

\* Reviewer justification for authorizing license amendment.

Roldan, Lizette

**From:** Stephen Payne [spayne@nrdstaticcontrol.com]  
**Sent:** Friday, September 21, 2012 3:11 PM  
**To:** Roldan, Lizette  
**Subject:** re: Clarification for Ni-63 source

Control 578005

Hi Lizette,

I went over your email with my RSO and everything we discussed and you stated is accurate.

If you have any further questions, or there is anything else I can help you with, please feel free to contact me.

Thank you, and have a great weekend,

Stephen

Stephen Payne  
Customer Service

NRD LLC  
2937 Alt Blvd North  
Grand Island NY 14072  
(800) 525-8076 Ext. 320  
(716) 773-7744 Fax  
[www.nrdinc.com](http://www.nrdinc.com)

>

Hi Steve,

We have a licensee that is requesting to add two Ni-63 sources (15 mCi and 10 mCi) to their license that are in mass spectrometers. The licensee could not provide us with a model number for the foils. They state NRD, LLC manufactured the sources to certain specifications in order to fit the housing on the mass spectrometer, and therefore are not standard ECD type of Ni-63 sealed sources.

You explained to me that these sources fall under the SDDR NY-502-S1-03-U, which is a Ni-63 foil source with maximum activity of 15 mCi. In addition, you stated that at times, NRD will manufacturer these foils to customer specification regarding dimensions and activity without compromising the integrity of the foil. Therefore, the model number for both these sources would be the aforementioned SDDR number with Model N-1001.

Please let me know if I have accurately captured what we discussed today over the phone. Also, feel free to add or expand regarding the Ni-63 source.

Thank you so much for your assistance in this matter.

Sincerely,

Lizette Roldán-Otero, Ph.D.  
Health Physicist  
U.S. Nuclear Regulatory Commission  
1600 E. Lamar Blvd.  
Arlington, TX 76011-4511  
Office: 817-200-1596  
Fax: 817-200-1188

<

**PUBLIC**

- Immediate Release  
 Normal Release

**NON-PUBLIC**

- A.3 Sensitive-Security Related  
 A.7 Sensitive Internal  
 Other: \_\_\_\_\_

Reviewer: Am

10/11/12



**Figure 5.1 Calibration and Reference Sources.** *Calibration and reference sources may not need evaluation and registration by NRC or Agreement States.*

### 5.1.2 PRODUCTS USED IN RESEARCH AND DEVELOPMENT OR BY BROAD SCOPE LICENSEES

Sealed sources or devices containing sealed sources that are intended only for use under research and development or broad scope licenses need not be registered by NRC or the Agreement State if the following is valid:

- For unregistered sources, or registered sealed sources not possessed and used in accordance with the registration – the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material.
- For registered sealed sources contained in unregistered devices – the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form.

NRC has granted broad scope licensees the authority to use sealed sources and/or devices that have been fabricated by or obtained from licensed vendors without prior NRC or Agreement State review and registration. However, broad scope licensees also have the responsibility for appropriately evaluating the sealed source or device and conducting activities responsibly and safely. For example, for Type A specific licensees of broad scope, 10 CFR 33.13(c)(3)(iii) requires the review and approval of these safety evaluations by the radiation safety committee. This is especially important with the advent of emerging medical technologies used under 10 CFR Part 35. U.S. Food and Drug Administration reviews for medical efficacy of a product cannot be substituted for this evaluation. The review should determine if a source or device can be safely used from a radiological standpoint and provide adequate radiological protection for its intended use at the institution. This review should be commensurate with the level of risk that could be reasonably anticipated from the source or device for its intended use and likely accident

*\* Approved IAW guidance*

conditions. It is the licensee's responsibility to perform this review, obtain any necessary design and test information from the vendor and, if needed, conduct operational tests or other tests to discover and evaluate potential radiation safety hazards.

If a research and development or broad scope licensee wishes to transfer a sealed source or device to another specific licensee, then the recipient must meet the criteria listed above, or the sealed source or device must be registered in accordance with 10 CFR 32.210 prior to transfer.

Licensing officials should utilize the following standard license condition for those recipients of the registered sealed source contained in unregistered devices:

The licensee shall use only sealed sources for which a sealed source registration certificate has been issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210(e) or an Agreement State. Possession and use of the sealed sources used must adhere to the conditions and limitations of the registration certificate and the commitments made in the license application.

### 5.1.3 CUSTOM SEALED SOURCES OR DEVICES

Sealed sources or devices containing sealed sources built to the unique specifications of a given user (custom) need not be sent to NRC or the Agreement State for registration if: (a) they contain less than 7.4 GBq (200 mCi) of radioactive material or less than 740 GBq (20 Ci) of tritium, and (b) the licensing reviewer has made a determination that the applicant is qualified by training and experience and has adequate facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form. Thus, the applicant would not have to rely on the intrinsic safety of the sealed source or device to demonstrate compliance with 10 CFR 30.33. Custom sealed sources and devices which contain an activity greater than that listed above must be submitted to NRC or the Agreement State for evaluation and registration.

To license these custom sealed sources and/or devices, license reviewers need to identify the isotope in Item 6 of the material license (NRC Form 374), use the statement "custom source" (for unregistered sources) or "sealed source" (for registered sealed sources) including a unique identifier (e.g., drawing or model number), if possible, in Item 7, and state the maximum quantity of radionuclide per source or device in Item 8. In Item 9 (authorized use) license reviewers need to describe, as clearly as possible, the actual use of the custom source or device — examples include "for use in a Model A analyzer custom built for the licensee by ABC Company in Anytown" or "custom source for use in XYZ Model 100 gauge."

The authorization to use sources or devices described above, that have not been evaluated and registered by NRC or the Agreement State, apply to only to the custom user of the product. Licensees with custom sealed sources and devices should inactivate the custom registration in accordance with Section 13.4 of this guide when the sources/devices are permanently disposed

*Approved JAW  
Guidance underlined  
9/24/12*