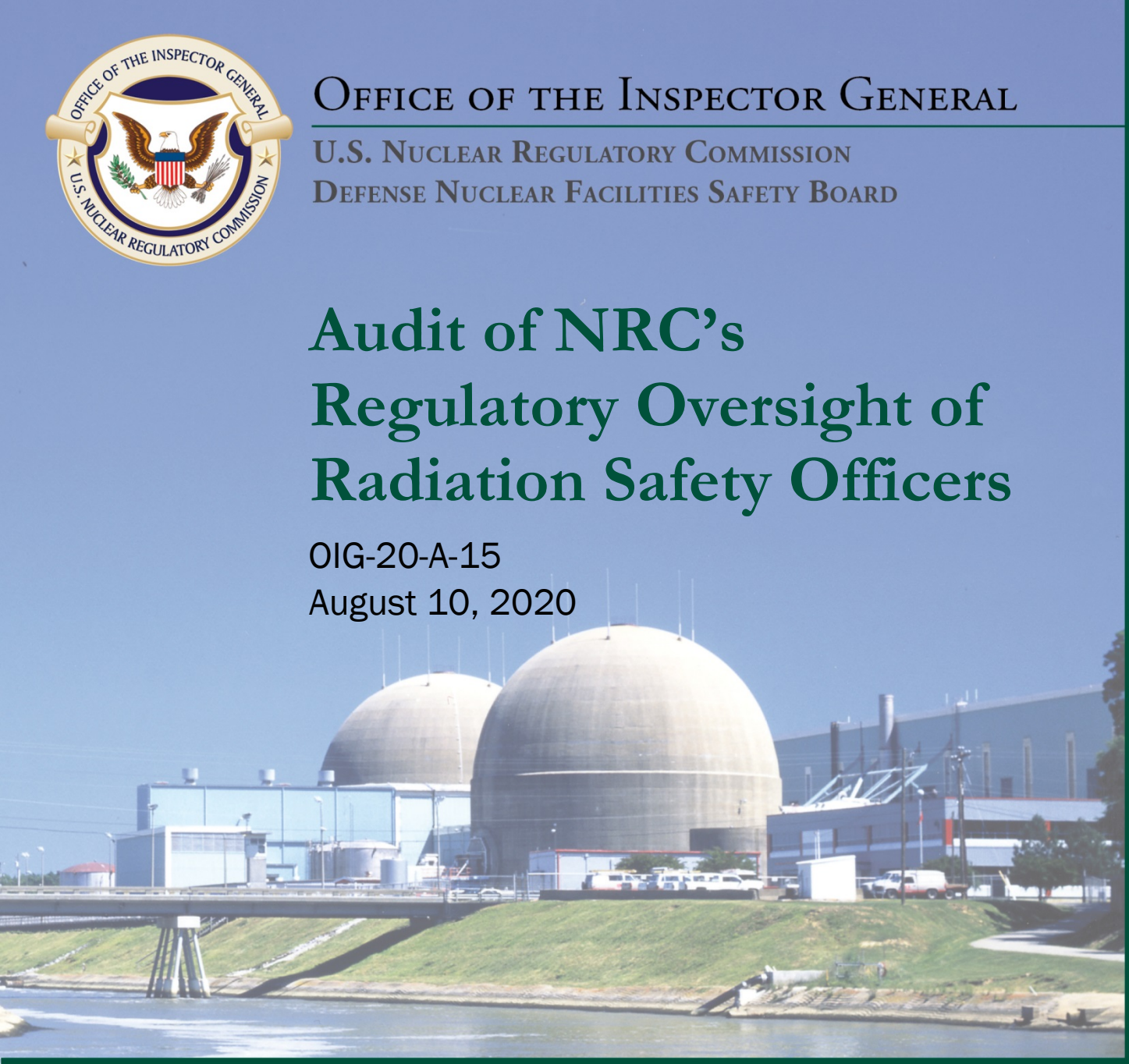
OFFICE OF THE INSPECTOR GENERAL

U.S. NUCLEAR REGULATORY COMMISSION
DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Audit of NRC's Regulatory Oversight of Radiation Safety Officers

