

U.S. NUCLEAR REGULATORY COMMISSION

NRC-2012-XXXX

**Notice of Public Meeting and Request for Comment on the
Branch Technical Position on the Import of non-U.S. Origin Radioactive Sources**

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Request for Comment on Issues Related to the proposed Branch Technical Position (BTP) on the Import of non-U.S. Origin Radioactive Sources.

SUMMARY: In 2010, the NRC published a final rule amending Title 10 of the Code of Federal Regulations (10 CFR) Part 110 (75 FR 44072; July 28, 2010). Among other things, it added the phrase “Of U.S. origin” to the first exclusion to the definition of “radioactive waste” in §110.2. The phrase was added to the final rule in response to a public comment on the proposed rule to clarify the exclusion. Since publication of the final rule, NRC staff has been engaged with industry in response to concerns raised regarding established industry practices and the need for guidance on implementation of the “U.S.-origin” exclusion.

DATES: Members of the public may submit written comments on the issues discussed in this notice. Comments on the issues presented in this notice should be postmarked no later than [60 days after publication]. Comments received after this date will be considered if it is practical to do so. NRC plans to consider these stakeholder views in the development of a final BTP.

Written comments may be sent to the address listed in the **ADDRESSES** section.

Replies should be directed to the points of contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

The supplemental information below also contains a copy of the proposed BTP. The proposed BTP is available in the Agencywide Documents Access and Management System (ADAMS) under ML12278A170.

As a result of the Federal Register Notice (77 FR 2924) "Notice of Public Meeting and Request for Comment on the Branch Technical Position on the Import of Non-U.S. Origin Radioactive Sources," published January 20, 2012, five comment letters were received for consideration by the NRC. At that time, the BTP was a working draft document with the intent of using feedback to enhance the document for publication of the revised proposed BTP for formal public comment. Of the comments made on the original draft BTP, most were comments on the existing rule rather than in the guidance that the BTP provides. The NRC response to these informal comments can be found at ML1255A106. Most of the comments did not oppose the underlying policy rationale and justification for the BTP's proposal to construe "non-U.S. origin" disused sources as "U.S. origin" for the purpose of the first exclusion to the definition of "radioactive waste" under certain circumstances; instead, the comments appear to request NRC to revise or clarify the existing exclusions. Therefore, NRC did not consider these comments to be within the scope of the BTP. As a result of these comments, there are no substantive changes to the draft BTP. However, minor editorial changes were made to the draft BTP to provide greater clarity. This proposed BTP does not change the regulations in 10 CFR Part 110, it clarifies what is meant by "U.S. origin" and details how the NRC interprets this exclusion to the definition of "radioactive waste."

ADDRESSES: Please include Docket ID NRC-2012-XXXX in the subject line of your comments. For additional instructions on submitting comments and instructions on accessing

documents related to this action, see “Submitting Comments and Accessing Information” in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods:

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search NRC-2011-XXXX. Address questions about NRC dockets to Carol Gallagher, telephone: 301-492-3668; email: Carol.Gallagher@nrc.gov.
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
- *Fax comments to:* RADB at 301-492-3456.

FOR FURTHER INFORMATION CONTACT: Jennifer Tobin Wollenweber, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone 301-415-2328; e-mail Jennifer.Tobin@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Website and on the Federal rulemaking Website, <http://www.regulations.gov>. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this action using the following methods:

- *NRC's Public Document Room (PDR)*: The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *ADAMS*: Publicly available documents created or received at the NRC are available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of the 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's PDR reference staff at 1-800-397-4209, 301-415-4737, or via e-mail to pdr.resource@nrc.gov. The Branch Technical Position paper is accessible under ADAMS Accession No. ML11300A194.
- *Federal Rulemaking Web Site*: Public comments and supporting materials related to this proposed Branch Technical Position paper can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2011-XXXX.

II. Branch Technical Position

A. Introduction

The NRC's regulations in 10 CFR Part 110 (Part 110), "Export and Import of Nuclear Equipment and Material," establishes the general and specific export and import licensing requirements for special nuclear, source, and byproduct material including radioactive waste. "Radioactive waste" is defined in 10 CFR § 110.2 as "[a]ny material that contains or is contaminated with source, byproduct or special nuclear material that by its possession would require a specific radioactive material license in accordance with this Chapter [10 CFR Chapter I] and is imported or exported for the purposes of disposal in a land disposal facility as defined in 10 CFR Part 61, a disposal area as defined in Appendix A of 10 CFR Part 40, or an equivalent facility."

