For Immediate Release
August 30, 2024

Lucerno Welcomes NRC Progress on Extravasation Reporting

Lucerno Dynamics CEO: NRC needs to go further, move faster

Lucerno Dynamics, a North Carolina medical technology company, today responded to the Nuclear Regulatory Commission (NRC) publication of Draft Regulatory Guide DG-8062. The draft guide partially closes a 44 year-old NRC reporting loophole and would require certain nuclear medicine extravasations be reported as medical events.

"NRC's proposed rule and Draft Regulatory Guide regarding the reporting of radiopharmaceutical extravasations are positive steps for patient safety, improved care, and transparency," said Ron Lattanze, CEO of Lucerno Dynamics.

Radiopharmaceutical extravasations are an insidious medical error. When a radioactive drug is accidentally injected into the tissue rather than into the patient's vein as intended, it almost always goes undetected. Patients don't feel it. Technologists don't see swelling. And physicians reading the images don't know it, since the injection site is rarely in the field of view. Evidence proves that large extravasations of high energy therapeutic or even low-energy diagnostic radiopharmaceuticals can cause tissue and skin damage over time and compromise the nuclear medicine procedure.

In 2020, Lucerno officially petitioned the NRC to remove an incorrect policy that allowed all radiopharmaceutical extravasations to go unreported, even if they resulted in radiation doses that were known to be incredibly dangerous, and even if they exceeded the level of radiation doses that NRC should have reported to Congress. In December 2022, NRC accepted Lucerno's petition and agreed the exemption needed updating.

NRC's draft rule and guidance in response to the Lucerno petition would partially close the 44 year-old loophole in NRC's medical event reporting by requiring nuclear medicine centers to report diagnostic and therapeutic radiopharmaceutical extravasations that have caused injury or have the potential to cause injury. The rule and guidance also require that nuclear medicine centers document processes that will provide high confidence in detecting if a medical event has happened, so prompt medical attention can be given to extravasated patients. Lattanze cautioned, "While the proposed rule and draft guide are positive steps, they are watered down by using harm and subjective physician determination to guide reporting. This is not the way NRC approaches other accidental exposures, and it is just not good enough. Thousands of patients continue to experience large extravasations every day. NRC needs to go further, move faster."

NRC has made clear in many other instances that medical event reporting is to be neither subjective nor harm-based. At the same time that extravasations were incorrectly exempted from reporting in 1980, NRC established reporting for all other medical events, but purposely steered clear of using subjective criteria. In the May 14, 1980, Federal Register, NRC officially rejected the idea of allowing physicians to determine if a misadministration of a radioactive drug could potentially result in a "clinically detectable" injury. NRC abandoned this possible reporting approach because of concerns of physicians having "too much leeway in making the determination" to report and because radiation "adverse effects" were too subjective, too much of a "moving target." Additionally, medical event reporting requirements, as stated on the medical event form itself, make clear that patient harm is not a criterion for reporting. Rather, reporting is intended to provide an early warning on whether a nuclear medicine center is having a potential issue in handling radioactive material.

NRC can improve the proposed rule and the draft guidance by requiring extravasations be reported if they exceed the same risk-informed, objective radiation dose-based reporting threshold used for all other medical events. An objective reporting criterion will ensure that these avoidable errors are reported. A subjective reporting criterion will lead to under-reporting of these errors. It will also lead to the bizarre situation wherein a radioactive drug spilled *on* the patient requires use of an objective dose-based threshold to determine reporting, but a radioactive drug spilled *into* the patient allows physician leeway to subjectively determine potential radiation injury and possible reporting.

"A dose-based reporting threshold is best for reporting and for the patient. The most objective and effective way to assess the effect of a radiopharmaceutical extravasation on the patient and their procedure is to characterize the extravasation using dosimetry," Lattanze pointed out. "Today, in 2024, new technology or imaging the arm during the injection process can provide immediate insight if a patient is being extravasated, so clinicians can mitigate the radiation damage as soon as possible. And free dosimetry software can quickly and easily characterize the amount of radioactivity left at the injection site over time, which is not only important for accurate reporting but also for patients. Patients want to know how the severity of an extravasation could affect their health, as well as their image or therapy procedure. And all of this information needs to be documented in the patient's medical record. It is a basic patient right."

Lattanze concluded, "While I am happy that NRC is headed in the right direction, I am sure that patients, their physicians, international radiation protection organizations, and global experts will agree with me that more is needed. NRC should follow the lead of the International Atomic Energy Agency (IAEA) and International Commission on Radiological Protection (ICRP). These organizations recommend monitoring for extravasations during radiopharmaceutical administrations, using dosimetry to characterize extravasations, and reporting extravasations that exceed a certain radiation dose."

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