OIG-20-A-15
August 10, 2020



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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
INSPECTOR GENERAL

August 10, 2020

MEMORANDUM TO: Margaret M. Doane
Executive Director for Operations

FROM: Dr. Brett M. Baker ***/RA/***
Assistant Inspector General for Audits

SUBJECT: AUDIT OF NRC'S REGULATORY OVERSIGHT OF RADIATION SAFETY OFFICERS (OIG-20-A-15)

Attached is the Office of the Inspector General's (OIG) audit report titled *Audit of NRC's Regulatory Oversight of Radiation Safety Officers*.

The report presents the results of the subject audit. Following the July 22, 2020, exit conference, agency staff indicated that they had no formal comments for inclusion in this report.

Please provide information on actions taken or planned on the recommendation within 30 days of the date of this memorandum. Actions taken or planned are subject to OIG follow-up as stated in Management Directive 6.1.

We appreciate the cooperation extended to us by members of your staff during the audit. If you have any questions or comments about our report, please contact me at (301) 415-5915 or Mike Blair, Team Leader, at (301) 415-8399.

Attachment: As stated

Office of the Inspector General

U.S. Nuclear Regulatory Commission
Defense Nuclear Facilities Safety Board

OIG-20-A-15

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Results in Brief

Why We Did This Review

The Nuclear Regulatory Commission (NRC) issues licenses for medical, industrial, and academic uses of source, byproduct, and special nuclear materials. The NRC expects that licensees will assign a qualified individual to serve as the Radiation Safety Officer (RSO) for licensed activities and name that individual on the license.

The RSO is the person responsible for the licensee's radiation protection program and is key to overseeing and ensuring safe operation of the licensee's radiation protection program. As of April 30, 2020, there are 1,887 RSOs under NRC jurisdiction. The NRC provides oversight of RSOs through licensing activities and inspections carried out by its Regional offices.

The audit objective was to determine the adequacy of the NRC's regulatory oversight of RSOs.

Audit of NRC's Regulatory Oversight of Radiation Safety Officers

What We Found

The NRC provides adequate regulatory oversight of RSOs through its licensing and inspection activities. However, an opportunity exists to enhance oversight of temporary RSOs by formally tracking the number of days an individual fulfills this role.

For up to 60 days each year, a licensee may permit an individual to function as a temporary RSO. However, the NRC does not formally track the amount of time that temporary RSOs fulfill their position. This is because there is no formal mechanism for tracking temporary RSOs. As a result, licensees could be in non-compliance with the NRC's regulations.

What We Recommend

This report makes one recommendation to evaluate and document the benefits of strengthening internal controls to ensure temporary RSOs appointments are established and terminated in accordance with NRC policy. Agency management opted not to provide formal comments for inclusion in this report.

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ABBREVIATIONS AND ACRONYMS

CFR	Code of Federal Regulations
NRC	Nuclear Regulatory Commission
OIG	Office of the Inspector General
RSO	Radiation Safety Officer
WBL	Web-Based Licensing

I. BACKGROUND

Regulation of Radioactive Materials

The United States Nuclear Regulatory Commission (NRC) is the federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of radioactive materials. The NRC regulates the use of these radioactive materials through Title 10, Part 20, of the *Code of Federal Regulations* (10 CFR Part 20), "Standards for Protection Against Radiation," which spells out the agency's requirements for aspects of radiation protection.

