RULEMAKING ISSUE
(Notation Vote)

July 2, 2004 SECY-04-0110

FOR: The Commissioners

FROM: Janice Dunn Lee, Director
Office of International Programs /RA/

SUBJECT: HIGH-RISK MATERIAL - PROPOSED RULE TO AMEND 10 CFR PART 110, "EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL"

PURPOSE:

Staff is requesting Commission review and approval of a draft proposed rule to amend Title 10 of the Code of Federal Regulations (CFR), Part 110, "Export and Import of Nuclear Equipment and Material." The proposed rule would require specific licenses for the import and export of certain high-risk radioactive material. High-risk radioactive material encompasses those radioactive sources recommended for export/import control measures in the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (the Code of Conduct). As the U.S. and recipient countries gain more experience in enhancing security measures pursuant to the Code of Conduct, the staff anticipates issuing broad specific export and import licenses for high-risk radioactive material. For example, exports of Iridium-192 that include multiple shipments from or to different countries over a five year period would be permitted under a single license. The proposed rule is intended to update Part 110 with respect to Executive Branch policy, U.S. Government commitments to support the recommendations of the Code of Conduct, and international nuclear export control standards.

Contact: Marvin Peterson, OIP
301-415-1771

BACKGROUND:

In light of the events of September 11, 2001, the Commission has undertaken a comprehensive review of nuclear material security requirements, with particular focus on high-risk radioactive material. Historically, the Commission's regulatory position was that safety requirements imposed on high-risk radioactive material, including its export and import, provided adequate security measures. Additional security-specific requirements applicable to high-risk radioactive material were considered unnecessary. The Commission concludes this is no longer the case and, for exports and imports of high-risk radioactive material under its authority, has directed the staff to develop a proposed rule with appropriate enhancements to Part 110 (see Staff Requirements Memorandum (SRM) - SECY-03-0210 - Security Enhancements for Export/Import Controls on High-Risk Sources, January 8, 2004).

The Commission has played a leading role for the U.S. Government in the development of the revised Code of Conduct, as approved by the IAEA Board of Governors and the General Conference in September 2003. The Code of Conduct is intended to provide common international guidelines for safety and security measures on radioactive sources. In February 2004 the staff participated in negotiations among 39 IAEA Member States in Vienna to prepare a document entitled "Guidance for the Import and Export of Radioactive Sources in Accordance with the Code of Conduct." It is anticipated that final international agreement of this guidance document will occur after the next international negotiation session in July 2004. On June 9, 2004, the Group of Eight Industrial Countries (the G-8), issued an "Action Plan on Nonproliferation" that included agreement on export and import control guidance for high-risk radioactive sources and support for implementing the Code of Conduct and the Guidance document by the end of 2005. The timing and the substance contained in the proposed rule are intended to be consistent with these two key international documents, and the G-8 supported implementation date.

DISCUSSION

In response to the Commission's SRM of January 8, 2004, the staff developed a proposed rule amending Part 110 to require specific export and import licenses for shipments of high-risk radioactive material that meet or exceed the threshold levels in the Code of Conduct (Attachment 1). The companion regulatory analysis is in Attachment 2. Unlike the Code of Conduct, however, the proposed rule encompasses import and export shipments of bulk material, in addition to sealed sources. The proposed changes require specific licenses for all exports and imports of high-risk radioactive material listed in a new Appendix P, if the amounts involved meet or exceed that set out in the Appendix[1]. The new Appendix P includes a list of radioactive materials with activities corresponding to thresholds of concern that is essentially identical to those found in the Code of Conduct. Although Radium-226 is encompassed by the Code of Conduct, it is not covered by the proposed regulation because radium, as a naturally occurring radioactive material, is not subject to NRC's licensing authority. However, radium-226

[1]To support nonproliferation goals, specific licenses are already required for exports of plutonium in quantities exceeding those listed in § 110.21. These quantities will continue to be the controlling quantities for exports of plutonium.

is subject to export/import controls administered by the Department of Commerce and the Executive Branch is considering appropriate enhancements to Commerce's export/import controls.

The staff also notes the proposed rule will not cover some radioactive materials that the Commission has required the staff to track for the interim radioactive source database and that will likely be included on the National Source Tracking System (NTS). However, in developing a position on the Code of Conduct, the Commission specifically requested certain radioactive materials be excluded from the list of high-risk radioactive materials listed in the Code. These materials are Ac-227, Th-228, Th-229, Pu-236, Pu-239, Pu-240 and Po-210. The fact that imports and exports of these radioactive materials will not be licensed or tracked may result in discrepancies within NRC's database. It should be recognized that these discrepancies will occur and that they will have to be resolved on a case-by-case basis in the future. Furthermore, the staff points out that the Department of Energy/National Nuclear Security Agency (DOE/NNSA) continues to use a different list of high-risk isotopes in its domestic and international activities. The staff has raised this issue with DOE and DOS, but has made no progress in resolving this issue.

