

# PUBLIC SUBMISSION

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**Docket:** NRC-2022-0218  
Reporting Nuclear Medicine Injection Extravasations as Medical Events

**Comment On:** NRC-2022-0218-0004  
Reporting Nuclear Medicine Injection Extravasations as Medical Events

**Document:** NRC-2022-0218-DRAFT-0025  
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## General Comment

See attached file(s)

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## Attachments

Drew Garner Response to Richard Harvey Comments

As I was in the process of submitting my comment to the NRC, I noticed that Mr. Richard Harvey submitted a written comment. Mr. Harvey was on the call on May 24<sup>th</sup>, so I was very interested in what he had to say. I also understand he is a member of the ACMUI. I will copy Mr. Harvey when I submit my comment in the hopes that he will publicly respond with another submission.

Mr. Harvey believes that extravasations are an important QA issue that needs to be addressed at the organizational level where the licensee administers the radiopharmaceutical.

I have questions for Mr. Harvey.

1. What specifically has been done in your center to address extravasations? How exactly does your team “detect any extravasations? How do they mitigate the effects? How do they provide patients who have been extravasated with excellent support? Do they provide the patient with a list of all the possible symptoms they may experience and the time period in which these symptoms can happen? I had a Tc99 administration. If that extravasated, I would not expect to see symptoms on my skin. So, exactly what are your technologist communicating to extravasated patients. And how do your technologist determine how severe the extravasation is? Do they perform dosimetry? Do you? What kind of doses do they see? What volume do they use as the area of concern. Is it so large that the resulting dose will be very low? Or do they use a reasonable volume of tissue? How do you or the nuclear medicine clinician determine which extravasations require reimaging? A quantitative approach or is it very subjective. I have several more questions to ask but would love to see your answers to these first. Pam Kohl, a patient I saw on an extravasation webinar sent questions to the NRC that every center should answer. You should get those questions. Ask these questions of your center and tell me how they responded.
2. As a patient, I wonder something else. You say all the right things, and still based on my questions above, I bet that hardly any of these questions can be answered right now. I bet that your team does not even have a protocol on what to do in case of an extravasation. I bet the technologists would all do something different. Not because they are bad people, but because no one has addressed extravasations in nuclear medicine centers. I can only find one hospital that seems to take this seriously. They are based in Virginia. I bring this up, because, Mr. Harvey, you say all the right things, but have you read other comments from the original petition and even the other ones submitted for this rulemaking. Have you heard yourself and your fellow ACMUI members? Nobody in the community really wants to report. You all think there is nothing or concern. It is disingenuous of you to suggest that this issue will get better if left to individual providers. I don't believe it for one second!

You also state that radiopharmaceutical administrations should be divided into two categories: diagnostic and therapeutic. I listened to a webinar with Dr. Darrell Fisher on this topic. I think he would disagree with you. He would tell you that it does not matter if it is therapy or diagnostic. He would tell you what matters is the amount of energy being deposited in a certain volume, and that diagnostics and therapeutics, depending on the extravasated activity can both lead to very high absorbed tissue dose.

You also state that you have never seen or even heard of a diagnostic extravasation causing injury. Tell me how hard you have looked. Did you talk to Pam Kohl? She had almost all of her MDP administration dumped in her tissue. It hurts her. But it does not show on her skin. She is approaching two years after the extravasation. She says it still hurts. I have also listened to the co-inventor of the PET/CT scanner and several nuclear medicine physicians who clearly understand how an extravasation can compromise or

even invalidate a diagnostic image. I also know how an extravasation in my nuclear cardiology administration could affect my diagnosis. So, let me ask you, Mr. Harvey, just because you haven't seen injury in your extensive career, should I be any less concerned about being extravasated? I can assure you that you are right when you mention the "misconceptions" of patient harm not being accurate; you and your peers are the ones with misconceptions.

Your lack of concern about patient injury or harm is extremely discouraging in another way. In fact, I can't adequately express how disappointed I am that a Radiation Safety Officer who sits on the ACMUI doesn't understand that medical event reporting is NOT dependent on patient injury. The whole purpose of medical event reporting is to identify centers that may have a **potential** problem in handling radiation properly. If these errors are caused by lack of tools, training, protocols, or by a human error AND they cause a high accidental dose to patient tissue, skin or organs these events are supposed to be reported to the patient and the NRC. If some centers don't extravasate and others do, isn't that the exact situation the NRC and a patient want to know about. If you don't want to report medical events then do what is necessary to ensure that no one on your team causes a medical event. Your lack of understanding of the medical event requirements that exist today shows that the NRC has not trained you. And your peers. And the community they regulate. But I am not surprised...because now the NRC is actually considering changing everything they have stated for the past 43 years about patient harm. All of you are failing patients.

You have made it clear that you "don't believe there is real value in considering extravasations as a medical event." I am quoting you. I am quoting a member of the ACMUI. I am quoting a Radiation Safety Officer. What I think you really care about is what you said: "the extra burden to licensees and the NRC is not justified and will not greatly benefit patients..." I think what you care about is spending some time and money to ensure that administrations are done properly. If we could go back to almost any patient safety issue in the hospital setting, I would bet that the same arguments were made over and over again. Frankly, all you and your peers on ACMUI seem concerned about is your profitability. Your schedule being affected. I have close friends who worked their entire careers in the medical device and pharma world. They would have been excoriated if a member of their team made such a comment about the quality of their products.

You also mention the importance of these administrations being done by professionals in nuclear medicine. You said, "nuclear medicine professionals are the most highly skilled individuals for administration of unsealed sources of radioactive material in medicine." Really? If they are so highly skilled, why are they routinely using straight sticks in administering radiation to a patient. Why do they routinely go to areas of flexion in a patient's arm? Why do they use needle gauges that are not appropriate for adults? You, are misinformed. These individuals may be trained in how to handle radiation, but I don't think you or the nuclear medicine community has any idea about the best way to physically ensure that patients are not extravasated. In my comment I just submitted, I mention my father-in-law. He just had his last chemotherapy administration. I spoke to the nurses who are responsible for administering chemo in the same patient population that get nuclear medicine scans. Many use ports now, but they still do far more IV administrations than any nuclear medicine technologist. That's all they do. And when I mention straight stick. 24 gauge needles. They laugh. They say, let me guess..."nuclear med techs?" I suggest you and others in SNMMI find out what are the best practices for administering radiopharmaceuticals and compare them to what happens when a guy like me gets an administration of Tc99. And let me be clear, I am not suggesting chemo nurses administer

radiopharmaceuticals, but I am suggesting it makes sense for technologists to get the same intense training that chemo nurses get. And that these technologists have to demonstrate they still have the skill year after year.

I will end this comment the same way I ended my other comment. I will copy my members of Congress on this letter as well. I want them to see what is going on in nuclear medicine, what is going on at the NRC, and what is going on with the ACMUI. I think it needs close attention. Patients deserve it.

Sincerely,

Drew Garner