

**Summary of Major Agreement State Comments**  
**and Staff Response**

*Medical Event Definition for Permanent Implant Brachytherapy*

**Issue** - Four states and the Organization of Agreement States (OAS) commented on the statement in the discussion section of the medical event (ME) criteria that the revised definitions for MEs are designed to identify situations where harm or potential harm to the patient may occur. One state asserted that virtually any medical action results in potential harm to a patient and that basing a rule on such non-specific criteria was not inspectable and was not advisable. The OAS and these states recommended removing this statement from the discussion to ensure that the regulations address identified risks, not potential risks. The OAS noted that having the regulations identify situations for potential harm represents a significant departure from the current definition for MEs and will eliminate the opportunity for the licensees to identify precursor events and make process improvements.

Response - No changes were made in response to these comments. There is a long-standing U.S. Nuclear Regulatory Commission (NRC) position that an ME may be indicative of “potential problems in a medical facility’s use of radioactive materials” and “does not necessarily result in harm to the patient.” That position continues to be reflected in this proposed rule. In redefining the ME criteria for permanent implant brachytherapy, reflecting the Advisory Committee on the Medical Uses of Isotopes recommendations, the proposed ME criteria are now consistent with the criteria for other treatment modalities by reflecting circumstances in which there may be harm or potential harm to a patient being treated. The proposed criteria were reviewed and determined to be specific and not subjective.

**Issue** - One state disagreed with eliminating the dose-based option for identifying MEs to the treatment site for permanent implant brachytherapy. Since 2010, this state’s brachytherapy licensees have developed quantitative dose-based criteria for identifying MEs in prostate brachytherapy, including overdoses and under doses to the prostate and overdoses to normal surrounding tissue. Developing such dose-based criteria has not led to an increase in medical events reported, the state commented. Another state commented that it did not support a dose-based methodology for establishing ME’s for permanent implants.

Response - No changes were made in response to these comments. One of the principal objectives of the proposed changes to the written directive (WD) and ME reporting criteria for permanent implant brachytherapy is to eliminate the dose-based criteria for the treatment site, changing it to a source-strength criteria, to move away from a metric (delivered dose compared to prescribed dose) over which the authorized user (AU) has limited control.

**Issue** – One state supported the use of the “maximally exposed 5 contiguous cubic centimeters” as a reasonable volume of tissue over which to conduct a dose volume evaluation with regard to determining whether an ME occurred related to assessment of dose to normal tissue, whereas one state recommended removing the prescriptive volume requirements and allowing licensees to identify a reasonable volume in the written directive.

Response - For uniformity of ME reporting among licensees, uniform criteria for excess dose to normal tissues should be established. The size of the minimum volume to be considered for

maximum dose determinations is an item/issue about which stakeholder input is specifically being sought by including it as a specific question in the *Federal Register* notice for the proposed rule.

**Issue** – With regard to the proposed WD requirements for permanent implant brachytherapy in § 35.41, the OAS and one state recommended moving the new requirement that would require a licensee to make certain assessments related to the permanent implant brachytherapy implantation within 60 days after the procedure from § 35.41 into a new section. They felt that so doing would bring more attention to this requirement. One state suggested that the 60-day dose assessment should apply to all brachytherapy, including lung implants.

Response - No changes have been made to the rule text in response to these comments. Section 35.41(b) includes the minimum required items that must be addressed in the licensee's written procedures. Paragraph (b)(6) is a subset of this; it is one of the items that must be in the licensee's procedures. Also, paragraph (b)(6) is similar to paragraphs (b)(2) and (b)(5), in that it addresses post-implant items. For these reasons, the staff determined that the procedural requirement in paragraph (b)(6) should remain as part of section 35.41.

#### *Compatibility Category for Training and Experience Requirements*

**Issue** - Two states and the OAS commented that all training and experience in Part 35 should be designated as an Agreement State compatibility category "C" or lower. They argued that each individual state already licenses medical doctors through their own process and the individual states should be able to identify issues to be addressed by their process.

