

March 15, 2011

Ms. Janet Schlueter, Director  
Fuel & Materials Safety  
Nuclear Generation Division  
Nuclear Energy Institute  
1776 I Street NW, Suite 400  
Washington, D.C. 20006-3708

Dear Ms. Schlueter:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated December 3, 2010 that provides industry comments on the final rule, "Export and Import of Nuclear Equipment and Material; Updates and Clarifications" amending 10 CFR Part 110 (Part 110) that became effective on August 27, 2010. The letter commented in particular on the phrase "U.S. origin" as used in the first exclusion to the definition of "radioactive waste" in §110.2.

On July 28, 2010, the NRC published a final rule in the *Federal Register* (75 FR 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. This final rule revised the definition of "radioactive waste" in Part 110 to improve consistency with and eliminate differences between the licensing requirements for export and import and the domestic licensing requirements for possession. The revised definition links the specific license requirement for the export and import of radioactive waste to those materials (in the form of waste) that require a specific license in accordance with NRC's or Agreement State's domestic regulations. As a result, the final rule required a specific export or import license for any material that requires a specific NRC or Agreement State license to possess domestically, in accordance with the requirements in 10 CFR Chapter 110, that is exported or imported for the sole purposes of (1) disposal in a land disposal facility as defined in Part 61, a disposal area as defined in Appendix A to Part 40, or an equivalent facility; or (2) recycling, waste treatment or other waste management process that generates radioactive material for disposal in a land disposal facility as defined in Part 61, a disposal area as defined in Appendix A to Part 40, or an equivalent facility.

In response to public comments, the NRC confirmed that the first exclusion to the definition of "radioactive waste" applies only to sources of U.S. origin that are being returned to a domestic licensee. Disused sources that originated in a country other than the United States are considered "radioactive waste" under Part 110 and require a specific import license unless an exclusion to the definition of "radioactive waste" applies.

The enclosure addresses the four concerns that you raised in your letter and provides an explanation of the NRC interpretation and implementation for the recent amendments to the regulations in Part 110. As discussed in the attachment, the NRC's regulations in Part 110, as amended in 1995, did not exclude all disused sources from the definition of "radioactive waste,"

J. Schlueter

- 2 -

only the ones being returned to any manufacturer qualified to receive and possess them. Furthermore, the NRC is not inclined to broaden the scope of "U.S. origin" based on the experiences of one importer, especially considering the complex foreign waste disposal issues in the United States, which are not acknowledged or discussed in your letter.

If you have additional questions on this matter, please contact Ms. Brooke Smith at (301) 415-2347 or at [brooke.smith@nrc.gov](mailto:brooke.smith@nrc.gov) or Ms. Jennifer Tobin Wollenweber at (301) 415-2328 or at [jennifer.tobin@nrc.gov](mailto:jennifer.tobin@nrc.gov).

Sincerely,

**R/A**

Nader L. Mamish, Acting Deputy Director  
Office of International Programs

Enclosure: As stated

cc: K. Roughan, QSA  
A. Cuthbertson, DOE/NNSA - (GTRI)  
C. Miller, FSME  
R. Lewis, FSME/DMSSA  
C. Bladey, ADM/DAS/RADB

J. Schlueter

- 2 -

only the ones being returned to any manufacturer qualified to receive and possess them. Furthermore, the NRC is not inclined to broaden the scope of "U.S. origin" based on the experiences of one importer, especially considering the complex foreign waste disposal issues in the United States, which are not acknowledged or discussed in your letter.

If you have additional questions on this matter, please contact Ms. Brooke Smith at (301) 415-2347 or at brooke.smith@nrc.gov or Ms. Jennifer Tobin Wollenweber at (301) 415-2328 or at jennifer.tobin@nrc.gov.

Sincerely,

Nader L. Mamish, Acting Deputy Director  
Office of International Programs

Enclosure: As stated

cc: K. Roughan, QSA  
A. Cuthbertson, DOE/NNSA - (GTRI)  
C. Miller, FSME  
R. Lewis, FSME/DMSSA  
C. Bladey, ADM/DAS/RADB

**Distribution:**

OIP r/f

**ADAMS ACCESSION NO: Pkg ML110550764**

\*Concurrence via email

Publicly Available     Non-Publicly Available     Sensitive     Non-Sensitive

OFFICE	ECIO/OIP	ECIO/OIP	BC :ECIO/OIP	OE	FSME	OGC	DD :OIP
NAME	J.T. Wollenweber: JTW	B. Smith:	J. Owens:	R. Summers*	S. Moore*	K. Grace*	N. Mamish: NM
DATE	02/22/11	03/ 11 /11	02/22/11	02/24/11	02/28/11	03/02/11	03/15/11