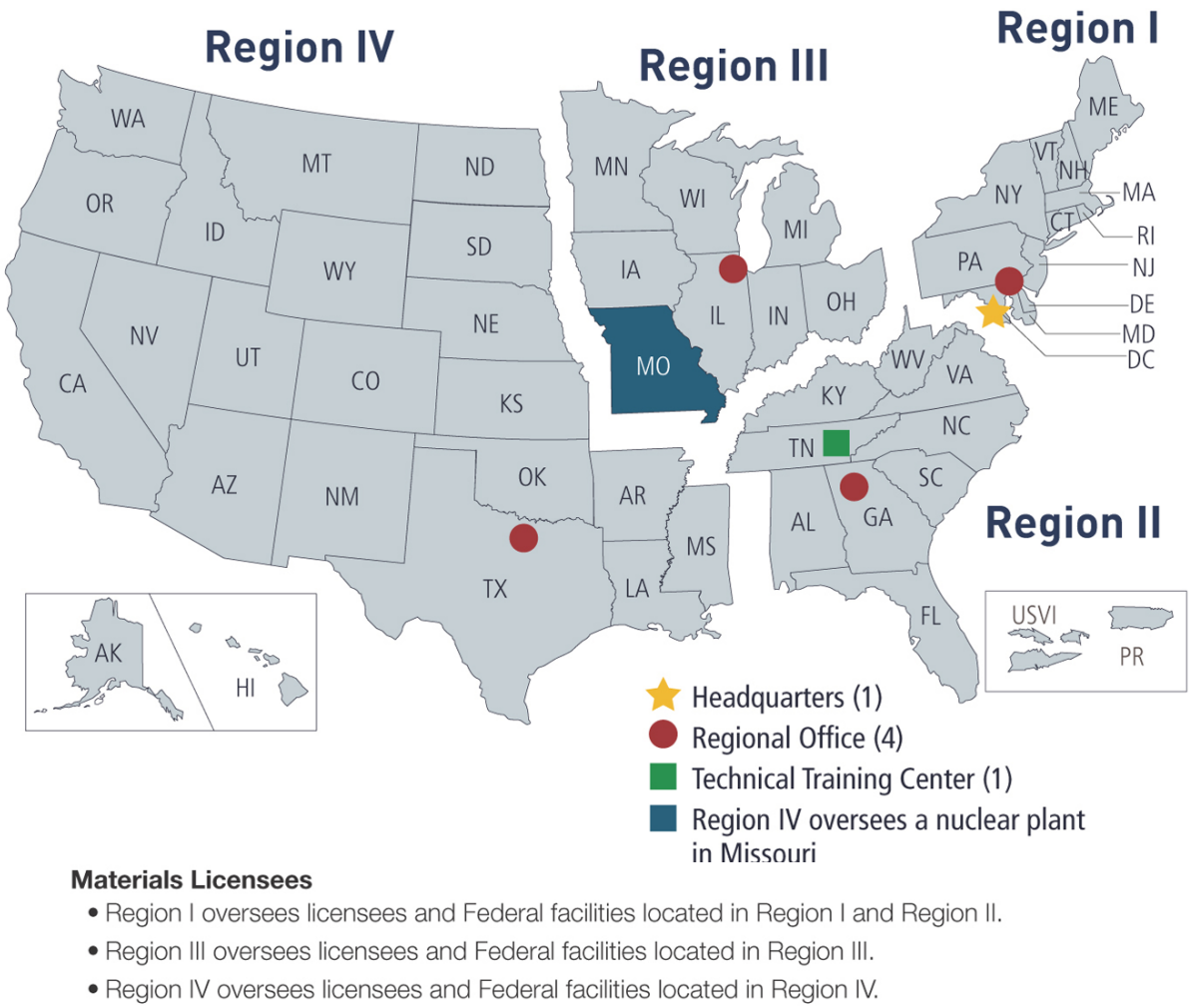
The NRC issues specific licenses for possession and use of byproduct,[1] source,[2] and special nuclear material.[3] A company that wishes to obtain a license to use nuclear materials must submit an application to the NRC. This application must demonstrate how the use of these materials will meet the safety requirements in NRC regulations and must provide information on the radiation protection program. If the NRC approves the application, a license is issued. The license may contain certain conditions imposed by the NRC and agreed to by the licensee. Applications for possession and use of nuclear material are submitted to the NRC's regional offices. (See Figure 1)

[1] Byproduct material refers to the tailings or waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes.

[2] Source material refers to uranium or thorium, or any combination thereof, in any physical or chemical form, or ores which contain greater than 0.05 percent by weight of uranium and/or thorium.

