[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

RIN 3150- AH88

Implementation of the Nuclear Export and Import Provisions of the Energy Policy Act of 2005

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations that govern the export and import of nuclear equipment and material to implement provisions of the Energy Policy Act of 2005 signed into law on August 8, 2005. This amendment will facilitate exports to specified countries of high-enriched uranium for medical isotope production in reactors that are either utilizing low-enriched uranium (LEU) fuel or have agreed to convert to the use of LEU fuel. In addition, this final rule revises the definition of byproduct material to include discrete sources of radium-226, accelerator-produced radioactive material, and discrete sources of naturally occurring radioactive material. Finally, the rule will require specific licenses for exports and imports of radium-226 that meet the threshold values of the International Atomic Energy Agency's Code of Conduct on the Safety and Security of Radioactive Sources.

DATES: This final rule will become effective August 7, 2006.

ADDRESSES: Copies of the final rule and related documents may be viewed electronically on the public computers located 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 *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. For further information contact the PDR reference staff at 1 (800) 387-4209, (301) 415-4737 or by e-mail to *pdr@nrc.gov*. The final rule and related documents are also available on the NRC's rulemaking Web site at *http://ruleforum.llnl.gov*. Address questions about our rulemaking Web site to Carol Gallagher (301) 415-5905; e-mail *cag@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Brooke G. Smith, International Policy Analyst, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-2347, e-mail *bgs@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Summary and Background

The purpose of this final rule is to amend the Commission's regulations at 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material," to implement sections 630, 651(d), and 651(e) of the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005.

Section 630, "Medical Isotope Production," of the EPAct, amended section 134 of the Atomic Energy Act of 1954, as amended (AEA), to facilitate the timely export to a "Recipient

Country" of high-enriched uranium (HEU) for medical isotope production in reactors that are either utilizing low-enriched uranium (LEU) fuel or have agreed to convert to the use of LEU fuel. A "Recipient Country" is defined in section 630 as Canada, Belgium, France, Germany, and the Netherlands. The EPAct also requires the Commission to review and impose, via license conditions or other appropriate means, physical protection requirements that are applicable to the transportation and storage of HEU for medical isotope production or control of residual material after irradiation and extraction of medical isotopes.

Specifically, before issuing licenses authorizing the export of HEU in the form of fuel or targets for the production of medical isotopes to Canada, Belgium, France, Germany, and the Netherlands, the Commission must find that the Recipient Country has provided the United States with written assurances that any intermediate consignees and the ultimate consignee specified in the export application are required to use the HEU solely to produce medical isotopes. Further, the Commission must determine that the HEU will be irradiated in a reactor in a Recipient Country that uses an alternative nuclear reactor fuel, e.g., LEU, or is the subject of an agreement with the U.S. to convert to an alternative nuclear fuel when that fuel can be used in the reactor.

Section 630 suspends for the Recipient Countries (until the Secretary of Energy makes certain findings) the portions of section 134 of the AEA that required the Commission to make certain findings with respect to the use of LEU targets to produce medical isotopes before issuing an export license for HEU for medical isotope production.

This final rule amends § 110.42(a)(9) to reflect the revised export criteria with regard to export applications to Recipient Countries for medical isotope production. Although the implementing regulations promulgated will not take effect until August 7, 2006, NRC export licensing decisions have been governed by section 134 of the AEA, as amended by section 630

of the EPAct, since August 8, 2005. The NRC already evaluates the adequacy of the proposed physical protection measures under § 110.42(a)(3) when it evaluates individual export license applications, and has the authority to impose additional requirements in the license as the Commission deems necessary. Therefore, no rule changes are necessary to implement the statutory provision.

Section 651(d), "Radiation Source Protection," of the EPAct amended the AEA by imposing new requirements pertaining to the export or import of Category 1 or Category 2 radiation sources as defined by the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) (and any other material that poses a threat, as determined by the Commission, other than spent nuclear fuel and special nuclear materials). The Code of Conduct includes sixteen categories of byproduct material sources, including radium-226. On July 1, 2005 (70 FR 37985), the Commission issued final regulations amending Part 110 that together with other existing regulations satisfy the requirements of section 651(d) for the export and import of radioactive sources. However, at the time the July 2005 rule was issued, the Commission did not have authority to regulate radium-226; therefore, radium-226 was not listed in Appendix P to Part 110 or covered by the scope of the July 2005 rule. The Commission provided notice that radium-226 would be added to Appendix P to Part 110, consistent with the Code of Conduct, if Congress conferred upon the Commission jurisdiction over radium-226. Section 651(e) of the EPAct amended the definition of byproduct material in section 11e. of the AEA to include discrete sources of radium-226. Consistent with the notice provided in the July 2005 rule and the authority conferred upon the Commission by Congress in section 651(e) of the EPAct, this rule amends Appendix P to include Category 1 and Category 2 quantities of discrete sources of radium-226.

