#### **NUCLEAR REGULATORY COMMISSION**

#### 10 CFR Part 110

#### RIN 3150-AH44

**Export and Import of Radioactive Materials: Security Policies** 

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final rule.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is amending its regulations pertaining to the export and import of radioactive materials. The amendments implement recent changes to the nuclear and radioactive material security policies of both the Commission and the Executive Branch. The final rule takes into account provisions in the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) concerning the import and export of radioactive sources, and the supplemental IAEA Guidance on the Import and Export of Radioactive Sources (Guidance document) on internationally harmonized guidance for the import and export of radioactive sources. The amendments provide for enhanced tracking of certain exports and imports of radioactive sealed sources and bulk material for certain radionuclides. The amended regulation includes new specific export and import license 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. The amendments apply to a small number of radioactive materials when exported or imported in amounts exceeding

clearly defined International System (SI) limits. The amended regulation provides 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 radioactive material.

**PUBLICATION IN THE FEDERAL REGISTER]** to allow a period of six months for exporters and importers to apply for and receive required specific export and import licenses.

ADDRESSES: Copies of the final rule, the regulatory analysis, public comments received and related documents may be examined on public computers and copied for a fee at the NRC's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Public File Area O1F21, Rockville, Maryland. These documents are also available electronically at the NRC's Public Electronic Reading Room on the Internet at <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>. 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. For further information contact the PDR reference staff at 1 (800) 387-4209, (301) 415-4737 or by e-mail to <a href="mailto:pdr@nrc.gov">pdr@nrc.gov</a>. The final rule and related documents are also available on the NRC's rulemaking Website at <a href="mailto:http://ruleforum.llnl.gov">http://ruleforum.llnl.gov</a>. Address questions about our rulemaking Website to Carol Gallagher (301) 415-5905; e-mail: <a href="mailto:cag@nrc.gov">cag@nrc.gov</a>.

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: <a href="mailto:ssh@nrc.gov">ssh@nrc.gov</a>.

#### SUPPLEMENTARY INFORMATION:

### I. Background and Summary

On September 16, 2004, the NRC published in the **Federal Register** a proposed rule that would amend 10 CFR Part 110 pertaining to the export and import of nuclear material and equipment (69 FR 55785). The NRC is now issuing a final rule based on the comments received on the proposed rule. This final rule takes into account the results of the NRC's comprehensive review of nuclear and radioactive material security requirements in the post-September 11, 2001 environment and the resulting Orders issued to domestic licensees of the NRC and Agreement States under the Commission's authority under the Atomic Energy Act of 1954, as amended (AEA), to assure the common defense and security. The Orders are separate from this rulemaking and remain in effect for domestic shipments. The final rule codifies provisions in the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) for the import and export of radioactive material, and the supplemental IAEA Guidance on the Import and Export of Radioactive Sources (Guidance document). Paragraphs 23-29 of the Code of Conduct are intended to guide countries in the development and harmonization of policies and laws on certain exports and imports of radioactive sources, which if handled improperly, may pose a significant risk to individuals, society and the environment, to ensure that such sources are only exported to authorized end-users in countries with adequate regulatory controls, and that they are not diverted for illicit use. The U.S. and many other countries have politically committed to follow the Guidance contained in the Code of Conduct and Guidance document, which were each approved by the IAEA Board of Governors in 2003 and endorsed by the IAEA General Conference in 2004. The final rule also goes beyond the Code of Conduct and its Guidance

document in the area of bulk material to reflect the post September 11, 2001 security policies of the Commission and the Executive Branch. Material in "bulk" or "loose" form raises security concerns that equal or exceed those for material in sealed sources.

The specific radioactive material and quantities that will be covered by this final rule are listed in Table 1 of the new Appendix P to Part 110. Table 1 is essentially identical to the list of radioactive materials in Categories 1 and 2 in Annex 1, Table 1, of the Code of Conduct. The amendments to Part 110 require NRC authorization of certain exports and imports by specific license of radioactive material at the Category 2 level and above of the IAEA Code of Conduct and the Guidance document which may pose a significant risk to individuals, society and the environment if handled improperly. Exports and imports of these radioactive materials will take place with prior notification to the NRC and the importing country authority. Exports of Category 1 quantities of such material will require the consent of the government of the importing country prior to shipment.<sup>1</sup> While prior notification of the importing government authority may originate from either the exporting licensee or exporting government authority, consent to the import of Category 1 material is to be provided on a government to government basis. The NRC will not issue a license for Category 1 exports prior to receiving consent from the importing government. In cases where the recipient does not have an authorization to possess the radioactive material and/or the importing country does not have the technical and administrative capability, resources, and regulatory structure needed to ensure that the radioactive source will be managed in a manner consistent with the provisions of the Code of Conduct, the NRC may, at its discretion, authorize an export of Category 1 and 2 radioactive material in cases of exceptional circumstances, as defined in § 110.2. Category 1 and 2 exports will not be permitted under exceptional circumstances unless the government of the importing state

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<sup>&</sup>lt;sup>1</sup> The more restrictive requirements for the export of plutonium 238 and 239 contained in § 110.21 will continue to be the limiting controls.

provides its consent to the United States Government for the import.

Although the provision for "exceptional circumstances" in the Guidance document applies to both imports and exports, this final rule will only address such circumstances as they apply to exports. This is because the U.S. has the technical and administrative capability, resources and regulatory structure needed to ensure that radioactive sources will be managed in the United States in a manner consistent with the provisions of the Code of Conduct, and to ensure that the domestic recipient is authorized to receive and possess the source under U.S. national law.