There are six exclusions in 10 CFR § 110.2 to the definition of “radioactive waste.” The sealed source exclusion (exclusion one) is defined as radioactive material that is “[o]f U.S. origin and contained in a sealed source, or device containing a sealed source, that is being returned to a manufacturer, distributor or other entity which is authorized to receive and possess the sealed source or the device containing a sealed source.”¹ Disused sources that satisfy an exclusion to the definition of “radioactive waste” may be imported under the general license in 10 CFR § 110.27, which requires that the U.S. consignee be authorized to receive and possess the material under the relevant NRC or Agreement State regulations and that the importer satisfy the terms for the general license set forth in 10 CFR § 110.50.

The NRC has developed this technical position to provide guidance to source manufacturers, distributors, or other entity on the NRC’s application of the sealed source exclusion to imports into the U.S. of non-U.S. origin disused sources.²

B. Background

On July 28, 2010, the NRC published a final rule in the *Federal Register* (75 Fed. Reg. 44072) that amended several provisions in Part 110 to improve NRC’s regulatory framework for the export and import of nuclear equipment, material, and radioactive waste. The sealed source exclusion to the definition of “radioactive waste” was revised, in response to a comment, to

¹ The NRC provided the following guidance on the scope of “U.S. origin” on NRC’s Export and Import Web page at (<http://www.nrc.gov/about-nrc/ip/export-import.html>):

“U.S. origin was added in the first exclusion to the definition of radioactive waste to clarify that the exclusion only applies to sources of U.S. origin. U.S. origin sources may include sources with U.S. origin material and sources or devices manufactured, assembled or distributed by a U.S. company from a licensed domestic facility. Disused sources that originated in a country other than the United States would require a specific license if being exported or imported for disposal.”

² The terms “supplier” and “importer” are used interchangeably in this document with “manufacturers, distributors, or other entity.”

confirm that the exclusion only applies to sources of “U.S. origin” being returned to an authorized domestic licensee. The addition of the term “U.S. origin” to the sealed source exclusion was consistent with the original intent of the exclusion, initially adopted in a 1995 rule.³ In accordance with International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources and the IAEA supplemental Guidance on the Import and Export of Radioactive Sources, the NRC believed that encouraging return of disused sources to the country of origin would help prevent sources from becoming “orphaned” by facilitating responsible handling of sources at the end of their life cycle. See *Import and Export of Radioactive Waste*, 57 Fed. Reg. 17859, 17861 (July 21, 1992) (proposed rule) (“the return of used or depleted sealed sources, gauges, and similar items to the U.S. or to another original exporting country for reconditioning, recycling or disposal may...help ensure that such materials are handled responsibly and not left in dispersed and perhaps unregulated locations around the world”). The NRC’s willingness to embrace this policy was in large part informed by U.S. industry comments that there is a “widely accepted practice, usually rooted in a sales or leasing contract or other agreement, of returning depleted sealed radioactive sources, used gauges, and other instruments containing radioactive materials...to the original supplier-manufacturer for recycle or disposal.” 57 Fed. Reg. at 17864. See *also*, e.g., *id.* at 17861 (“the sale of a source is often conditioned on later return of the source for disposal”). Accordingly, central to the sealed source exclusion was the NRC’s understanding, based on U.S. industry representations, that new and disused sources are routinely exchanged on a “one-for-one” basis – *i.e.*, a new source is exchanged for a disused source⁴ – with the result that the number of disused sources imported is not greater than the number of new sources exported.

³ *Import and Export of Radioactive Waste*, 60 Fed. Reg. 37556 (July 21, 1995).

⁴ The sealed sources are changed out when the decay of the source limits the usefulness of the material. At this point, a supplier typically will send a new source and the user will return the used source in the same shielded container. This practice is typically formalized in the contract between the user and the supplier. Sometimes the sources are still useful and can be recycled for re-use in a different application. In that case, the sixth exclusion to the definition of

After the addition of “U.S. origin” to the sealed source exclusion in the 2010 rule, it came to the staff’s attention that, while it remains a widespread industry practice to exchange new and disused sources on a “one-for-one” basis, in light of the current global supply market it is not always possible for a supplier to definitively ascertain the origin of a particular disused source that is exchanged for a new one before import and receipt of the disused source. With established customers, the disused sources will generally be of U.S. origin; however, for new customers, some of the sources initially being returned may not be of U.S. origin.

