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

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NRC INFORMATION NOTICE 2021-02: RECENT ISSUES ASSOCIATED WITH MONITORING OCCUPATIONAL EXPOSURE TO RADIATION FROM LICENSED AND UNLICENSED RADIATION SOURCES

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) materials licensees. All Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice (IN) to inform addressees of recent issues associated with monitoring occupational exposure to radiation from licensed and unlicensed radiation sources under the licensee's control. The NRC expects that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. Any suggestions contained in the IN are not new NRC requirements; therefore, no specific action or written response is required. The NRC is providing this IN to the Agreement States for their information and for distribution to their licensees as appropriate.

DESCRIPTION OF CIRCUMSTANCES

From August 2018 to October 2020, the NRC identified issues at seven NRC medical-use licensees involving compliance issues associated with monitoring individuals' occupational exposure to radiation from licensed and unlicensed radiation sources that were under the control of the licensees. The issues were associated with occupational radiation exposures received by interventional radiology (IR) physicians who were involved in the conduct of NRC-licensed activities under the provisions of 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material." Although the issues described in this IN were identified at NRC medical-use licensees, the information provided is applicable to all NRC licensees where occupational radiation exposures from licensed and unlicensed radiation sources can occur.

Monitoring Exposure to Unlicensed Radiation Sources Under Licensee Control

The IR physicians performed activities involving the administration of yttrium-90 microspheres, which is an NRC-licensed radioactive byproduct material. Additionally, the IR physicians were exposed to unlicensed radiation sources. Unlicensed radiation sources are not licensed by the NRC and include radiation from certain radiation-producing devices, such as fluoroscopy equipment and other x-ray-generating devices. Although not licensed by the NRC, these sources of radiation may be subject to registration with state regulatory agencies.

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Specifically, at the seven NRC medical-use licensees, IR physicians used fluoroscopic (x-ray) guidance to place an intraarterial microcatheter to the targeted delivery area for the yttrium-90 microspheres. The IR physicians who administered the yttrium-90 microspheres also performed numerous other IR procedures using fluoroscopic guidance that did not involve the use of NRC-licensed radiation sources.

During NRC inspections at the medical-use licensees, the NRC identified several issues, including licensees' understanding of the NRC regulatory requirement in 10 CFR 20.1502(a). This regulation requires that each licensee monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits specified in 10 CFR Part 20, "Standards for protection against radiation." In accordance with 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," requires monitoring of exposure to licensed and unlicensed radiation sources under the control of the licensee:

> As a minimum, each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by— (1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a); (2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv); (3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and (4) Individuals entering a high or very high radiation area.

The NRC observed that some IR physicians wore assigned individual monitoring devices (personnel dosimeters) inconsistently. For example, some IR physicians wore the assigned personnel dosimeter only during yttrium-90 procedures, but not during IR procedures that did not involve yttrium-90, under the misunderstanding that their exposure to unlicensed x-ray sources was not required to be monitored. The inspectors also observed that some IR physicians did not wear assigned personnel dosimeters at all when working with either licensed or unlicensed radiation sources.

In accordance with 10 CFR 20.1101(a), licensees are required to develop, document, and implement radiation protection programs commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20, "Standards for protection against radiation." NRC inspectors found that licensees' radiation protection programs, specifically their policies and procedures for occupational dosimetry programs, often did not have provisions to address 10 CFR 20.1201(f) and 10 CFR 20.2104, "Determination of prior occupational dose." As a result, licensees did not account for occupational radiation exposure received by individuals either: (1) concurrently while employed at other facilities, including other NRC-licensed facilities, Agreement State-licensed facilities, or unlicensed facilities, or (2) during the same calendar year, prior to the individual performing licensed activities under the licensee's control. Consequently, licensees were not cognizant of the total radiation dose received by those individuals and whether this additional occupational dose would result in any radiation doses in excess of the NRC's regulatory limits.

Improper Use and Implementation of Dosimetry Approaches

The NRC found that the proper use of personnel dosimeters varied significantly among IR physicians. In some cases, IR physicians wore their personnel dosimeter improperly, which included not wearing the personnel dosimeter in the assigned location in accordance with licensees' policies (e.g., collar vs. waist, or above lead shielding vs. under lead shielding). At one licensee, personnel dosimeters not being worn were stored improperly in a radiation area. Several IR physicians did not exchange assigned personnel dosimeters at the indicated frequency or often wore them significantly beyond the monitoring period indicated on the dosimeter.