Section 651(e) of the EPAct amends section 11e. of the AEA to place accelerator-produced material, discrete sources of radium-226, and certain discrete sources of naturally-occurring radioactive material, other than source material, under NRC regulatory authority if produced, extracted, or converted for use in commercial, medical, or research activities. This rule amends Appendix L to Part 110, "Illustrative List of Byproduct Materials under NRC Export/Import Licensing Authority," to include discrete sources of radium-226 and accelerator-produced radioactive material. Prior to the enactment of the EPAct, the Department of Commerce (DOC) had jurisdiction over the export of radium-226. As provided by the EPAct, discrete sources of radium-226 will fall under NRC's jurisdiction; however, jurisdiction over the export of non-discrete sources of radium-226 will remain in DOC's jurisdiction. The Commission intends to define the term "discrete source" in a separate rulemaking.

Waiver of Notice and Comment Requirement

This rule revises the Commission's regulations solely to incorporate provisions pertaining to the export and import licensing included in the EPAct. This rule tracks statutory provisions and the drafting of it did not involve the exercise of discretionary decision-making. Good cause exists under 5 U.S.C. 553(b)(3)(B) to publish this final rule without soliciting public comment because public comment under these circumstances would serve no useful purpose and therefore, is unnecessary and contrary to the public interest.

Effective Date of Rule and Expiration of Time-Limited Waiver

The effective date of this rule, August 7, 2006, coincides with the expiration of a time-limited waiver pertaining to NRC regulation of the import and export of the new categories of byproduct material added to AEA section 11e. by the EPAct. *See* Energy Policy Act of 2005

Requirements; Treatment of Accelerator-Produced and other Radioactive Material as Byproduct Material; Waiver, 70 Fed. Reg. 51581 (August 31, 2005).

The NRC has determined that this rule will pose no unreasonable risk to the public health and safety or the common defense and security.

II. Section by Section Analysis of Substantive Changes

Subpart A—General Provisions

Section 110.2. The definition of "byproduct material" has been revised to be consistent with section 651(e)(1) of the EPAct which amended the definition of byproduct material in section 11e. of the AEA to place accelerator-produced material, discrete sources of radium-226, and certain discrete sources of naturally occurring radioactive material, other than source material, under NRC regulatory authority if they are produced, extracted, or converted for use in commercial, medical, or research activities.

The terms "medical isotope," "radiopharmaceutical," and "Recipient Country" have been added to this section consistent with the section 630 of the EPAct which amended section 134 of the AEA.

Subpart D—Review of License Applications

Section 110.42. Paragraph (a)(9) is amended to incorporate the requirements set forth in section 630 of the EPAct regarding medical isotope production.

Appendix L to Part 110—Illustrative List of Byproduct Materials Under NRC Export/Import Licensing Authority. The list of byproduct material in Appendix L is amended to add radium-226. Under the EPAct, the definition of byproduct material was expanded to include discrete sources of radium-226. The import or export of discrete sources of radium-226 that are below the threshold limits for radium-226 listed in Appendix P to Part 110 may be

accomplished through a general license set forth in 10 CFR §110.23. In addition, a footnote is added to Appendix L to indicate that the NRC has import and export authority over any accelerator-produced material that was produced, extracted or converted for use for a commercial, medical, or research activity. A second footnote is added to Appendix L to indicate that NRC has import and export authority over discrete sources of radium-226.

Appendix P to Part 110—Category 1 and 2 Radioactive Material

Table 1.—Import and Export Threshold Limits

The list of Category 1 and 2 radioactive material in Appendix P is amended to add radium-226 and the corresponding threshold limits for Category 1 and 2 quantities consistent with the values in Table 1 of the IAEA Code of Conduct. A specific license is required for the import or export of discrete sources of radium-226 meeting the threshold quantities listed in Table 1 of Appendix P. A footnote is added to the list in Appendix P to indicate that the NRC has import and export authority over discrete sources of radium-226.

Voluntary Consensus Standards

The National Technology Transfer and Advancement 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 using such a standard is inconsistent with applicable law or otherwise impractical. This final rule does not constitute the establishment of a standard for which the use of a voluntary consensus standard would be applicable.

Environmental Impact: Categorical Exclusion

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 final rule.

Paperwork Reduction Act Statement

This final rule implements the provisions of the Energy Policy Act of 2005, sections 630, 651(d), and 651(e). The final rule does not impact the information collection burden for 10 CFR Part 110 licensees. Any burden for licensing actions would be against NRC Form 7 (3150-0027). However, few, if any, licensing actions are expected to be submitted. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the OMB, approval number 3150-0036.

