

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

August 26, 2019

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 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, which is a small percentage of the total number of medical treatments using radioactive material completed in the United States during that time period. The events are broken down by regulatory use and modality in the following table.

| <b>Regulatory Use</b>           | <b>Types of Use (Modality)</b>                              | <b>Number of Events</b> |
|---------------------------------|---|-------------------------|
| 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<br>10 CFR 35.1000 | Gamma Stereotactic Units                                    | 15                      |
| 10 CFR 35.1000                  | Radioactive Seed Localization                               | 4                       |
| 10 CFR 35.1000                  | Yttrium-90 Microsphere                                      | 91                      |

## **DISCUSSION**

The ACMUI identified two overarching themes associated with medical events. First, the need to have timeouts immediately before administration, as conducted in surgical and other medical settings. This has the potential to prevent many of the events across the different modalities.

The ACMUI noted that the events involving radiopharmaceutical uses (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”), were attributed to the administration of the wrong drug, 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 that they planned to administer were in accordance with the written directive. 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 use 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 treatment plans, many of these events might have been avoided. Finally, for yttrium-90 microsphere brachytherapy, ten of the events involved the administration of a dosage that differed from that stated in the written directive. 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 all 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 radioactive seed localization.

Second, the ACMUI identified that infrequent or lack of recent performance of a specific type of treatment may have been a contributing factor in several medical events. For example, in six events, the radioactive 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 concluded 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 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.

### **/RA/**

Christopher G. Miller, Director  
Division of Inspection and Regional  
Support  
Office of Nuclear Reactor Regulation

### **/RA/**

Andrea L. Kock, Director  
Division of Materials Safety, Security,  
State, and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Technical Contact: Katie Tapp, NMSS  
301-415-0236  
e-mail: [Katherine.Tapp@nrc.gov](mailto:Katherine.Tapp@nrc.gov)

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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\*concurrent via email

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