As noted, the G-8, including the U.S., endorsed implementing the Code of Conduct and the Guidance document by December 2005. It should be possible to meet the December 2005 implementation schedule for all import licenses and most export licenses anticipated as a result of the rule. Following Commission approval of the proposed rule, it will be published in the *Federal Register* with a 75-day comment period. The staff anticipates submitting to the Commission a final rule within two months after the 75-day comment period expires. However, this goal will depend on the comments received. Affected companies will then have six months to apply for and receive required export and import licenses.

For imports, the staff believes that meeting the December 2005 date is feasible, because existing NRC and Agreement State licensing programs provide the necessary infrastructure. For exports there is less certainty that December 2005 is a feasible implementation date, as the proposed rule requires a finding that the "receiving country has the appropriate technical and administrative capability, resources and regulatory structure to manage the material in a secure manner." The staff is currently determining which countries have received exports of high-risk radioactive materials from the U.S. as a first step in evaluating their capability to receive such material. The proposed rule also requires confirmation that the recipient is authorized to receive and possess the material. Depending on comments received, the staff may propose giving exporters more time to apply for and receive any necessary specific export licenses in order to minimize impacts on normal commercial trade. This approach should have limited impact on security given that there is no evidence of any malicious use of high-risk material exported under NRC's general export license regime currently in place.

At the present time, the staff believes that a final decision on the implementation date for the specific export licenses required by the proposed rule can be delayed until the Commission's decision on the final rule. At that time, the Commission will have comments available from exporters on the impact of the proposed rule. Furthermore, the staff will be working with the Departments of State and Energy and the IAEA in efforts to assess and enhance the regulatory infrastructure of the countries receiving NRC licensed exports of high-risk sources.

A preliminary review of the Office of Nuclear Materials Safety and Safeguards's (NMSS) interim database of high-risk sources in the U.S. shows that export and import shipments for calendar year 2003 involved only four radionuclides meeting or exceeding the threshold limits: Iridium-192, Americium-241, Cobalt-60 and Cesium-137. There were approximately 740 export shipments of these four radionuclides. Of these, approximately 700, or over 95%, involved Category 2 shipments of Iridium-192 by two companies to approximately 30 different countries, with about 500 shipments made to five countries: South Korea, Malaysia, Canada, Mexico and Singapore. The only export shipments in the Category 1 range involved Cobalt-60. There were 10 such shipments of Cobalt-60, all to Canada, by seven different companies with amounts ranging from 1 to 999 kilo-curies. For Americium-241, there were approximately 20 export shipments of Category 2 amounts by three well logging companies. Finally, there was only one export shipment, to Singapore, of Category 2 amounts of Cesium-137. The staff's conclusion from this preliminary analysis is that the principal impact of the proposed rule is on the two companies involved in Iridium-192 exports. Accordingly, the staff intends to focus on these exports as it prepares its analysis for the final rule.

Transshipments of high-risk material sources though U.S. territory are not covered by the Commission's export/import regulations and are therefore not covered by this proposed rule. As directed by the Commission's SRM of January 8, 2004, the staff is continuing to consult with other government agencies on the issue of transshipments.

COORDINATION:

The Executive Branch was requested to provide comments on the proposed rule in early June. While formal Executive Branch comments have not been received, staff contacts with the relevant Executive Branch agencies indicate strong support for the proposed rule. Since NRC has sole authority for the import and export of material, the compatibility category for this rule is "NRC." The compatibility category "NRC" means the rule is adopted and implemented solely by NRC concerning import and exports of material by both NRC and Agreement State licensees. Therefore there is no requirement for Agreement States to adopt this rule. Staff will coordinate and seek comment from the Agreement States during the public comment period. The CFO and the EDO concur in this paper. OGC has no legal objection.

The Office of the Chief Information Officer has reviewed the proposed rule for information management implications and concurs in it. However, the rule contains changes in information collection requirements that must be submitted to the Office of Management and Budget (OMB) no later than the date the proposed rule is forwarded to the Federal Register for publication.

RESOURCES:

The initial burden on NRC's export licensing staff is expected to significantly increase following implementation of the final rule as staff assists the exporter/importer community in understanding and implementing the provisions of the rule, including, as necessary, contacting foreign regulatory agencies and using the services of the Department of State to contact competent authorities to grant consent for import of high-risk radioactive materials. However, the resources are within OIP's budget. Resources currently dedicated to the rulemaking and development of procedures will be shifted to processing license applications. Further, the

Commission will be required to review and approve first-of-the-kind cases as applications involving exceptional circumstances are received.

RECOMMENDATION:

The staff recommends that the Commission approve the attached proposed rulemaking.

OMB review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is forwarded to the Office of the Federal Register for publication.

This paper, including the attachments, should be withheld from public disclosure until the Commission issues a decision unless the Commission determines otherwise.

Janice Dunn Lee, Director
Office of International Programs

Attachment: 1. Proposed Rule
2. Regulatory Analysis

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

3150-AH44

Export and Import of Nuclear Equipment and Radioactive Materials: Security Policies

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations pertaining to the export and import of nuclear equipment and radioactive materials. This proposed rule is intended to reflect recent changes to the nuclear and radioactive material security policies of the Commission and the Executive Branch, for the import and export of radioactive material. A specific license will be required for the import and export of high-risk radioactive material.

DATES: Submit comments by [Insert the date 75 days after publication in the Federal Register]. 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: You may submit comments by any one of the following methods. Please include the following number **RIN 3150-AH44** in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personally identifiable information, such as your home e-mail address, will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email cag@nrc.gov. Comments can also be submitted via the Federal Rulemaking Portal http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this site, the public can gain entry into the NRC's Agencywide Document 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 Public

Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Suzanne Schuyler-Hayes, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington DC. 20555-0001, telephone (301) 415-2333, e-mail: ssh@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

As a result of the terrorist attacks in the United States on September 11, 2001, the Nuclear Regulatory Commission has undertaken a comprehensive review of nuclear and radioactive material security requirements, with particular focus on high-risk radioactive material. This material, including certain quantities of cobalt-60, cesium-137, iridium-192 and americium-241 isotopes, has the potential to be used in a radiological dispersion device (RDD) or a radiological exposure device (RED) in the absence of proper security measures. This review takes into consideration the changing domestic and international threat environments and related U.S. Government supported international initiatives in the nuclear security area, particularly activities conducted by the International Atomic Energy Agency (IAEA).

Recently, the Commission issued a series of domestic Orders concerning security measures applicable to high-risk radioactive material. These Orders include enhanced security requirements which are also known as "Additional Security Measures," or ASMs. The ASMs have been issued to domestic licensees of the Commission and Agreement States, under the

Commission's exclusive authority to provide for the common defense and security. They have not been made available to the general public because they contain sensitive security information that is protected from public disclosure as Safeguards information in accordance with section 147 of the Atomic Energy Act. The ASMs include several provisions that pertain to export and import shipments, particularly concerning security during transportation and advance notice of proposed shipments. It is anticipated that these orders will be further refined based on feedback from stakeholders and will eventually be reflected in the U.S. Code of Federal Regulations covering radioactive material (primarily revisions to 10 CFR Parts 30-36 and 70).

The Commission has also supported U.S. Government efforts to establish common international guidelines governing the export and import of high-risk radioactive materials. This effort has resulted in a major revision to the International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct). The revised Code of Conduct was approved by the IAEA Board of Governors in September 2003, and is available on the IAEA website at http://www.iaea.org/Publications/Standards/index.html. Following approval of the Code of Conduct, the Commission has played a key role in multilateral meetings to develop a related document providing internationally accepted guidance for export and import activities involving high-risk radioactive material. This export/import guidance document is expected to be approved later this year, when it will be published as an IAEA Information Circular (INFCIRC).

The Code of Conduct recommends that IAEA member Countries develop specified export/import controls, discussed below, covering sources in Categories 1 and 2 in Table 1 of Annex 1 of the Code. Table 1 includes a list of high-risk radionuclides with activities corresponding to thresholds of concern that is essentially identical to the list found in the

proposed Appendix P to be added to 10 CFR Part 110. While the radionuclides and threshold quantities are the same, the proposed Part 110 appendix uses the more encompassing term "radioactive material" rather than "sources." Therefore, unlike the Code of Conduct, the proposed rule encompasses the import and export shipments of bulk radioactive material, in addition to sealed sources.

The U.S. Government has formally notified the Director General of the IAEA of its support for the Code of Conduct. Although the Code does not have the stature of an international treaty, and its provisions are non-binding on IAEA member Countries, the Commission nevertheless believes it is essential for NRC to update its export/import regulations to incorporate the Code of Conduct recommendations consistent with our responsibilities under the Atomic Energy Act and the NRC's mission of ensuring the common defense and security. This proposed rule is intended to do so.

