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Docket: NRC-2020-0141
Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2020-0141-0004
Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

Document: NRC-2020-0141-DRAFT-0367
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General Comment

See attached file(s)

Attachments

extravasation letter

I am writing to the NRC in regard to Docket ID NRC-2020-0141

While I see that your questions are primarily oriented towards licensees, I think it is important that you receive a patient's perspective. I am a patient who relies on accurate diagnostic nuclear medicine procedures to help guide my treatment. I am also a patient advocate.

On January 31, 2017, I was diagnosed with stage IV metastatic breast cancer, 7 years after being treated for stage 1 estrogen positive breast cancer. This stage IV cancer was NOT expected in that I had a very small tumor and had no lymph node involvement with my original diagnosis. Unfortunately, in December of 2016, I was diagnosed with what **was thought to be a local recurrence** of the original breast cancer. I believe patients should play a major role in their care and pushed to have a PET/CT scan just to be certain it was just a local recurrence. After finally receiving the PET/CT scan, two nodules in lymph nodes near my lungs were discovered, then biopsied, and I received the hard and scary Stage IV metastatic breast cancer diagnosis based on that PET/CT scan.

That PET/CT scan enabled me to be diagnosed at a very early stage of metastatic disease and I immediately began treatment to prolong my life. I am approaching four years past the diagnosis and have remained stable enough to stay on my first line of treatment, which is very good news. As someone who has undergone numerous nuclear medicine procedures in order to diagnose, treat and monitor my Stage IV metastatic breast cancer, I feel strongly that nuclear medicine centers should use best practices to ensure the proper administration of the radiopharmaceutical. As a result, I have been following this extravasation issue closely – last year I shared my thoughts with your team regarding the ACMUI recommendation to retain the extravasation exemption. I have also read the petition and am familiar with many of the references. Recently, the Society of Nuclear Medicine and Molecular Imaging, the Society of Nuclear Medicine and Molecular Imaging – Technology Section, the American Society of Nuclear Cardiology, and the American College of Nuclear Medicine posted a consensus position statement on the petition in question. It seems they have encouraged all their members to forward this position on to the NRC. And while I was dismayed to see some of their statements (extravasations are virtually impossible to avoid, extravasations are the result of passive patient intervention, etc.), it was sobering for me as a patient to see their acknowledgment that extravasations happen frequently and their confirmation of "the effect that extravasation of diagnostic radiopharmaceuticals may have on the quality of diagnostic images, particularly on quantitative studies". This statement leads to many questions. The societies have known about this for years - what have they done in the past? How do they monitor? How do they measure extravasations? Do they tell their patients? Many of these questions have been answered in the public comments I have read.

The public comments, many from nuclear medicine clinicians regarding extravasations, are even more dismaying. Some doctors think that the NRC would be "intruding into medical judgements" by requiring the reporting of significant extravasations. What possible medical judgement could be involved in unintentionally irradiating my tissue with a high dose of radiation that also compromises my images? Another doctor called extravasations a "practice of medicine issue" and "reporting significant extravasations would represent severe interference with medical practice." The only thing reporting would interfere with is bad medical practice. I believe, *to answer injection quality monitoring question 4*, reporting significant extravasations will lead centers that do not inject well to get better, like the many centers that do a good job today.

Many doctors mention that extravasations of diagnostic doses do not harm patients, yet their own community recognizes that a dose of 1.0 Sv is the threshold for adverse tissue reactions. How many of these doctors actually performed the needed dosimetry to estimate the dose to extravasated patients? None. Did they look at the petition? I did. Did they see case after case of diagnostic extravasations that

have led to very high tissue doses? I did. Are they aware that injury to tissue will come months or even years later? Based on their comments, I don't think they are. Unless these clinicians follow their patients for many years, I am not sure any of them can adequately *answer injection quality monitoring question 3*.

I have also read pages and pages of transcripts from the Advisory Committee on the Medical Uses of Isotopes meetings where members discussed their thoughts on extravasations. These NRC "advisers" admitted extravasations happen frequently. They admitted they can result in very high doses. They admitted that if they took more care, they could prevent them. Yet they told the NRC to retain the reporting exemption. Why? Because they don't want to worry about a patient who has been irradiated with a high dose of even up to 3-5 Sv. They don't want to tell the referring physician. And they certainly don't want to be bothered with the reporting. And these are physicians the NRC relies on for clinical advice. As a patient I am so disappointed. Here is an actual quote from these meetings:

> "DR. NAG: However, the first thing before us is, should NRC consider it as a medical event. Now if we consider this as a medical event, if we go through all the procedures and identify whatever-3 or 4 or 5-- the patient will have to be informed; the physician have to be informed, **blah blah blah**, and the – [sic] you have to go into all the reporting mechanisms. And therefore, I am thoroughly against this being reported as a medical event."

