

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, DC 20555-0001

September 18, 2014

**NRC REGULATORY ISSUE SUMMARY 2014-10
REQUIREMENTS FOR EXEMPT DISTRIBUTION LICENSEE
ANNUAL TRANSFER REPORTS**

ADDRESSEES

All holders of, and applicants for, an exempt distribution materials license in accordance with the provisions of Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR), Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," Subpart A; or 10 CFR Part 40, "Domestic Licensing of Source Material." All Agreement State Radiation Control Program Directors.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to clarify the information that must be contained in annual transfer reports submitted by holders of exempt distribution materials licenses, as required under 10 CFR Parts 32 and 40. This RIS does not transmit any new requirements or new staff positions. No specific action or written response is required. The NRC is providing this RIS to the Agreement States for their information and for distribution to their licensees, as appropriate.

BACKGROUND

In 2007, the NRC issued a final rule, "Improved Reporting of Distribution to Persons Exempt From Licensing Requirements" (2007 Rule) (*Federal Register*, 72 FR 58487; October 16, 2007). This rule amended "the reporting and recordkeeping requirements for distributors of products containing byproduct material to persons exempt from licensing [requirements] to improve the quality of data available to the NRC."

Primarily, the 2007 Rule amended associated sections of 10 CFR Part 32 in such a way as to require licensees to submit transfer reports annually, rather than every five years. Prior to 1983, the NRC had originally required that these reports be submitted annually, but in 1983 the NRC amended its regulations to require that reports only be submitted every five years. However, experience over subsequent years proved that a five-year reporting frequency did not provide the NRC with complete, accurate, or timely information. This limited the NRC's ability to evaluate the impact of exempt distribution products on public health and safety. Furthermore, the NRC's evaluation of reporting requirements suggested that an annual reporting frequency

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might also be more administratively efficient for licensees than a five-year frequency, in that it reduces the likelihood of issues arising from missing reports and also relieves licensees from the need to maintain transfer records for over a year (72 FR 58475).

The 2007 Rule also introduced requirements that reports include the following information:

- identification of the specific licensee submitting the report, including the license number;
- identification of the specific exemption provision under which the products or materials will be used by recipients; and
- the model number(s) of transferred products or devices, when applicable.

Additionally, the regulations no longer require licensees to send a copy of transfer reports to the Regional offices. Instead, the information is distributed internally by the NRC to the appropriate personnel. Furthermore, the 2007 Rule changed the regulatory requirements to require that final transfer reports be submitted 30 days after ceasing authorized activities, rather than at the point of notifying the Commission of the decision to cease these activities (72 FR 58475).

In 2013, the NRC Issued another final rule, “Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions” (2013 Rule) (78 FR 32310). With this rule, The NRC amended its regulations to require that the initial distribution of source material to exempt persons or to general licensees be explicitly authorized by a specific license. This rule also introduced reporting requirements for these licensees.

As a result of the changes introduced by the 2007 Rule and 2013 Rule, “the NRC expects to receive information on distribution to exempt persons that is more useful for evaluating both potential individual... and collective doses to the public,” allowing the NRC to better inform the public about associated radiation exposures. “These changes also will provide a better basis for considering any future regulatory changes... and for allocating NRC resources (72 FR 58476).” Furthermore, the revised “reporting and recordkeeping requirements are expected to impose a minimal burden on those persons requiring a specific license for initial distribution of source material, particularly given the current state of information technology (78 FR 32310).”

SUMMARY OF ISSUE

10 CFR Parts 30 and 40 provide exemptions from the requirements for an NRC license to persons who receive, possess, use, transfer, own, or acquire byproduct and source material, respectively, in certain products. However, initial transfer or distribution of these exempt distribution products can only be made by holders of an NRC-issued license under 10 CFR 32.11, 10 CFR 32.14, 10 CFR 32.18, 10 CFR 32.21, 10 CFR 32.22, 10 CFR 32.26, 10 CFR 32.30, or 10 CFR 40.52. The reporting and recordkeeping requirements for these licensees are found in 10 CFR 32.12, 10 CFR 32.16, 10 CFR 32.20, 10 CFR 32.25(c), 10 CFR 32.29(c), 10 CFR 32.32(c), and 10 CFR 40.53(c). These requirements include the provision that each licensee (except for those licensed under 10 CFR 32.21) submit an annual report to the NRC detailing the transfers that took place during the previous calendar year. Furthermore, licensees must maintain the record of a transfer for one year after the transfer has been included in a report to the NRC.

10 CFR Part 32 and Part 40 list the information that licensees are required to include in their annual transfer reports. The information required to be included in submitted reports can vary, depending on the type of material or product being distributed and the specific regulation under which the licensee is authorized to transfer byproduct material. **Enclosure 1 contains a detailed list of the specific information licensees must include in transfer reports.**

Exempt distribution licensees should note that transfer reports do not need to list each individual transfer (e.g. by date or by recipient) or each individual unit transferred (e.g. by serial number).¹ Reports only need to list the total number of units of each product type or model transferred, such that the report communicates the total quantity of each radionuclide transferred by the licensee in a calendar year and the devices/forms in which that radionuclide was transferred.