Discussion

The Nuclear Regulatory Commission proposes to require specific licenses for the export and import of high-risk radioactive material. This proposed rule follows the guidance contained in the IAEA's Code of Conduct and is consistent with the recommendations in the Code's section on "Import and Exports of Radioactive Sources" (paragraphs 23-29). This section of the Code is intended to guide countries in the development and harmonization of policies and laws on international movements of high-risk radioactive sources to ensure their safe and secure handling. A basic principle of the Code of Conduct is that international movements of such radioactive material should take place with the prior notification of the exporting and importing countries. Additionally, international movements of Category 1 quantities of such material

require the consent of the importing country. While prior notification by the exporter or importer is required for each export or import shipment, consents must be government to government. The Code of Conduct contemplates that, other than in exceptional circumstances, a receiving country should not permit the import of high-risk radioactive material unless it has the technical and administrative capability, resources and regulatory structure needed to ensure that the radioactive material will be managed in a manner consistent with the provisions of the Code. The proposed rule requirements would apply to all identified licensees, both NRC and Agreement State.

The specific radioactive material and amounts defined as high-risk are listed in the proposed Appendix P to Part 110 and are essentially identical to the list of high-risk radioactive materials in Table 1 attached to the Code of Conduct. With the exception of plutonium, the high-risk radioactive materials listed in Appendix P are categorized as byproduct material as defined in the Atomic Energy Act of 1954, as amended. Although Radium-226 is encompassed by the Code of Conduct, it is not listed in Appendix P or covered by the proposed regulation because radium, as a naturally occurring radioactive material, is not subject to NRC's licensing authority. However, radium-226 is subject to export/import controls administered by the Department of Commerce. It should be noted that, in response to NRC's request for information, to date no NRC or Agreement State licensee reported possessing, importing, or exporting Category 1 or 2 amounts of radium.

Exports. Under the Atomic Energy Act of 1954, as amended, and 10 CFR Part 110, the principal criterion for approving exports of the materials listed in Appendix P is a finding that the export is not inimical to the common defense and security of the United States. The non-inimicality finding is relevant to both the nuclear proliferation significance of exports and the

related security concerns of high-risk radioactive material falling into the hands of non-state organizations, including terrorist groups. In making its inimicality determination, the Commission will, consistent with the Code's guidance, consider whether the importing country has the long-term technical and administrative capability and the resources and regulatory structure to manage the high-risk radioactive material in a secure manner, and has authorized the recipient to receive and possess this material. For proposed exports of Category 1 amounts of high-risk radioactive material listed in Appendix P, the Commission will also assess whether the importing country has provided formal governmental consent for the import. The Commission will require the applicant for the export license to provide it with pertinent documentation demonstrating that the recipient of the radioactive material has the necessary authorization under the laws and regulations of the importing country to import, receive, and possess the material. In making these decisions, the Commission may seek the advice of the Executive Branch. Consistent with the Code, where a receiving state may be lacking in technical and administrative capability, resources, or regulatory structure, the Commission will, in exceptional circumstances, also consider as part of its overall inimicality determination whether an alternative arrangement has been made to manage the radioactive material in a safe and secure manner. In examining these and other factors that may be pertinent to assessing whether the proposed export will be inimical to the U.S. common defense and security, the Commission will take into account information it receives as part of regular interactions with its foreign regulatory counterparts, the IAEA, and the Executive Branch. The Commission anticipates that further guidance on what constitutes "exceptional circumstances" and other aspects of the Code will be set forth in the IAEA guidance document discussed above. Finally, because security concerns applicable to non-state organizations arise primarily

during transportation to the foreign recipient and its use abroad, the proposed changes to Part 110 will require prior notification by U.S. exporters to the importing country and NRC of individual shipments.

Imports. For imports, the licensing criteria are (1) non-inimicality to the U.S. common defense and security and (2) a finding that the import does not constitute an unreasonable risk to the public health and safety. All recipients in the U.S. must be properly authorized by the NRC, an Agreement State, or the Department of Energy to possess such radioactive material. Therefore, the proposed changes to Part 110 for imports under NRC's licensing authority of high-risk radioactive material will simply require (1) confirmation by the NRC that the U.S. recipient is properly authorized to receive and possess the radioactive material and (2) prior notification to the NRC of individual shipments. The Commission will expect the applicant for the import license to provide it with pertinent documentation that each recipient of the radioactive material has the necessary authorization to receive and possess this material. For proposed imports into the U.S. of Category 1 amounts of high-risk radioactive material listed in Appendix P, the Commission will also be responsible for providing formal U.S. Government consent to the export authority of the exporting country.

