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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0162
Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

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Submitter Information

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Organization: State of Wisconsin
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Government Agency: Wisconsin Department of Health Services

General Comment

See attached file(s)

Attachments

STC-19-023 Wisconsin Comments

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July 3, 2019

Sarah Lopas
U.S. Nuclear Regulatory Commission
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards

RE: U.S. NUCLEAR REGULATORY COMMISSION FEDERAL REGISTER NOTICE AND PUBLIC MEETINGS REGARDING DRAFT APPROACHES FOR TRAINING AND EXPERIENCE REQUIREMENTS FOR RADIOPHARMACEUTICALS (STC-19-023)(Docket ID NRC-2018-0230)

Dear Ms. Lopas,

The State of Wisconsin, Radioactive Materials Program has reviewed the above document and submits the comments below. Opening the discussion with the four proposed approaches is appreciated and further discourse is absolutely necessary before rule making is initiated.

While not specifically requested, Wisconsin submits that the ideal approach for T&E requirements for radiopharmaceuticals would:

1. Be simple and functionally adaptable to future medical uses without additional rule making actions.
2. Establish competencies that are evidentially connected to the mission of radiation safety.
3. Shift in focus from the physician authorized user to an authorized administrator (who may or may not be a physician).

Although the scope of this Federal Register notice was limited to 35.390 radiopharmaceuticals, Wisconsin supports conforming changes to other medical modalities.

Wisconsin notes that, in most cases, physicians have a similar level of involvement in use of x-ray devices as they do in the use of radioactive material. However, training requirements for physicians using or prescribing x-rays are not overseen on a federal level (or, in most cases, even on a state level). Wisconsin is not aware of any disparities in outcome (anecdotal or otherwise) for patients receiving x-rays, as compared to patients receiving radioactive material, due to the lack of federal regulation concerning physician training requirements for x-ray devices.

The T&E requirements being considered are inherently entangled with the practiced of medicine. Wisconsin believes that a shift in focus of T&E requirements to individuals who handle radioactive material would provide justifiable relief to licensees and regulatory agencies

concerning physician authorized users, while strengthening our regulatory efforts to ensure public health and safety. Regardless of what action is taken, all efforts should be made to limit the undue intrusion into the practice of medicine.

Wisconsin's comments to the proposed approaches are in bold following the questions provided in the Federal Register. Every effort was made to address the questions provided but supplementary comments are included to prompt further discussion.

1. If the "Status Quo" is maintained, how should the NRC ready itself for the expected increase in number and complexity of future radiopharmaceuticals?

   Wisconsin does not support the continuation of the "Status Quo". However, if maintained, significant efforts should be made to provide transparency in the categorization of new therapeutic drugs (35.1000 versus 35.390 etc.). A framework should be developed to decide how drugs are categorized in order to maintain consistency, which is currently lacking. Wisconsin supports the current broad categorizations for diagnostic radiopharmaceuticals since they do not present the same hazards as therapeutic drugs.

2. Is there a challenge with the current T&E requirements—such as concerns regarding patient access to radiopharmaceuticals—that should be addressed through a rulemaking?

   Wisconsin has not observed any specific instances where the current training and experience (T&E) requirements have limited patient access to radiopharmaceuticals. There are currently a variety of T&E pathways for licensees to pursue but there are challenges with the current structure. Board certifications, case studies, training hours, recentness of training, and preceptor attestations provide complexity for licensees and license reviewers. The current T&E requirements act as formalities during the licensing process but do not measure radiation safety competence of the individuals administering radioactive material. Emphasis should be placed on the T&E of the individuals actually handling and administering radioactive material to patients.

3. How should the complexity of the radiopharmaceutical administration protocol be considered in establishing the T&E requirements for the limited approaches described in Sections B.1 and B.2 below?

   Wisconsin does not support tailored T&E requirements or the concept of "limited authorized users (AU)". This seems like an extension of the existing fragmentation present within the "Status Quo" which will exacerbate the current regulatory/licensing burden. It is likely that advancements in treatment would outpace the ability to update standards for approval.

   The proposed limited approaches also suggest hours-based requirements which do not emphasize the quality of the T&E. This will not ensure radiation safety competency and presents ambiguity in the applicability of the T&E hours (Could

licensees reuse training hours for different categories?). Assigning hours for qualification should be avoided as it is inherently arbitrary as each individual retains and applies information/concepts at differing rates.

4. How should the NRC categorize radiopharmaceuticals with mixed emissions?

5. Under what conditions should a radiopharmaceutical be considered "patient ready" such that the T&E requirements could be tailored?

   The following statements apply to Questions 4 and 5:

   Wisconsin does not support a tailored T&E approach. However, if a Tailored T&E approach is pursued, categorization of radiopharmaceuticals and conditions when a radiopharmaceutical is considered "patient ready" should follow a risk-informed approach. Potential factors to consider would include the annual limit on intake, emission type(s), physical form, administrative technique, and dose preparation.

6. How could a competency-based evaluation ensure appropriate training and experience for AUs administering radiopharmaceuticals?

