

April 12, 2011

Mr. Grant Malkoske, President
International Source Suppliers
and Producers Association
447 March Rd.
Ottawa, ON K2K 1X8
Canada

Dear Mr. Malkoske:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated December 23, 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. You asked about the addition of the phrase "U.S. origin" as used in the first exclusion to the definition of "radioactive waste" in §110.2 and indicated that use of this term will have a significant impact on well established and regulated practices within industry.

The NRC added the phrase "Of U.S. origin" in response to comments received on the proposed rule. 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 if they are being 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. Such exports and imports require a specific export or import license unless an exclusion to the definition "radioactive waste" applies.

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 requires a specific export or import license for radioactive waste that requires a specific NRC or Agreement State license to possess domestically, in accordance with the requirements in 10 CFR Chapter 1.

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. Due to questions regarding "Of U.S. origin", the NRC provided guidance on the Export/Import Licensing Web page at <http://www.nrc.gov/about-nrc/ip/part110-update.html#QA7>.

The enclosure addresses the three concerns that you raised in your letter in detail: 1) realignment of companies bought or sold by U.S. entities; 2) one-for-one exchange of sources occurring in radiography and gamma processing industries; and 3) recycling efforts to extend the life of radioactive sources. The NRC has performed a regulatory analysis and believes that previous regulatory oversight practices are being maintained.

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

Sincerely,

R/A

Nader Mamish, Acting Deputy Director
Office of International Programs

cc: J. Schleuter, NEI
K. Roughan, QSA
A. Cuthbertson, DOE/NNSA - (GTRI)
C. Miller, FSME
R. Lewis, FSME/DMSSA
C. Bladey, ADM/DAS/RADB
G. Kim, OGC
J. Kennedy, FSME/DWMEP

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Cc w/enclosures:

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Implementation of U.S. Origin Provision

The first issue raised in your December 23, 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 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.” Therefore, the 2010 change, in response to a comment, merely clarified the original intent of the 1995 rule – that the exclusion only applies to the return of disused sources to the originating country.

The second issue raised in your letter 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. You indicated that 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. The “one-for-one exchange” may imply that as U.S. companies build international markets, the potential existed for a U.S. company to import foreign origin source(s) during the first source change-out. The “Of U.S. origin” and “return to” phrases in exclusion one confirm 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. 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 third issue raised in your letter was the realignment of companies through normal commercial transactions, where foreign companies may be bought or sold by U.S. entities. To our knowledge, this appears to be a unique situation, without appreciable industry-wide impact. Furthermore, the NRC does not see this issue as a long-term problem – the past acquisition of foreign company(ies) that occurred several years ago would not be relevant due, in part, to the half-lives of the isotopes involved that limit the useful life of these foreign manufactured sources. The NRC does not anticipate similar foreign acquisitions in the future, and believes that such matters may warrant consideration with respect domestic licensing actions.

The fourth issue raised in your letter was the recycling efforts to extend the life of sources. Exclusion six of the definition of “radioactive waste” 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 to the “radioactive waste” definition may authorize the import under a general license of disused sources when the casings or other components of the devices can be recycled.

In your letter, you expressed a concern regarding the potential for this rule change to affect international trade and implementation of the IAEA’s Code of Conduct on the Safety and Security of Radioactive Sources (and the associated Guidance document on Import and Export of such sources). The NRC does not foresee that implementation of this new rule will negatively impact NRC’s implementation of the Code and Guidance. However, we will be discussing this further with our fellow regulators at international fora in the future. The safety and security of these sources remain a high priority in the U.S., the NRC doesn’t believe this amendment to Part 110 will have an adverse impact.