And this 2009 blah, blah, blah, viewpoint is alive and well in 2020. Another physician publicly commented that significant extravasations are "trivial", and he would not want to bother a patient with this information when they have more important things to worry about. Early in my metastatic battle, I had PET/CT scans every 12 weeks to monitor disease progression. Let me explain to nuclear medicine physicians how a patient views this situation. My entire treatment plan depended on the accuracy of the scans. It is not an overstatement to say that my LIFE depends on the accuracy of the scans. I am student of the extravasation issue. I know that the injection process is critical to the accuracy of my images. I am also aware that the injection process will depend on the effectiveness of my technologists at the moment of my injection. If any of my multiple injections had been compromised, it is concerning to me that radiologists and treating physicians may have unknowingly under-staged or over-staged my disease – or otherwise made a therapeutic planning error – as a result of an undetected injection issue. It is even more concerning that I would be unaware of this situation. If a patient is extravasated, it is the duty of the physician to use all their resources and do all they can to characterize that extravasation. If it is not significant, I need to know. That gives me peace of mind. If it is significant, my physician and I need to know. We need to understand the implication to my images, my care, and possibly my arm tissue. I need to know if I should repeat the imaging procedure. I know the NRC is committed to ensuring patients know the facts about their care. It is obvious that the ACMUI and many nuclear medicine clinicians are not committed to ensuring that patients know. That must change. The NRC should also revisit the role of the ACMUI. I hope each member of the NRC medical staff and each Commissioner reads these 2008 and 2009 transcripts line by line. I am certainly asking my members of Congress to read these transcripts.

To answer injection quality monitoring question 5, since extravasations negatively affect image quality and quantification, as described by the four nuclear medicine societies and by so many of the references I have read in the petition, and since extravasations also result in unintentional dose to the tissue, forcing the nuclear medicine community to address extravasations would most certainly improve patient's radiological health and safety and their overall health.

Before I was ready to submit these comments, I was unaware that the **NRC encourages licensees to use available technology to deliver the administration that the physician intended**. As I wrote last year, I think nuclear medicine providers and federal regulators should be doing everything in their power to improve the quality of these injections so that images reflect reality and treating physicians can plan treatment accordingly. **I have no conflict of interest with the petitioner**. But, since they are headquartered near my hometown, I am very familiar with the company. I am aware, through published papers and through meeting physicians who use their product, that it is technology that can help clinicians improve their technique. They have proven that extravasations are avoidable. The results were published by JNMT last year and were statistically significant ($p<.0001$). The NRC already knows these events are avoidable; they overheard their advisers discussing this years ago. And now, I have read that the product can help provide a much more accurate dosimetry calculation. I understand that the petition does not in any way require the use of the petitioner's technology. However, it would seem to me that technology that can help clinicians identify when an injection may not be going well and thus allow mitigation to happen immediately, that can help prevent them from happening in the future when used in a quality improvement process, and that can help clinicians identify whether or not the extravasation is serious or not is exactly what the community needs to fix this issue once and for all. The public comments that suggest correcting a regulatory mistake and fixing a problem that will improve patient images and safety is a conflict of interest seem to have it backwards. As a patient, I think the company should be rewarded. If any conflict of interest exists, it has been clearly shown by the comments of the ACMUI members and the clinicians not supporting the petition.

I strongly urge the NRC to immediately remove the extravasation reporting exemption. While I am not a fan of the petition suggesting a grace period (I want to know as soon as possible which centers are good at injections and which centers should be avoided), I agree that the grace period should only be restricted to regulatory reporting. Patients and our doctors must be told starting now. We should be given the choice to repeat the imaging procedure rather than have our doctors use a below average image to help determine our care.

As I mentioned earlier, I am not only a patient, but I am an advocate. I am submitting this comment to the NRC and I am sharing it with all other advocates I know. I am sending it to my members of Congress. I am sending it to the Radioactive Materials Branch in North Carolina. I am sending it to the presidents of the societies mentioned earlier. I welcome the opportunity to communicate directly with all of these groups, and especially the NRC medical staff and the Commissioners, if they are interested in hearing the perspective of a nuclear medicine patient on this matter. Reporting of significant extravasations have been ignored for over 40 years now. It is time to address it. If we do…in less than two years, there will be very little to discuss. I am confident that caregivers, once they start monitoring this issue, will improve rapidly. That's what patients want and I hope that is what the NRC wants, too.

Sincerely,

Pam Kohl
Raleigh, North Carolina