TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL: OTHER OPTIONS CONSIDERED

In its evaluation of the training and experience (T&E) requirements for radiopharmaceuticals, the U.S. Nuclear Regulatory Commission (NRC) staff considered maintaining the status quo and several rulemaking options. The options below are presented for completeness, but the staff does not recommend them for Commission consideration. Although they could address stakeholder concerns regarding T&E requirements, these options would counter the NRC's Principles of Good Regulation[1] by requiring significant additional licensing resources for the NRC, Agreement States, and in some cases, the licensees, and by adding unnecessary complexity to the T&E requirements.

"Emerging Radiopharmaceuticals," would involve conducting individual reviews of each emerging radiopharmaceutical to determine drug-specific tailored T&E and other requirements (e.g., physical presence) as necessary, similar to the current construct under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

Pros:

- This option would address the complexities of and operating experience with emerging radiopharmaceuticals.
- This option could create additional authorized user (AU) pathways for specific physicians and may address concerns about burdensome T&E.

Cons:

- This option would require extensive licensing and inspection resources.
- Individual reviews could delay access to emerging radiopharmaceuticals, and licensee resources would be required to train licensee staff on each unique guidance.
- This option could create regulatory uncertainty for manufacturers, licensees, and AUs.
- This option would not address concerns about T&E for existing radiopharmaceuticals.
- No stakeholders supported this option due to the required licensing resources and concerns about potentially lengthy reviews delaying mass-market availability of new radiopharmaceuticals.

"**Team-Based Requirements,"** would create an additional alternate pathway in which T&E requirements for AUs would be reduced based on pairing AUs with other individuals who have radiation safety T&E. These approaches could include pairing AUs with authorized nuclear pharmacists (ANPs) or an "authorized administrator," or requiring a "nuclear medicine team" for administration of therapeutic radiopharmaceuticals (minimally consisting of an AU, a nuclear medicine technologist, and a radiation safety officer).

[1] The NRC's Principles of Good Regulation are available at https://www.nrc.gov/about-nrc/values.html#principles.

Pros:

- This option would create additional AU pathways and might address concerns about T&E.

- The presence of more trained professionals could provide an additional measure of radiation safety while permitting flexibility in the T&E requirements for AUs.

Cons:

- Pairing AUs with ANPs may be impractical or infeasible because of legal, clinical, financial, and other professional issues outside the purview of the NRC.

- This option would be very complex to inspect and license.

- A team-based option could create gaps in responsibility for certain radiation safety aspects.

- Team-based options have minimal stakeholder support. Specifically, stakeholders oppose pairing AUs with ANPs because the T&E for ANPs does not address patient care or fully cover the radiation safety aspects of administration.

"Licensee Credentialing," would require licensees to develop their own procedures to determine whether their physicians are adequately trained to safely use radiopharmaceuticals. The NRC would review and approve these procedures based on high-level requirements, and the procedures would be enforceable as license conditions.

Pros:

- This option could address stakeholder concerns about T&E through increased involvement by the medical community in setting T&E requirements.

- This option would better align with the Medical Policy Statement[2] than the existing T&E regulatory framework: the less prescriptive nature of this option and increased medical community involvement in setting T&E requirements and credentialing AUs would encroach less on the practice of medicine and better consider industry and professional standards.

- While still reviewing and approving licensee developed procedures, the NRC and Agreement States would require fewer licensing resources because they would no longer review and approve T&E for individual AUs.

- This option is agile and transformative in that it offers the flexibility needed to accommodate emerging and future radiopharmaceuticals; licensees could revise their T&E requirements as new radiopharmaceuticals are developed.

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[2] "Medical Use of Byproduct Material; Policy Statement, Revision" (65 FR 47654; August 3, 2000).

Cons:

- The medical community could view this option as an abdication of the NRC's regulatory responsibilities.
- This option could create disparities in AU radiation safety competency across the National Materials Program.
- Licensees may object to expending additional resources needed to develop their own policies, procedures, and training programs.
- This option would initially require additional licensing resources from the NRC and Agreement States to review and approve licensee policies and procedures.
- No stakeholders supported this option, citing concerns about safety, practical implementation, and discrepancies in AU credentialing across the National Materials Program.