part 61, a disposal area as defined in Appendix A to Part 40, or an equivalent facility. Radioactive waste does not include radioactive material that is—
>
> > (1) Contained in a sealed source, or device containing a sealed source, that is being returned to a manufacturer, distributor or other entity which is authorized to receive and possess the sealed source or the device containing a sealed source;
> >
> > (2) A contaminant on any non-radioactive material used in a nuclear facility (including service tools and protective clothing), if the material is being shipped for recovery and beneficial use of the non-radioactive material in a nuclear facility and not solely for waste management purposes or disposal.
> >
> > (3) Exempted from regulation by the Nuclear Regulatory Commission or equivalent Agreement State regulations.
> >
> > (4) Generated or used in a U.S. Government waste research and development testing program under international arrangements; or
> >
> > (5) Being returned by or for the U.S. Government or military to a facility that is authorized to possess the material.

A *specific* license would be required for the export and import of radioactive waste if a specific radioactive material license is required to possess the material domestically in accordance with the NRC's regulations in 10 CFR Chapter 1 (e.g., Parts 30, 40, and 70). This revision would link the specific license requirement for the export and import of radioactive waste to those materials (in the form of waste) that require a specific license in accordance with NRC's domestic regulations. This would eliminate the need for a specific license to export or import materials that do not require a specific license to possess under NRC's regulations in 10 CFR Chapter 1. In addition, this proposed change would improve consistency and would eliminate some of the differences between the domestic licensing requirements for possession and the licensing requirements for export and import. This change would simplify the regulatory framework by clearly stating that exporting or importing material for recycling, waste treatment, or other waste management process that generates radioactive material to be disposed of in a land disposal facility as defined in Part 61, a disposal area as defined in Appendix A to Part 40, or an equivalent facility (as licensed by an Agreement State or for purposes of export) would require a specific export or import license.

This proposed rule would also remove the definition of "incidental radioactive material" from 10 CFR Part 110. The purpose of this proposed change is to clarify the scope of "radioactive waste" and to address confusion created by the current definition of IRM. While the proposed rule would remove the definition of IRM, the rule would incorporate aspects of the IRM definition

into the revised definition of radioactive waste and the exclusions from the definition of radioactive waste. For example, the current scope of the exclusion related to contamination on service equipment (including service tools) used in nuclear facilities (if the service equipment is being shipped for use in another nuclear facility and not for waste management purposes or disposal) would be expanded and broadened to include some of the material that currently falls under the definition of IRM such as launderable protective clothing.

In addition to the proposed revisions to the definition of "radioactive waste," the staff proposes to amend § 110.43 to clarify that, with respect to the import of radioactive waste, the NRC consults with the host State(s), and, if applicable, the appropriate low-level waste compact commission(s) to confirm that an appropriate facility has agreed to accept and is authorized to possess the waste for management or disposal. Commission policy, as noted in the 1995 final rule on the export and import of radioactive waste, states that:

> The NRC will not grant an import license for waste intended for disposal unless it is clear that the waste will be accepted by a disposal facility, host State, and compact (where applicable). This will be part of the determination regarding the appropriateness of the facility that has agreed to accept the waste for management or disposal.

See Final Rule, Import and Export of Radioactive Waste, 60 FR 27556 (July 21, 1995). This proposed change would address the questions that the NRC receives on the scope of the host State and low-level waste compact commission's (if applicable) role regarding the NRC's review of import applications for radioactive waste by clearly stating that the NRC will seek confirmation that the facility is authorized to possess the waste for management or disposal. The affected State(s) and low-level waste compact commission(s) are consulted regarding all proposed imports of material meeting the definition of radioactive waste (SRM M081106C).

3. General License for the Export of Byproduct Material

The NRC staff regularly receives questions regarding the application of § 110.23, "General license for the export of byproduct material," from the regulated community. Our experience has demonstrated the need to revise several requirements for the export of byproduct material in order to clarify the requirements and to address inconsistencies inadvertently resulting from prior changes to the section in 1994 (September 26, 1994; 59 FR 48994) and 2000 (November 22, 2000; 65 FR 70287).

Prior to 1994, a general license was issued to any person to export any byproduct material, except for tritium, polonium-210, neptunium-237, and americium-241, to any country not listed in § 110.28 (embargoed destinations). In 1994, the NRC revoked the general license for Nuclear Supplier Group (NSG)-controlled alpha-emitters and International Atomic Energy List of the Coordinating Committee on Multilateral Export Controls (COCOM)-controlled transuranic isotopes. The NRC established a new general license to permit the export of the specified alpha-emitting radionuclides to NSG member countries and to permit the export of the specified alpha-emitting radionuclides to most other countries when in a device, or in a source for use in a device, containing less than 3.7×10^{-3} TBq (100 millicuries) of alpha activity per device or source. The NRC also revoked the general license permitting exports of americium-242m, californium-249, californium-251, curium-245, and curium-247 (transuranic isotopes) to conform NRC's regulations with the COCOM control list.

As a result of the 2000 amendments, the NSG-controlled and COCOM-controlled radionuclides were merged into a single paragraph (*see* § 110.23(a)(2) (2000)). All of the radioisotopes listed

in that subsection could be exported under a general license up to 3.7 x 10^{-3} TBq (100 milliuries). In the proposed rule, new sub-paragraph (a)(2) would contain the requirements for COCOM-controlled radionuclides and new sub-paragraph (a)(4) would contain the general license for the NSG-controlled alpha-emitting radionuclides.

