PUBLIC SUBMISSION

As of: 7/2/19 9:16 AM
Received: July 01, 2019
Status: Pending_Post
Tracking No. 1k3-9asf-rwid
Comments Due: July 03, 2019
Submission Type: Web

Docket: NRC-2018-0230
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

Document: NRC-2018-0230-DRAFT-0192
Comment on FR Doc # 2019-10760

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General Comment

Please see the attached comment letter from the American Medical Association.

Attachments

2019-7-1_Comment Letter to NRC

AMA
AMERICAN MEDICAL ASSOCIATION

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July 1, 2019

The Honorable Kristine Svinicki
Chairman
U.S. Nuclear Regulatory Commission
Office of Administration
Mail Stop: TWFN-7-A60M
Washington, DC 20555-0001

ATTN: Program Management, Announcements and Editing Staff

Re: Docket ID NRC-2018-0230

Dear Chairman Svinicki:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments to the U.S. Nuclear Regulatory Commission (NRC) regarding the Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive (draft approaches). Specifically, the AMA is concerned that proposed changes to Section 10 of the Code of Federal Regulations (CFR) Part 35 would weaken the requirements for Authorized Users of Radiopharmaceuticals (AUs), including shortening the training and experience requirements and the use of additional alternative pathways for AUs and urge the NRC to maintain the status quo. The status quo presents no changes to the current training and experience (T&E) requirements for radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

The proposed changes would create a tailored "limited-scope AU" pathway for uses under 10 CFR Part 35, featuring less comprehensive training and experience requirements for clinicians. While the NRC has emphasized that the proposed changes would not allow non-physicians to become AUs, we are deeply concerned that under the proposal non-expert providers and inexperienced staff handling unsealed therapeutic radiopharmaceuticals, when there are already appropriately trained experts to provide these therapies, would introduce high levels of risk and significantly decrease public trust in NRC's ability to adequately oversee these materials. We oppose these proposed changes and urge the NRC to avoid any further weakening of the T&E requirements for AUs by expanding the use of non-physicians.

We believe that current pathways for obtaining AU status under 10 CFR 35 are reasonable and accessible. We have no evidence that there is a shortage of AUs and have found no data to support a potential shortage. As a result, there is no need to develop new T&E pathways. We believe that to ensure patient safety and quality the NRC should maintain the status quo. However, the NRC has indicated that the draft approaches were, in part, designed to inform the use of new therapies by urologists, medical oncologists, and other physicians who may not meet the current T&E requirements to become an AU. As the NRC evaluates any future changes to T&E requirements, we urge the NRC to seek input from medical specialties and stakeholders on how to effectively incorporate knowledge topics in the current alternative pathways in residency programs so that the training residents receive could be recognized within a

specialty board. This would ensure the status quo with regards to current T&E requirements are maintained while looking ahead to the expected increase in number and complexity of future radiopharmaceuticals.

We thank you for the opportunity to provide input on the Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD