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

November 16, 2018

BRP INFORMATION NOTICE 2018-05

MEDICAL USE OF BYPRODUCT MATERIAL — MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS

ADDRESSEES

All Pennsylvania Department of Environmental Protection (DEP) Specific Medical Licensees.

PURPOSE

The DEP is issuing this Information Notice (IN) to bring to the attention of PA Medical licensees, the recent amendments to federal regulations DEP incorporates by reference. The final regulations were published in the Federal Register, and cover Medical Events Definitions, Training and Experience, and other Clarifying Amendments to 10 CFR Parts 30, 32, and 35. They take effect on January 14, 2019. See: https://www.federalregister.gov/documents/2018/07/16/2018-14852/medical-use-of-byproduct-material-medical-event-definitions-training-and-experience-and-clarifying

DISCUSSION

The NRC has revised parts 30, 32, and 35 of title 10 of the Code of Federal Regulations (10 CFR). These regulations were last amended in their entirety in 2002. This new ruling was completed to address technological advances and changes in medical procedures and to enhance patient safety. Summaries of the amendments are as follows:

- **Reporting and notification requirements for a medical event (ME) for permanent implant brachytherapy**

  Establishes separate requirements for identifying and reporting MEs involving permanent implant brachytherapy. These new regulations require reporting of an event in which there is actual or potential harm to a patient resulting from an ME. The licensees are required to develop, implement, and maintain procedures for determining if an ME has occurred, including procedures for verifying certain aspects of a permanent implant brachytherapy treatment within 60 days from the date the treatment was performed.

- **Training and Experience (T&E) requirements to remove from multiple sections the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State**

Training and experience requirements are amended in multiple sections to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC has determined that certification by these specialty boards, coupled with meeting the recentness of training requirements, is sufficient to demonstrate that an individual seeking authorization on a license has met the T&E requirements and has the requisite current knowledge. Therefore, additional attestation by a preceptor is unnecessary. Individuals who are not board certified will still need to obtain a written attestation; however, the language of the attestation is modified. Additionally, residency program directors will be allowed to provide these written attestations.

- **Exempting certain board-certified individuals from certain T&E requirements (i.e., "grandfather" these individuals)**

  The rule addresses the issues raised in a petition for rulemaking (PRM–35–20) that was submitted to the NRC in 2006. The petition requested that experienced board-certified Radiation Safety Officers (RSOs) and medical physicists not named on a license who had practiced certain modalities prior to October 24, 2005, be exempt from the specific T&E requirements in §§ 35.50 and 35.51, respectively. In effect, they will be "grandfathered" for these training requirements for the modalities that they practiced as of October 24, 2005. This petition is discussed in detail in Section II., Petition for Rulemaking, PRM–35–20, of this Federal Register.

- **Requirements for measuring molybdenum contamination & new requirements for the reporting of failed technetium and rubidium generators**

  The requirements for measuring the molybdenum-99 (Mo-99) concentration for elutions of Mo-99/Technetium-99m (Tc-99m) generators are changed and requirements are added for reporting and notification of a generator eluate exceeding permissible Mo-99, strontium-82 (Sr-82), or strontium-85 (Sr-85) concentrations. The current requirement to measure the Mo-99 concentrations after the first eluate is changed to require that the Mo-99 concentration be measured in each eluate. This requirement is changed in response to several breakthrough incidents reported to the NRC.

- **Naming Associate Radiation Safety Officers (ARSOs) on a medical license.**

  Licensees will be allowed to appoint a qualified individual with expertise in certain uses of byproduct material to be named on a license to serve as an ARSO. This will make it easier for an individual to become an RSO on other medical licenses and will increase the number of individuals who are available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs.

CONTACT

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

Issued By:
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