UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NEW REACTORS
WASHINGTON, D.C. 20555

March 12, 2013

NRC REGULATORY ISSUE SUMMARY 2013-01
USE OF AFTERMARKET SEALED SOURCES REGISTERED UNDER 10 CFR 32.210

ADDRESSEES

All holders of and applicants for a possession and use of byproduct material license for the processing or manufacturing of items that contain byproduct material for commercial distribution under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material;" all holders of and applicants for a possession and use of byproduct material license for research and development under 10 CFR Part 30;" and all Radiation Control Program Directors and State Liaison Officers.

All holders of an operating license or construction permit for a nuclear power reactor under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," that also hold a license under Part 30.

All holders of and applicants for a power reactor early site permit, combined license, standard design certification, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," that also hold a license under Part 30.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to provide guidance regarding the use, in devices, of replacement, also called "aftermarket," sealed sources that might be equivalent to original sources, but are not identified as such in the device registration certificate. No specific action or written response is required.

BACKGROUND INFORMATION

Users of sealed sources or devices (SSDs) containing byproduct material must obtain a specific license under 10 CFR 30.32, "Application for Specific Licenses." In the application for the license, in accordance with section 30.32(g), the applicant must identify the source or the device by manufacturer and model number as registered with the NRC under 10 CFR 32.210, "Registration of Product Information" or with an Agreement State under equivalent regulations, or provide the information identified in section 32.210(c). The registration, as conducted by the NRC, consists of issuance of a registration certificate which (a) confirms that the SSD design meets the regulatory requirements under 10 CFR 32.210, and (b) lists provisions of use for the

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product. Regarding devices, the provisions of the registration certificate identify the make and model of the source(s) which are authorized for use in the device. Sources, other than the makes and models listed in the device registration, are not authorized to be used.

Some source manufacturers produce sources that physically, chemically, and radiologically are either similar or identical to those produced by other source manufacturers; these sources could be considered equivalent. Thus, it can be reasonably assumed that such sources could be substituted for one another. However, if such a source were installed in a device, the device would not be in compliance with the registration certificate. In addition, it must also be considered that in certain devices the source activity decays beyond its useful range and fresh source(s) must be installed so that the device could maintain its intended function. Consequently, the use of replacement or aftermarket sources must be addressed.

SUMMARY OF ISSUE

In order to ensure that aftermarket sources may be safely used as replacements for the ones listed in the device registration under 10 CFR 30.32 and 10 CFR 32.210, two criteria must be met: (1) the equivalency of the physical, chemical, and radiological properties of the sources, and (2) the registration requirements. This RIS provides assistance in addressing both of these issues.

1. Equivalency of the physical, chemical, and radiological properties:

In order to determine the equivalency of the physical, chemical, and radiological properties of aftermarket sources, an SSD safety evaluation similar to that conducted for the registration of all products under 10 CFR 32.210 is required. The NRC staff conducts the SSD safety evaluations in accordance with the guidance in NUREG-1556, Vol. 3, “Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.” However, in cases where the aftermarket source has been issued a registration certificate, the SSD safety evaluation can be limited to confirming the following:

- The NRC or an Agreement State has conducted a safety evaluation of the aftermarket source, which is listed in a registration certificate.
- The registration certificate of the aftermarket source must state which other sources the aftermarket source can be substituted for.
- The aftermarket source has been prototype tested to meet or exceed the performance classification (e.g., standards classification, such as ANSI N43.6 or ISO2919) of the original source in the device as registered.
- The aftermarket source geometry and manufacturing tolerances are compatible with the source holder configuration in the device.
- The materials of the aftermarket source design, such as encapsulation, and the methods of construction are equivalent to the original source.
- The aftermarket source activity is within the design specifications of the device.

- The aftermarket source has been designed, tested, and manufactured by a licensed manufacturer with a quality assurance program which the NRC or an Agreement State found acceptable.

2. Compliance with registration requirements:

Under the regulations, five alternative pathways may be followed to authorize the use of aftermarket sources. Each of these pathways is delineated below. Note that Pathway (a) is the preferred pathway, because this course of action is most closely related to the original device registration.

(a) Amendment of the Existing Device Registration: The aftermarket source manufacturer may contact and request that the device manufacturer add the aftermarket source to the device registration. The device manufacturer could accomplish this by requesting, from its respective regulatory authority (the NRC or Agreement State), an amendment of the device registration to list additional sources including the aftermarket source. The use of the aftermarket source then will be authorized in accordance with the provisions of 10 CFR 32.210 and can be licensed on the basis of 10 CFR 30.32(g)(1) or equivalent Agreement State regulations. This course of action provides for a broad-based approach to the issue because the amended device registration would be applicable for all licensees in all NRC and Agreement States.

