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

August 22, 2024

BRP INFORMATION NOTICE 2024-01 RECENT MEDICAL EVENTS INVOLVING ADMINISTRATION OF THERAPEUTIC RADIOPHARMACEUTICALS

ADDRESSEES

All Pennsylvania Department of Environmental Protection (DEP) Specific Licensees that are authorized for medical use under Title 10 of the Code of Federal Regulations (10 CFR) 35.300, “Unsealed Byproduct Material—Written Directive Required.”

PURPOSE

The DEP is issuing this Information Notice (IN) based on the August 9, 2024 NRC IN 2024-04 (Attached). The purpose of the notice is to inform licensees of recent reported medical events that involved the administration of therapeutic radiopharmaceuticals. The DEP expects that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar medical events.

DISSCUSSION

This IN is intended to provide licensees with awareness of recent medical events involving therapeutic radiopharmaceuticals. In accordance with 10 CFR 35.41, “Procedures for administrations requiring a written directive,” licensees are required to develop, implement, and maintain written procedures to provide confidence that each administration is in accordance with the written directive for any therapeutic administration. When licensees are considering adding new treatment protocols, they should update their procedures to ensure that the new therapeutic radiopharmaceuticals can be administered in accordance with the written directive. Licensees are encouraged to consider the medical events noted here to help aid in developing new procedures. These medical events show the importance of validating the written directive information immediately before administration. It is also especially important to verify that the correct radiopharmaceutical is being administered to the patient.

Licensees should consider which staff members may be involved in the procedures to ensure they have the necessary training. Mock runs, before treating the first patient, may minimize the risk of medical events associated with inadequate setup. To prevent incidents involving a failure to adhere to administration protocols, licensees could consider providing training for all staff involved in these procedures. In addition, the nuclear medicine staff should confirm protocols are being followed before the administration of the radiopharmaceutical. Licensees are encouraged to communicate with their peers in the industry or with manufacturers to identify additional best practices to minimize the potential for medical events, especially when they begin using a new radiopharmaceutical, equipment, or protocol.

CONTACT

If you have any questions about the information within this notice, please contact the Radiation Control Division at 717-787-3720.

Issued By:
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