With the exception of plutonium, the radioactive materials listed in Appendix P, Table 1, are categorized as byproduct material as defined in the AEA. Although radium-226 is encompassed by the Code of Conduct, it is not listed in Appendix P, Table 1, or covered by the scope of this final rule because, as a naturally occurring radioactive material, under the AEA, it is not under the jurisdiction of the NRC. The Department of Commerce regulates the export of radium-226. The NRC is seeking legislation from Congress that will confer upon it licensing jurisdiction over discrete sources of radium-226. Should that legislation be enacted, the NRC will amend its export and import regulations in a manner consistent with the Code.

It should be noted that yttrium-90 has been added to Appendix P, Table 1, as a decay product of strontium-90, consistent with Annex 1, Table 1 of the Code of Conduct. Also, the final rule makes clear that the threshold amounts in Table 1 are specified by terabequerels (TBq). Curie values are provided by NRC for informational purposes only, since the values have been rounded after conversion. Any conversion to the curie must still meet the TBq limit. Appendix P also prescribes the methodology, "sum of fractions," to be used for calculating the shipment of bulk material and/or multiple radionuclides. This methodology is used in 10 CFR Part 71, Appendix A, for calculating the transport of multiple radionuclides. The requirements

described in this final rule apply to all identified licensees, both NRC and Agreement State.	

Consistent with the scope of Part 110, this rule does not apply to the Departments of Defense and Energy for activities authorized by sections 54, 64, 82 and 91 of the AEA, except when the Department of Energy seeks an export license under section 111 of the AEA (see §110.1(b)(1)). In addition, paragraph F.5 of the Guidance document notes that "States should construe this non-legally binding Guidance in accordance with activities furthering non-proliferation, nuclear security, and the avoidance of malicious acts using radioactive sources."

Exports. Under the AEA 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 about radioactive material falling into the hands of non-country organizations, including terrorist groups. In making its inimicality determination, the Commission will, under the rule and consistent with the Guidance document, and in consultation with the Executive Branch, consider whether the importing country has the technical and administrative capability and the resources and regulatory structure to manage the radioactive material in a safe and secure manner, and has authorized the recipient to receive and possess this material. For proposed exports of Category 1 amounts of radioactive material listed in Appendix P, the Commission will also assess whether the government of the importing country has provided its consent to the import. For both Category 1 and Category 2 exports, the Commission will require the applicant for the export license to provide the NRC 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 receive and possess the material.

The Code of Conduct and the Guidance document provide for exports and imports in situations where a potential recipient lacks the necessary authorization to receive and possess

the radioactive material, or where a receiving country is lacking in technical and administrative capability, resources, or regulatory structure, under "exceptional circumstances." The Commission has considered that guidance in preparation of this final rule, and therefore will consider as part of its overall inimicality determination whether the export qualifies as an "exceptional circumstance." In such a case, the Commission will also consider whether the government of the importing country has provided its consent to the import of Category 1 or Category 2 amounts of radioactive material.

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, as appropriate, seek the advice of the Executive Branch and will take into account information it receives as part of regular interactions with its foreign regulatory counterparts, the IAEA, and the Executive Branch. If, after considering the above information, the Commission authorizes the export, then export licensees will be required to provide prior notification of individual shipments to the importing country authority and to the NRC.

Imports. For imports, the licensing criteria are non-inimicality to the U.S. common defense and security and a finding that the import does not constitute an unreasonable risk to the public health and safety. The final rule incorporates the Guidance document's criteria for making these determinations. Since all recipients in the U.S. must be properly authorized by the NRC, an Agreement State, or the Department of Energy to receive and possess such radioactive material, import licenses under NRC's licensing authority of radioactive material will simply require that the recipient licensee provide (1) a copy of its authorization to the exporter or exporting country authority (or alternatively that the NRC confirm to the exporting country's authority that the U.S. recipient is authorized to receive and possess the radioactive material), (2) prior notification to the NRC of individual shipments, and (3) pertinent documentation to the

NRC that each recipient of the radioactive material has the necessary authorization to possess this material. For proposed imports into the U.S. of Category 1 amounts of radioactive material, specified in Appendix P to Part 110, the Commission will be responsible for providing the necessary formal U.S. Government consent to the export authority of the exporting country.

Elexibility. The Commission will evaluate each license application on a case-by-case basis, but may exercise some discretion on whether a license may cover multiple shipments. For example, the Commission may wish to limit exports made to new recipients or to a country/destination with limited experience with its regulatory infrastructure to single shipments of radioactive material. On the other hand, for countries with mature regulatory infrastructures with known and competent recipients, the Commission intends to use the provisions of § 110.31(e) to issue broad specific export and import licenses for multiple radionuclides, shipments, and destinations and with authorizations valid for multiple years. The duration of the import or export authorization will be consistent with the expiration date of the recipient's authorization to receive and possess the radioactive material. In all cases, each shipment will require prior notification as discussed previously.

### II. Comments on the Proposed Rule

On October 19, 2004, the staff held a public meeting at NRC to answer questions and address concerns about the proposed rule and how it would be implemented. A summary of the October 2004 public meeting and a list of questions and answers prepared by the NRC staff for discussion at the public meeting, are available on the NRC's rulemaking web site at <a href="http://ruleforum.llnl.gov">http://ruleforum.llnl.gov</a> (ADAMS accession nos. ML043020582 and ML042930012, respectively). Another public meeting was held on February 16, 2005.

Written comments on the proposed rule were due to the NRC by November 30, 2004.

The Commission received eighteen letters from the public commenting on the proposed rule.

In general, the comments received related either to the scope of the rule or the effect of its

implementation on licensees, from the potential for disruption of supply to the cost of fees required to obtain the new licenses that would be required.

**Comment:** With regard to comments on the scope of the proposed rule, several private individuals indicated that it is not broad enough because it does not address radiological safety or fully address security concerns due to the basic international decision to limit government imposed controls to exports and imports of Category 1 and 2 material, leaving Category 3 material uncontrolled.

