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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

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## General Comment

Please see attached file, "Comments submitted in respect to Petition for Rulemaking_22Nov2020.pdf".
Comment Docket ID: NRC-2020-0141

## Attachments

Comments submitted in respect to Petition for Rulemaking_22Nov2020

**Comments submitted in respect to Petition for Rulemaking (Docket No. PRM-35-22).**

Thank you for considering my comments related to the NRC's stance and policy on reporting certain nuclear medicine injection extravasations as medical events. I am in support of the petition, but unlike the many comments already submitted by medical professionals, I offer the perspective of patients and family caregivers. While the committee's questions regarding the petition are directed toward the medical community – the very group that would be subject to any new measurement – I implore you to consider the viewpoint of patients and their family caregivers when it comes to executing your purpose of developing a "system of radiation protection that reflects the world's improved understanding of the effects of radiation."[1]

In the past 11 years, I closely followed the diagnoses and treatments of cancer in two loved ones and began researching this matter in 2014. My father was diagnosed with prostate cancer in 2008 and died in 2015. A dear friend and business partner was diagnosed with breast cancer in 2016 and died in 2019 (after having been declared cancer-free just two months prior). In the course of these tragic events, my wife and I researched the diagnosis and treatment processes in the cancer journey. While each patient case is unique, and our personal sample size is small, we discovered the concerning issue of nuclear medicine injection extravasations in the diagnostic and treatment journey. I learned of the NRC's role in this process and I agree with the NRC's position as stated in Policy Statements published August 3, 2000: "the commission has an active role in assuring accurate delivery of byproduct material to patients."[2] Thus, my comments are based on the simple question, *how can you assure accurate delivery if you are not measuring the accuracy of the actual delivery (injection)?*

**Background**

As a management and technology consultant in the life sciences industry, my firm counts nuclear medicine developers and manufacturers among its clients. I am aware of the immense effort and regulatory overhead that goes into safely developing, manufacturing, and distributing radiopharmaceuticals. Our specific work in the industry centers around the design, implementation, and support of CGxP manufacturing, supply chain, and laboratory systems. The attention to detail, level of documentation, and required reporting in these validated environments is, at times, staggering; but understood and appreciated as necessary to ensure the health and well-being of the end patient. Therefore, I found it more than troubling that the final, and critical leg of a radioactive nuclear medicine's journey – the injection into a patient's arm – is NOT monitored. There is no rigorous control of this process compared to the entire supply chain that comes before the injection. It is **assumed** that the byproduct material was properly injected completely into the venous system. In contrast, I am not aware of any CGxP regulation, rule or best practice, that **assumes** a drug is handled properly. Left unmeasured, current practices are inconsistent, at best, at even capturing the injection site on the image. And when a suspicious image is captured, healthcare providers are not measuring the dose remaining in the arm. Whether out of apathy or fear of recourse (either of which is appalling when it comes to a patient's health), the administering clinicians do not routinely tell the physician or patient of the potential issues from the suspected extravasation.

If extravasations were truly an isolated and remarkably rare occurrence, I may not be as concerned. But when I learned of the frequency of nuclear medicine injection extravasations, and the potential harmful effects, my concern heightened. As noted in the petition, the NRC declares that patient exposure to more than 500 millisieverts is deemed a reportable event, yet recent studies show that extravasations

resulting in exposures greater than 10x this "risk-informed" limit are occurring.[3] Four nuclear medicine societies have published a statement acknowledging extravasations happen frequently and may negatively affect images and quantification.[4] The petition cites 22 cases identified in the short window of study. Yet, in reviewing public comments submitted thus far, there appears to be overwhelming resistance – dare I say, even a defensive posture – by medical providers to measuring and reporting the issue. These are the very same people who dedicate their lives to caring for patients and they show an attitude of "mind your own business" when portraying what patients should or should not know during their journey. With every attempt to curb my frustration with certain medical providers who referred to such exposures as 'trivial', I further researched the issue.

Please consider the following three main themes of my comments:

1. **Accurate nuclear medicine imaging determines treatment course of action.** I am first and foremost concerned with the potential inaccuracy of nuclear medicine imaging in the diagnostic process. The ultimate safety of patients relies on exposure limits **AND** the expected outcomes of the use of radioactive material. Nuclear medicine technologists undertake painstaking procedures to ensure a remarkably precise amount of radiotracer is injected into the patient so the resulting image is accurate. Even slight variations in the amount administered can skew the reliability of the image. Technologists even subtract the residual dose left in the syringe after flushing it with saline from the administered dose. In the cases of both my father and my friend, was each radiopharmaceutical properly administered in every one of their imaging procedures? In both cases, imaging diagnostics suggested their cancer was contained or eradicated, yet both were met with rapid spread and resulting death. I cannot say whether an extravasation contributed to the diagnoses and resulting treatment regimens…which is the point of my frustration – ***not knowing*** is the hardest part for a patient or loved one. As mentioned above, the SNMMI, SNMMI-TS, ASNC and ACNM *recognizes the effect that extravasation of diagnostic radiopharmaceuticals may have on the quality of diagnostic image*[5]. I appreciate their position that this is a quality-control issue and suggest extravasation reporting can immensely help in quality control. If we don't even report when an extravasation occurs, how do we know the ensuing diagnosis and treatment plan is based on sound data? And then to have the head of nuclear medicine from the very cancer hospital that treated my father submit a public comment to the NRC declaring extravasations that exceed medical event reporting limits as 'trivial' is infuriating. To suggest that a patient has too many other things to worry about and shouldn't be bothered with information that could affect the accuracy of diagnosis and/or relevancy of the treatment plan is reprehensible. In those doctor visits, my father, mother, sisters, and I were hungry for any morsel of information to assure us that the doctors thought of everything. Was something missed because the wrong amount of radiotracer's reached the active cancer sites for imaging? Would my father's or friend's treatment plans have been different? When methods of collecting this information exist, why wouldn't we strive for the same quality levels in drug delivery as in every prior step of the supply chain? Wouldn't any of you as NRC staff want to know if you or a loved one were being improperly injected with radioactive material?
2. **Extravasations are not JUST about quality control.** As described above, nuclear medicine technologists go to great lengths to monitor the handling of radioactive materials. Remarkably precise dosing measurements are taken throughout the process of transferring radioactive material from the source container to the syringe. Why?

