

# PUBLIC SUBMISSION

<b>As of:</b> 6/23/23, 10:26 AM
<b>Received:</b> June 03, 2023
<b>Status:</b> Pending Post
<b>Tracking No.</b> lig-c4id-wmf6
<b>Comments Due:</b> July 18, 2023
<b>Submission Type:</b> Web

**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-0024  
Comment on FR Doc # 2023-08238

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## Submitter Information

**Name:** Drew Garner  
**Address:**  
St Petersburg, FL, 33704  
**Email:** drewuga79@gail.com  
**Phone:** 678-592-5774

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## General Comment

I am a nuclear medicine patient and have attached a file commenting on rulemaking regarding extravasations.

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## Attachments

Drew Garner Comments on NRC rulemaking regarding Extravasations - Final 6\_3\_2023

I am a nuclear medicine patient. I had a radiopharmaceutical administration as part of a cardiology procedure a couple of years ago and was very disappointed in the casual approach and lack of interest displayed by my technologist while administering radiation into my body.

After that experience, I began researching this process and it was right around that same time the NRC was soliciting comments about extravasations in public meetings.

I have prepared several points that I would like to make. In preparing these comments, please know I have read the petition approval, the commissioner's comments, the staff requirements document, and the staff document that the commissioners used to make their decision.

I am an accountant, not a physicist or clinician. But I still know that accidentally depositing radiation into my tissue, rather than my vein is not good. It is not good for my procedure, and it is not good for the tissue that is within a few millimeters of where the isotope has been deposited. As an accountant, I am analytical; I like numbers and from what I have learned an extravasation of a few millicuries of F-18 or 15-20 millicuries of Tech 99 will literally result in trillions...yes, trillions of decays happening within the tissue right next to the isotope. Adding up these decays can result in a high absorbed tissue dose. Sometimes several gray or even more. There is no doubt that the accidental deposit of large doses of radiation into patients' tissue needs to be reported.

I can also tell you that of my peers who also have had nuclear medicine scans, I am the most informed. Most, if not all, my peers had nuclear medicine scans because their oncologist or cardiologist told them they needed the scan. Most, if not all, of them did not know that they were injected with radiation.

So, that leads me to one specific point I want to make sure the NRC understands. A reporting criterion that puts any of the reporting responsibility on the patient is ludicrous. Absolutely ludicrous. Patients are not equipped to take on this responsibility. That is not our job. It is the job of the hospital or outpatient clinic we go to. They should use the latest and greatest technology to tell me that they injected the radiation properly. If they did not, they should immediately do whatever they can to minimize my exposure and they should tell me verbally and in my medical record how much radiation I was exposed to because of that accident. And they should tell my doctor.

So, to the members of the NRC that even proposed such an idea of having patients report when they are injured, I think you are doing what the ACMUI or the medical societies suggest. But it is not the NRC's job to assuage the concerns of the those they regulate. Your job is to provide me, as a patient, with reasonable assurance that I will be protected from accidental radiation exposures (I will refer you to your Mission Statement). Your actions do not meet this mission goal. In fact, they ensure that I will not be protected. They ensure that all of the patients who receive large doses of radiation moving forward are NOT protected, nor is their exposure immediately mitigated.

The next main point I want to make is that the staff document that the commissioners used to make their decision was so embarrassingly wrong that there should be administrative proceedings taken against the authors. I am an accountant, and I can see that. The Commissioners should be embarrassed by this product. I am familiar with the information correction request process. I have read the information correction request from last year that the Patients for Safer Nuclear Medicine submitted.

I have also read the most recent correction request about this medical staff document. Again, you do not have to be a physicist or a doctor to know after reading just one of the nearly three dozen examples provided to the NRC that the Commissioners were misled into treating extravasations differently than all other medical events. And if they reached this decision on their own, then I am even more worried.

My final comments are about the very disturbing perspective that is often shared by the nuclear medicine community, the advisory committee, and medical staff. These comments have shaped that document the staff provided the Commissioners, and these comments are wrong as I have previously pointed out. But because I can even tell they are wrong, that makes me reach one of two conclusions:

- First, the members of the medical staff just don't understand their jobs. That really scares me. But for a physician or technologist or physicist to say that there is nothing to be concerned about if I was extravasated with 10 millicuries of 18F or 20 millicuries of Tech 99 is irresponsible and scary.
- Another possibility is that these folks are deliberately trying to mislead the public and the NRC.

I have read some public statements by the ACR, AAPM, HPS, SNMMI. I have listened to the ACMUI Meetings. By the way, hopefully everyone knows that ACMUI members almost all come from the societies I just mentioned. These public comments can only be interpreted as deliberate falsehoods. And these groups continue to deny there is an issue.

At the last ACMUI meeting the RADIATION SAFETY OFFICER said **he did not believe an extravasation should be reported**. REALLY? So, if a technologist makes a mistake and dumps 25 millicuries of Tech 99 into a patient's tissue, that's not a medical event? That's not an issue that the NRC and the nuclear medicine community considers to be reportable? These issues are caused by lack of training and tools and they don't even have procedures telling technologists how to do an injection or how to take care of an extravasation. I've mentioned this before, when I was injected with Tc99, my technologist was more interested in telling his buddy about the date he had gone on the night before than he was in my injection or in me as a patient.

Another ACMUI member tried to tell the NRC about how there was a new study out that showed the extravasation rate was “really low” and no one has ever been hurt. I read that paper too. It used information from radiology reports. You simply cannot rely on that information. It did not look at images of the injection site. It did not use technology that exists to prospectively monitor for extravasations. These are not ignorant people; their eyes are wide open. I believe there is a concerted effort by the medical community to ignore, minimize or at worst hide these events. What are they afraid of.....being sued? Do they just not want to do the work to get better?

My 87 year-old father-in-law is being treated for tongue and throat cancer. He had a PET scan recently. We asked the tech to monitor the injection, so we know my father-in-law was not extravasated. The tech told us he had never, ever extravasated and if he had, he would know. That is just not a true statement. He is a great example of a nuclear medicine patient, with multiple complications including a pulmonary blood clot and infections, while navigating daily cancer treatments. He has chemo/radiation brain fog. He has been poked & probed countless times over many days and if he survives, you expect him to be able to identify that he has been harmed by an extravasation? No way! This is not some clinical trial setting where variables can be isolated to determine cause & effect. This is the real world and what many nuclear medicine patients face.

I appreciate the opportunity to let the NRC know what a patient thinks. I am also sharing this information with my members of Congress, and I am asking them to look into what is going on with the NRC and the societies they regulate. After this recent attempt to put the burden on patients like me and my 87 year-old father-in-law, I have lost all confidence in the NRC to protect nuclear medicine patients.

The NRC Commissioners can right this ship and fulfill their Mission Statement with humility & courage....humility to admit their current decision is wrong and courage to face the constituents they regulate.

Thank you.

Drew Garner