[3] Special nuclear material refers to plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235.

Figure 1: NRC Regions



Materials Licensees

- Region I oversees licensees and Federal facilities located in Region I and Region II.
- Region III oversees licensees and Federal facilities located in Region III.
- Region IV oversees licensees and Federal facilities located in Region IV.

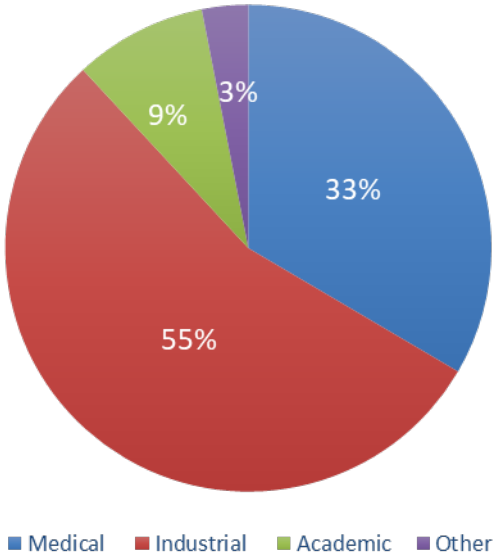
Source: NRC Website

Radioactive Materials Licenses

The NRC issues licenses for medical, industrial, and academic uses of source, byproduct, and special nuclear materials. As of February 5, 2020, the NRC has issued 2,209 materials licenses. Of these 2,209 materials licenses, the NRC has issued 1,207 radioactive material licenses for industrial use, 739 radioactive material licenses for medical use, 195 radioactive material licenses for academic use, and 68 radioactive material licenses for other uses.[4]

[4] Other uses can include civil defense, veterinarian, and licenses undergoing decommissioning.

Figure 2: NRC Radioactive Material Licenses by Type



Source: OIG analysis based on NRC data

Radiation Safety Officers

The radiation safety officer (RSO) is the person responsible for the licensee's radiation protection program. The RSO is key to overseeing and ensuring safe operation of the licensee's radiation protection program. Some of the typical duties and responsibilities of the RSO include stopping unsafe activities, identifying radiation safety problems and verifying implementation of corrective actions, developing and maintaining a program to ensure radiation exposures are kept as low as is reasonably achievable, interacting with the NRC, ensuring proper use and routine maintenance, monitoring inventory, maintaining records, and ensuring personnel are trained.

The NRC expects that the licensee's (or applicant's) management will appoint an RSO, who agrees, in writing, to be responsible for implementing the radiation protection program. Licensee management must provide the RSO with sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding NRC regulations and license provisions. The NRC expects that the licensee's management will provide the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and

that the named individual knows of his or her designation as RSO. Licensees must notify the NRC and obtain a license amendment before changing their RSO.

As of April 30, 2020, there are 1,887 RSOs under NRC jurisdiction.

Involved NRC Offices

The Division of Materials Safety, Security, State, and Tribal Programs within the Office of Nuclear Material Safety and Safeguards oversees and implements the National Materials Program[5] to enable the safe and secure use of radioactive materials in medical, industrial, and academic applications. The Division of Materials Safety, Security, State, and Tribal Programs also develops policy and procedures for assessing performance and provides technical support and guidance to the Regions for materials licensing, inspection, and enforcement activities.

The Enforcement Branch within the Office of Enforcement oversees, manages, and directs the development and implementation of policies and programs for enforcement of NRC requirements. The Enforcement Branch also coordinates enforcement actions with the Regions.

Regions I, III, and IV have radioactive materials licensing and inspection responsibility for those states within their respective jurisdictions.[6] Applications to possess or use licensed material in any State within NRC jurisdiction are filed with the appropriate NRC regional office. The Division of Nuclear Materials Safety within Regions I, III, and IV provides implementation, policy oversight, and direction for the materials licensing and inspection programs.