Conclusion. The criteria and proposed guidelines for approving specific export and import licenses for high-risk radioactive material will provide the Commission with the necessary flexibility to process each application on a case by case basis. For example, the Commission may wish to limit exports to new recipients or to a country with limited experience with its regulatory infrastructure to single shipments of radioactive material. On the other hand, in countries with mature regulatory infrastructures with known and competent recipients, the Commission intends to use the provisions of §110.31(e) by issuing broad specific export and import licenses that allow shipments of multiple radionuclides to multiple destinations and with

authorizations for up to five years or more. The duration of the import or export authorization will be consistent with the expiration date of the recipient's authorization to possess or use the radioactive material. However, each shipment under these broad export/import licenses that meet or exceed the Category 2 limits in Appendix P will require advance notification as discussed above[1].

Implementing Date

The final rule will have an implementation date which will allow a period of six months for exporters and importers to apply for and receive required specific export and import licenses.

Summary

The proposed changes to the Commission's export/import regulations in Part 110 apply to a small number of high-risk radioactive materials when exported or imported in amounts exceeding clearly defined limits. They also provide the Commission with flexibility to treat each export and import license application on a case-by-case basis, with the ability to accommodate the still evolving domestic and international security measures for high-risk radioactive material.

Section by Section Analysis

Subpart C - Licenses. Proposed changes would indicate that all exports and imports of high-risk radioactive material listed in a new Appendix P to this Part require specific licenses if amounts involved meet or exceed that set out in that appendix.

In §110.23, paragraph (a)(3) would clarify that individual export shipments of americium-241 under a general license must be less than the amounts specified in Category 2 of Appendix P to this Part. (Currently, this section authorizes individual shipments of several 20 curie

[1]The more restrictive requirements for the export of plutonium 238 and 239 contained in § 110.21 will continue to be the limiting controls.

quantities of americium-241 to most countries as long as the 200 curie per country limit is not exceeded.) Also, a new paragraph (a)(7) would require that individual export shipments of the high-risk radioactive material listed in a new Appendix P to this Part and conducted under the general license provisions of this paragraph be below the amounts indicated for Category 2.

In §110.27, a new paragraph (f) would require that individual import shipments of high-risk radioactive material listed in a new Appendix P to this Part and conducted under the general license provisions of this paragraph be below the amounts indicated for Category 2.

In §110.32, a new paragraph (h) is added to clarify documentation requirements accompanying an export license application for radioactive material listed in proposed new Appendix P.

Subpart D - Review of License Applications. Proposed changes would indicate licensing criteria for high-risk radioactive material exports and imports.

In §110.42 a new paragraph (e) would specify the licensing criteria for the export of high-risk radioactive material listed in a new Appendix P to this Part in amounts indicated for Categories 1 and 2.

In §110.43 a new paragraph (e) would specify the licensing criteria for the import of high-risk radioactive material listed in a new Appendix P to this Part in amounts indicated for Categories 1 and 2.

In §110.45 a new paragraph (b)(5) would describe the requirements for issuing import licenses for high-risk radioactive material listed in a new Appendix P to this Part in amounts specified in Categories 1 and 2.

Subpart E - License Terms and Related Provisions. Proposed changes would clarify that transportation issues are covered by NRC's domestic regulations.

In §110.50, a new paragraph (b)(4) would be added covering advance notification

requirements. Also, the word "transport" would be added after "use" in paragraph (a)(3); and the number "71" would be added after "70" in (renumbered) paragraph (b)(5). This would clarify that "transportation" is not covered directly in Part 110 and to indicate that 10 CFR Part 71 of NRC's domestic regulations cover transportation.

A new Appendix P to Part 110 would list the high-risk radioactive material and quantities requiring specific export and import licenses.

Agreement State Compatibility

Since NRC has sole authority for the import and export of material, the compatibility category for this rule is “NRC.” The compatibility category “NRC” means the rule is adopted and implemented solely by NRC concerning import and exports of material by both NRC and Agreement State licensees. Therefore there is no requirement for Agreement States to adopt this rule.

Voluntary Consensus Standards

The National Technology Transfer 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 the use of such a standard is inconsistent with applicable law or otherwise impractical. There are no voluntary consensus standards addressing this subject matter.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this rule.