Once a source is imported and received, the manufacturer, distributor, or other entity technically has the ability to determine the source’s origin. However, the only way for the supplier to accomplish this is by exposing its personnel to additional radiation doses. Specifically, the supplier must use a glove-box to take the source out of its casing to read the serial numbers and correlate those numbers to different manufacturer’s coding patterns.

C. Regulatory Position

The NRC has construed the “U.S. origin” provision in the context of the industry’s recent clarification of international source exchange practices. The NRC recognizes that in some circumstances it may not be feasible for the importer to determine the country of origin for disused sources it seeks to exchange prior to import. If, after a good faith effort, the U.S. manufacturer, distributor, or other entity cannot determine whether an imported disused source that has been exchanged for a new source is of U.S. origin without exposing personnel to additional doses, the source in question shall be deemed to be of U.S. origin for the purposes of

“radioactive waste” applies and the source can be imported under a general license even if it is non-U.S. origin. Guidance on this exclusion can be found on NRC’s Export and Import Web page at <http://www.nrc.gov/about-nrc/ip/export-import.html> and is in harmony with this position paper.

the sealed source exclusion to the definition of “radioactive waste” in 10 CFR § 110.2.⁵ This application of the sealed source exclusion is limited to disused sources imported into the United States that have been exchanged for a new source in a foreign country on a “one-for-one” basis. Accordingly, it is the NRC’s expectation that the number of disused sources imported by the manufacturer or distributor into the United States must not be greater than the number of new or refurbished sources exported by that manufacturer or distributor.

The NRC believes that this application of the sealed source exclusion reasonably balances the interests of public health and safety and international policy interests in responsible handling of sources at the end of their useful life. The approach preserves the fundamental policy rationale underlying the original exclusion – to prevent sources from being dispersed in unregulated locations around the world by facilitating a “one-for one” exchange of U.S.-supplied new and disused sources – while achieving occupational doses to workers that are as low as reasonably achievable (ALARA), as specified in 10 CFR § 20.1101(b).

The NRC expects U.S. manufacturers, distributors, and suppliers to inform their customers about U.S. import licensing requirements for disused sources. It is recommended that U.S. importers retain copies of their communications with their foreign customers regarding U.S. import requirements. The U.S. importer at all times must comply with the specific license requirement for disused sources known to be of non-U.S. origin prior to import into the United States. A good faith effort by the importer may include communication of U.S. import requirements with its foreign customers, examination of a photograph of the source the customer seeks to exchange, and other relevant information related to the disused sources’ origin.

⁵ The definition of “radioactive waste” in this Branch Technical Position paper pertains solely to export and import. It does not affect or alter the domestic regulations of “waste” as defined in 10 CFR 20.1003.

Consistent with 10 CFR 110.53, the NRC may inspect the licensee's records, premises and activities pertaining to its exports and imports to ensure compliance with the sealed source exclusion to the definition of "radioactive waste" by trying to determine source origin (from user paperwork and communication) before an import occurs.

This position is being distributed to all Agreement States and material licensees.

Additionally, the NRC has coordinated this position with the Department of Energy/National Nuclear Security Administration's (DOE/NNSA) Global Threat Reduction Initiative (GTRI). One of GTRI's programs repatriates sources from around the world that are in unsafe or insecure locations. The NRC does not have import licensing jurisdiction when U.S. companies import disused sources on behalf of NNSA's GTRI program; therefore, the licensing requirements in Part 110 would not apply to such imports.

D. Implementation

This technical position reflects the current NRC staff position on acceptable use of the general license for import of disused radioactive sources. Therefore, except in those cases in which the source manufacturer or distributor proposes an acceptable alternative method for complying with the definition of "radioactive waste" in Section 110.2, the guidance described herein will be used in the evaluation of the use of the general import license for disused sources.

III. Procedural Requirements

Paperwork Reduction Act

This proposed policy statement does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0136.

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.

Congressional Review Act

In accordance with the Congressional Review Act (5 U.S.C. 801-808), 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.

Dated at Rockville, Maryland, this 2nd day of October, 2012

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Margaret M. Doane, Director
Office of International Programs