[5] The National Materials Program is the broad collective effort within which both the NRC and Agreement States function in carrying out their respective regulatory programs for agreement material. In accordance with Section 274 of the *Atomic Energy Act*, as amended, the NRC may relinquish its authority to license and regulate byproduct, source, and limited quantities of special nuclear material to States. Agreement States are States that have entered into an agreement assuming regulatory authority from the NRC.

[6] Region I oversees licensees and Federal facilities located in Region I and Region II.

Oversight of RSOs

The NRC provides oversight of RSOs through licensing activities and inspections carried out by the Regions.

When an applicant or licensee submits a license application, license renewal, or license amendment to name a new RSO, the applicant or licensee must submit documentation to show the proposed RSO meets the training and qualification requirements. License reviewers in the Regions review this documentation to ensure the RSO meets certain qualifications[7] prior to adding the RSO to the license. If the proposed RSO does not meet the qualifications, the license reviewers will not add the RSO to the license.

Regional inspectors conduct inspections at materials licensees' facilities on a periodic basis to ensure activities are conducted in a manner that will protect the health and safety of workers and the general public, and programs are conducted in accordance with NRC requirements. During routine inspections at materials licensees' facilities, inspectors evaluate the adequacy of licensees' radiation protection programs and assess the performance of the RSO, among other things. Through interviews, observations, and review of records, inspectors verify that the RSO is knowledgeable about the licensee's radiation protection program and ensures that activities are being performed in accordance with approved procedures and the regulations. If inspectors identify violations, the violation is assessed and dispositioned in accordance with NRC's Enforcement Policy. In Fiscal Year 2019, nuclear materials inspections (not including enforcement, allegations, or event evaluation) performed by staff in Regions I, III, and IV had a total of 19.5 dedicated full-time equivalents and a budget of $3,589,000.

[7] The NUREG-1556 volumes provide program-specific guidance to assist applicants and licensees in preparing applications for various categories of materials licenses and provide NRC staff with the criteria for evaluating such applications.

II. OBJECTIVE

The audit objective was to determine the adequacy of the NRC's regulatory oversight of RSOs. The scope of this audit is RSOs under NRC jurisdiction. The report appendix contains information on the audit scope and methodology.

III. FINDING

The NRC provides adequate regulatory oversight of RSOs through its licensing and inspection activities. However, an opportunity exists to enhance oversight of temporary RSOs by formally tracking the number of days an individual fulfills this role.

A. No Formal Tracking of Temporary RSOs

For up to 60 days each year, a licensee may permit an individual to function as a temporary RSO. However, the NRC does not formally track the amount of time that temporary RSOs fulfill their position. This is because there is no formal mechanism for tracking temporary RSOs. As a result, licensees could be in non-compliance with the NRC's regulations.

What Is Required

For Up To 60 days Each Year, a Licensee May Permit an Individual To Function as a Temporary RSO

10 CFR Part 35, "Medical Use of Byproduct Material," provides in pertinent part that for up to 60 days each year, a licensee may permit an individual qualified to be an RSO to function as a temporary RSO and to perform the functions of an RSO contingent upon meeting certain Part 35 requirements, such as notifying the NRC within 30 days of the appointment of the temporary RSO. In addition to temporary RSOs, Part

35 also allows licensees to appoint associate RSOs, who must possess the same qualifications as the permanent RSO and can serve as temporary RSO.

Further, as a regulatory agency, it is the NRC's responsibility to establish and enforce requirements. While safety is the fundamental regulatory objective, compliance with NRC requirements plays an important role in giving the NRC confidence that safety is being maintained.

What We Found

The NRC Does Not Formally Track the Amount of Time That Temporary RSOs Fulfill Their Position

Licensees[8] are required to notify the NRC within 30 days of appointing a temporary RSO. However, when the NRC receives this notification, the NRC does not formally track the amount of time that temporary RSOs remain in their role.

The license reviewer's role is two-fold, (1) to engage the licensee to share plans for appointing a permanent RSO during the license amendment review process and (2) to clarify that if a permanent RSO is not appointed after the 60-day period is over, the licensee could be found non-compliant.