For Category 3 material, comments suggested that the Commission should do three things: (1) modify the current general export license by requiring the exporter to notify the NRC in advance of each shipment, (2) require that all exports under the general license be to specific end-users whose bona fides have been verified, and (3) differentiate among Category 3 exports by establishing subcategories of specific concern and authorizing exports under the general license to a limited number of countries.

Commenters also indicated that the final rule should require shipments of radioactive sources, and the devices containing them, to comply with standards for radiation safety and when applicable, for patient safety, prior to export. It should also require date and confirmation of receipt by the intended recipients of the radioactive sources scheduled for export, in order to complete the security linkage governing transfers.

NRC Response: While it is conceivable that additional security measures for Category 3 material are possible in the future, an attempt to achieve such enhanced controls would extensively delay the implementation of the final rule. At this time, there is no international export/import guidance relating to Category 3 sources. This issue was discussed at length during the meetings sponsored by the IAEA which led to the adoption of the Code of Conduct

and the Guidance document. Balancing security and the need to provide a reliable and commercially viable radioactive source industry, the involved countries decided to limit internationally harmonized export/import controls to Category 1 and 2 sources. In so doing, the involved countries recognized the need for proper security for Category 3 sources, but concluded that such security measures could be adequately addressed by a combination of domestic safety/security regulatory oversight and by recognizing the overall competence of the radioactive source industry. Providing additional government authority over such material, without clear indications of wider government and industry support for such measures, would likely be counterproductive and harm the larger public interest by impeding international commerce in the use of Category 3 sources.

Confirmation of receipt by the intended recipients of the radioactive sources scheduled for export, in order to complete the security linkage governing transfers, is required in the recipient's certification to the licensee.

Comment: Several comments from industry indicated that the scope of the proposed rule should be relaxed for certain exports and imports being placed under specific license requirements to avoid potential supply disruptions. One commenter requested that exports of smoke detectors containing less than one microcurie of americium-241 be exempted from Part 110 licensing, and if this is not possible that it be exempted from specific license and the reporting requirements as listed in § 110.23(b). Several commenters requested that instead of requiring a specific license, that the following be allowed under general license: exports and imports of americium-241 and AmBe contained in industrial process control equipment or petroleum exploration equipment, to any country not listed in § 110.28 (embargoed destinations); the return or import of used sources to the U.S. exporter; the use of end-user

statements instead of specific licenses; and the use by exporters/shippers of local quality assurance procedures to validate the legitimacy of the end user using standard business practices in accordance with already existing Customs requirements. Commenters suggested that, for Category 2 shipments, the regulations should allow e-mail notifications to NRC at the time of shipment, currently done under the Commission's Orders; and for Category 2 exports, the owner or licensee should be able to determine if the foreign recipient is properly authorized to receive material which is authorized by the Code of Conduct Guidance. Finally, it was suggested that the IAEA standard should be used for verifying suitability of an importing country instead of redundant assessments by multiple countries. In connection with this, the NRC should provide a list of countries which meet the suitability requirements.

NRC Response: While NRC is not excluding such byproduct material from Part 110 coverage, essentially all such exports are covered by the general licenses in § 110.23(a). Also, the reporting requirement for americium-241 in § 110.23 (b) must remain due to a commitment among the U.S. Government and the governments of the United Kingdom, France, the Russian Federation and Japan to exchange annual reports of americium-241 and neptunium-237 as "alternate nuclear materials."

With regard to comments that favored the control of Category 2 shipments under the general license in § 110.23(a), the Commission has determined that its security policy for the export and import of Appendix P radioactive material will require specific export and import licenses, including Category 2 shipments.

In response to the Commission's requirement of export and import licenses, and the public's view that they will cause supply disruptions, NRC will employ a series of steps to prevent this scenario from developing. First, the NRC will issue specific licenses that are carefully crafted and contain appropriate conditions. Second, licenses can be issued for broad

periods of time to multiple destinations. Third, staff resources in the Office of International Programs that were used in the development of this rule will be devoted to implementing it and reviewing the export and import license applications so that licenses can be issued on a timely basis. Fourth, to the extent possible, the NRC and Executive Branch will consider information from the importing countries, the IAEA, and other sources when deciding on whether to license an export to an importing country. Because there is no single set of criteria to determine whether an importing country has adequate regulatory controls, this assessment in most cases will rely on multiple sources of information. In that regard, the Commission plans to (1) initiate contacts with NRC's foreign regulatory counterparts in key countries in an effort to obtain information on their capabilities in handling Appendix P radioactive material, and (2) obtain any publicly available information from the IAEA. Fifth, during the early stages of rule implementation, the Commission will rely on its authority to issue specific export licenses under the "exceptional circumstances" clause (as reflected in § 110.42(e)(3)), where appropriate, in order to avoid serious supply disruptions while at the same time being mindful of security concerns.

Comment: Several commenters indicated that the scope of the NRC proposed rule does not conform to the Code of Conduct because (1) it includes bulk material; (2) the threshold value or regulatory standard needs to be in metric units, or U.S. shipments will exceed international standards; (3) it requires a specific license instead of an authorization; and (4) the notification requirement is 10 days instead of 7. Other commenters were concerned as to the conformance of the export/import rule with domestic transportation regulations.

**NRC Response:** The Commission believes that shipments of bulk material need to be within the scope of this rule in the new security environment. While international guidance does

not as yet cover such exports or imports, NRC does not anticipate any difficulty in the timely processing of such export or import requests since they are less frequent (compared to radioactive source exports and imports) and each request can be handled on a case-by-case

basis with appropriate interaction between NRC, the importing country and the importing facility owner or licensee.