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 EPAct, which was signed into law on August 8, 2005, amended the definition of byproduct material in the Atomic Energy Act of 1954, as amended to include discrete sources of radium-226 and conferred regulatory authority of it to the NRC. Previously, radium-226 was under the jurisdiction of the U.S. Department of Commerce. The NRC is amending its regulations at 10 CFR Part 110 to add radium-226 to the list of radioactive material in Appendix P to Part 110. Shipments of radium-226 at or above the Category 2 level will require a specific license. This change to Part 110 fulfills the mandate from Congress in sections 651(d) and (e) of the EPAct and with the IAEA Code of Conduct. Additionally, to implement section 630, "Medical Isotope Production," of the EPAct, this final rule amends 10 CFR 110.42, "Export licensing criteria." There is no alternative to amending the regulations at 10 CFR Part 110 to reflect changes in law. This final rule is expected to have an insignificant increase in the information collection burden and cost to the public for applications to export or import radium-226 at the quantities listed in Appendix P to Part 110.

Backfit Analysis

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

Congressional Review Act

Under the Congressional Review 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, Export, 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 Atomic Energy Act of 1954, as amended; 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 is revised to read as follows:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 134, 161, 170H., 181, 182, 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, 2160d., 2201, 2210h., 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 (42U.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 (42U.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 110.30-110.135 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 *Byproduct material* is revised, and definitions for *Medical isotope*, *Radiopharmaceutical*, and *Recipient Country* are added in alphabetical order to read as follows:

§ 110.2 Definitions.

* * * * *

Byproduct material means

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore (see 10 CFR 20.1003);

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after August 8, 2005 for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005 is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

Medical isotope, for the purposes of § 110.42 (a)(9), includes molybdenum 99, iodine 131, xenon 133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.

* * * * *

Radiopharmaceutical, for the purposes of § 110.42 (a)(9), means a radioactive isotope that contains byproduct material combined with chemical or biological material and is designed to accumulate temporarily in a part of the body for therapeutic purposes or for enabling the production of a useful image for use in a diagnosis of a medical condition.

Recipient Country, for the purposes of § 110.42(a)(9), means Canada, Belgium, France, Germany, and the Netherlands.

* * * * *

3. In §110.42, paragraph (a)(9)(i) is revised, paragraph (a)(9)(ii) is redesignated as paragraph (a)(9)(iii), and new paragraph (a)(9)(ii) is added to read as follows:

§ 110.42 Export licensing criteria.

(a) * * *

(9)(i) Except as provided in paragraph (ii) of this section, with respect to exports of high-enriched uranium to be used as a fuel or target in a nuclear research or test reactor, the Commission determines that:

(A) There is no alternative nuclear reactor fuel or target enriched to less than 20 percent in the isotope U-235 that can be used in that reactor;

(B) The proposed recipient of the uranium has provided assurances that, whenever an alternative nuclear reactor fuel or target can be used in that reactor, it will use that alternative fuel or target in lieu of highly-enriched uranium; and

(C) The United States Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.

(ii) With regard to a Recipient Country, the Commission may issue a license authorizing the export of high-enriched uranium for medical isotope production, including shipment to and use at intermediate and ultimate consignees, if the Commission determines that:

(A) The Recipient Country has supplied an assurance letter to the United States Government in connection with the consideration by the Commission of the export license

application has informed the United States Government that any intermediate consignees and the ultimate consignee specified in the export license application are required to use the high-enriched uranium solely for the production of medical isotopes; and

(B) The high-enriched uranium will be irradiated only in a reactor in the Recipient Country that—

(1) Uses an alternative nuclear reactor fuel; or

(2) Is the subject of an agreement with the United States Government to convert to an alternative nuclear reactor fuel when alternative nuclear reactor fuel can be used in the reactor.

* * * * *

4. Appendix L to Part 110 is amended by adding new footnote 1 to the title of Appendix L, by revising the list of byproduct material by adding “Radium 226 (Ra 226)" in alphabetical order, and by adding new footnote 2, to read as follows:

Appendix L to Part 110—Illustrative List of Byproduct Materials Under NRC Export/Import Licensing Authority [1]

* * * * *

Radium 226 (Ra 226) [2]

* * * * *

[1] This list includes any accelerator-produced material produced, extracted, or converted for use for a commercial, medical, or research activity.

[2] Discrete sources of radium-226 (Ra-226).

5. Appendix P to Part 110 is revised by adding “Radium-226" in alphabetical order to Table 1. and new footnote 3 to read as follows:

Appendix P to Part 110—High Risk Radioactive Material

Table 1.—Import and Export Threshold Limits

Radioactive Material	Category 1		Category 2	
	Terabequerels (TBq)	Curies (Ci)[1]	Terabequerels (TBq)	Curies (Ci)[1]
* * *				
Radium-226 [3]	40	1,100	0.4	11
* * *				

[1] * * *

[2] * * *

[3] Discrete sources of radium-226.

Dated at Rockville, Maryland, this ___4__day of _____April_____, 2006.

For the Nuclear Regulatory Commission.

/RA/

Luis A. Reyes,
Executive Director For Operations.