



For Immediate Release
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Petition for Rulemaking Calls on NRC to Prioritize Patient Safety, Transparency

Outdated NRC Policy Allows Injection Errors to be Hidden from Patients & Treating Physicians

CARY, NC – Lucerno Dynamics, a North Carolina-based medical technology company, submitted a formal [petition for rulemaking](#) to the U.S. Nuclear Regulatory Commission (NRC) yesterday, which calls on the agency to update a 1980 policy that allows nuclear medicine injection errors (extravasations) to remain hidden from patients, treating physicians, and NRC itself.

Ron Lattanze, CEO of Lucerno Dynamics, said, “Extravasations can irradiate patient tissue with high doses of radiation and should never be hidden. When an extravasation irradiation exceeds NRC limits, it should be reported as a medical event just like any other misadministration with high doses. For the sake of patients’ safety, the effectiveness of their treatment, and general transparency in medical care, the patient, their physician, and regulators should be informed when an injection error results in excess irradiation to tissue.”

Momentum has been building to update this policy that puts patients at risk and hides information that patients and their treating physician deserve to know.

In January, the NRC announced an independent review of the extravasation issue.

In February, the Organization of Agreement States (OAS), whose member states regulate 88% of the nation’s radioactive materials users, wrote a letter to the NRC supporting the Commission’s independent review and supporting a change to its outdated policy. [The OAS letter says](#), “The Board is happy to hear the Commission has directed an independent review of extravasations.” The letter continued, “[Medical events] are possible by the injection of the radiopharmaceutical into an unintended tissue and should be reported upon occurrence.”

Additionally, Dr. David Townsend, co-inventor of the PET-CT scanner, published [an opinion column in STAT](#) yesterday arguing that the NRC’s current “inconsistent reporting requirements make little sense.” Dr. Townsend argued that updating this 40-year-old policy to require consistent medical event reporting requirement “would be a small step for hospitals to implement but a big step towards improving patient care.”

While the NRC has stated it is conducting an independent evaluation of the issue, the [rulemaking petition](#) and public comment process provide another opportunity for subject matter experts, patient advocates, state-based regulators, and the general public to convey their support for prioritizing patient safety and transparency.

Background

The NRC requires nuclear medicine providers to report medical events that result in unintended irradiation of greater than 0.5 Sieverts to a patient’s tissue. However, since 1980, a loophole in this rule has exempted extravasations (also known as infiltrations) from these reporting requirements. An extravasation occurs when a radiotracer is mistakenly injected—in whole or in part—into the soft tissue near the injection site rather than into the vein as intended. In creating this loophole 40 years ago, the NRC’s belief was that infiltrations occur frequently and are “virtually impossible to avoid.”

For more than a year, Lucerno Dynamics has presented scientific and clinical evidence to the NRC, including recent cases of patients irradiated at levels far in excess of NRC reporting requirements. Cases like these are not required to be reported to the NRC, to the patient, or to the treating physician due to the existing loophole in the NRC policy. The evidence also included letters of support from leaders in nuclear medicine, imaging technology, and patient advocacy. Additionally, Lucerno Dynamics provided the recently published results from a multi-center quality improvement study demonstrating that providers can drastically reduce the occurrence of infiltrations with dedicated monitoring and feedback to technologists.

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