

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

July 16, 2003

**NRC REGULATORY ISSUE SUMMARY 2003-11
REPORTING REQUIREMENTS FOR DISTRIBUTORS OF DEVICES
SUBJECT TO THE GENERAL LICENSE REQUIREMENTS
OF 10 CFR 31.5**

ADDRESSEES

All licensees authorized to distribute devices containing byproduct material under 10 CFR 32.51, or equivalent Agreement State regulation.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Regulatory Issue Summary (RIS) to remind addressees of the requirement to make accurate and timely transfer reports to NRC, pursuant to 10 CFR 32.52, or equivalent Agreement State regulations/license conditions.

BACKGROUND

On February 16, 2001, new reporting requirements described in 10 CFR 32.52 became effective for all NRC licensees. On August 16, 2001, Agreement States were required to implement new regulations or legally binding requirements, such as license conditions, to become compatible with these new requirements. Because of the increased emphasis on tracking generally licensed devices, attention needs to be focused on the quality of information being reported to NRC and Agreement States by vendors, in accordance with the above referenced regulations. Vendors are specific licensees who are authorized to distribute byproduct material in devices for use under a general license (GL) granted by 10 CFR 31.5, or equivalent Agreement State regulations.

SUMMARY OF ISSUE

Since the regulations became effective in 2001, several reports have been submitted to NRC without the required information, or have contained inaccurate and incomplete information. Therefore, NRC is issuing this RIS to remind all licensees that they must meet the reporting requirements in accordance with 10 CFR 32.52, or equivalent Agreement State regulations or license conditions. Licensees are advised that failure to provide complete and accurate information as required by 10 CFR 30.9 and 32.52 may subject them to civil and criminal penalties.

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Please review the regulations referenced above for complete information about reporting requirements. A copy is available on the Internet at: <http://www.nrc.gov/reading-rm/doc-collections/cfr/part032/part032-0052.html>. The information required to be reported is that which is required by NRC Form 653, "Transfers of Industrial Devices Report." This form is available on the Internet at: <http://www.nrc.gov/reading-rm/doc-collections/forms/>.

The following sections represent the areas of the report that are most often submitted in error:

The Report or Cover Letter

- Provide the name of the vendor (specific licensee) submitting the report and the license number authorizing distribution of GL devices. Reference [10 CFR 32.52(a)(6) and 32.52(b)(6)].
- Identify the period for which the report is being submitted, e.g., 2nd Quarter 2003, or April 1- June 30, 2003. [Reference 10 CFR 32.52(a)(5) and 32.52(b)(5)]
- Submit one (1) completed quarterly report within 30 days after the end of a calendar quarter to the General License Tracking System (GLTS) at the following address (do not send quarterly reports to the NRC regional offices) [Reference 10 CFR 32.52(a), 32.52(a)(5) and 32.52(b)(5)].

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- If no transfers have occurred within the reporting period, a report must still be submitted indicating that no device transfers occurred within the reporting period. [Reference 10 CFR 32.52(a)(7) and 32.52(b)(7)].

The following item is not required, but would be helpful.

- For contact purposes, the name, phone number, fax number, and e-mail of the vendor's radiation safety officer should be submitted with each quarterly transfer report (this information would be helpful but it is not required.)

Requirements for Providing Information

- Provide the complete name and address (including zip code) for the "location of use" of the device(s). A post office box number, alone, is not acceptable. The actual physical "location of use" of the device(s) must be reported. If the mailing address for the general licensee is different than the "location of use" address, provide the correct mailing address, as well as the location of use. [Reference 10 CFR 32.52(a)(1)(i) and 32.52(b)(1)(i)].
- Provide the responsible person's name, title, and phone number (all three are required). [Reference 10 CFR 32.52(a)(1)(ii) and 32.52(b)(1)(ii)]. Additional information (fax

Requirements for Providing Device Information

number, e-mail address, secondary responsible person information) is helpful, but not required.

- Provide the date of transfer or return of the GL device. [Reference 10 CFR 32.52(a)(3) and 32.52(b)(3)].
- Provide the type [Sealed Source and Device (SSD) certificate principal use code], model number of the device according to the SSD certificate, and serial number of the GL device transferred (not the source serial number). [Reference 10 CFR 32.52(a)(1)(iv) and 32.52(b)(1)(iv)].
- Provide the activity and isotope of byproduct material contained in the device [e.g., 370 MBq (10 millicuries) of Cesium-137]. [Reference 10 CFR 32.52(a)(1)(v) and 32.52(b)(1)(v)].

NOTE: The sources (source model number and source serial number) contained in a generally licensed device are not tracked because the general license does not authorize tampering with the source. However, source information must be reported in cases where a change to the source would change the information on the label of a GL device. This rule also applies to source replacements; only report them when the label changes on the device. Examples include cases where the device serial number is the same as the source serial number and changing the source in effect changes the device serial number. Another example is when the source is replaced with a different quantity and type. [Reference 10 CFR 32.52(a)(4) and 32.52(b)(4)].

Report Format

- The use of NRC Form 653, "Transfers of Industrial Devices Report" is encouraged, or reports must be submitted in a clear and legible format containing all the data required by NRC Form 653. [Reference 10 CFR 32.52(a) and 32.52(b)].
- Also, the vendor shall submit a consolidated report for each calendar quarter within 30 days after the end of the quarter. A separate report for each transfer during the quarter is not acceptable. [Reference 10 CFR 32.52(a), 32.52(a)(5), 32.52(b), and 32.52(b)(5)].

Reportable Information

- Report to NRC only device(s) transferred for use under a general license to persons in non-Agreement States, all Federal facilities, and all U.S. Territories or possessions. Report "no devices transferred" if none were transferred to these jurisdictions during the quarter. Foreign transfers/exports are not reportable. [Reference 10 CFR 31.5, 32.52(a), and 32.52(b)].
- Report to each Agreement State all devices transferred to GLs in that state, or if the Agreement State requests, that no devices were transferred for that quarter. [Reference 10 CFR 32.52(b) and 32.52(b)(7)].
- Report only devices distributed to GLs for use under 10 CFR 31.5, 32.56 or equivalent Agreement State regulations. Do not report devices approved for use by specific licensees, as identified by the SSD certificate. [Reference 10 CFR 32.52(a) and 32.52(b)].

While not required, a vendor who becomes aware of lost, stolen, or destroyed GL devices should remind customers that this information is required to be reported to the NRC. [Reference 10 CFR 20.2201, 20.2202, and 31.5(c)(10)]

Additional information about NRC's general license registration and tracking program is available on the Internet at <http://www.nrc.gov/materials/miau/general-use.html>.

BACKFIT DISCUSSION

This RIS is provided for information and guidance about existing regulations, and does not require any action nor written response; therefore, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTICE

A notice of opportunity for public comment was not published in the *Federal Register* because this RIS provides information that does not represent a departure from current regulatory requirements.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not request any information collection and, therefore, is not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

If you have any questions about this RIS, please e-mail or telephone the technical contact person listed below.

/RA/ PHolahan for

Charles L. Miller, Director
Division of Industrial and
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Office of Nuclear Material Safety
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Attachment: List of Recently Issued NRC Regulatory Issue Summaries