From: Sine Thieme
To: RulemakingComments Resource
Cc: Irene Wu
Subject: [External_Sender] Public comment: Docket ID NRC–2022–0218
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To Whom it May Concern:

I am writing to provide feedback regarding the proposed extravasation reporting rulemaking.

A note upfront: while I am a medical provider senior executive, I have zero conflict of interest in this matter. I am not in the nuclear medicine profession. I will not see more patients or make more money if I do or do not have to ensure that radiopharmaceuticals are administered properly every time. Nor do I have any financial interests in companies who might benefit from ensuring that radiopharmaceuticals are administered properly every time. I am not an employee or investor in any company that manufactures or sells radiopharmaceuticals, imaging systems, geiger counters, ion chambers, or nuclear medicine probes.

But based on my profession, my team and I always focus on the patient. With that perspective, I have several observations for the NRC to consider.

The proposed rulemaking does not seem consistent with any other medical event reporting at the NRC. Therefore, I don't think it is appropriate to answer many of the proposed questions.

In posted comments, patients have clearly expressed that they are not the appropriate individuals to determine if a nuclear medicine provider has possibly mishandled radioactive material during an administration of a radiopharmaceutical. I agree with them. In fact, I am quite shocked to see the proposed rulemaking and questions.

In my role for our providers, I personally handle patient complaints. I am not sure the NRC understands just how difficult it is for a patient to even consider suggesting to their provider that they may have experienced a less than satisfactory experience. These patients understand that they will likely continue to seek care from the same provider. And in the case of extravasations of radioactive isotopes, it is my understanding from thoroughly studying this matter that the vast majority of patients would be unaware that they had been extravasated, much less associate any discomfort that may manifest sometime in the future with an unknown administration issue. To anyone outside of the nuclear medicine community, the idea of patients being responsible for any role in the reporting of these potential handling issues seems absurd.

In the same group of posted comments, I see others suggesting extravasations are not an issue that happens frequently enough to warrant concern. And if they do happen, they are not meaningful from a radiation protection standpoint. One commenter even suggested that they are all clearly identifiable today. In previous public comments and on some recent public conference calls, many clinicians claimed that they were administering these radiopharmaceuticals using best practices. After having studied this issue for almost two years now, I am extremely comfortable making the following comments. These individuals are intentionally misleading the NRC or they are not well trained in this field. If extravasations are not happening, can't result in large doses of radiation in patients that suggests a problem handling radiation, and are identifiable, what is the community concerned about? The act of monitoring the injection of radiation into a patient for an important procedure? How is that not being done today for every single radiation administration? Are these clinicians hesitant to invest the time and money to ensure the nuclear medicine community reaches a proficiency level in vascular access that is necessary to almost eliminate the issue of extravasation entirely. The presentation in Public comment 28 needs to be reviewed by everyone in nuclear medicine.

The NRC is aware that extravasations can happen, can result in high radiation doses, and that providers have ways that cost NO ADDITIONAL MONEY or very minimal amounts of money and time to identify extravasations as they happen. So, why would the NRC want to wait for patients to be injured? THAT MAKES NO SENSE. Isn't the point of regulations to protect patients? What am I missing? If it is simply that providers don't want to take the extra step, then that is unacceptable.

I have one final important point to make. A recent paper by Bahl et al. was published on July 3, 2023 in the International Journal of Nursing and Health Care Research. www.doi.org/10.29011/2688-9501.101436.

This paper clearly shows that there are clinical and economic consequences to extravasations. More importantly, the paper highlights that they are not infrequent (and likely underreported) and can be reduced. Additionally, the paper shows there is a great need for vascular access tools/training, effective monitoring technology, and that mitigating the effects of an extravasation is critical to patient care.

Isn't the NRC interested in minimizing unnecessary radiation exposure to patients? This is simple. Existing tools are clinically proven to be able to identify an extravasation early in the administration of a radiopharmaceutical. Why is the NRC not instructing every center that administers radiation to patients to use these tools and to mitigate exposures when extravasations are detected? Why wait for future injury? I am at a loss. Patients are too. In my view, the NRC needs to first and foremost protect patients.

This paper also clearly shows the factors that affect the absorbed dose to the patient tissue, and highlights the need for standardized dosimetry reporting using the initial amount of paravenous radioactivity, the mass of infiltrated tissue (which clearly should include a standard volume and total affected volume) the type of radiopharmaceutical, and the residence time (which is patient specific).

In summary, now that the NRC has ruled that their old reporting exemption is no longer appropriate, they need to ensure that radiopharmaceuticals are effectively monitored. And if a patient is extravasated, then these extravasations should be assessed using standardized dosimetry, mitigated, and reported if they exceed the existing dose-based threshold. This approach removes the patient from the reporting process and puts the burden of responsibility on those most capable of handing it, the nuclear medicine clinicians!

Respectfully,

Eva M. Thieme