Dosimetry vendors often offer single- and double-dosimeter approaches with correction factors to take nonuniform radiation exposures into account, such as those occupational exposures received when wearing a lead apron during the performance of IR procedures. Some licensees did not establish policies or procedures to address the dosimetry approach used.

As a result, licensees inconsistently applied correction factors, which most often occurred with double-dosimeter approaches. Double-dosimeter approaches typically rely on one dosimeter to be worn at the collar outside of the lead, and one dosimeter to be worn at the waist under the lead. Licensees that used a double-dosimeter approach often did not have policies and procedures that addressed issues that would reasonably be expected to arise from this dosimetry approach. For example, licensees did not have policies or procedures for actions to be taken if one or both assigned personnel dosimeters were not turned in for processing at the end of the assigned wear period. Licensees' policies often did not address actions to be taken if the personnel dosimeters were not worn at the assigned location, such as if the waist dosimeter were worn at the collar outside of the lead. The NRC observed that when this occurred, the licensee-assigned radiation exposures were often higher, and in some cases grossly higher, than those that would have been expected for the individual IR physician caseload.

Radiation Safety Programs: Training and Oversight

The NRC also identified various deficiencies regarding licensees' implementation and oversight of their radiation safety programs. These included deficiencies in licensees' radiation safety program content and implementation and their training programs. Licensees also did not implement corrective actions to address identified personnel dosimetry issues.

In the area of licensees' radiation safety program content and implementation, the inspectors found that licensees did not comply with 10 CFR 20.1101(a), which requires that licensees develop, document, and implement radiation protection programs that are commensurate with the scope and extent of licensed activities and sufficient to assure compliance with 10 CFR Part 20. For several of the medical-use licensees involved in these cases, the NRC found that the licensees' radiation safety policies and procedures did not adequately describe their personnel dosimetry program or to require the use of individual monitoring devices.

In some cases, through routine audit and oversight activities, licensees or their third-party auditors identified issues with individuals not wearing, or improperly wearing, their assigned personnel dosimeters. However, when issues were identified, licensees either did not

investigate these matters and implement corrective actions, or the corrective actions that they implemented were not sufficient to correct the issues and prevent recurrence.

Although the NRC found most licensees' policies and procedures for occupational dosimetry programs to have established thresholds to identify unusually high radiation exposures, the licensees did not to establish mechanisms to identify occupational radiation exposure values that were unusually lower than expected, or where no results were reported. For example, several IR physicians performed over 100 IR procedures a month, but their monthly personnel dosimeter reading was less than 1 millirem. It is unlikely that the performance of over 100 IR procedures in 1 month would result in little to no measurable radiation dose. These licensees did not have mechanisms to identify or flag these unusually low dosimeter readings for further review or investigation.

Some licensees performed routine reviews of dosimeter results and identified unusually high radiation exposures for IR physicians. However, in many cases, the licensees did not investigate the cause of these excessively high or anomalous dosimeter readings. In some cases, the licensees' investigations consisted of a written warning to the IR physicians, but the licensees did not actually investigate or attempt to understand the causes of the high or anomalous dosimeter readings. In one case, a licensee observed high dosimeter results for an IR physician and investigated the matter. The licensee determined that the IR physician was wearing the assigned dosimeter correctly, while the other IR physicians with lower dosimeter results were not wearing their assigned dosimeters correctly. However, the licensee took no corrective actions to address the noncompliant dosimeter use by the other IR physicians.

Licensees also did not provide adequate instruction to individuals in accordance with 10 CFR 19.12, "Instruction to workers." In all cases, the NRC found that the licensees provided the IR physicians with personnel dosimeters, but the IR physicians rarely received instruction or training in the licensees' policies and procedures for dosimeter use. NRC inspectors observed that some licensees assumed that IR physicians would already possess such knowledge, based on their education and credentials, and that licensee-specific training was not required or necessary. Some licensees simply did not include IR physicians in licensee training programs. This was observed to be more prevalent when the IR physicians were contracted individuals or independent radiology providers rather than licensee employees.

DISCUSSION

The NRC regulates the possession and use of radioactive byproduct material, special nuclear material, and source material. Licensed radiation sources are byproduct material, special nuclear material, and source material that are (1) authorized by a specific license issued by the NRC or (2) authorized under a general license as specified in the NRC regulations. Unlicensed radiation sources are those radiation sources that are not licensed by the NRC under a specific or general license. Unlicensed sources include radiation from certain radiation-producing devices, such as fluoroscopy equipment and other x-ray-generating devices. These unlicensed sources of radiation may be subject to registration with state regulatory agencies.