With regard to the regulatory standard, the final rule makes it clear that the threshold amounts in Table 1 of Appendix P are specified in the International System (SI) of weights and measures of TBq. Any conversion to curies must meet the SI or TBq limit. Therefore, curies cannot be rounded up if they violate that limit. Also, the 10-day prior notification period in the proposed rule in § 110.50(b)(4), is being changed to 7 days in the final rule, in conformance with the Guidance document. With regard to possible conflicts in the domestic transport of radioactive materials, NRC is closely monitoring requirements in the transportation area to ensure that there is no conflict. Conversely, any security-related enhancements in the domestic area may impact the Commission's export/import regulations, not only as they pertain to Appendix P material, but also with respect to the NRC's standard provisions for handling other exports (such as source and special nuclear material). The NRC is working with other agencies and the international community to address the issue of possible discrepancies between this rule and any future transportation standards.

Comment: Several comments concerned the potential cost of the many export and import licenses that would be required, and the cost of disrupting supply and commerce.

Several commenters indicated that the NRC license fees are high and will drive some small companies out of business, because the fee and/or amendment request could prove more expensive than the source itself. They noted the lack of relief for small business entities.

Additionally, commenters expressed concern that it would be necessary to apply for many NRC specific licenses for each foreign end user. A globally harmonized approach is needed to ensure a level playing field for commerce. Commenters argued that for radiography and oil well

logging, particularly for producers and shippers of americium-241, AmBe, and iridium-192, a delay in receiving the source can jeopardize the project or critical safety inspections.

A number of comments pointed to the specific license requirements in the proposed rule, suggesting these would adversely affect commerce in the following ways. First, the commenters noted the estimated burden of 15 minutes per advance notification is inaccurate, and is expected to take 30 minutes or more. Second, the commenters noted the requirement to list all foreign end users on each export license application, if required for each new foreign customer, would exceed NRC's domestic licensing regulations. Third, the commenters noted that new rule will require a potentially large number of licenses that will be required by the proposed rule, e.g., if a new license is required for each foreign end-user. Fourth, the commenters noted that there is a possible three- to four-month time period required to process each application which already exists with current Part 110 procedures. Fifth, the commenters noted that there is uncertainty over whether a U.S. company doing business in another country will require a specific license that has been issued by the other country. Sixth, some countries issue import permits for each shipment, which could complicate the process of issuing the related NRC export license. Seventh, some countries may not be able to receive shipments from the U.S. because in that country the material is not regulated or there is no regulatory authority to implement the Code of Conduct.

NRC Response: To alleviate some of the concerns about the costs of this rule, the Commission intends to issue broad specific licenses which will allow spreading the licensing fees over several shipments. With regard to the burden estimate for submitting advance notifications to the NRC prior to shipment, comments received from industry during the Public Meeting of October 19, 2004, indicated that the estimated 15 minutes per advance notification will take closer to 30 minutes each. Therefore, in the final rule, the estimated burden for each

advance notification to the NRC by the licensee is being changed to 30 minutes. In § 110.50 paragraph (b)(4) of the proposed rule, advance notifications were due to the NRC at least 24 hours in advance of each shipment, and to the extent practical, 10 days in advance of each shipment, consistent with comments received by the Commission in the development of the Commission Additional Security Measures (ASMs). In the final rule, "to the extent practical" has been adjusted downward to 7 days for consistency with the Guidance document. Hence, although the final rule requires at least 24-hours advance notification prior to shipment, such notifications under § 110.50(b)(4) are expected within 7 days, "to the extent practical." Further, the U.S. is actively encouraging other countries to follow the Code of Conduct and Guidance document to harmonize import and export procedures. The NRC has the discretion to consider exceptional circumstances, defined in § 110.2, if a country does not have the regulatory structure needed to ensure that radioactive sources will be managed in a manner consistent with the Code of Conduct.

**Comment:** Several individuals indicated that the six-month implementation period is not long enough to provide adequate time for the U.S. and other governments to ensure that all end users are properly qualified and licensed to receive and possess the material. The commenters also pointed out that Part 110 does not indicate what penalties are to be used to punish those countries which choose to violate NRC's regulations.

NRC Response: NRC expects that the majority of new licenses required by the rule will be issued within the six-month period following its publication in the Federal Register, particularly to those entities in countries with known, competent nuclear regulatory systems. To address the issue of countries and/or end users that may have difficulty in meeting all the new requirements, the Commission can rely on certain "exceptional circumstances," where present,

as the basis for issuing export licenses.

The penalties to be applied for violating NRC's export/import regulations are addressed in Part 110, Subpart F. The U.S. is actively encouraging other countries to follow the guidance in the Code of Conduct and Guidance document. It is to the advantage of all suppliers that the export and import procedures be applied in a harmonized manner to avoid undercutting and to help ensure a level playing field.

## III. Section by Section Analysis of the Final Rule

Section 110.2. A definition of "exceptional circumstances" consistent with the Code of Conduct and Guidance document is being added to the final rule. Also, the definition of "specific activity" is being revised in the final rule to reflect the TBq SI unit as the regulatory standard. This will make Part 110 consistent with the Commission's 1996 metrication policy. Any conversion to curies must not exceed the TBq limit. New sources to be exported or imported under the general license will have to conform to the TBq limits by the time the final rule is implemented.

<u>Subpart C - Licenses</u>. The final rule requires specific licenses for all exports and imports of radioactive material listed in Table 1 of the new Appendix P to Part 110, if the shipment amounts meet or exceed those listed.

Section 110.21. In paragraph (a)(4), the curie value is replaced by the SI unit of TBq to make § 110.21 consistent with the SI units used in Appendix P.

Section 110.22. In paragraph (a)(3), the curie value is replaced by the SI unit of TBq to make § 110.22 consistent with the SI units used in Appendix P.

Section 110.23. In paragraphs (a)(2), (3), (5), and (6) of this section, the curie and gram values are replaced by TBq to make these paragraphs consistent with the SI units used in Appendix P. In paragraph (a)(2), a sentence is added to indicate that individual shipments must

be less than the TBq values specified in Category 2 of Appendix P to this Part. In paragraph (a)(3), a sentence is added to require that individual shipments be less than the TBq values specified in Category 2 of Appendix P to this Part. Paragraphs (a)(3) and (7) of the proposed rule are not being adopted. Proposed paragraph (a)(3) contained a drafting error which conflicts with the Nuclear Suppliers Group (NSG) Part 2 controls for certain alpha-emitting radionuclides. Proposed paragraph (a)(7) is no longer necessary because the sentences being added to paragraphs (a)(2) and (3) contain the relevant information.

Section 110.27. Paragraph (a) is revised to include a reference to the new paragraph (f) in this section. A new paragraph (f) is inserted that requires that individual import shipments of radioactive material listed in the new Appendix P to Part 110 and conducted under the general license provisions of § 110.27(a) be below the amounts for Category 2.

Section 110.32. In paragraph (f)(1), the curie value is replaced with TBq to make this paragraph consistent with the SI units used in Appendix P. A new paragraph (g) describing the documentation that must accompany an import application for radioactive material listed in the new Appendix P is added. Also, a new paragraph (h) describing the documentation that must accompany an export license application for radioactive material listed in the new Appendix P is added.

<u>Subpart D - Review of License Applications</u>. Licensing criteria for radioactive material exports and imports, listed in Appendix P, are being added to this subpart.

Section 110.40. In paragraph (b)(6)(iv), the curie value is replaced with TBq to make this paragraph consistent with the SI units used in Appendix P.

<u>Section 110.41</u>. In paragraph (a)(3), the curie value is replaced with TBq to make this paragraph consistent with the SI units used in Appendix P.

Section 110.42. New paragraph (e) is added to specify the licensing criteria for the

export of Category 1 and 2 shipments of radioactive material listed in the new Appendix P.	

Section 110.43. New paragraphs (e) and (f) specify the licensing criteria for the import of radioactive material listed in the new Appendix P in amounts indicated for Categories 1 and 2.

Section 110.45. A new paragraph (b)(5) describes the requirements for issuing import licenses for the radioactive material listed in the new Appendix P in amounts specified in Categories 1 and 2. Also, the final rule renumbers paragraphs (c) and (d) as paragraphs (d) and (e) and adds a new paragraph (c) that describes the appropriate steps that the U.S. Government will take to inform the exporting country that the recipient is authorized to receive and possess the source or sources to be exported.

## Subpart E - License Terms and Related Provisions.

Section 110.50. In accordance with the proposed rule, existing paragraph (a)(3) had the word "transport" added after the word "use." Existing paragraphs (b)(4) and (b)(5) are redesignated as paragraphs (b)(5) and (b)(6) and a new paragraph (b)(4) is added to specify the advance notification requirements for the licensee exporting or importing material listed in Appendix P. Paragraph (b)(4) in the final rule differs from the proposed rule language in the following respects: (1) it is revised to indicate that a list of points of contact in the importing countries will be made available on the NRC Office of International Programs external website <a href="http://www@nrc.gov">http://www@nrc.gov</a>; (2) it is revised to indicate that the point of contact for receiving advance notifications for all export and import shipments is the NRC Operations Center and that relevant contact information will be provided on each export and import license; and (3) the requirement for advance notification of shipment within 10 days "to the extent practical" is changed to require notification within 7 days "to the extent practical," to conform with the Guidance document. Paragraph (a)(3) is revised to make it clear that transport within the United States of radioactive material is not authorized by a general or specific export or import license issued

under Part 110. Redesignated paragraph (b)(5) is revised to clarify that Part 110 licensees must comply with the NRC's domestic regulations covering transportation in 10 CFR Part 71. Also, a new paragraph (b)(7) is added to indicate that advance notifications containing information on shipment dates for the quantities of the radionuclides in Appendix P should be controlled as sensitive, unclassified information.

Appendix P to Part 110. The new Appendix P lists the radioactive material and the quantities requiring specific licenses. A new footnote added to Table 1 of Appendix P in the final rule states that the threshold values are specified in TBq, the regulatory standard consistent with the Code of Conduct. The curie value is given in parentheses only for information purposes and has been rounded after conversion from the TBq value. This change is necessary for two reasons. First, it will ensure the consistency of these regulations with the Code of Conduct and will facilitate advance shipment notifications to other competent government regulatory authorities which use the SI unit of TBq, not curies. Second, as was noted by a licensee during the Public Meeting of October 19, 2004, purchasers of sealed sources are, in some cases, already ordering the sources to be sized at just under the perceived Category 2 limit. For example, ordering a sealed source containing 19.75 curies of Am-241, just under the "20 curie" limit will result in a violation of the SI limit because a precise conversion of the 0.6 TBq Category 2 limit for Am-241 equates to a 16.2 curie limit. Therefore, a lack of clarity in the regulatory standard would impede licensees' planning to coordinate their operational and investment plans with these regulations. In order to minimize the potential for conversion mistakes, the final rule differs from the proposed rule and the Code of Conduct in that the curie values in Appendix P have been rounded to two significant figures instead of one.