Paperwork Reduction Act Statement

This proposed rule contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The burden to the public for these information collections is estimated to average 2 hours per application and 15 minutes per notification, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5

F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0036), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The regulatory analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852. Single copies of the analysis may be obtained from the Office of International Programs, U.S. Nuclear Regulatory Commission, at 301-415-2333 or by e-mail at <ssh@nrc.gov>. The Commission requests public comment on the regulatory analysis. Comments on the analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this proposed rule does not have a significant impact on a substantial number of small entities. This rule is necessary to reflect the nuclear and radioactive material security policies of the Executive Branch and to comply with evolving international agreements to which the U.S. Government subscribes.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this proposed rule and a backfill analysis is not required, because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. The rule does not constitute a backfit rule because it does not propose any changes or additions to requirements for existing structures, systems, components, procedures, organizations or designs associated with the construction or operation of a facility.

List of Subjects in 10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Exports, Imports, Incorporation by reference, Intergovernmental relations, Nuclear and radioactive materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

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; and 5 U.S.C. 553; notice is hereby given that the NRC is proposing to adopt the following amendments to 10 CFR Part 110.

PART 110--EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

1. The authority citation for part 110 continues to read as follows:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 161, 181, 182, 183, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 948, 953, 954, 955, 956, as amended (42 U.S.C. 2071, 2073, 2074, 2077, 2092-2095, 2111, 2112, 2133, 2134, 2139, 2139a, 2141, 2154-2158, 2201, 2231-2233, 2237, 2239); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 5, Pub. L. 101-575, 104 Stat. 2835 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Sections 110.1(b)(2) and 110.1(b)(3) also issued under Pub. L. 96-92, 93 Stat. 710 (22 U.S.C. 2403). Section 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d, 88 Stat. 473, 475 (42 U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99-440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80-110.113 also issued under 5 U.S.C. 552, 554. Sections 110.130-110.135 also issued under 5 U.S.C. 553. Sections 110.2 and 110.42(a)(9) also issued under sec. 903, Pub. L. 102-496 (42 U.S.C. 2151 et seq.).

2. In §110.23, paragraph (a)(3) is revised and a new paragraph (a)(7) is added to read as follows:

§110.23 General license for the export of byproduct material.

(a) * * *

(3) For americium-241, exports must not exceed one curie (308 milligrams) per shipment or 100 curies (30.8 grams) per year to any country listed in §110.29, and must be

contained in industrial process control equipment or petroleum exploration equipment in individual shipments less than the amounts specified in Category 2 of Appendix P to this Part.

* * * * *

(7) Individual export shipments of byproduct material must be less than the amounts specified in Category 2 of Appendix P to this Part.

* * * * *

3. In §110.27, the introductory text of paragraph (a) is revised and paragraph (f) is added to read as follows:

§110.27 General license for import.

(a) Except as provided for in paragraphs (b), (c), and (f) of this section, a general license is issued to any person to import byproduct, source, or special nuclear material if the consignee is authorized to possess the material under:

* * * * *

(f) Individual import shipments of radioactive material must be less than the amounts specified in Category 2 of Appendix P to this Part.

4. In §110.32, a new paragraph (g) is added to read as follows:

§110.32 Information required in an application for a specific license/NRC Form 7.

* * * * *

(g) For proposed exports of material listed in Appendix P to this part, pertinent documentation that the recipient of the material has the necessary authorization under the laws and regulations of the importing country to import, receive, and possess the material.

5. In §110.42, paragraphs (e) and (f) are added to read as follows:

§110.42 Export licensing criteria.

* * * * *

(e) In making its findings under paragraphs (a)(8) and (c) of this section for proposed exports of radioactive material listed in Appendix P to this Part, the Commission shall consider whether:

(1) The receiving country has the appropriate technical and administrative capability, resources and regulatory structure to manage the material in a secure manner; and

(2) The foreign recipient is authorized to receive and possess the material; and

(3) For proposed exports of Category 1 amounts of radioactive material listed in Appendix P to this Part, the receiving country consents to the import of the material;

or

(4) In exceptional circumstances, that an alternative arrangement has been made to manage the material in a safe and secure manner.

7. In §110.43, paragraph (e) is added to read as follows:

§110.43 Import licensing criteria.

* * * * *

(e) With respect to the import of radioactive material listed in Appendix P to this Part, the U.S. recipient is authorized to possess the material under a contract with the Department of Energy or a license issued by the Commission or a State with which the Commission has entered into an agreement under Section 274b. of the Atomic Energy Act.

8. In §110.45, paragraph (b)(5) is added to read as follows:

§110.45 Issuance or denial of license.

