From:	Matt Dennis
To:	Irene Wu
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From: Pam Kohl <pamkohl52@gmail.com>
Sent: Tuesday, August 15, 2023 5:09 PM
To: Rulemaking.Comments@nrc.gov
Cc: Matt Dennis <MDennis@dc-crd.com>; Irene.wu@nrc.gov
Subject: Docket ID NRC-2022-0218

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I am submitting this comment and a link to a peer-reviewed paper that I authored and that was published in the journal, Frontiers in Nuclear Medicine a few months ago. My paper is on the patient perspective regarding the need for transparency around radiopharmaceutical extravasations. I am including a link to the paper along with a written comment.

https://www.frontiersin.org/articles/10.3389/fnume.2023.1127692/full

For this public comment I would like to address eight points from this paper.

First Point - I am a fan of nuclear medicine. I am not bashing the nuclear medicine community. But it has become evident to me that the community needs regulation to improve. I know how important nuclear medicine is in determining my staging and assessing the effectiveness of my treatment. As a patient, when I am told by my oncologist that I need a nuclear medicine scan, I get one. Without them, I would not be here today. But let me clear. Cancer patients, cardiology patients, neurology patients, all patients who are told by their doctor they need to get a nuclear medicine scan will get one if it matters to their life like it matters to mine. But we expect these procedures and need these procedures to be done with the highest level of quality. Extravasations negatively affect the images that guide our care. They must be done right.

Many past comments and even some comments you may have or will receive from the nuclear medicine community dismiss the significance of a radiopharmaceutical extravasation - their frequency and their impact. **Point 2 - Extravasations are not insignificant to patients.** I know because I am a patient and I have been extravasated.

I have now received at least 46 radiopharmaceutical administrations during my treatment. I know what they feel like. When I was extravasated, I knew something felt different. Now, if this had been my first injection, I am not sure I would have said anything. But based on my prior experiences, I sensed something was wrong. And my technologist did not believe she had extravasated me. I demanded an image of my injection site and sure enough, I was extravasated. With approximately

20 mCi of technetium. **Point 3 - nuclear medicine clinicians do not always know when they extravasate patients. Patients will also not always know. It is important for the radiation protection of patients to somehow monitor that the administration was performed ideally.** Let me be clear: I have no financial connection to any company. I am a patient. I don't care how a center monitors my injection, but I want it monitored. And so should the NRC!!!! Look, there are some technologists that are fantastic at delivering these radioactive drugs. Some are not. That is a radiation protection issue. And patients and the NRC need to know that.

Point 4 - if a radiopharmaceutical administration is not ideal and results in a large radiation dose in the patient tissue, patients have a right to know and a need to know. Patients want to know how much radiation was left in their tissue and what is the impact to their procedure. Many doctors, including ones at local NC hospitals have publicly stated or suggested that patients should not be told when extravasated with a large amount of radiation. This is ridiculous. It is our body. Our lives. If we are extravasated, we MUST be told.

Point 5. If a patient has been extravasated they would expect the center to do what is necessary to try and minimize the radiation dose. They DO NOT expect the center to ignore it and hope the patient doesn't put 2 + 2 together and come back later and report pain at the injection site.

My damage was done to my underlying tissue. It hurt. A lot. It still hurts and this August will mark 2 years since my extravasation. How is a physician going to examine my arm and tell me whether or not that was caused by radiation? Why in the world would they report that? If a patient is not told they have been extravasated, they will not associate the pain with radiation. Why would they? **Point 6 - patients do not want to be responsible for reporting and certainly don't want the criteria to be subjective.** Centers should measure the activity and report radiation doses that exceed a threshold that the NRC has already determined constitutes a medical event. If that threshold is appropriate for other accidental exposures, why is it not appropriate for extravasations? Because the nuclear medicine community says so???

This position of keeping patients in the dark is consistent with the transcripts I have read from the NRC ACMUI meetings held back in 2008 and 2009 where Dr. Nag specifically said that he wanted to retain the extravasation reporting exemption so he would not have to tell patients and their doctors when the patient got really large doses to their tissue. And he didn't want to be bothered with all the "blah blah blah" of reporting. The NRC has been aware from these 2008 and 2009 meetings with ACMUI that extravasations were not virtually impossible to avoid and that patients were getting high doses from diagnostic radiopharmaceuticals. **Point 7 - NRC needs to stop doing what the industry says and do what they should be doing. Protecting patients.** The ACMUI is completely conflicted; they are members of the community that is being regulated. The NRC is asking the community they regulate if they want to report extravasations. Why does the NRC listen to this group on a topic like this? It makes no sense from the patient's perspective. This group is lobbying you to keep this issue hidden.

Final point. Point 8 - the NRC decision to use patient injury as the reporting criterion goes against every radiation protection standard you have espoused for the past 20 plus years. I have seen the document that the Commissioners relied on to make their decision. That document is full of the

wrong information. And unfortunately, it reinforces my belief that the regulated industry is running the NRC. It runs counter to current reports of spills on patients being reported. In your own database there is a case of lutetium leaking on a patient that led to a reportable dose. Then Fox Chase Cancer center extravasated a patient with almost 200 mCi of lutetium but that is not reportable. This inconsistency cannot be defended. This is bad for patients. Your current objective dose-based threshold works for all other events but not extravasations?? Why is that? And not only is your proposed patient criterion a bad decision for its inconsistency with all other reportable events, this patient injury decision exacerbates healthcare inequities. I have been involved with breast cancer as an advocate for over a decade. I know a lot about the disease and the treatments. I have been especially focused in recent years on the inequities in patients of color. How is it possible that the NRC would make an already bad situation--the reporting exemption for all extravasations even worse by now suggesting that patients are responsible for reporting. This decision really affects patients of color because it puts the burden on them to go back to the center that extravasated them and complain? How tone deaf is the NRC? I was on the call with Chairman Hanson last November. He heard directly from African American patients that they are more reluctant to complain. Yet, he and his fellow commissioners are recommending that NRC replace an objective reporting criterion used for all other medical events with a subjective reporting criterion – one that increases the burden on patients!! An especially heavy burden on many patients of color, who would have to proactively complain and schedule and pay for a visit to ensure that a medical event is reported to you. REALLY? And, as I suspected all along, it is more difficult for technologists to find veins in patients with darker skin. In the US, nuclear medicine technologists rarely use vein finding equipment to help them select veins for vascular access. A study from India found that vein finding equipment was very helpful in reducing extravasations in patients with darker skin. So, here we are in the year 2023 and it is probable that darker skinned patients are being extravasated more frequently and the NRC is recommending that these patients should report the issue to the center that extravasated them and specifically to the physician who is an authorized user. Absolutely tone deaf to the inequity issue.

Thank you for allowing me the opportunity to make a public comment.

Pam Kohl
Patient Advocate
Founder, Komen Metastatic Breast Cancer Collaborative Research Initiative
p: (919) 606-1704
pamkohl52@gmail.com

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