- First, for the medical staff's own safety – technologists need to be assured that they personally are not exposed to dangerous amounts of radiation that could have spilled during the imaging process. That makes perfect sense – we should go to great lengths to protect the medical professionals that tirelessly work to care for us and our loved ones. Those great lengths include reporting to the NRC when even trace amounts of byproduct material are spilled in the facility or on the technologist's body.
- Second, technologists are *presumed* to be concerned about the accuracy of the image and are *presumed* to understand the physics of medical nuclear imaging. Life-saving medical decisions are to be made from the imaging results and delivering the exact expected amount of radiotracers is paramount to the reliability of the image. Trained technologists are presumed to understand that injecting the wrong amount of radiotracers could alter the image and thus the patient's course of treatment. So they carefully and precisely measure how much they prepare to inject into their subject.

Would it not stand to reason, then, that if all the above care is taken to avoid unnecessary (and unintentional) exposure AND deliver accurate imaging, that the same care would be taken when actually injecting the radioactive material into the body of the person you are trying to save? Is the absurdity of this lost on the medical community? How dare a leader in the medical profession consider the reporting of such a critical step in the diagnosis and care journey as "trivial".

3. **"You can't improve what you don't measure."** It is here that my operations and supply chain sensibilities take over. While, in 1980 – *some 40 years ago*, the NRC introduced the exception for reporting extravasations based on the 1980's-era-technology assumption that extravasations could not be improved[6], today's NRC is right to consider 2020-era technology and practices and at least expect the medical community to ***try*** and improve. Very well-intended members of the medical community have commented on this petition suggesting they do their very best every day and cannot possibly improve. To this, I respond with the old adage, "you can't improve what you don't measure." While I presume good intentions, the cavalier attitude in several comments portrays an unwillingness to even monitor the injection process. Some comments even suggest that these professionals entrusted by the NRC to safely administer byproduct material don't understand the physics of diagnostic radiopharmaceuticals. If they understood the impacts of various energies emitting from the radiotracer and their effects on human tissue, they would not dismiss the risk because they simply can't see tissue damage at the time of injection. These professionals should understand that negative impacts would not present for months or even years.

   If modern technology could allow swift, accurate and inexpensive measurement, why not report to find areas to improve? The petition and its supporting study provide evidence that we can improve – but first we have to measure and monitor the injection process. Imagine what we could improve upon if only we measured the frequency and extent of extravasations:

   - **Train medical staff** Identify practices and trends among the best-performing clinics and technologists; design training to mimic best practices (and avoid risky practices)

- **Assess and mitigate risk** Identify correlative patient traits that present risk of extravasation; help medical professionals identify when a patient may be at higher risk of extravasation (e.g., thinning vein walls) and adjust accordingly
- **Improve diagnostic accuracy and resulting treatment plan** Identify extravasations at moment of occurrence and alter or reschedule the ensuing imaging process; ensure proper treatment plan with reliable imaging output
- **Reduce cost**
  - ~ Avoid readministering expensive drug quantity
  - ~ Avoid the much higher costs associated with improper treatment resulting from compromised images
- **Enhance trust** Increase patient and caregiver trust through transparency and partnership in the diagnosis and treatment journey

Lastly, I'll leave you with one of my father's favorite pearls of wisdom: "Measure twice, cut once." Now that we can measure all steps of the nuclear medicine journey – including the most critical step at point of injection – we can improve life saving medical diagnoses and treatments by simply measuring and reporting nuclear medicine injection extravasations as medical events.

Thank you for considering a perspective from the patient and caregiver community.

Kyle Montgomery

References

[1] Nuclear Regulatory Commission website, 'How NRC Protects You'. https://www.nrc.gov/about-nrc/radiation/protects-you/protection-principles.html

[2] United States Nuclear Regulatory Commission Rules and Regulations, Title 10, Chapter 1, Code of Federal Regulations – Energy, 85CR 47654. August 30, 2000. p. PS-MU-5. https://www.nrc.gov/reading-rm/doc-collections/commission/policy/65fr47654.pdf

[3] Guide for Diagnostic Nuclear Medicine, Jeffrey A. Siegel, PhD, Society of Nuclear Medicine. 2002. https://www.nrc.gov/materials/miau/miau-reg-initiatives/guide_2002.pdf

[4] SNMMI, ACNM, ASNC joint statement. Signed Alan B. Packard, PhD; Tina M. Buehner, PhD; Yang Lu, MD, PhD; Sharmila Dorbala, MD. http://s3.amazonaws.com/rdcms-snmmi/files/production/public/SNMMI%20statement_final%20signed%20w%20letterhead%209-29-20.pdf

[5] ditto

[6] Federal Register, Vol. 45, No. 45 Rules and Regulations. May 14, 1980. P. 31701. https://tile.loc.gov/storage-services/service/ll/fedreg/fr045/fr045095/fr045095.pdf