In the final rule, Appendix P, Table 1, also includes Y-90, a decay product of the radionuclide, Sr-90, to maintain consistency with the Code of Conduct. A new footnote has

been added to prescribe the methodology "sum of the fractions" for calculating effective

quantities for combinations of radionuclides being transported together. The proposed rule did

not contain any provisions on threshold limits for import and export shipments of multiple sealed

sources or bulk material of the same radionuclide or multiple radionuclides. A "sum of

fractions" methodology, already used by the NRC in 10 CFR Part 71, Appendix A, when

evaluating the transportation limits of combination shipments of radionuclides, is included in

Appendix P and is to be used for calculating shipments of bulk material and multiple sources

and/or radionuclides.

**Agreement State Compatibility** 

Regulatory authority over the export and import of sources of concern is reserved to

NRC under the AEA. Therefore, under the "Policy Statement on Adequacy and Compatibility of

Agreement State Programs," approved by the Commission on June 30, 1997, and published

September 3, 1997 (62 FR 46517), the rules being adopted are classified as compatibility

Category "NRC." Agreement States should not adopt equivalent rules.

**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** 

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The NRC has determined that this final 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 final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). These requirements were approved by the Office of Management and Budget (OMB), approval numbers 3150-0036 and 3150-0027.

The burden to the public for these information collections is estimated to average 2.4 hours per application, 30 minutes per licensee advance notification to the NRC, and 15 minutes per recipient's certification to the licensee, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of 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 <a href="INFOCOLLECTS@nrc.gov">INFOCOLLECTS@nrc.gov</a>; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0036 and 3150-0027), Office of Management and Budget, Washington, DC 20503.

#### **Public Protection Notification**

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

#### Regulatory Analysis

The Commission has prepared a regulatory analysis for this final rule. The analysis examines the cost and benefits of the alternatives considered by the Commission. The regulatory analysis is available in ADAMS (Accession No. ML051430150) and on the NRC's

rulemaking Website at <a href="http://ruleforum.llnl.gov">http://ruleforum.llnl.gov</a>. See also the discussion under Regulatory Flexibility Certification.

### **Regulatory Flexibility Certification**

This rule is necessary to reflect the nuclear and radioactive material security policies of the Executive Branch and to comply with international agreements and guidance to which the U.S. Government subscribes. On the basis of information available to the Commission, the final rule will not have a significant economic impact on a substantial number of small entities.

### **Backfit Analysis**

The NRC has determined that a backfit analysis is not required for this rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

### **Small Business Regulatory Enforcement Fairness Act**

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

### List of Subjects in 10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Exports, Import, Intergovernmental relations, Nuclear 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 AEA; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting 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 § 110.2, the definition of "exceptional circumstances" is added, and the definition of "specific activity" is revised to read as follows:

## § 110.2 Definitions.

\* \* \* \* \*

Exceptional circumstances means, with respect to exports from the United States of radioactive material listed in Table 1 of Appendix P:

- (1) Cases of considerable health or medical need as acknowledged by the U.S.
  Government and the government of the importing country;
- (2) Cases where there is an imminent radiological hazard or security threat presented by one or more radioactive sources; and
- (3) Cases in which the exporting facility or U.S. Government maintains control of the radioactive material throughout the period the material is outside of the U.S. and removes the material at the conclusion of this period.

\* \* \* \*

Specific activity means the radioactivity of a radionuclide per unit mass of that nuclide, expressed in the SI unit of Terabequerels per gram (TBq/g). Values of specific activity are found in Appendix A to Part 71 of this chapter.

\* \* \* \* \* \*

## § 110.21 [Amended]

3. In § 110.21, paragraph (a)(4) is amended by removing "100 millicuries" and adding in its place "3.7x10<sup>-5</sup> TBq (100 millicuries)."

## § 110.22 [Amended]

- 4. In § 110.22, paragraph (a)(3) is amended by removing "100 millicuries" and adding in its place "3.7x10<sup>-5</sup> TBq (100 millicuries)."
  - 5. In § 110.23, paragraphs (a)(2), (a)(3), (a)(5), and (a)(6) are revised as follows:

### § 110.23 General license for the export of byproduct material.

- (a) \*\*\*
- (2) Actinium-225 and -227, americium-241 and -242m, californium-248, -249, -250, -251, -252, -253, and -254, curium-240, -241, -242, -243, -244, -245, -246 and -247, einsteinium-252, -253, -254 and -255, fermium-257, gadolinium-148, mendelevium-258, neptunium-235 and -237, polonium-210, and radium-223 must be contained in a device, or a source for use in a device, in quantities of less than 3.7x10<sup>-5</sup> TBq (100 millicuries) of alpha activity per device or source, unless the export is to a country listed in Sec. 110.30. Individual shipments must be less than the TBq values specified in Category 2 of Table 1 of Appendix P to this Part. Exports of americium and neptunium are subject to the reporting requirements listed in paragraph (b) of this section.
- (3) For americium-241, exports must not exceed 0.6 TBq (16 curies) per device or 60 TBq (1,600 curies) to any one country listed in § 110.29, and must be contained in industrial process control equipment or petroleum exploration equipment in quantities of less than 0.6 TBq (16 curies) per device and per shipment, not to exceed 60 TBq (1,600 curies) per year to any one country. Individual shipments to all countries other than those listed in §§ 110.28 and 110.29 must be less than 0.6 TBq (16 curies) per shipment, consistent with Appendix P to this Part.

- (5) For polonium-210, the material must be contained in static eliminators and may not exceed 3.7 TBq (100 curies) per individual shipment.
- (6) For tritium in any dispersed form, except for recovery or recycle purposes (e.g., luminescent light sources and paint, accelerator targets, calibration standards, labeled compounds), exports must not exceed the quantity of 0.37 TBq (10 curies (1.03 milligrams)) or less per item, not to exceed 37 TBq (1,000 curies (103 milligrams)) per shipment or 370 TBq

(10,000 curies (1.03 grams)) per year to any one country. Exports of tritium to the countries listed in § 110.30 must not exceed the quantity of 1.48 TBq (40 curies (4.12 milligrams)) or less per item, not to exceed 37 TBq (1,000 curies (103 milligrams)) per shipment or 370 TBq (10,000 curies (1.03 grams)) per year to any, one country, and exports of tritium in luminescent safety devices installed in aircraft must not exceed a quantity of 1.48 TBq (40 curies (4.12 milligrams)) or less per light source.