<u>The NRC Enforces the 60-Day Requirement Through Inspections</u>

Although temporary RSOs aren't formally tracked by licensing staff when they receive the temporary RSO notification from the licensee, the NRC maintains awareness of temporary RSOs and enforces the 60-day requirement for temporary RSOs through inspections. During periodic, routine inspections at licensee sites, NRC inspectors evaluate the implementation of the radiation protection program, which is the RSO's responsibility. Prior to conducting the inspection, inspectors review the licensee's docket which would contain information on the temporary RSO if the licensee reported the appointment of the temporary RSO to the NRC, as required by the regulations. If the licensee did not notify the NRC of the temporary RSO appointment, inspectors could identify that the

[8] Medical licensees, governed by 10 CFR Part 35, are the only category of licensees permitted to appoint temporary RSOs.

licensee had a temporary RSO through review of the licensee's annual audit, review of quarterly radiation safety committee meeting minutes, interviews with personnel, review of records, and review of the license and license-related documents. If an inspector identifies that the licensee appointed a temporary RSO, the inspector would calculate the amount of time the temporary RSO served in that role. If the temporary RSO exceeded the 60-day period, the NRC could pursue enforcement action against the licensee, as appropriate.

Although the NRC enforces the 60-day requirement for temporary RSOs through inspections, medical materials licensees are only routinely inspected anywhere from every 2 to 5 years. Therefore, the NRC may inspect the licensee well after the temporary RSO's period of service has ended. This means an individual could serve as a temporary RSO for several months or years, and the NRC may not become aware of the non-compliance until the next inspection. However, this would not necessarily constitute or pose a safety issue to the public as the existing regulations require that temporary RSOs meet the same qualifications as permanent RSOs. The NRC already has processes in place to identify any potential risks to public health and safety as a result of a licensee's non-compliance with the 60-day requirement for temporary RSOs.

Staff Perspectives

During interviews with regional licensing and inspection staff, some staff opined that as long as the temporary RSO is qualified, there is little-to-no safety consequence associated with exceeding the 60-day period. Further, regional staff and management told the OIG that temporary RSO use is not prevalent with medical materials licensees. Conversely, some staff believe that formally tracking temporary RSOs would be beneficial. A staff member explained that temporary RSOs should be tracked because it is important for the NRC to know who is fulfilling the position and who the NRC can contact in case of an emergency.[9] One license reviewer opined that the NRC has a lack of oversight during the time a temporary RSO is in place. Some staff told the OIG that because the 60-day period is in the NRC's regulations, it makes sense to track it.

[9] Per 10 CFR Part 35, medical licenses list the names of any associate RSOs and authorized users. Further, for a large subset of licensees, the NRC has additional licensee contacts, as required by the regulations. In case of an emergency, NRC can contact any of these individuals.

Why This Occurred

There is No Formal Mechanism for Tracking Temporary RSOs

Regions I, III, and IV do not have a formal tracking system to track how long temporary RSOs remain in their position.

Web-Based Licensing System

Staff cited the NRC's Web-Based Licensing (WBL) system[10] as a mechanism through which staff could formally track temporary RSOs. Staff opined that the WBL system would be a good system for tracking temporary RSOs as all three Regions use it for licensing and inspection metrics. The WBL system also can generate reports. The WBL system currently stores information on a variety of licensee staff and contacts (e.g. RSOs, associate RSOs, authorized users). However, it does not currently have a field for input of temporary RSOs.

Some staff do not believe that modifications to the WBL system are necessary as they do not consider tracking temporary RSOs to be a risk-informed or risk-significant activity. However, other staff suggested a modification to the WBL system that would allow staff to input the temporary RSO notification such that a "tickler" would be created for that action. This would alert staff within a certain number of days of the expiration of the 60-day period, and staff could reach out to the licensee to determine their status with regard to finding a permanent RSO.

A senior regional manager advised that if a field were to be added to the WBL system to capture temporary RSO time limits, it would have to be searchable and trackable to have meaning to the program. The field should be something that could be run and included in routine reports to review licensing metrics.