The general license for americium-241 would also be revised. In 2000, when § 110.23 was clarified for ease of reading, americium-241 (and neptunium-237) were included in the "merged" list of NSG- and COCOM-controlled radionuclides even though they were not NSG- or COCOM-controlled (*see* § 110.23(a)(2) (2000)). The effect of the 2000 amendments was to restrict the general license for exports of americium-241 to 3.7 x 10^{-3} TBq (100 mCi). Prior to changes in 2000, there were no activity restrictions on exports to countries not listed in §§ 110.29 (restricted destinations) and 110.28 (embargoed destinations). Americium-241 exports under a general license could not exceed 3.7 x 10^{-2} TBq (one curie) per year or 3.7 TBq (100 curies) per year to any one country listed in § 110.29. For exports to § 110.29 countries that exceeded the limit above, the americium-241 must be contained in petroleum exploration or industrial process control equipment in quantities not exceeding 0.74 TBq (20 curies) per device or 7.4 TBq (200 curies) per year to any one restricted country.

In 2005, the Commission published a final rule that conformed NRC's export and import regulations to the provisions of the IAEA Code of Conduct (July 5, 2005; 70 FR 37985). The specific radioactive material and quantities added by this rule are listed in Table 1 of Appendix P to Part 110. Americium-241 is one of the materials listed in this Table. As a result of the 2005 rule, an NRC specific license was required to export (and import) these radioactive materials at Category 2 and above quantities. For americium-241, the Category 2 threshold limit was set at 0.6 TBq (16 Ci). As part of the 2005 rulemaking, changes were made to the general license for americium-241 in an effort to conform it to the threshold for americium-241 in Table 1 of Appendix P. The staff is now proposing to remove americium-241 from § 110.23 (a)(2) which currently controls it at 3.7 x 10^{-3} TBq (100 mCi) and rewrite the general license for americium-241 in proposed § 110.23 (a)(5) to address the inconsistencies inadvertently resulting from prior changes to the section and to take into account the Appendix P thresholds for americium-241.

Likewise, the general license for the export of neptunium-237 would be revised to address inconsistencies resulting from the 2000 rule change. Under this proposed rule the general license for the export of neptunium-237 would cover shipments that do not exceed one gram for individual shipment and do not exceed a cumulative total of 10 grams per year to any one country. The general license would be found in § 110.23(a)(6) of this proposed rule.

AGREEMENT STATE ISSUES:

NRC staff has analyzed the proposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." Staff has determined that the proposed rule is classified as Compatibility Category "NRC." The NRC program elements in this category are those that relate directly to areas of regulation reserved to NRC by the Atomic Energy Act of 1954, as amended, as implemented in the provisions of Title 10 of the *Code of Federal Regulations*. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendments to Part 110 (Enclosure 1).

2. Note:

   a. That the proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.

   b. That 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).

   c. That the Executive Branch (Departments of State, Energy, Commerce, and Defense) has concurred on this rule. (Enclosure 2).

   d. That appropriate Congressional committees will be informed of this action.

   e. Office of Management and Budget approval of the proposed rule is not required because the information collection burden is determined as insignificant.

RESOURCES:

To complete and implement this rulemaking, 1.25 full-time equivalent positions are budgeted in FY2009. These FTE are not identified as FTE to be deferred in the FY 2009 Continuing Resolution.

SENSITIVITY:

This document is “Official Use Only – Sensitive Internal Information” because the views provided by the Executive Branch in Enclosure 2 are considered “Sensitive but Unclassified” by the Department of State.

COORDINATION:

The Office of the General Counsel (OGC) has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objection. The Office of Information Services has reviewed this final rule and concurs that there will be no information technology impacts.

/RA/

Margaret M. Doane, Director
Office of International Programs

Enclosures:
1. Federal Register Notice
2. Executive Branch views

cc: SECY
OGC
OCA

COORDINATION:

The Office of the General Counsel (OGC) has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objection. The Office of Information Services has reviewed this final rule and concurs that there will be no information technology impacts.

/RA/

Margaret M. Doane, Director
Office of International Programs

Enclosures:
1. Federal Register Notice
2. Executive Branch views

cc: SECY
OGC
OCA

DISTRIBUTION:

T. Rothschild/G. Kim, OGC	K. McDaniel, FSME/DILR	M. Horn, FSME
B. Horn, NMSS	S. Aguilar, NMSS	T. Harris, NSIR
OIP r/f	D. Broaddus, FSME/MSSA	J. Kennedy, FSME/DWMEP
S Dembek, OIP	A. Love-Blair, ADM	M. Williams, NMSS
B Smith, OIP	E. Hayden, OPA	C. Clemons-Webb, FSME/DILR

DOCUMENT NAME: C:\MyFiles\Checkout\Part 110 Update, Commission Paper_proposed rule_NOV25.doc
ADAMS Accession Number: **ML082960087**

To receive a copy of this document, indicate in the box: "**C**" = Copy without attachment/enclosure "**E**" = Copy with attachment/enclosure "**N**" = No copy
*concurrence received via e-mail
☐ Publicly Available Non-Publicly Available Sensitive ☐ Non-Sensitive

OFFICE:	OIP		OIP/BC		OIP/DD		OCFO	
NAME:	BSmith		SDembek		SMoore		RMitchell*	
DATE:	09/26/2008		09/26/2008		10/17/2008		11/12/2008	
OFFICE:	FSME		NSIR		ADM		OIS	
NAME:	CMiller		RCorreia		MLesar		GTrussell	
DATE:	11/14/2008		11/13/2008		11/18/2008		11/14/2008	
OFFICE:	NRR		OE		OGC		NMSS	
NAME:	JWiggins		CCarpenter		GKim		MWeber	
DATE:	11/13/2008		10/28/2008		12/04/2008		11/05/2008	
OFFICE:	EDO		OIP/D					
NAME:	RWBorchardt (MVirgilio for)		MDoane					
DATE:	01/15/2009		01/ /2009					

OFFICIAL RECORD COPY