\* \* \* \* \* \*

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

## § 110.27 General license for import.

(a) Except as provided 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 receive and possess the material under:

\* \* \* \* \* \*

- (f) Individual import shipments of radioactive material listed in Appendix P must be less than the amounts specified in Category 2 in Table 1 of Appendix P to this Part.
- 7. In § 110.32, paragraph (f)(1) is revised and new paragraphs (g) and (h) are added to read as follows:

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

\* \* \* \* \* \*

- (f) \*\*\*
- (1) Maximum quantity of material in grams or kilograms (terabequerels or TBq for byproduct material) and its chemical and physical form.

- (g) For proposed imports of material listed in Table 1 of Appendix P to this part, a copy of the applicant's authorization to receive and possess the radioactive material to be imported for each recipient.
- (h) For proposed exports of material listed in Table 1 of 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 receive and possess the material. Pertinent documentation shall consist of a copy of the recipient's authorization to receive and possess the material to be exported or a confirmation from the government of the importing country that the recipient is so authorized. The recipient authorization shall include the following information:
  - (1) Name of the recipient
  - (2) Recipient location and legal address or principal place of business
- (3) Relevant radionuclides and radioactivity being imported or that the recipient is authorized to receive and possess
  - (4) Uses, if appropriate
  - (5) The expiration date of the recipient's authorization (if any)

### § 110.40 [Amended]

8. In § 110.40, paragraph (b)(6)(iv) is amended by removing "1,000 curies of tritium" and adding in its place "37 TBg (1,000 curies) of tritium."

#### § 110.41 [Amended]

- 9. In § 110.41, paragraph (a)(3) is amended by removing "100 curies of tritium" and adding in its place "3.7 TBq (100 curies) of tritium."
  - 10. In § 110.42, new paragraph (e) is 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 NRC shall consider:
- (1) Whether the foreign recipient is authorized based on the authorization or confirmation required by § 110.32 (g) to receive and possess the material under the laws and regulations of the importing country;
- (2) Whether the importing country has the appropriate technical and administrative capability, resources and regulatory structure to manage the material in a safe and secure manner;
- (3) For proposed exports of Category 1 amounts of radioactive material listed in Table 1 of Appendix P to this Part, whether the government of the importing country provides consent to the United States Government for the import of the material;
- (4) In cases where the importing country does not have the technical and administrative capability described in paragraph (e)(2) of this section, and in cases where there is insufficient evidence of the recipient's authorization to receive and possess the material to be exported, described in paragraph (e)(1) of this section, whether exceptional circumstances exist, and if so, whether the export should be licensed in light of those exceptional circumstances and the risks, if any, to the common defense and security of the proposed export;
- (5) For proposed exports under exceptional circumstances of Category 1 or Category 2 amounts of radioactive material listed in Table 1 of Appendix P to this Part, whether the government of the importing country provides consent to the United States Government for the import of the material;
- (6) For proposed exports of radioactive material listed in Table 1 of Appendix P to this

  Part under the exceptional circumstance in which there is a considerable health or medical

  need as acknowledged by the U.S. Government and the importing country, whether the United

  States and the importing country have, to the extent practicable, made arrangements for the

safe and secure management of the radioactive sources during and at the end of their useful life;

- (7) Based upon the available information, whether the foreign recipient has engaged in clandestine or illegal procurement of radioactive material listed in Table 1 of Appendix P to the Part;
- (8) Based upon available information, whether an import or export authorization for radioactive material listed in Table 1 of Appendix P to this Part has been denied to the recipient or importing country, or whether the recipient or importing country has diverted any import or export of radioactive material previously authorized; and
- (9) Based upon available information, whether there is a risk of diversion or malicious acts involving radioactive material in Table 1 of Appendix P to this Part.
  - 11. In § 110.43, new paragraphs (e) and (f) are added to read as follows:

## § 110.43 Import licensing criteria.

\* \* \* \* \*

- (e) With respect to proposed imports of radioactive material listed in Appendix P to this Part, the NRC shall consider whether 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 AEA.
- (f) In making its findings under paragraphs (a) and (b) of this section for proposed imports of radioactive material listed in Appendix P to this Part, the NRC shall consider:
- (1) Based upon available information, whether the applicant has been engaged in clandestine or illegal procurement of radioactive material listed in Table 1 of Appendix P to this Part;

- (2) Based upon available information, whether an import or export authorization for radioactive material has been denied to the applicant or whether the applicant has diverted any import or export of radioactive material previously authorized; and
- (3) Based upon available information, whether a risk of diversion or malicious acts involving the radioactive material listed in Table 1 of Appendix P to this Part.
- 12. In § 110.45, paragraphs (c) and (d) are redesignated as paragraphs (d) and (e), respectively, and new paragraphs (b)(5) and (c) are added as follows:

### § 110.45 Issuance or denial of license.

\* \* \* \* \*

- (b) \* \* \*
- (5) With respect to a proposed import of radioactive material listed in Table 1 of Appendix P to this Part, the U.S. recipient is authorized to receive and 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.
- (c) With respect to a proposed import of radioactive material listed in Table 1 of Appendix P to this Part:
- (1) If the Commission authorizes a proposed import of Category 1 or Category 2 amounts of radioactive material, it will take appropriate steps to ensure that a copy of the recipient authorization, or confirmation by the U.S. Government that the recipient is authorized to receive and possess the source or sources to be exported, is provided to the Government of the exporting country or to the exporting facility.
- (2) If the Commission authorizes a proposed import of Category 1 amounts of radioactive material, it will take appropriate steps to ensure that a copy of the consent of the

United States Government to the import is provided to the government of the exporting country in cases where it is requested by such government.