[10] The WBL system is a materials licensing system that supports the NRC and Agreements States in managing the licensing information of businesses that use radioactive materials. Designed to maintain information on materials licensees, the WBL system supports the entry of licensing information that enables the NRC and Agreement States to manage the licensing life cycle from initial application through license issuance, amendment, reporting, and termination.

Another senior regional manager told the OIG that staff should engage with licensees and pay attention to whether they are submitting a license amendment to appoint a permanent RSO. The manager further explained that the NRC needs to track the fact that they receive an amendment for the permanent RSO. The manager added that the NRC cannot file the notification paperwork and then forget about it, and the NRC needs to make sure licensees are working towards getting a permanent RSO on their license.

Why This Is Important

Licensees Could Be in Non-Compliance with the NRC's Regulations

If a licensee's temporary RSO remains in their position for more than 60 days, the licensee is in non-compliance with the NRC's regulations.

The OIG conducted an analysis of escalated enforcement actions for materials licensees from 2011 to 2020. OIG identified one violation for a temporary RSO exceeding the 60-day period during that time frame. While no safety concerns have been identified as a result of not formally tracking temporary RSOs, formally tracking temporary RSOs in a system could prompt NRC staff to engage with the licensee to ensure they are remaining compliant and actively working towards identifying a full-time, permanent RSO to be named on their license.

Recommendation

The OIG recommends that the Executive Director for Operations

1. Evaluate and document the benefits of strengthening internal controls to ensure temporary RSOs appointments are established and terminated in accordance with NRC policy.

IV. AGENCY COMMENTS

An exit conference was held with the agency on July 22, 2020. After reviewing a discussion draft, agency management provided comments that have been incorporated into this report, as appropriate. As a result, agency management opted not to provide formal comments for inclusion in this report.

Appendix A

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to determine the adequacy of the NRC's regulatory oversight of RSOs.

Scope

The audit focused on RSOs in NRC jurisdiction. We conducted this performance audit at NRC headquarters (Rockville, Maryland) from January 2020 through June 2020. Internal controls related to the audit objective were reviewed and analyzed.

Methodology

The OIG reviewed relevant criteria and guidance documents for this audit including

- The *Atomic Energy Act of 1954*, as amended.
- 10 CFR Part 20, "Standards for Protection Against Radiation."
- 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material."
- 10 CFR Part 35, "Medical Use of Byproduct Material."
- NUREG-1556, "Consolidated Guidance About Materials Licenses", Volumes 1 through 21.
- Inspection Manual Chapter 2800, "Materials Inspection Program," and associated Inspection Procedures.

The OIG interviewed staff and management from the Office of Nuclear Material Safety and Safeguards and Regions I, III, and IV to gain an understanding of the NRC's oversight of RSOs at byproduct materials licensee facilities. Auditors also interviewed Office of Enforcement staff and management to identify the applicability of the NRC's enforcement program to byproduct materials licensees who are identified as non-compliant with the NRC's requirements for RSOs. The OIG also

conducted an analysis of escalated enforcement actions issued to materials licensees from 2011 through 2020 to determine the prevalence of non-compliance with RSO-related requirements. In addition, auditors performed analyses of WBL search results to determine the total number of RSOs in NRC jurisdiction and the number of licenses each RSO is listed on. Also, auditors reached out to a judgmental sample of 24 byproduct materials licensees' RSOs and licensee representatives to obtain their perspectives on the NRC's regulatory oversight of RSOs. The sample consisted of RSOs and licensee representatives from all three Regions and across various categories of materials licensees.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Throughout the audit, auditors considered the possibility of fraud, waste, and abuse in the program.

The audit was conducted by Mike Blair, Team Leader; Regina Revinzon, Audit Manager; Roxana Hartsock, Senior Auditor; and Connor McCune, Management Analyst.

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COMMENTS AND SUGGESTIONS

If you wish to provide comments on this report, please email the OIG using this link.

In addition, if you have suggestions for future OIG audits, please provide them using this link.