Organization of Agreement States

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July 3, 2019

Office of Administration
Mail Stop TWFN-7-A60 M
US Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Program Management, Announcements, and Editing Staff

Docket ID: NRC-2018-0230

To Whom It May Concern:

The Organization of Agreement States (OAS) Executive Board (Board) reviewed the Federal Register Notice (FRN) of May 2, 2019 (84 FRN 18874) and offers the following comments related to the approaches being considered and the questions asked in the FRN.

To summarize the Board's position, we believe the time is right to question the status quo and affirm the role of the National Materials Program to focus on the radiation safety of workers and the general public. The Board believes that by removing the time-consuming responsibilities of verifying training and experience, developing training and experience requirements for new radiopharmaceuticals, and licensing Authorized Users (AUs) it would allow regulators to devote more time to radiation protection practices for both current and future pharmaceuticals. The Board believes that our regulatory authority is established to protect public health and safety and we recognize that this authority is in tension with our need to stay out of the practice of medicine. The existing regulatory structure with its very specific training requirements for physician authorized users, many of whom do not actually handle radioactive material, is at odds with a risk-informed, performance-based approach to radioactive materials regulation.

III. Draft Approaches for Comment
A. Status Quo

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

The Board believes there is adequate and robust regulatory framework to support future radiopharmaceuticals through current practices at 10 CFR 35.1000. The National Materials Program will continue to review new drugs for specialized handling criteria and other radiation safety concerns so that additional guidance can be generated if necessary.

Question 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?

There does not appear to the Board, or Agreement States, that there are concerns regarding patient access to radiopharmaceuticals. The Board notes that the NRC did not present any evidence of patient access concerns other than by the pharmaceutical company that would likely profit from these tailored approaches. Without documented patient access concerns, the Board believes that Section B is moot.

B. Tailored Training and Experience Requirements

Question 3: - Question 5:

The Board does not believe that tailored approaches are necessary or desirable. The Board believes that by tailoring T&E requirements to classes of radiopharmaceuticals, the licensing and inspection will be too burdensome and confusing. As it is now, numerous correspondences are necessary to establish the correct credentials to list an Authorized User (AU) on a license. Facilities with many modalities will have so many different means of acquiring T&E that the regulator will likely spend a considerable amount of time sorting it all out and crafting a license. The Board believes that the National Materials Program should be striving for less complicated and more robust licensing documents, not the reverse. Adding this complication is unnecessary and counter-productive.

C. Performance-Based

The Board notes that the NRC has not concluded that medical events have been caused by deficient AU training. Regulator experience with medical licensees confirms that the vast majority of the operations related to those required in the training and experience in 10 CFR 35.390 are routinely and, for some, exclusively performed by the nuclear medicine technologists, the medical physicists, or the radiation safety officers involved in the procedure. It has been mentioned, by members of the regulatory community, that authorized user training is important for the selection of a procedure to best adhere to the ALARA standard regarding patient radiation safety when considering medical procedures or their alternatives. While this may be a reasonable concern that relates to who is authorized to prepare the written directive, there is nothing inherent in the training and experience requirements beyond the basic requirement to be a physician that relates to this particular issue.

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

The Board believes that competency-based evaluations in radiation safety topics and radiation related job duties in the form of an examination has merit. The examination should be required at a specified interval determined by the NRC in cooperation with the medical specialty boards to provide assurance that individuals who rarely administer radiopharmaceuticals remain

competent in these important topics. The Board would also like to note that no state would want to develop and administer their own examinations. We believe it should be done on a national level.

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

Regarding the credentialing of AUs, the Board agrees that the National Materials Program should get out of the business of credentialing, however, we believe that it should be performed by existing medical specialty boards, not left to the licensee to develop and use their own policies and procedures to make self-determinations of the appropriate training and experience. The NRC should establish and update a national database of any medical specialty board so that credentials and expiration dates can be easily accessed for any individual. In addition, the Board believes that the NRC should perform audits of these medical specialty boards periodically. One state reported that the specialty board accepted the training of a physician who was to perform Tc-99m administrations without the required training in generator procedures. The Board believes that if the national medical specialty boards did the credentialing, small practices would not be at a disadvantage.

D. Team-Based

The Board does not support the Team-Based approach with its arbitrary number of hours of training and requirements to have multiple individuals present during treatment. An authorized Administrator would seem to be the equivalent of a licensed nuclear medicine technologist for which many states already have regulations. There is little justification provided for this Team-Based approach.

IV. Additional Questions for Consideration

Question 10: What are the advantages and disadvantages of the draft approaches?
The advantages of the getting out of the credentialing business and licensing AUs would mean less hours spent on licensing and verifying credentials and more time devoted to radiation protection of existing and future radiopharmaceuticals. The disadvantage of the draft approaches is that the licensing agencies could be overwhelmed with processing a number of amendments involving new subcategories of authorization. This could lead to multiple requests for additional authorizations as the AUs seek to increase their number and type of authorizations over time as they incorporate the uses of new or additional radiopharmaceuticals.

Question 11: Are there significant costs or benefits associated with any of the approaches?
See response to #10. The costs for the regulator in the short-term would be higher for rulemaking, but in the long-term the costs would go down because of less time spent on licensing.

Question 14: Should the NRC consider inclusion of a formal radiation safety competency assessment and periodic reassessments for any of the draft approaches above? Yes.

If so, who should establish and administer these assessments? NRC with the assistance of states in the form of a working group to establish the competency assessment. The administration should be through the NRC. This could be through national computer-based examination facilities.

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

Question 17: Are there any unintended consequences of the draft approaches? As mentioned in the response to Question 10, there could be a significant increase in amendments for licensing agencies and with many agencies working on a limited staff this is a real concern.

Question 18: Which of the draft approaches best positions the NRC to effectively regulate future radiopharmaceuticals? Credentialing by medical specialty boards. NRC and Agreement states could concentrate on radiation protection of future pharmaceuticals.

Question 19: Should the NRC continue to play a role in the review and approval of AUs? Regarding 10 CFR 35.300 uses and 10 CFR 35.390 approvals, no, not beyond the requirements to be a physician certified by a medical specialty board in order to prepare a written directive. The Board believes that auditing medical specialty boards and examination development and administration would ensure that radiation protection practices are adhered to.

We appreciate the chance to comment on this subject and stand ready to answer any questions you may have.

Sincerely,

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FOR

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