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

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NRC INFORMATION NOTICE 2019-07: METHODS TO PREVENT MEDICAL EVENTS

ADDRESSEES

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

PURPOSE

The purpose of this information notice (IN) is to provide licensees with the results of an evaluation of medical events and to provide strategies to reduce or to prevent medical events. On September 20, 2018, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) presented the results of the Medical Events Subcommittee's evaluation of recent years' medical events (Agencywide Documents Access and Management System Accession No. ML19038A495). During this presentation, the ACMUI recommended that the NRC develop this IN to inform licensees of past medical events and methods for licensee consideration to prevent similar medical events in the future. The NRC is issuing this IN to inform licensees of this evaluation and methods developed by the ACMUI and the NRC for licensee consideration to prevent similar medical events in the future. The NRC expects that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. Information contained in this IN does not constitute 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 medical licensees, as appropriate.

DESCRIPTION OF CIRCUMSTANCES

Licensees are required to report medical events that meet the criteria defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.3045, "Report and Notification of a Medical Event," except those that result from patient intervention. While a medical event rarely means that a patient has been harmed, it is important to minimize the number of events, as they have the potential to cause harm and may indicate a potential problem with how a medical facility administers radioactive materials or radiation from radioactive materials. The purpose of medical event reporting is to identify the causes of the events in order to correct them, to prevent their recurrence, and to allow the NRC to notify other licensees of the events so they can avoid them. Both the NRC staff and the ACMUI perform annual reviews of medical event reports to determine any trends or patterns, to identify generic issues or generic concerns, and to recognize any inadequacies or unreliability of specific equipment or procedures. The NRC staff and the ACMUI present their findings at biannual ACMUI meetings. The presentations from recent years are posted on the NRC Medical Uses Licensee Toolkit Webpage, https://www.nrc.gov/materials/miau/med-use-toolkit.html.

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In 2018, the ACMUI Medical Events Subcommittee chose to review four years of medical event reports to identify any common causes and recommended methods to prevent future medical events. In the four-year period reviewed, the ACMUI determined that 212 events were reported across all medical modalities, as broken down by regulatory use and modality in the following table.

Regulatory Use	Types of Use (Modality)	Number of Events
10 CFR 35.200	Imaging and Localization Using Unsealed Byproduct Material	21
10 CFR 35.300	Unsealed Byproduct Material with Written Directive Required	20
10 CFR 35.400	Manual Brachytherapy	27
10 CFR 35.600	Afterloader Brachytherapy	34
10 CFR 35.600 10 CFR 35.1000	Gamma Stereotactic Units	15
10 CFR 35.1000	Radiation Seed Localization	4
10 CFR 35.1000	Yttrium-90 Microsphere	91

DISCUSSION

Through its evaluation, the ACMUI identified two overarching themes associated with medical events. First, the need to have timeouts immediately before administration, such as done in surgery and other medical settings. This has the potential to prevent many of the events across the different modalities. The ACMUI stated that in radiopharmaceutical uses (in accordance with 10 CFR 35.200, "Use of Unsealed Byproduct Material for Imaging and Localization Studies for which a Written Directive Is Not Required," and 10 CFR 35.300, "Use of Unsealed Byproduct Material for which a Written Directive Is Required"), numerous events involved the administration of the wrong drug or dosage or the administration of the drug to the wrong patient. The ACMUI stated that, if licensee staff had taken a timeout immediately before the administration to verify that the drug, dose, and patient were in accordance with the written directive, many, if not all, of these events could have been avoided.

For manual brachytherapy, four of the events involved a different implanted source strength than that prescribed in the written directive. These events might have been prevented if the licensee staff had taken a timeout before implantation to verify whether the values found in the written directive were reasonable. For afterloader brachytherapy, five of the events involved use of the wrong plan; two events involved recording the wrong dose or source strength; and seven events involved application of the wrong reference length. These events might have been prevented if the licensee staff had taken a timeout before treatment to verify the plan against the patient's chart, to confirm the accurate dose or source strength recorded on the plan, and to check the reference length.

For gamma stereotactic radiosurgery, multiple events were associated with patient setup errors and the wrong site selected on the treatment plan. If the licensee staff had taken timeouts to verify these setups and patient plans, many of these events might have been avoided. Finally, for yttrium-90 microsphere brachytherapy, ten of the events involved the administration of a radioactivity that differed from that stated in the written directive, in many cases as a result of treatment plan calculation errors. An additional ten events were associated with the selection of the wrong catheter placement. If timeouts had been taken to verify that all elements of the treatment, especially the activity and general catheter location, matched the written directives, many of the medical events might have been prevented.

Based on the findings described above, the ACMUI recommended taking timeouts that include the following specific elements. For all modalities, the patient should be identified by using two identifiers (e.g., name and date of birth), and the licensee should ensure that the procedure to be performed, the isotope to be used, the activity, the dose, and the anatomic location are verified. In addition, the ACMUI recommended, as applicable, using timeouts to verify units of activity for low dose rate prostate brachytherapy; completing an independent second check of the treatment plan; checking the reference length for high dose rate (HDR) brachytherapy; and verifying the implant site location for radiation seed localization.

Second, the ACMUI identified that infrequent or lack of recent performance of a specific administration or use of a device may have been a contributing factor in several medical events. For example, in six events, the seeds were implanted into the wrong site during manual brachytherapy. While it was difficult to determine from the information reported to the NRC, the ACMUI assumed that many of these events were associated with users who perform the treatment infrequently. The ACMUI recommended that authorized users take refresher training for procedures that are performed infrequently to reduce the risk of medical events. Specifically, the ACMUI recommended consideration of the following types of refresher training: (1) taking a review course from a professional society; (2) reading review articles; (3) speaking to colleagues with more experience with the procedure; (4) performing a dry run of the procedure with the team; and (5) reviewing the mechanics of the device setup and its operation.

In addition to the ACMUI recommendations presented in 2018, the NRC staff identified another contributing cause to several medical events in recent years: failure to provide adequate training to appropriate staff following the introduction of new equipment or software, or updates to existing software. Specifically, the NRC staff noted that several of the applicator reference length errors in HDR afterloader events occurred after the licensee changed applicators. Additionally, HDR afterloader events have occurred in which where licensees incorrectly switched the starting end of the catheter when using new or updated software, resulting in treatment of the wrong site. These events might have been avoided if the authorized user and authorized medical physicists were trained in the new applicators or software.

CONTACT

This IN requires no specific action or written response. Please direct any questions about this matter to the technical contact listed below or the appropriate regional office.

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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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