   Wisconsin supports the idea of a radiation safety competency-based evaluation to ensure appropriate T&E for AUs. Core competency areas should be established within the administrative rule for different modalities (diagnostic, therapeutic, sealed, unsealed etc.) An evaluation of radiation safety competency should be extended to individuals handling, administering, ordering, and receiving radioactive material and not remain limited to AUs. Guidance on testing and documenting competencies should also be developed for both initial evaluations and recurrent competency assessments.

7. How could physicians in small practices be credentialed (e.g., physicians not associated with hospitals or other large institutions and their credentialing boards)?

   This would be no different than under the current structure; one option would be to rely on medical institutions or board-certifying entities to include radiation safety competency-based evaluations as part of their certification process.

8. How should the AU's radiation safety responsibilities be clearly distinguished from other members of the team?

9. How should the radiation safety responsibilities be divided between the AU and ANP?

   The following statements apply to Questions 8 and 9:

   Wisconsin does not support a Team-Based approach to T&E as proposed. This approach adds additional layers of complexity and is difficult to inspect and license practically. The competency of a team is difficult to evaluate, internal processes may

vary between licensees, and defining a complete team is difficult. For example would referring physicians be part of the Team?

However, Wisconsin does support the concept of an authorized administrator (AA). AAs could be nuclear medicine technologists or physicians and should be the individuals who actually administer licensed material to patients.

AAs could be set up so that board certified individuals are automatically granted AA status and wouldn't need to be listed on the license. This approach would be similar to how industrial radiographers are certified but not listed on the license. For example, industrial radiography licensees are required to provide specific training on new source/device combinations to radiographers, prior to first use. This concept could be extended to medical licensees, and licensees could commit to provide training on certain topic areas to individuals involved in handling new 35.390 radiopharmaceuticals, prior to first use.

Wisconsin also urges NRC to re-evaluate supervision in 35.27, to de-emphasize the role of physicians. The language within the administrative rule pertaining to supervision under an AU should be changed to reference an AA (35.27).

10. What are the advantages and disadvantages of the draft approaches?

    Movement toward a competency-based approach presents an advantage in simplifying the licensing process and maintaining consistency with performance-based inspections. Placing more emphasis on individuals handling, administering, shipping, and receiving licensed materials, versus physicians ordering doses, more accurately addresses the hazards associated with medical procedures. Disadvantages of some of the approaches would include additional complexity from separating more T&E pathways.

11. Are there significant costs of benefits associated with any of the approaches?

    Easily identifiable costs would include the time required for the establishment of the new regulatory framework in the short term. The benefits gained from new approaches could significantly reduce the burden on license reviewers in the future.

12. Would any of the draft approaches impact patient access to radiopharmaceuticals or address stakeholder concerns of overly burdensome (regulatory) requirements?

    Depending on the draft approach used, patient access to radiopharmaceuticals could be increased or decreased. In this context, patient access to radiopharmaceuticals has an inverse relationship with the complexity of regulatory requirements.

13. For the draft approaches that consider tailored hours of T&E, what are the appropriate numbers of hours and what radiation safety topics should comprise the limited T&E?

See Wisconsin's response to Question 3.

14. Should the NRC consider inclusion of a formal radiation safety competency assessment and periodic reassessments for any of the draft approaches above? If so, who should establish and administer these assessments?

    Wisconsin supports the inclusion of formal radiation safety competency assessments and periodic reassessments for the draft approaches above. Professional medical organizations and board-certifying entities could tailor their programs to meet new competency-based requirements.

15. How would the draft approaches impact the medical organizations that use the NRC's T&E requirements as a basis for establishing their training programs?

    These organizations would need to adapt their programs to address any changes introduced in the regulations.

16. Are there concerns regarding implementation and/or viability for any of the approaches discussed above?

    Wisconsin's concerns about implementation and/or viability of the draft approaches have been addressed in the comments to previous questions.

17. Are there any unintended consequences of the draft approaches?

    There is risk for unintended consequences with any rule revision but Wisconsin is confident that they can be addressed if identified early in the rule making process.

18. Which of the draft approaches best positions the NRC to effectively regulate future radiopharmaceuticals?

    A competency-based approach will be the most effective to regulate future radiopharmaceuticals.

    Wisconsin would also support eliminating AU training requirements altogether for unsealed radioactive material requiring a written directive. Licensing agencies could instead authorize facilities or specific licenses (not individual authorized users) on a drug-by-drug basis. This would ensure that policies and procedures address specific radiation hazards such as major/minor spill designations, contamination control, waste management, and patient release before receiving material that presents a new hazard. To date, Ra-223 Xofigo® is the only "new" radiopharmaceutical therapy routinely used at non-broadscope licensees in the last 10 years; therefore, Wisconsin does not believe this would present a significant licensing burden. The additional licensing requirements would be offset by the reduced inspection burden of licensees that don't address these issues prior to using new therapeutic drugs.

19. Should the NRC continue to play a role in the review and approval of AUs?

    Yes, to the extent that a physician is involved in radiation safety. However, substantive changes to the current process would provide benefits to both licensees and regulatory agencies.

Sincerely,

David Reindl
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Radioactive Materials Program
State of Wisconsin