Organization of Agreement States

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December 21, 2021

Sarah Lopas
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Ms. Lopas,

The OAS Executive Board (Board) appreciates the opportunity to comment on the Nuclear Regulatory Commission's (NRC) Draft Commission Paper: "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events" (RCPD-21-012).

The Board agrees with the NRC that Option 1 "No Action" is no longer a sufficient option for reporting extravasations. The status quo would continue to exclude extravasations resulting in patient harm as medical events. The Board lends its support to Option 3 of the Rulemaking Plan as we feel that this option would capture radiation-safety significant extravasations, would improve patient safety, allow for tracking and trending of events, prevent undue burden to licensees, and allow for information sharing.

Of the comment letters received by the Board, each of the three options of the Rulemaking Plan were supported. Comments are listed below. The Board has also summarized some common themes from the comment letters we received, and from the Government-to-Government meeting held on November 4, 2021, in order to bring focused attention to these topics.

Our membership has expressed that there is a lack of data that makes it difficult to formulate an opinion on the best approach for reporting extravasations. The lack of data also makes it difficult to predict the financial impact to Agreement State programs and licensees. There are questions about the appropriateness of 10 CFR 35.2 and 35.3045 as the reporting mechanism. And lastly, there is doubt about how requiring reporting will affect change in the occurrence of extravasations, how it will affect the prevention of extravasations, and how states will handle compliance response. The Board looks forward to discussing these issues further as this rulemaking proceeds.

<u>Option 1 "No Action":</u>

- Colorado: "Of the three options presented in the petition of rulemaking, option 1 (no action) would be the option recommended by the state of Colorado. Colorado agrees with the NRC that extravasations are not medical events in that they are not delivering radioactive materials via the wrong route of administration.

  No persuasive information is available to provide support to suggest that increased reporting would lead to an increase in patient safety. Reporting extravasations would likely result in an added administrative burden for licensees and regulators with no tangible benefits."

Option 2, "50-rem dose threshold":

- Colorado: "Option 2 is not feasible based on the cost versus the benefit as well as the low potential benefit to reporting at the 50 rem to tissue threshold."

- Oklahoma: "We concur with the NRC and do not offer support for the petitioned rulemaking to report at the 50-rem dose threshold."

- North Carolina: "North Carolina strongly supports Option 2 as this most closely resembles their current interpretation and application of the medical event rules. It will also provide a rule outcome more effective at overall change and improving patient safety."

Option 3 "Extravasation events that require medical attention for a suspected radiation injury":

- Colorado: "Option 3 is subjective in that potential injuries that are suspected to have been caused by an extravasation would be reportable. It will lead to inconsistent regulation across the national materials program and have minimal patient safety improvements."

- Oklahoma "We do recognize the benefit in gathering data to track and trend risk-significant events. This benefit is why we offer our support for the NRC's proposed Rulemaking Plan for radiation-safety significant extravasations that require medical attention for suspected radiation injury. We believe that the Rulemaking Plan is in alignment with the NRC's medical use policy statement "When justified by the risk to patients, regulate radiation safety of patients primarily to assure medical use is in accordance with the physician's directions."

- Tennessee: "We are in support of option three, reporting extravasation events that require medical attention for suspected radiation injury. We believe this option would capture radiation-safety significant extravasations and would improve patient safety while avoiding undue burden to licensees. We believe that option two would create significant licensee and regulatory burden with negligible additional benefit to patient safety. This would be financially unfeasible for many of Tennessee's small and/or rural licensees."

Additional Comments:

- Colorado: "If, in fact, extravasations are as common as suggested, the NRC may be better served by funding or conducting a focused research study or project concentrating on radiopharmaceutical injections at a limited number of specific locations to identify the likelihood of extravasation events that cause harm; to evaluate the efficacy of training and injection techniques to reduce extravasations that may cause harm; to identify specific event attributes that contribute to the likelihood of patient harm such as patient condition, anatomy, prescribed dose, etc.; and to better establish that this is a significant patient safety issue and that the resources required to implement a change in regulation would be expended in line with the priorities of the national materials program at a time when resources are limited and there are a number of other significant patient and radiation safety concerns that require resources at this time."

- New Jersey: "The New Jersey Department of Environmental Protection (the Department) agrees that some level of studying of extravasations is appropriate. It is important to the Department that monitoring and reporting of these events serve to improve health and safety goals and not be implemented if no improvement can be verified.

  The Department believes that extravasations above this NRC-determined threshold should be studied. Before any regulatory action is taken, clear guidelines should be developed along with dosimetry calculations. It is believed that such calculations would be fraught with uncertainties and perhaps bounding calculations would be more appropriate."

  Regulatory reporting requirements should have the goal of improving health and safety by determining the root cause and implementing a permanent correction. What are the root causes of extravasations? Will reporting provide the information necessary to prevent or minimize the extravasations? What are the consequences for the medical facility? Will there be enforcement if extravasations continue to occur at a certain level? If the answer to these questions is no, then what is the purpose of reporting?

  We note that the petition for rulemaking comes from a manufacturer of a device that does not prevent extravasations but will detect when they occur. Would monitoring improve the dose outcome to the patient so that the injection could be stopped before more of the radioactive material is deposited into an unintended location in the body? How soon after the radioactive material is injected would the licensee be aware an extravasation event is occurring?"

Once again, the Board appreciates this opportunity to comment. We are available should you have any questions or need clarifications to our responses.

Sincerely,

Augustinus Ong, Chair
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