Although the NRC identified the issues described in this IN at its medical-use licensees, 10 CFR 20.1501(a) is applicable to all NRC licensees where occupational radiation exposures from licensed and unlicensed radiation sources can occur. For example, some

industrial radiography licensees use radiographic exposure devices with NRC-licensed byproduct material radioactive sources, such as cobalt-60 and iridium-192, and also use radiographic exposure devices that employ x-ray-generating sources, which are not licensed by the NRC. If occupationally exposed individuals, such as industrial radiographers, use byproduct material radioactive sources and x-ray-generating sources under the control of the licensee, the licensee is required to monitor the occupational radiation exposures to these individuals from both of these radiation sources.

In accordance with 10 CFR 20.1502(a), licensees are to supply and require the use of individual monitoring devices for the specified categories of occupationally exposed individuals. It is only through the proper use of these individual monitoring devices that licensees can evaluate radiation doses to determine compliance with the NRC's occupational dose limits.

The NRC identified compliance issues associated with the licensees' occupational radiation monitoring programs resulted in escalated enforcement action against several licensees and required extensive licensee actions to correct the deficiencies. The licensees' efforts included significant revisions to licensees' radiation safety programs, procedures and policies, training programs, and oversight practices. Further, licensees' corrective actions included complex evaluations of radiation exposure data to determine radiation dose estimates. Many of the licensees had to make radiation dose estimates for multiple IR physicians for occupational radiation exposures that occurred over several years for licensed and unlicensed radiation sources under the control of the licensees. Although licensees' radiation dose estimates resulted in no individual exceeding the NRC's occupational dose limits specified in 10 CFR Part 20, several individuals closely approached those limits.

The NRC expects that licensees will develop, implement, and maintain radiation protection programs, including programs for monitoring occupational radiation exposures, that are commensurate with the scope and extent of their activities, in accordance with 10 CFR 20.1101(a). NRC inspectors have found that effective licensee radiation protection programs include policies and procedures associated with monitoring occupational radiation exposures. NRC inspectors found that comprehensive and effective policies and procedures for monitoring occupational radiation exposures included provisions to address: (1) criteria for occupational monitoring at the licensee's facility; (2) prior or concurrent occupational radiation exposures to licensed and unlicensed radiation sources; (3) responsibilities for individuals to properly wear dosimeters; (4) licensee-specified dosimeter wear locations; (5) expectations for turning in dosimeters for processing at the end of assigned wear periods; (6) lost or missing dosimeters; (7) proper storage of dosimeters when not in use; (8) prompt evaluation of dosimeter results; (9) criteria to evaluate or investigate unusually low or high dosimeter results; and (10) periodic reviews and oversight of licensee dosimetry programs. Because dosimetry approaches and programs vary widely, it is important for individuals to receive licensee-specific training on the policies and procedures that pertain to dosimeter use.

In accordance with 10 CFR 20.1101(c), licensees shall periodically (at least annually) review the radiation safety program content and implementation. Effective auditing and radiation safety program reviews may allow licensees to promptly identify compliance issues associated with occupational monitoring programs and take actions to correct any identified deficiencies and prevent recurrence. Licensees with effective auditing programs typically use a combination of auditing techniques, including records review and direct observation of

occupationally exposed individuals. For records reviews, licensees may find it beneficial to compare dosimeter results data with information or data related to individuals' licensed activities (i.e., radioisotopes used, quantity used, frequency of use) and unlicensed activities (i.e., characteristics of specific x-ray-generating devices used, duration of use, frequency of use). Some licensees have found that such comparisons can be accomplished through automated data collection systems that can flag discrepant data or be set to flag or identify values that meet certain thresholds established by the licensee. For direct observation, licensees may elect to perform periodic spot-checks of occupationally exposed individuals during licensed and unlicensed activities to determine whether dosimeters are being worn properly. If licensee evaluations determine that occupational radiation doses exceed the limits in 10 CFR Part 20, licensees are required report to the NRC in accordance with 10 CFR 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits."

CONTACT

This IN requires no specific action or written response. If you have any questions about the information in this notice, please notify the technical contact listed below or the appropriate regional office.

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