Licensees should also note that reports are, by default, made publicly available through the NRC's Agencywide Documents Access and Management System (ADAMS). If a licensee wishes to withhold information contained in a report from being made publicly available, that licensee must submit a request and a notarized affidavit, in accordance with the requirements listed in 10 CFR 2.390.

Annual transfer reports associated with exempt distribution licenses must be submitted by January 31, covering all transfers that took place during the preceding calendar year. If no transfers have taken place during a given calendar year, the licensee is still required to submit a transfer report to the NRC indicating so. This report should provide all other required information and simply indicate a zero quantity amount where applicable.

Licensees should submit reports by mailing them to the following address:

ATTN: Document Control Desk/Exempt Distribution
Director, Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

or by some other means listed in 10 CFR 30.6(a) or 40.5(a). Annual transfer reports should not be sent directly to any individual NRC employee or group, other than that listed in the address above.

¹ These requirements are different from those for distributing products under a general license. Requirements pertaining to generally licensed products are listed in 10 CFR 31. Subpart B.

BACKFIT DISCUSSION

This RIS requires no action or written response beyond that already required by the NRC regulations. Any additional 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 this RIS is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808).

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing information collection requirements were approved by the Office of Management and Budget (OMB), approval numbers 3150-0001 and 3150-0215.

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 RIS requires no specific action or written response. If you have any questions about this summary, please contact the technical contact listed below or the appropriate regional office.

/RA/

Laura A. Dudes, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contacts: Justin A. Vazquez, FSME/MSSA/LB
(301) 415-6684
E-mail: Justin.Vazquez@nrc.gov

Shirley S. Xu, FSME/MSSA/LB
(301) 415-7640
E-mail: Shirley.Xu@nrc.gov

Enclosures:

- (1) Information Required for Exempt
Distribution Annual Transfer Reports
- (2) List of Recently Issued FSME
Generic Communications

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*via email

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|-------------|--------------|--------------|----------------|--------------|
| OFC | FSME/MSSA/LB | FSME/MSSA/LB | FSME/MSSA/RMSB | FSME/MSSA/LB |
| NAME | JVazquez | SXu | AMcIntosh | MKotzalas |
| DATE | 06/30/2014 | 07/01/2014 | 07/25/2014 | 8/6/2014 |
| OFC | OE* | OIS* | OGC-CRA* | OGC-NLO* |
| NAME | JWray | TDonnell | JAdler | BJones |
| DATE | 08/14/2014 | 08/13/2014 | 08/26/2014 | 08/26/2014 |
| OFC | FSME/MSSA | | | |
| NAME | LDudes | | | |
| DATE | 9/18/2014 | | | |

OFFICIAL RECORD COPY

Information Required for Exempt Distribution Annual Transfer Reports

Licensees introducing byproduct material into and transferring products under **10 CFR 32.11** must include the following information in their reports:

- identification of the licensee, including the license number of the licensee;
- indication that the products are transferred for use under 10 CFR 30.14 or equivalent Agreement State regulation(s);
- the type and quantity of each product or material into which byproduct material has been introduced during the reporting period;
- the name(s) and address(es) of the individual(s) who owned or possessed the product(s) or material(s), into which byproduct material has been introduced, at the time of introduction
- the type and quantity of radionuclide introduced into each product or material; and
- the initial concentration of the radionuclide(s) in the product(s) or material(s) at time of transfer of the byproduct material by the licensee.

Licensees transferring products under **10 CFR 32.14** must include the following information in their annual transfer reports:

- identification of the licensee, including the license number of the licensee;
- indication that the products are transferred for use under 10 CFR 30.15, giving the specific paragraph designation (for example, 10 CFR 30.15(a)(8) for electron tubes), or equivalent Agreement State regulation(s);
- a description and/or identification of the type of each product, including the model number if applicable;
- the total quantity of each radionuclide contained in each type of product/model; and
- the number of units of each type of product transferred, by model number (if applicable), during the reporting period.

Licensees transferring products under **10 CFR 32.18** must include the following information in their annual transfer reports:

- identification of the licensee, including the license number of the licensee;
- indication that the products are transferred for use under 10 CFR 30.18 or equivalent Agreement State regulation(s); and
- the total quantity and the physical form (e.g. "solid," "liquid," "gas," "powder," "solution," "sealed source," etc.) of each radionuclide in each physical form transferred during the reporting period.