**OFFICIAL RECORD COPY**

## Implementation of U.S. Origin Provision

The first issue raised in your December 3, 2010, letter was that the phrase “U.S. origin” was not included in the proposed rule, therefore not receiving public comment, and that the term was not defined in the regulation. As discussed in the Statement of Consideration to the final rule, the first exclusion to the definition of “radioactive waste” was revised, in response to a comment, to confirm that the exclusion only applied to sources of U.S. origin. The addition of “U.S. origin” to the first exclusion is consistent with the original intent of the pre-existing rule. Prior to the 2010 amendments to Part 110, the exclusion read as follows: “...radioactive material that is contained in a sealed source . . . that is *being returned to* any manufacturer qualified to receive and possess the sealed source.” (emphasis added) This definition was added in the 1995 rulemaking that amended Part 110. The plain and ordinary meaning of the words “being returned to” is that the radioactive material has to be sent to the place where that source originated – hence the “return” (defined in Webster’s as “to go or come back, as to a former condition or place”). If the 1995 rule were intended to exclude all sealed sources sent to any qualified manufacturer from the definition of “radioactive waste” as implied in your letter, the NRC would not have used the word “return.” In addition, reading the phrase “any manufacturer” to mean *any* and *all* manufacturers would place total reliance on the term “any” without giving any meaningful effect to the term “return.” Applying the language of the exclusion in its proper context, it is clear that the choice of the term “any” was intended to allow “return” of a disused source to any manufacturer in the country of origin that possessed the required qualifications -- *i.e.*, authorization to “receive and possess” the sealed source. If a manufacturer in the country of origin was not qualified to receive and possess the disused sealed source, it would not be permitted to receive it and the exclusion would not apply. The regulatory history of the 1995 rule supports this interpretation.

In response to industry request and prior to the effective date of the final rule, the NRC provided the following guidance on the scope of the term “U.S. origin”:

“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.”

The scope of U.S. origin was written in broad terms to recognize the global supply chain and to provide a common understanding of the term among NRC import licensees.

This guidance was also provided on the NRC’s Export/Import Licensing Web page at <http://www.nrc.gov/about-nrc/ip/part110-update.html#QA7>.

The second issue raised in your letter was the acquisition of a foreign company, by an NRC-licensed U.S. company. You requested that the NRC consider the sources manufactured by the foreign company (that is now owned by a U.S. company) to be considered U.S. origin. According to the information provided in your letter and by industry, these sources were manufactured by the predecessor company and used outside of the United States. No other

Enclosure

information was provided that would indicate that these sources could be considered U.S. origin. Additionally, this appears to be a unique situation, limited to one U.S. company, and without any industry-wide impact. Furthermore, the NRC does not see this issue as a long-term problem – the acquisition of the foreign company occurred several years ago and the half-lives of the isotopes involved limit the useful life of the foreign manufactured sources. The NRC does not anticipate similar foreign acquisitions in the future.

The third issue that your letter raised was the international industry practice of doing a “one-for-one exchange” in which a source, when replaced, is sent back to the provider of the new source. This exchange practice has not been concerned with the origin of the source and thus may mean that disused sources were not being returned to the company/country of origin but instead were sent to the company/country that supplied the new source. According to your letter, as U.S. companies build international markets, the potential existed for a U.S. company to import a foreign origin source during the first source change-out. The “U.S. origin” and “return to” phrases in exclusion one confirms that the general license for import only applies when the “one-for-one exchange” involves U.S. origin, disused sources being returned to the U.S. supplier.

In addition to exclusion one, there are additional exclusions to the definition of radioactive waste that may apply to the import of disused sources. For example, exclusion six allows the import of disused sources under a general import license provided that it is “imported solely for the purposes of recycling and not for waste management or disposal where there is a market for the recycled material and evidence of a contract or business agreement can be produced upon request by the NRC.” This exclusion may apply to many long-lived, high-activity radioisotopes that are recycled or recovered for use in new sources. In certain circumstances, exclusion two may authorize the import under a general license of disused sources when the casings or other components of the devices can be recycled. Nothing in the Part 110 regulations precludes U.S. companies from using a “one-for-one exchange”; however, non-U.S. origin, disused sources that meet the definition of “radioactive waste” in Part 110 and that do not meet one of the exclusions to the definition of “radioactive waste, require a specific license to import.

The fourth issue raised in your letter was the inclusion of below International Atomic Energy Agency (IAEA) Category 2 quantities in the definition of “radioactive waste.” You stated in your letter that below Category 2 sources were not previously considered waste. Prior to the 2010 rule change, the regulations in Part 110 did not categorically exclude any IAEA Category of material from the definition of radioactive waste. In accordance with the revised definition of “radioactive waste,” the final rule requires a specific export or import license for any material that requires a specific NRC license to possess domestically, in accordance with the requirements in 10 CFR Chapter 1, that is exported or imported for the sole purposes of (1) disposal in a land disposal facility as defined in Part 61, a disposal area as defined in Appendix A to Part 40, or an equivalent facility; or (2) recycling, waste treatment or other waste management process that generates radioactive material for disposal in a land disposal facility as defined in Part 61, a disposal area as defined in Appendix A to Part 40, or an equivalent facility.

As part of the fourth issue raised in your letter, you highlighted the successful Department of Energy (DOE)/National Nuclear Security Administration (NNSA) Global Threat Reduction Initiative (GTRI) as performing activities that NRC’s new rule may counter. In response, the NRC has discussed the implementation of amendments to Part 110 with GTRI staff to ensure that our respective programs are harmonized to implement the IAEA’s Code of Conduct and take U.S. foreign policy concerns into consideration. It is important to note that the Atomic

Energy Act of 1954, as amended, does not give the NRC jurisdiction over imports by or conducted on behalf of DOE. 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 an import.