COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
OFFICE OF WASTE, AIR, RADIATION AND REMEDIATION
BUREAU OF RADIATION PROTECTION
HARRISBURG, PA 17101

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BRP INFORMATION NOTICE 2021-01 METHODS TO PREVENT MEDICAL EVENTS

ADDRESSEES

All Pennsylvania Department of Environmental Protection (DEP) Specific Licensees authorized for medical use.

PURPOSE

The DEP is issuing this Information Notice (IN) based on recent Nuclear Regulatory Commission (NRC) Information Notice 2019-07. NRC wants to provide licensees with the results of an evaluation of medical events and to provide strategies to reduce or to prevent medical events. The hope is to raise awareness and help reduce the occurrence of similar medical events. This IN should be regarded as "lessons learned" to help outline reoccurring issues with these medical procedures, and to help avoid similar problems or situations.

DESCRIPTION OF CIRCUMSTANCES

In 2018, the ACMUI Medical Events Subcommittee reviewed 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 only 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.

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	Radioactive Seed Localization	4
10 CFR 35.1000	Yttrium-90 Microsphere	91

DISCUSSION

The ACMUI identified two (2) 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.

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.
Please refer to the attached NRC Information Notice for further information on these issues along with issues including the remaining modalities.

CONTACT

This Information Notice requires no specific action or response. If you have any questions about the information in this notice, please contact the Radiation Control Division at 717-787-3720.

Issued By:
David J. Allard, CHP, Director
Bureau of Radiation Protection

Attachment: NRC Information Notice 2019-07