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DEPT. OF HEALTH AND HUMAN SERVICES



MEMORANDUM

TO:

Licensees Required to Report Transfers to the

National Source Tracking System

FROM:

Julia A. Schmitt, Manager

Radiation Control Program

DATE:

July 23, 2019

SUBJECT:

Guidance for Reporting Transactions to the National Source

Tracking System Involving Sealed Bulk Material (STC-19-043)

Attached is the U.S. Nuclear Regulatory Commission's guidance for reporting transactions to the National Source Tracking System involving sealed bulk material (STC-19-043). We are sending you this notice for informational purposes.

Should you have any questions, please contact our office at 402-471-2168.



UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

July 15, 2019

ALL AGREEMENT STATES, VERMONT

GUIDANCE FOR REPORTING TRANSACTIONS TO THE NATIONAL SOURCE TRACKING SYSTEM INVOLVING SEALED BULK MATERIAL (STC-19-043)

Purpose: To inform the Agreement States, as well as any States with pending Agreement State applications, of new guidance regarding the National Source Tracking System (NSTS) reporting requirements involving Category 1 or Category 2 sealed sources that a manufacturer identifies as bulk material.

Background: The requirements in Title 10 of the *Code of Federal Regulations* (CFR) 20.2207, "Reports of Transactions Involving Nationally Tracked Sources," require licensees to report to the NSTS the manufacture, transfer, receipt, disassembly, and disposal of nationally tracked sealed sources. The reporting requirements, however, are not specific when it comes to nationally tracked sources that a manufacturer designates as bulk material¹.

Discussion: The Statements of Consideration for the NSTS final rule (Volume 71 of the *Federal Register*, page 65686 (71 FR 65686; November 8, 2006)) discuss the applicability of the NSTS requirements to bulk material possessed by a licensee. Specifically, it states that "The National Source Tracking System will only have information on sealed sources and will not contain information on sources that are not considered sealed or on any bulk material that a licensee may possess."

Consistent with this policy, Category 1 or Category 2² sealed sources manufactured and stored on site that meet the requirements of a nationally tracked source, and which are identified by the manufacturer as bulk material, do not need to be reported to the NSTS as long as the manufacturer has information available during inspection that clearly differentiates the bulk material sources from the sources it intends to distribute.

In the case where bulk material is being distributed, such as when a byproduct material producer ships the bulk material in sealed special form capsules to the manufacturer (either through a domestic transfer or by importing the material), the receipt and eventual disassembly of the special form capsules by the manufacturer are subject to the NSTS reporting requirements in 10 CFR 20.2207(c) and 10 CFR 20.2207(d), respectively.

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¹ Source manufacturers typically use the term "bulk" to refer to the precursor radioactive material that eventually is fabricated into a commercially distributed sealed source. Byproduct material producers normally ship bulk material to the manufacturer as special form radioactive material (as defined by 10 CFR 71.75, "Qualification of Special Form Radioactive Material"), which the manufacturer stores at its facility until it is needed to manufacture sealed sources for distribution. With respect to sources received from other licensees, the manufacturer usually disassembles the sources, combines the radioactive material from the disassembled source if necessary, encapsulates the resulting bulk radioactive material, and stores it until needed for fabrication of sources that will be commercially distributed.

² The Category 1 and 2 quantities of radioactive sources are established in the *Code of Conduct on the Safety and Security of Radioactive Sources*, which the International Atomic Energy Agency issued in January 2004. Specifically, the NRC determined that these sources are to be tracked nationally; however, the U.S. Nuclear Regulatory Commission also expanded the list of nationally tracked sources by adding four extra materials (i.e., actinium-227, polonium-210, thorium-228, and thorium-229).

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Enclosure 1 to this letter includes three frequently asked questions (FAQs) providing this guidance. The FAQs are posted on the "Frequently Asked Questions About the National Source Tracking System" public webpage located at https://www.nrc.gov/security/byproduct/ismp/nsts/faqs.html under the hyperlink titled, "Source Transfers Regarding Bulk Material".

To facilitate dissemination of this guidance, we would appreciate your assistance in providing this correspondence to your applicable materials licensees. An NSTS Blog notification to registered licensees regarding these FAQs is also planned to be issued.

If you have any questions on this correspondence, please contact the individual named below:

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/RA/

Paul Michalak, Branch Chief State Agreement and Liaison Programs Division of Materials Safety, Security, State, and Tribal Programs Office of Nuclear Material Safety and Safeguards

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Enclosure: Frequently Asked Questions

Regarding the Applicability of the National Source Tracking System Requirements Involving Sealed

Bulk Material

Frequently Asked Questions Regarding the Applicability of the National Source Tracking System Requirements Involving Sealed Bulk Material

1. The term "bulk material" is mentioned in the Statements of Consideration for the NSTS final rule, but it is not defined in the "Definitions" section of the rule. What does the term mean?

Source manufacturers typically use the term "bulk material" to refer to the precursor radioactive material that eventually is fabricated into a commercially distributed sealed source. Manufacturers store this "bulk material" at their site in either sealed capsules or in unsealed containers depending on the conditions of their license. When receiving bulk material from byproduct material producers, the material is shipped as special form radioactive material (as defined by 10 CFR 71.75, "Qualification of Special Form Radioactive Material"), which the manufacturer stores at its facility until it is needed to manufacture sealed sources for distribution. Some manufacturers also receive used or otherwise unwanted sealed sources from other licensees, which the manufacturer usually disassembles, combines the radioactive material from other disassembled sources if necessary, encapsulates the resulting bulk radioactive material, and stores it until needed for fabrication of sources that will be commercially distributed.

2. If the bulk material is sealed in a capsule and the encased material meets the threshold of a Category 1 or Category 2 quantity of radioactive material, does this sealed source need to be reported to the NSTS?

The Statements of Consideration for the NSTS final rule discuss the applicability of the NSTS requirements to bulk material possessed by a licensee. Specifically, it states that "The National Source Tracking System will only have information on sealed sources and will not contain information on sources that are not considered sealed or on any bulk material that a licensee may possess." Therefore, Category 1 or Category 2 sealed sources manufactured and stored on site that otherwise meet the requirements of a nationally tracked source, but that are identified by the manufacturer as bulk material, and for which distribution is not intended in the near term, do not need to be reported to the NSTS.

3. If a manufacturer receives bulk material from a byproduct material producer in a special form capsule, and the quantity of radioactive material in the capsule meets the Category 1 or Category 2 threshold, does this sealed source need to be reported to the NSTS?

Yes. In the case where bulk material is being distributed, such as when a byproduct material producer ships the bulk material in sealed special form capsules to the manufacturer (either through a domestic transfer or by importing the material), the receipt and eventual disassembly of the special form capsules by the manufacturer are subject to the NSTS reporting requirements in 10 CFR 20.2207(c) and 10 CFR 20.2207(d), respectively.