PUBLIC SUBMISSION

As of: 1/30/19 12:49 PM
Received: January 29, 2019
Status: Pending_Post
Tracking No. 1k3-97yn-yfx4
Comments Due: January 29, 2019
Submission Type: Web

Docket: NRC-2018-0230
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0001
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Document: NRC-2018-0230-DRAFT-0127
Comment on FR Doc # 2018-23521

Submitter Information

Name: David Reindl
Submitter's Representative: David Reindl
Organization: State of Wisconsin
Government Agency Type: State
Government Agency: Department of Health Services

General Comment

See attached file(s)

Attachments

STC-18-065 Wisconsin Comments

Tony Evers
Governor

Andrea Palm
Secretary

DIVISION OF PUBLIC HEALTH

1 WEST WILSON STREET
PO BOX 2659
MADISON WI 53701-2659

State of Wisconsin
Department of Health Services

Telephone: 608-267-4797
Fax: 608-267-3695
TTY: 711 or 800-947-3529

January 29, 2019

Daniel S. Collins
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 TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS (STC-18-065)

Dear Mr. Collins,

The State of Wisconsin, Radioactive Materials Program has reviewed the above document and submits the following comments; Wisconsin's comments are in bold following the questions provided in the Federal Register notice:

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.
Yes, from Wisconsin's perspective, most authorized user candidates have the appropriate training and experience to be added to a license via the existing alternate pathway.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.
Yes, Wisconsin has seen no evidence to the contrary. Medical events are an infrequent occurrence and the few that do occur have minimal impact on patient outcomes. Additionally, these medical events present negligible public health and safety risk.

3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged.
Wisconsin's position is that new T&E pathways can be considered and pharmaceuticals should be grouped into categories as described in the Federal Register notice. Wisconsin supports categorization based on radiation characteristics.
If new pathways are to be considered, the pharmaceuticals should be grouped into categories and there should not be pathways for
[Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (*e.g.,* radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]

4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
Yes, an alternate pathway for an authorized user should not be lower standard of entry.

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
a. Describe what the requirements should include:
i. Classroom and laboratory training—What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [*Note:* The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
Wisconsin provides no comments on this question.

ii. Work experience—What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
Wisconsin provides no comments on this question.

iii. Competency—How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
Wisconsin provides no comments on this question.

b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
Yes, preceptor attestations should be required for the fundamental T&E. Wisconsin maintains that the preceptor attestation solidifies the legitimacy and autonomy of the prospective authorized user via the preceptor's qualifications and reputation.

c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.
No, Wisconsin's perspective is that radiopharmaceutical manufacturers are unlikely to be in a position to adequately attest to all of the qualifications of an authorized user. Additionally, radiopharmaceutical manufacturers have a financial incentive to approve authorized users.

d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
Wisconsin provides no comments on this question.

e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?
Wisconsin's position is that it is not necessary to periodically assess the competency of authorized users. However, a standardized competency assessment may be useful in satisfying recentness of training requirements.

B. NRC's Recognition of Medical Specialty Boards
The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit website (*https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html*). The

NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
Wisconsin provides no comments on this question.

2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?
Yes, based on the current radiation safety outcomes and risk, the NRC's medical specialty board recognition criteria are sufficient and may be more restrictive than necessary. The NRC could consider a non-binary recognition of medical specialty boards. If a medical specialty board does not satisfy all of the T&E requirements for a specific category of authorized user, the board could be evaluated for the T&E requirements that it does satisfy.

C. Patient Access
The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.
1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
Wisconsin has not seen evidence of a shortage of authorized users for medical uses under 10 CFR 35.300.

2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
Wisconsin provides no comments on this question.

3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
Wisconsin has not received this feedback from licensees nor observed it independently.

4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.
Wisconsin provides no comments on this question.

D. Other Suggested Changes to the T&E Regulations
In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?
Wisconsin provides no comments on this question.

2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?
Wisconsin provides no comments on this question.

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?
Wisconsin provides no comments on this question.

Sincerely,

David Reindl
Nuclear Engineer
Radioactive Materials Program
State of Wisconsin