



For Immediate Release

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Contact: Matt Dennis 703-615-1007

39 States Call on NRC to Update Nuclear Medicine Safety Policy

*Outdated NRC Policy Allows Nuclear Medicine Injection Errors to be
Hidden from Patients, Treating Physicians*

*39 States Tell NRC to Reject Misleading Recommendations from
Federal Advisory Committee; Update “Medical Event” Reporting
Requirements*

CARY, NC – The Organization of Agreement States (OAS) – 39 states that work with the U.S. Nuclear Regulatory Commission (NRC) to regulate medical use of radioactive material – has [called on NRC](#) 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, a North Carolina-based medical technology company, said, “It is commendable that the OAS has reached the correct conclusion regarding the reporting of extravasations. Extravasations that unintentionally expose patient tissue to high levels of radiation should not be hidden. These errors that exceed NRC limits should be reported as a medical event just like high exposure resulting from any other misadministration and the patient, their physicians, and regulators should be informed.”

[The letter from OAS](#) is notable in that the 39 states stand in square opposition to the NRC Advisory Committee on Medical Use of Isotopes (ACMUI) recommendations on whether these errors should be reported. The ACMUI recommended that NRC both retain the reporting loophole and enter into a formal rulemaking to classify extravasations as a “patient intervention,” suggesting the patient himself or herself is responsible for an injection error. A dissenting opinion from an ACMUI member noted that instances of high tissue exposure resulting from extravasations “should be reported just as any other misadministration of such magnitude would be reported.” The ACMUI recommendations were based on flawed or incomplete information, as detailed in a [submission of evidence and case studies by Lucerno Dynamics](#) in October 2019.

[The OAS letter says](#), “The Board is happy to hear the Commission has directed an independent review of extravasations. We support the ACMUI’s dissenting opinion in their final report, dated October 23, 2019, that [medical events] are possible by the injection of the radiopharmaceutical into an unintended tissue and should be reported upon occurrence. Whether there is immediate harm or not has no bearing on the reporting criteria; it is only a matter of dose with the current [medical event] rule.”

Background

NRC requires nuclear medicine providers to report medical events that result in unintended radiation exposure 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 of the arm rather than into the vein as intended. In creating this loophole 40 years ago, NRC’s belief was that infiltrations are inconsequential, occur frequently, and are “virtually impossible to avoid.”

In April 2019 and for the following six months, Lucerno Dynamics presented scientific and clinical evidence to NRC’s Advisory Committee on Medical use of Isotopes (ACMUI). This evidence included recent cases of patients exposed to radiation levels far in excess of NRC reporting requirements. These cases were never reported to NRC, to the patient, or to the treating physician due to the existing loophole in NRC policy. The evidence also included letters of support from nuclear medicine pioneers, including the co-inventor of the PET/CT scanner. 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.

Despite this evidence, in September 2019, the nuclear medicine community representatives comprising ACMUI recommended NRC maintain the current loophole allowing providers to avoid reporting these radiological medical events. On January 28, 2020 NRC stated it is conducting an “independent evaluation” of the issue to determine whether to accept or reject the recommendations of ACMUI.

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*Matt Dennis
CRD Associates, LLC
600 Maryland Ave. SW Suite 835
Washington, DC 20024
202-484-1100 ext.152
703-615-1007 cell*