* * * * *

(b) * * *

(5) With respect to a proposed import of radioactive material listed in Appendix P to this Part, the U.S. recipient is authorized to possess the material under a contract with the Department of Energy or a license issued by the Commission or a State with which the Commission has entered into an agreement under Section 274b. of the Atomic Energy Act.

9. Section 110.50 is amended as follows:

a. In paragraph (a)(3), add “transport” after the word “use,”

b. Paragraphs (b)(4) and (b)(5) are redesignated as (b)(5) and (b)(6),

c. Add the number “71” after “70” in newly redesignated paragraph (b)(5), and

d. Add a new paragraph (b)(4) to read as follows:

§110.50 Terms

* * * * *

(b)* * *

(4) A licensee authorized to export or import material listed in Appendix P to this Part is responsible for notifying NRC and the importing country in advance of each shipment. A list of points of contacts in importing countries is available at NRC’s Office of International Programs (see §110.4). The NRC office responsible for receiving advance notifications for all export and import shipments will be specified on each specific export and import license. Notifications

must be made at least 24 hours in advance of each shipment, and to the extent practical, 10 days in advance of each shipment. Notifications may be electronic or in writing and should contain the following information:

(i) A copy of the authorization applicable to export shipments as required by §110.42, paragraph (e)(2),

(ii) Estimated dates of when the shipment is to begin and end,

(iii) Exporting or importing facility,

(iv) Recipient,

(v) Radioactive material and specific activity,

(vi) Aggregate activity level, and

(vii) Number of radioactive sources and their unique identifiers (such as the manufacturer, model number and serial number). If the unique identifiers are not available, a description of the radioactive source shall be provided.

* * * * *

10. A new Appendix P to part 110 is added to read as follows:

Appendix P to Part 110 – High Risk Radioactive Material

	Category 1		Category 2	
Radioactive Material	Terabequerels (TBq)	Curies (Ci)	Terabequerels (Tbq)	Curies (Ci)
Americium-241:	60	2,000	.6	20
Americium-241/Be:	60	2,000	.6	20
Californium-252:	20	500	.2	5
Curium-244:	50	1,000	.5	10
Cobalt-60:	30	800	.3	8
Cesium-137:	100	3,000	1	30
Gadolinium-153:	1,000	30,000	10.0	300
Iridium-192:	80	2,000	.8	20
Plutonium-238[1]	60	2,000	.6	20
Plutonium-239/Be[1]	60	2,000	.6	20
Promethium-147:	40,000	1,000,000	400.0	10,000
Selenium-75:	200	5,000	2.0	50
Strontium-90:	1,000	30,000	10.0	300
Thulium-170:	20,000	500,000	200.0	5000
Ytterbium-169:	300	8,000	3.0	80

Dated at Rockville, Maryland, this --- day of ----- 2004

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission

[1]The limits for Pu-238 and Pu-239/Be in this table apply for imports to the U.S. The limits for exports of Pu-238 and Pu-239/Be can be found in § 110.21.

PROPOSED RULE

EXPORT/IMPORT OF HIGH-RISK RADIOACTIVE MATERIAL

REGULATORY ANALYSIS

NRC regulations provide regulatory control over the export of strategic nuclear material from a national security (nonproliferation) standpoint, but they have traditionally provided much less control over non-strategic materials, such as high-risk radioactive material (primarily “Byproduct Material” as defined in the Atomic Energy Act (AEA)). Such material has been called “Dirty Bomb” material by the News media. Many radioactive material imports and exports currently qualify for general licenses without specific review or approval by the NRC. Domestic regulations in the United States (U.S.) and abroad, and international transportation regulations, have provided the primary regulatory controls for health and safety, security, and environmental protection purposes. However, in recent years national and worldwide concerns about “high-risk” radioactive material have brought attention to the limited focus of the NRC's import and export regulations and the fact that most radioactive materials subject to NRC’s authority may be imported or exported without specific authorization by the NRC and without NRC's knowledge.

The International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (“The Code of Conduct”), which was approved by the IAEA General Conference in September 2003 with strong U.S.