Response - No change was made based on these comments. The NRC, in 2002 and 2005 Part 35 rulemakings, determined that all training and experience requirements for use of byproduct material have compatibility "B" designation because these requirements have significant direct transboundary implications. Additionally, changing the compatibility for all training and experience requirements in Part 35 is outside the scope of this rulemaking.

#### *Compatibility Category for Medical Event Reporting*

**Issue** - One state strongly supported the compatibility C category for ME requirements in § 35.3045. Another state believed that for consistency in reporting and to ensure a common basis for trend analysis, the reporting requirement in § 35.3045 should be a compatibility category B.

Response - Currently, the ME reporting is designated as compatibility category C. The issue is discussed in the draft FRN and a specific question on this issue is included.

#### *Naming Associate Radiation Safety Officer on a license*

**Issue** – The OAS and four states expressed concern regarding the proposal to allow an Associate Radiation Safety Officer (ARSO) to provide supervised training and to serve as a

preceptor for an individual seeking to be named as an Radiation Safety Officer (RSO). One state was concerned that the RSO designee (i.e., the ARSO) would still be allowed to operate without further license amendments, since there are many consultants who fulfill certain RSO duties.

Response - No changes have been made on the new ARSO designation in response to state comments. An ARSO can provide an attestation for an individual to be a RSO or ARSO for only similar types of use of byproduct material for which the attesting ARSO is authorized on a license. Because § 35.50 requires an ARSO to have the same radiation safety training and experience for the RSO-assigned duties and tasks as the RSO, he or she is qualified to be a preceptor for an individual seeking to serve as an RSO or ARSO for similar types of use of byproduct material. The naming of an ARSO is optional for a licensee. But the individual who is not listed on a license would not be recognized as an ARSO for regulatory purposes. Nothing in the current regulation or the proposed rule prohibits the naming of a consultant as an RSO on a medical license.

#### *Use of Sealed Sources and Devices for Medical Uses Not Listed in the Sealed Source and Device Registry*

**Issue** - The OAS and four states expressed concerns with regard to the proposal to allow an AU the flexibility to use sealed sources and devices for medical uses not specifically listed in the Sealed Source and Device Registry (SSDR). One state recommended that the NRC should approve each new use for a particular device and, if approved, issue a notice or add it to the Medical toolkit informing all the states that a new use has been approved for a certain source/device. One state wanted clarification on the approval process for off-label uses of brachytherapy sources.

Response - The discussion in the proposed rule on this issue has been revised to be more clear and include additional information to clarify that NRC recognizes that the treatment sites that included in the SSDR are not all inclusive and the proposed revision to the regulations would permit physicians to use manual brachytherapy sources to treat sites or diseases not listed in the SSDR. No approval will be required for uses under § 35.400(a) or § 35.600(a) when an AU wants to use the sources and devices for medical uses not listed in the SSDR as long as they are being used for manual brachytherapy uses (§ 35.400(a)), or HDR, teletherapy, or gamma stereotactic uses (§ 35.600(a)).

#### *Categories of Parenteral Administration of Radionuclides in which Work Experience is Required*

**Issue** - The OAS and 4 States commented on the proposed changes to the categories of parenteral administration of byproduct material for which work experience would be required and asked that more discussion be provided in the proposed rule.

Response - The discussion on this issue has been revised in the proposed rule in response to these comments.

### *Medical Use of Transmission Sources*

**Issue** - The OAS and four states commented on the use of transmission sources when they are used for patient diagnosis. One state asserted that calibration, transmission, and reference sources are not medical use sources.

Response - The NRC has determined that the use of transmission and references sources for diagnostic determinations on patients constitutes a medical use.

### *Effective Date for Final Rule*

**Issue** - The OAS and two States recommended that the effective date of the final rule be changed to 180 days from its publication in the *Federal Register* instead of the proposed 120 days. This would allow those Agreement States that incorporate these regulations by reference more time to ensure that their licensees are notified and their staffs are properly trained. This would also allow all Agreement States more time to prepare for amending their regulations in order to be compatible with this revision.

Response – The proposed effective date for the final rule was revised to be 180 days from the date of publication.