

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

February 8, 2017

NRC REGULATORY ISSUE SUMMARY 2017-02
APPLICABILITY OF TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* PART 37 TO
NON-MANUFACTURING AND DISTRIBUTION SERVICE PROVIDER LICENSEES

ADDRESSEES

All holders of, and applicants seeking, U.S. Nuclear Regulatory Commission (NRC) licenses that authorize the possession of Category 1 or 2 quantities of radioactive materials¹ (including licenses authorizing possession of Category 1 or 2 quantities of radioactive materials incidental to service), NRC Master Materials Licensees (MML), Agreement State Radiation Control Program Directors, and State Liaison Officers.

INTENT

The NRC is issuing this regulatory issue summary (RIS) to inform licensees of the applicability of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," to non-manufacturing and distribution (non-M&D) service provider licensees.² No specific action or written response is required. The NRC is providing this RIS to Agreement States for their information and for distribution to their licensees as appropriate.

BACKGROUND INFORMATION

Non-M&D service provider licensees provide a variety of commercial services to their customers (i.e., other specific and general licensees), but they are not themselves authorized to manufacture or distribute radioactive materials or devices containing radioactive materials.

¹ The Category 1 and Category 2 thresholds are based on the quantities established by the International Atomic Energy Agency in its "Code of Conduct on the Safety and Security of Radioactive Sources," which the United States has committed to and the NRC has endorsed. The Category 1 and Category 2 quantities of radioactive material are considered risk significant and are listed in Table A-1 of Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37.

² Non-M&D service provider activities may include, but are not limited to, installation, initial radiation survey, repair, and maintenance of components related to radiological safety; relocation, replacement, and alignment of sources into or removal of sources from devices containing radioactive materials; removal and shipping of radioactive material from devices from customers' facilities; transfer and disposal of sealed sources or devices; packaging and repackaging of customers' sources or devices containing radioactive material; or removal of sources from devices containing radioactive material. The types of sources or devices that non-M&D service providers service include, but are not limited to, self-shielded irradiators, gamma stereotactic radiosurgery units, and panoramic and underwater irradiators.

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Furthermore, non-M&D service providers typically are not authorized to possess radioactive material; however, possession of radioactive material is in certain cases incidental to performing services for their customers.

Before the implementation of 10 CFR Part 37, if NRC or Agreement State non-M&D service provider licensees wanted their employees to have unescorted access to Category 1 or Category 2 quantities of radioactive material at customers' facilities, they could voluntarily request from the NRC the Order Imposing Trustworthiness and Reliability Requirements for Unescorted Access to Certain Radioactive Material (Non-M&D Service Provider Order). This order required the non-M&D service provider licensee to implement specific measures to ensure the trustworthiness and reliability of service representatives who were allowed unescorted access to Category 1 or Category 2 quantities of radioactive material at customers' facilities. Alternatively, the customer licensee could choose to escort the non-M&D service provider licensees when service representatives needed access to Category 1 or Category 2 quantities of radioactive material.

SUMMARY OF ISSUE

The NRC has determined that 10 CFR Part 37, Subpart B, "Background Investigations and Access Control Program," can apply to non-M&D service provider licensees. The scope of the regulations (10 CFR 37.3(a)) indicates that Subpart B and Subpart C, "Physical Protection Requirements During Use," apply to any person who *possesses or uses* at any site an aggregated Category 1 or Category 2 quantity of radioactive material. However, under 10 CFR 37.21(a)(1), licensees that are not authorized to possess Category 1 or Category 2 quantities of material or whose possession is incidental to service, such as non-M&D service provider licensees, do not automatically fall within the provisions of Subpart B, and therefore, are not required to establish an access authorization program under Subpart B. Rather, 10 CFR 37.29(a)(13) permits "any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to Category 1 or Category 2 quantities of radioactive material" to be granted unescorted access by the client licensee. To demonstrate that this requirement has been met, the regulation requires the service provider to give written verification of its employee's trustworthiness and reliability to the client licensee, as required under the Non-M&D Service Provider Order. Therefore, although 10 CFR Part 37 does not require a non-M&D service provider licensee to establish an access authorization program, a non-M&D service provider licensee must establish an access authorization program compliant with 10 CFR Part 37, Subpart B if they intend to take advantage of the 10 CFR 37.29(a)(13) provision³.

Rescission Process

Unlike the orders that were issued for certain panoramic and underwater irradiators, large manufacturers and distributors, and certain transportation activities, the Non-M&D Service Provider Orders were not automatically rescinded on implementation of 10 CFR Part 37 because additional time was needed to resolve concerns about the enforceability of the regulations for this subset of licensees. The NRC continues to retain authority to inspect and

³ 10 CFR Part 37 does not *require* client licensees to allow unescorted access to service provider licensees, even if the service provider has been deemed trustworthy and reliable under the requirements of 10 CFR Part 37, Subpart B.

enforce such orders until their rescission. The Agreement States will assume responsibility for the access authorization programs of non-M&D service provider licensees within their jurisdictions when the NRC rescinds the Non-M&D Service Provider Orders. The inspection and enforcement of the access authorization programs of the non-M&D service provider licensees will then be under the authority of the Agreement States.

