



October 16, 2024

Chairman Hanson and Commissioners,

On behalf of [Patients for Safer Nuclear Medicine](#) (PSNM), a coalition comprised of more than 30 non-profit patient organizations representing patients across the U.S., I am writing to comment on the Nuclear Regulatory Commission's (NRC) [Draft Regulatory Guide DG-8062](#) for radiopharmaceutical extravasation reporting. This draft guide is deeply problematic but there is still time to do the right thing.

PSNM's primary objective since its formation in 2021 is to ensure the NRC requires medical reporting of large extravasations to both protect patients from harm and encourage systemic change that quickly reduces the number of extravasations.

Unfortunately, DG-8062 continues the pattern NRC has followed since PSNM first contacted the agency more than three years ago: half-hearted, deeply flawed attempts to placate the hundreds of thousands of patients we collectively represent. In essence, DG-8062 is an abdication of your role in regulating medical providers and protecting vulnerable patients.

The process of closing the 44-year old regulatory loophole that allows extravasations to remain unreported has been inexplicably lengthy, particularly since there is evidence that extravasations can not only result in very high doses to patients' tissue, but also cause a clear risk of patient harm. We reject DG-8062 and do not believe the NRC has thoroughly considered the ramifications of the current proposed policy.

First and foremost, the draft relies on the subjective opinion of the same doctors who have done everything in their power to prevent the reporting of extravasations in the first place. Rather than requiring your licensees use freely available software to provide a dosimetric measurement that can be compared to the same objective dose-based and risk-informed threshold used for all other medical event reporting, NRC proposes doctors themselves subjectively assess potential injury. How can that happen without using dosimetry?

A subjective criteria in the hands of a resistant medical community will undoubtedly lead to inconsistent reporting and underreporting. Physicians with the best intentions will report their extravasations. Those that don't want to report, won't report. Invariably some physicians will want to report but will feel pressure from their institutions to avoid reporting to prevent regulatory consequences and reputational damage. Centers that warrant attention for their inability to properly handle medical isotopes will continue to fly under the radar.

Based on how the medical community has rallied against reporting obvious extravasations that affect patients, it is likely you will get few, if any reports. Instead of continuing to cover up extravasations, NRC could use the same objective criterion used for all other medical events. That would force the medical community to address the root causes of extravasation.

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PSNM is also concerned about the lack of a requirement to retain documentation of extravasation assessments. A verifiable record is needed to establish that proper post-event procedures are followed. Without such oversight, unreported or mismanaged incidents may go unnoticed.

Additionally, PSNM is shocked that NRC is still considering harm or potential harm as criteria. The use of harm is problematic - an idea that your predecessors at NRC dismissed more than four decades ago for obvious reasons.

Despite the mountain of evidence to the contrary, many nuclear medicine providers believe that diagnostic extravasations don't cause harm. At the same time, they also admit diagnostic extravasations can negatively affect the resulting images. Is it acceptable to use the wrong image to guide or assess care? The obvious, resounding answer is no - and none of your other medical event reports require harm or potential.

Let's be clear: the proposed rule makes no sense whatsoever, but we will not abandon the fight for extravasation reporting based on the existing medical event criteria. Extravasations are not virtually impossible to avoid. That has been proven. Radiation spills *into* our tissue should be treated no differently than reporting a spill *onto* our skin.

While our efforts with NRC continue to be slow-walked with little regard for the patients who depend on accurate nuclear medicine procedures, PSNM strongly encourages Congress to pass the Nuclear Medicine Clarification Act (HR 6815). This bill would require NRC to treat large extravasations (irradiation above the existing dose-based limit) like any other medical event. The legislation encourages transparency and a proactive approach to safeguarding against extravasations, because unfortunately NRC has failed to get the job done on its own, for 44 years and counting.

The NRC has remained willfully blind to the problems caused by extravasation for far too long. At the same time, the outsized impact that medical societies and professional organizations have on NRC's decision-making continues to scare patients and has apparently played a large role in preventing NRC from doing the right thing for patients. While your own Office of the Inspector General (OIG) found earlier this year that taxpayer-paid NRC advisers were breaking federal ethics rules, NRC has still not effectively responded to five additional valid and supported allegations of improper behavior submitted to the OIG by members of PSNM over a year ago.

Your decisions have real-world consequences that can be felt for generations. We liken it to the history of peanut allergies, as recently recounted in a *New York Times* opinion piece illustrating how the flawed thinking of one powerful medical society - in this case, the American Academy of Pediatrics - can negatively impact the well-being of patients over time. The article is available at this link: [www.nytimes.com/2024/09/19/opinion/medicine-allergies-research.html?smid=url-share](https://www.nytimes.com/2024/09/19/opinion/medicine-allergies-research.html?smid=url-share)

One passage is particularly enlightening. The author states: **"Rather than remaining open to dissent, the medical profession frequently closes ranks, leaning toward established practice, consensus and groupthink...In this kind of environment, what begins as opinion can quickly become dogma, especially once the profession has become wed to an idea."**

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We hope you will take seriously not only our concerns but also the many comments you are undoubtedly receiving from others expressing deep patient dissatisfaction with DG-8062. We urge you to consider revising the proposal before entering it into the federal register for public comment.

The NRC can fix this by applying simple common sense. Making extravasations reportable and giving nuclear medicine centers a 12-month grace period to update their policies will quickly improve patient safety. Scientific evidence is clear on the potential harm from extravasation. Just as the *New York Times* opinion piece notes, professional organizations are capable of being on the wrong side of an issue, and that opposition can be destructive to patient health. Those who oppose medical event reporting of large extravasations are on the wrong side of this issue.

PSNM remains hopeful that you will arrive at a policy that is clear and simple: make extravasations reportable like any other medical event. Give providers time to fix the issue, but don't lose sight of your responsibility to patients. We stand ready to support that approach. We will help educate patients and providers if necessary - but first, you must do your job.

Sincerely,

A handwritten signature in black ink that reads "Simon Davies". The signature is written in a cursive, flowing style.

Simon Davies, Executive Director  
Teen Cancer America  
PSNM Spokesperson