Government support, provides, inter alia, that international shipments of high-risk radioactive material should take place only with the prior notification by the exporting country and, as appropriate, consent by the importing country. The Code of Conduct establishes three categories of radioactive sources and provides that no receiving country should permit the receipt of radioactive sources in Category 1 or 2 (“high-risk” material) unless it has the administrative and technical capacity and regulatory structure to manage and dispose of such material in a manner consistent with international safety and security standards. This proposed rule is intended to conform U.S. Government export/import regulations with these international guidelines. Although the Code of Conduct covers sealed radioactive sources, as generally used in international commerce, for completeness the Commission’s proposed rule also covers the export and import of bulk material. The proposed rule amends the Part 110 general license provisions applicable to the export and import of certain high-risk radioactive materials to state specifically that general licenses do not provide authority to import or export radioactive material of the types and amounts specified in a new Appendix P to Part 110. Instead, persons desiring to import or export high-risk radioactive material may do so only upon issuance of a specific license by the NRC. The rule is to provide appropriate controls on the import and export of high-risk material and is necessary to satisfy the U.S. Government's commitment to the Code of Conduct. There are no alternatives other than rulemaking for achieving the stated objective.

The requirements in the proposed rule for advance notification to NRC of individual export and import shipments are intended to parallel related requirements affecting domestic shipments of comparable high-risk material. These domestic requirements have been implemented by Commission orders.

Based on data collected through a voluntary survey of export/import shipments by U.S. companies during calendar year 2003, the proposed rule change will have the largest impact on those companies involved in the export of four radionuclides: Americium-241, Cobalt-60, Iridium-192 and Cesium-137. In 2003, there were approximately 740 export shipments of these four isotopes, and of these approximately 700, or over 95%, involved Category 2 amounts of Iridium-192 by two U.S. companies. These shipments of Iridium-192 were made to approximately 30 different countries, with about 500 shipments made to five countries: South Korea, Malaysia, Canada, Mexico and Singapore. The only export shipments in the Category 1 range involved Cobalt-60. There were 10 such shipments of Cobalt-60, all to Canada, by seven different companies with amounts ranging from 1 to 999 kilo-curies. For Americium-241, there were approximately 20 export shipments of Category 2 amounts by three companies. Finally, there was only one export of Cesium-137, 40 curies to Singapore.

The largest impact will be on exports because of the need to assess the adequacy of the importing country’s regulatory structure to appropriately control

the material upon receipt and confirm that the recipient is authorized to receive the material. The changes made by this rule will not significantly affect companies interested in importing high-risk radioactive material from other countries because the NRC has already implemented new domestic regulatory measures which meet Code of Conduct guidance for controlling imports and the U.S. Government already has a program in place for licensing domestic possession and use of radioactive materials. Note that the purpose of the proposed amendment to §110.43, which sets forth import licensing criteria, is to assure that all imports of high-risk radioactive material are to recipients in the U.S. already authorized by domestic regulations to possess such material.

The NRC has considered the resource implications for the agency in developing this proposed rule, and based on analogous NRC experience under Part 110, it is estimated that a typical high-risk material export licensing case resulting from this proposed rule will require 5 to 50 NRC staff hours for review and processing, with the higher number applying to a small number of cases requiring Commission and/or Executive Branch review due to exceptional circumstances.

The total annual cost to the NRC is expected to be approximately $750,000, which would be offset by the collection of application fees. The Commission anticipates that the principal impact on NRC staff costs will be required by §110.42(e), namely in evaluating “whether the recipient country has the

appropriate technical and administrative capability, resources and regulatory structure to manage the material in a secure manner." Additional staff time will be required in obtaining the consent of the importing country to proposed Category 1 exports from the U.S. NRC will consult as needed with the Executive Branch in obtaining such consents. The overall burden is expected to decline over time as the Commission, the license applicants and foreign recipients gain additional experience in processing cases and importing countries make further progress in enhancing the regulatory infrastructure necessary to meet the Code of Conduct recommendations. Ultimately, the Commission anticipates issuing broad specific export licenses that may cover both multiple shipments and multiple end-users in one or more countries. It is estimated that the cost associated with such review and processing will, on the average, be $5,000 to $10,000 per case, with cases involving exceptional circumstances at the high end.

The impact on applicants for import and export licenses includes the time to complete the application, the time spent providing prior notice of shipments, and the payment of the fee for processing the application.

For the reasons stated earlier, the resource implications for processing import license applications is expected to be far less, and, consequently, lower fees, probably $5,000 or less per application. (Fees for licensing services rendered by

the NRC pursuant to 10 CFR Part 110 are covered in 10 CFR Part 170.) We do not expect that an annual fee will be assessed because we do not foresee that any significant NRC inspection or enforcement activities will result from this proposed rule.

The proposed rule focuses greater attention on shipments of radioactive material from or into the U. S. This is consistent with the intent of the recommendations of the Code of Conduct. Overall, the NRC believes that requiring specific export and import licensing of high-risk radioactive material coming into the U.S. is a sound regulatory approach to help ensure that such shipments are handled in a safe and secure manner, and are subject to U.S. Government approval and the consent of other involved parties.