Non-M&D service provider licensees that had previously received Non-M&D Service Provider Orders that have not since been terminated will receive rescission letters from the NRC following issuance of this RIS. The NRC will notify Agreement States of the non-M&D service provider licensees within their jurisdictions that have received rescission letters via courtesy copies of the letters.

Non-M&D Service Provider Licensees' Compliance with 10 CFR Part 37, Subpart B

Those non-M&D service provider licensees that have previously implemented the Non-M&D Service Provider Order may continue to maintain an access authorization program upon rescission of the order; however, that program must be in compliance with 10 CFR Part 37, Subpart B, or the Agreement State equivalent. One important difference between the access authorization program under the order and that contained in 10 CFR Part 37, Subpart B, is that under Subpart B, licensees, not the NRC, are responsible for determining the trustworthiness and reliability of the reviewing official. However, reviewing officials previously approved in compliance with the order may continue to serve as reviewing officials under 10 CFR Part 37 without further action. Under 10 CFR 37.23(b)(2), licensees are required to provide to the NRC (or the appropriate Agreement State), under oath and affirmation, a certification that any new reviewing official is deemed to be trustworthy and reliable by the licensee.

Additionally, under 10 CFR 37.25(b)(1), individuals who were previously determined to be trustworthy and reliable for the purposes of unescorted access to Category 1 or Category 2 quantities of radioactive material are "grandfathered" and do not need to undergo further investigation. However, such individuals are subject to the 10-year reinvestigation requirement in 10 CFR 37.25(c). The reinvestigation must be completed within 10 years of the date on which the elements were last completed under the Non-M&D Service Provider Order. Until the reinvestigation is completed, licensees have to retain all the documentation that validates individuals as trustworthy and reliable, as well as documentation of the NRC's approval of the reviewing officials who were approved under the order.

Verification of Non-M&D Service Provider Licensees' Compliance

A licensee's compliance with the requirements in 10 CFR Part 37, Subpart B, will be verified through an NRC or an Agreement State inspection, whichever is appropriate. Inspectors will ascertain whether non-M&D service provider licensees have chosen to implement an access authorization program; and for those that have chosen to implement such a program, inspectors will ascertain whether that program is consistent with Subpart B. Inspectors can determine which non-M&D service provider licensees may have to be inspected for compliance with 10 CFR Part 37, Subpart B, in the following two ways:

- (1) Inspectors may review the applicable program codes assigned to licensees or discern possible applicability based on the types of related activities associated with the licensee's Category 1 or 2 quantities of radioactive material.

- (2) During inspections of licensees, such as those that are authorized to possess self-shielded irradiators, gamma stereotactic radiosurgery units, and panoramic and underwater irradiators, inspectors can ask whether service provider licensees were given unescorted access to Category 1 or Category 2 quantities of radioactive material. If the service provider licensee was given unescorted access, this can be flagged for review during the next routine inspection of the service provider. If the service provider licensee was given unescorted access and is working under reciprocity, the inspector can review the licensee's access authorization program for compliance with 10 CFR Part 37, Subpart B, or the information can be shared with the appropriate regulator for follow-up as the regulator deems appropriate.

Alternately, some regulatory authorities may decide to include license conditions on non-M&D service provider licenses that will require licensees to comply with applicable 10 CFR Part 37-compatible requirements if they want to establish an access authorization program in accordance with 10 CFR Part 37.

Inspectors may verify compliance with 10 CFR Part 37, Subpart B, by following the inspection guidance in Inspection Procedure 87137, "10 CFR Part 37 Materials Security Programs," Focus Area One, "Background Investigations and Access Authorization Program," or comparable Agreement State inspection guidance.

BACKFITTING AND ISSUE FINALITY DISCUSSION

This RIS informs licensees of the applicability of 10 CFR Part 37 to non-M&D service provider licensees. This RIS requires no action or written response beyond that already required by the NRC regulations. This RIS does not impose on the addressees, in their status as applicants, licensees, or holders of NRC regulatory approvals under 10 CFR Parts 50, 52, 70, or 72, either backfitting (as defined in those parts) or actions that are inconsistent with the issue finality requirements in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." This RIS provides further information on requirements contained in the final rulemaking for 10 CFR Part 37 (Volume 78 of the *Federal Register*, page 16,921 (78 FR 16921; March 19, 2013)). Therefore, the NRC did not prepare a backfit analysis for this RIS or further address the issue finality criteria in 10 CFR Part 52.

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 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget (OMB) under control number 3150-0214.

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

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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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