PUBLIC SUBMISSION

As of: 1/30/19 12:55 PM
Received: January 29, 2019
Status: Pending_Post
Tracking No. 1k3-97yo-2s7f
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-0128
Comment on FR Doc # 2018-23521

Submitter Information

Name: Jennifer Opila
Submitter's Representative: Jennifer Opila
Organization: Organization of Agreement States
Government Agency Type: State

General Comment

See attached file(s)

Attachments

STC-18-065 OAS comments (1)

January 29, 2019

May Ma
Office of Administration
Mail Stop: TWFN-7-A60M
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Docket ID NRC-2018-0230

Dear Ms. Ma:
The Organization of Agreement States (OAS) Executive Board (Board) reviewed the Federal Register Notice (FRN) of October 29, 2018 regarding Training and Experience Requirements for Different Categories of Radiopharmaceuticals and offers the following in response to some of the questions asked in the FRN.

A. *Tailored Training & Experience (T&E) Requirements*

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.

Most Agreement States find the current pathways for obtaining AU status reasonable and accessible.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.

The Board believes that the current pathways for obtaining AU status are adequate for protecting public health and safety. However, the Board believes that the NRC should conduct a comprehensive analysis of the root causes of medical misadministrations to answer this question.

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.

The Board did not find a consensus on this question from the Agreement States. Some individuals believe that there should be tailored T&E requirements for certain

radiopharmaceuticals. For example, who would be more qualified to inject an arthritic joint, a nuclear oncologist or an orthopedist? Some individuals believe that 700 hours with 200 hours of didactic training (or certified by a medical specialty board) should be maintained to obtain AU status. The Board believes that from a regulator's standpoint, tailored T&E requirements may need too many rule revisions as more and more radiopharmaceuticals are developed. Agreement state staff may be faced with making decisions based on insufficient information for new drugs and uses.

C. *Patient Access*

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.

The Board believes that there is not a shortage in the number of AUs but finds anecdotal evidence that some practices are delaying administration of certain radiopharmaceuticals until physicians can achieve AU status, even though there are nearby facilities that could administer the radiopharmaceuticals.

2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.

The Board understands that NRC staff is conducting a poll of Agreement States to ascertain if some Agreement States are experiencing any shortages of AUs.

D. Other Suggested Changes to the T&E Regulations

1. Should the NRC regulate the T&E of physicians for medical uses?

This is a very important question that should be fully analyzed, evaluated, and vetted. The Board is not opposed to changing the paradigm of regulating medical uses of radioactive materials. There is an assumption that supervised individuals are actually instructed to perform various tasks by the authorized user. In many instances (perhaps the vast majority) these instructions do not actually occur. This is because the supervised individuals are rarely employed by the same entity as the authorized user, and rarely is there a direct working relationship between the supervised individual and the authorized user. And while there are regulatory requirements that authorized users supervise allied medical professionals, such as technologist and therapist, there are no known instances where a licensee has been cited for the failure of an authorized user to provide the supervision required by the regulations. In addition, "supervision" is not defined in the regulations.

2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

It is highly unlikely that the required 700 hours of T&E are devoted entirely to radiation safety related topics. This question deserves considerable evaluation because the 700 hours of T&E is typically received in a medical specialty residency program where physicians obtain the

necessary training to become a radiation oncologist, a nuclear medicine physician, a radiologist, or other specialist that provides medical services involving radioactive materials. It is likely that many of the 700 hours involve clinical training as opposed to radiation safety training.

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?

The more general requirements in or based on 10 CFR Part 20 are adequate for the radiation protection of workers and the general public. Where things become more challenging is with the requirements for patient safety. The line between patient safety and the NRC's stated desire to not interfere in the practice of medicine has always been blurred and difficult to pinpoint. Keep in mind that 10 CFR 35.41 requires, in part, that each administration is in accordance with the written directive. Licensees are expected to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The NRC should consider limiting the regulations to this requirement alone. It is reasonable to argue that the regulatory responsibility for who actually prescribes (written directive) a drug or a procedure, and their training and experience lies with the State medical licensing boards. The NRC should consider limiting its role to only ensuring that once a prescription is written, the licensee has a strong program in place that ensures that the prescription is carried out.

Many highly skilled and experienced license reviewers who work for the NRC or Agreement States wonder why the regulations continue to contain requirements for T&E for physicians. Many of these highly skilled staff members would suggest, if given the opportunity, that these requirements be eliminated along with the practice of naming authorized users on the license. (See response to D.1a. and b., above)

Depending on the results of the evaluation in Section D, it is entirely possible that the other questions posed in this FRN will be rendered moot. We appreciate the chance to comment on this subject and stand ready to answer any questions you may have.

Sincerely,

Jennifer T. Opila

Jennifer T. Opila, MPA
OAS Chair
Division Director
Hazardous Materials and Waste Management Division
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, CO 80246-1530