\* \* \* \* \* \*

- 13. Section 110.50, is amended as follows:
- a. In paragraph (a)(3), add the word "transport" after the word "use,"
- b. Paragraphs (b)(4) and (b)(5) are redesignated as paragraphs (b)(5) and (b)(6),
- c. Add the number "71" after the number "70" in the newly redesignated paragraph (b)(5), and
  - d. Add new paragraphs (b)(4) and (b)(7) to read as follows:

### § 110.50 Terms.

\* \* \* \* \*

(b)\* \* \*

- (4) A licensee authorized to export or import the radioactive material listed in Appendix P to this Part is responsible for notifying NRC and, in cases of exports, the government of the importing country in advance of each shipment. A list of points of contact in importing countries is available at NRC's Office of International Programs website, accessible on the NRC Public Web Site by the following links to What We Do International Programs. The NRC's office responsible for receiving advance notifications for all export and import shipments is the NRC Operations Center. Specific details on where to send the information will be listed in each specific export and import license. Notifications must be received by the NRC at least 7 days in advance of each shipment, to the extent practical, but in no case less than 24 hours in advance of each shipment. Notifications may be electronic or in writing on business stationary, and must contain or be accompanied by the information which follows.
  - (I) For export notifications:
  - (A) Part 110 export license number and expiration date;

- (B) Name of the individual and licensee making the notification, address, and telephone number;
- (C) Foreign recipient name, address, and end use location(s) (if different than recipient's address);
  - (D) Radionuclides and activity level in TBq, both for single and aggregate shipments;
- (E) Make, model and serial number, for any Category 1 and 2 sealed sources, if available;
  - (F) End use in the importing country, if known;
  - (G) Shipment date;
- (H) A copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by § 110.32 paragraph (h).
  - (ii) For import notifications:
  - (A) Part 110 import license number and expiration date;
- (B) Name of individual and licensee making the notification, address, and telephone number:
  - (C) Recipient name, location, and address (if different than above);
  - (D) Radionuclides and activity level in TBq, both for single and aggregate shipments;
- (E) Make, model and serial number, radionuclide, and activity level for any Category 1 and 2 sealed sources, if available;
  - (F) End use in the U.S.;
- (G) Shipment date from exporting facility and estimated arrival date at the end use location;
- (H) NRC or Agreement State license number to possess the import in the U.S. and expiration date.

- (7) Advance notifications containing the above information must be controlled, handled, and transmitted in accordance with § 2.390 of this chapter and other applicable NRC requirements governing protection of sensitive information.
  - 14. A new Appendix P to Part 110 is added to read as follows:

# Appendix P to Part 110–Category 1 and 2 Radioactive Material

Table 1 - Import and Export Threshold Limits

	Category 1		Category 2	
Radioactive Material	Terabequerels	Curies	Terabequerels	Curies
	(TBq)	(Ci) <sup>1</sup>	(TBq)	(Ci) <sup>1</sup>
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Curium-244	50	1,400	0.5	14
Cobalt-60	30	810	0.3	8.1
Cesium-137	100	2,700	1.0	27
Gadolinium-153	1,000	27,000	10.0	270
Iridium-192	80	2,200	0.8	22
Plutonium-238 <sup>2</sup>	60	1,600	0.6	16
Plutonium-239/Be <sup>2</sup>	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Selenium-75	200	5,400	2.0	54
Strontium-90 (Y-90)	1,000	27,000	10.0	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3.0	81

<sup>&</sup>lt;sup>1</sup> The values to be used to determine whether a license is required are given in TBq. Curie (Ci) values are provided for practical usefulness only and are rounded after conversion.

<sup>&</sup>lt;sup>2</sup> 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.

## <u>Calculation of Shipments Containing Multiple Sources or Radionuclides</u>

The "sum of fractions" methodology for evaluating combinations of radionuclides being transported, is to be used when import or export shipments contain multiple sources or multiple radionuclides. The threshold limit values used in a sum of the fractions calculation must be the metric values (i.e., TBq).

- I. If multiple sources and/or multiple radionuclides are present in an import or export shipment, the sum of the fractions of the activity of each radionuclides must be determined to verify the shipment is less than the Category 1 or 2 limits of Table 1, as appropriate. If the calculated sum of the fractions ratio, using the following equation, is greater than or equal to 1.0, then the import or export shipment exceeds the threshold limits of Table 1 and the applicable security provisions of this part apply.
- II. Use the equation below to calculate the sum of the fractions ratio by inserting the actual activity of the applicable radionuclides or of the individual sources (of the same radionuclides) in the numerator of the equation and the corresponding threshold activity limit from the Table 1 in the denominator of the equation. Ensure the numerator and denominator values are in the same units and all calculations must be performed using the TBq (i.e., metric) values of Table 1.

 $R_1$  = activity for radionuclides or source number 1

 $R_2$  = activity for radionuclides or source number 2

 $R_N$  = activity for radionuclides or source number n

AR<sub>1</sub> = activity limit for radionuclides or source number 1

AR<sub>2</sub> = activity limit for radionuclides or source number 2

 $AR_N$  = activity limit for radionuclides or source number n

$$\sum_{1}^{n} \left[ \frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \frac{R_n}{AR_n} \right] \ge 1$$

Dated at Rockville, Maryland, this 27th day of June, 2005.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook, Secretary of the Commission.