Licensees transferring products under **10 CFR 32.22** must include the following information in their annual transfer reports:

- identification of the licensee, including the license number of the licensee;
- indication that the products are transferred for use under 10 CFR 30.19 or equivalent Agreement State regulation(s);

- indication that the products are transferred for use under 10 CFR 30.19 or equivalent Agreement State regulation(s);
- a description and/or identification of the type of each product, including the model number;
- the total quantity of each radionuclide contained in each type of product/model; and
- the number of units of each type of product transferred, by model number, during the reporting period.

Licensees transferring products under **10 CFR 32.26** must include the following information in their annual transfer reports:

- identification of the licensee, including the license number of the licensee;
- indication that the products are transferred for use under 10 CFR 30.20 or equivalent Agreement State regulation(s);
- a description and/or identification of the type of each product, including the model number;
- the total quantity of each radionuclide contained in each type of product/model; and
- the number of units of each type of product transferred, by model number, during the reporting period.

Licensees transferring products under **10 CFR 32.30** must include the following information in their annual transfer reports:

- identification of the licensee, including the license number of the licensee;
- indication that the products are transferred for use under 10 CFR 30.22 or equivalent Agreement State regulation(s);
- a description and/or identification of the type of each product, including the model number;
- the total quantity of each radionuclide contained in each type of product/model; and
- the number of units of each type of product transferred, by model number, during the reporting period.

Licensees transferring products under **10 CFR 40.52** must include the following information in their annual transfer reports:

- identification of the licensee, including the license number of the licensee;
- indication that the products are transferred for use under 10 CFR 40.13, giving the specific paragraph designation (for example, 10 CFR 40.13(c)(1)(iii) for welding rods), or equivalent Agreement State regulation(s);
- a description and/or identification of the type of each product, including the model number, if applicable;
- the total quantity of each type of source material contained in each type of product/model; and
- the number of units of each type of product transferred, by model number (if applicable), during the reporting period.

Note that, for licenses issued under 10 CFR 40.52, licensees are not required to list the specific radionuclides contained in each device, but simply the type of source material (e.g. "uranium," "depleted uranium," or "thorium," etc.).

| List of Recently Issued Office of Federal and State Materials and Environmental Management Programs Generic Communications | | | |
|---|-------------|--|--|
| Date | GC No. | Subject | Addressees |
| 06/20/2014 | IN 2014-09 | Spent Fuel Storage or Transportation System Mis-loading | All holders of an operating license or construction permit for a nuclear power reactor under Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have spent fuel stored in spent fuel pools (SFPs); all holders of or applicants for a combined license issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"; all holders of or applicants for a certificate of compliance (CoC) for a spent fuel transportation package design under 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; and all holders of or applicants for a general or site-specific license for storage of spent fuel, or for a spent fuel storage cask CoC under 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste |
| 05/27/2014 | RIS 2014-08 | Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses | All holders of, and applicants for, a specific materials license in accordance with the provisions of Title 10, "Energy," of the <i>Code of Federal Regulations</i> (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," or 10 CFR Part 40, "Domestic Licensing of Source Material." All Agreement State Radiation-Control Program Directors and State Liaison Officers. |
| 05/12/2014 | IN 2014-05 | Verifying Appropriate Dosimetry Evaluation | All NRC licensees and all Radiation Control Program Directors and State Liaison Officers. |

| List of Recently Issued Office of Federal and State Materials and Environmental Management Programs Generic Communications | | | |
|---|-------------|--|--|
| Date | GC No. | Subject | Addressees |
| 04/28/2014 | IN-2014-06 | Damage of Industrial Radiographic Equipment due to Falling Equipment and Improper Mounting | All U.S. Nuclear Regulatory Commission material licensees possessing industrial radiographic equipment, regulated under 10 CFR Part 34; all Agreement States Radiation Control Program Directors; all holders of and users of a transportation package certificate of compliance under Title 10 of the Code of Federal Regulations (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," that possess industrial radiographic equipment regulated under 10 CFR Part 34, and all holders of or applicants for an early site permit, standard design certification, standard design approval, manufacturing license, or combined license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." |
| 04/16/2014 | RIS-2014-02 | Withdrawal of NRC Generic Letter 95-08, "10 CFR 50.54(p) Process for Changes to Security Plans Without Prior NRC Approval" | All holders of and applicants for construction permits or operating licenses for nuclear power reactors under the provisions of Title 10, "Energy," of the <i>Code of Federal Regulations</i> (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." All holders of and applicants for a combined license, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Reactors." All applicants for a standard design certification, including such applicants after initial issuance of a design certification rule. |

| List of Recently Issued Office of Federal and State Materials and Environmental Management Programs Generic Communications | | | |
|--|-------------|--|--|
| 03/13/2014 | RIS-2014-03 | Notice of 10 CFR Part 37 Implementation Deadline for NRC Licensees | All holders of and applicants for U.S. Nuclear Regulatory Commission (NRC) licenses that possess Category 1 and Category 2 quantities of radioactive material, NRC Master Material Licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers |
| Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs. A full listing of all generic communications may be viewed at the NRC public Web site at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html | | | |