(b) Issuance of a New Device Registration: The aftermarket source manufacturer may seek through its regulatory authority a new evaluation of the device with the use of its aftermarket source. To accomplish this, the aftermarket source manufacturer would have to meet the criteria in 10 CFR 32.210, providing sufficient information such that the regulator could perform the requisite safety analysis and evaluation. Following satisfactory completion of that evaluation, a new registration certificate would be issued to the aftermarket source manufacturer approving use of that source in that device. Fees associated with the registration are specified in 10 CFR 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services, including Inspections, and Import and Export Licenses," and 10 CFR 171.16, "Annual Fees: Materials Licenses, Holders of Certificate of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC." This course of action provides for a broad-based approach for the issue because the new device registration will be applicable for all licensees in all NRC and Agreement States.

(c) Device "Custom" Registration: The device user may apply to the NRC for a "custom" registration certificate of the device to incorporate the aftermarket source as an authorized source. Such a custom registration certificate is issued under 10 CFR 30.32(g)(1). Guidance on the custom registration process is provided in NUREG-1556, Vol. 3, referenced above (i.e., Section 5.2 in Rev. 1). The NRC staff should consider the equivalency and suitability of the aftermarket source by using the principles for equivalency described above. In addition, the custom device with the aftermarket source also must be properly labeled in accordance with the requirements in 10 CFR 32.210. Fees associated with custom registration are specified in 10 CFR 170.31.9D and 10 CFR 171.16.9D. This course of action authorizes the use of the aftermarket source for one licensee only; the process must be repeated for each device user or licensee.

(d) License Amendment (License Condition): The device user may request from its regulatory authority the amendment of its license to add a license condition to its license which authorizes the use of the aftermarket replacement source in the device. This approach must comply with the provisions of 10 CFR 30.32(g)(2). In the request for license amendment, the device user must provide, for the aftermarket source, information identified in 10 CFR 32.210. The device user may obtain such information from the manufacturer of the aftermarket source. The licensee must retain the documentation, as required under 10 CFR 30.51, "Records," such as the application documents and installation information (e.g., date of installation; name, address, license number of the installer) as records related to the aftermarket source. The NRC staff should consider the equivalency and suitability of the aftermarket source by using the principles for equivalency described above. Regarding labeling, the original label must stay on the device because it is registered under its original registration certificate, but the device would require an additional label to indicate that the original source has been replaced with an aftermarket source. The additional label should indicate that a replacement source has been installed, and list such information as the make, model, serial number, and activity level of the replacement source as well as the date of installation. The NRC review schedule for granting a license condition depends on the complexity of the technical and safety issues involved, and may be longer than customary. This course of action will authorize the use of the aftermarket source for one licensee only, and must be repeated for each device user or licensee.

(e) Broad Scope License Use: In cases where the aftermarket manufacturer, holding a license under 10 CFR Part 30, wishes to distribute the replacement sources to broad scope licensees; i.e., entities licensed under 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," the broad scope licensee may approve the use of aftermarket sources for its own use under the conditions of its license provided that the following conditions are met: (i) the licensee's radiation safety committee approved such a use, (ii) the chemical and physical form of the byproduct material in the aftermarket source is in compliance with that specified in the license, and (iii) the activity of the aftermarket source does not exceed the quantities specified in the license. Approval of the use of aftermarket sources by the radiation safety committee applies only to the broad scope licensee's own devices.

BACKFIT DISCUSSION

This RIS requires no action or written response. Any action on the part of addressees in accordance with the guidance contained in this RIS is strictly voluntary and, therefore, is not a backfit under any requirement. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because it is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

The NRC has determined that this RIS is not a rule as designated by the Congressional Review Act (5 U.S.C. 801-808) and, therefore, is not subject to the Act.

PAPERWORK REDUCTION ACT STATEMENT

This RIS references information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval number 3150-0001.

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.

CONTACT

This regulatory issue summary requires neither specific action nor written response. If you have any questions about this summary, please contact the technical contact listed below or the appropriate regional office.

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Note: NRC generic communications may be found on the NRC public Web site, http://www.nrc.gov, under NRC Library/Document Collections.

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