

Congress of the United States
Washington, DC 20515

November 27, 2020

The Honorable Kristine L. Svinicki
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

RE: Docket No. PRM-35-22; Docket ID NRC-2020-0141

Dear Chairman Svinicki:

We write to respectfully urge the Nuclear Regulatory Commission (NRC) to expeditiously grant the petition for rulemaking Docket No. PRM-35-22 filed by Lucerno Dynamics, LLC. This petition would require licensees to report infiltrations - in which an injected radiopharmaceutical partially misses a vein and the dose is injected into a patient's soft tissue - that exceed existing medical event criteria to the NRC. There are serious concerns among our constituents that existing NRC policy fails to protect the safety of patients who undergo diagnostic and therapeutic nuclear medicine procedures. We hope that through a public rulemaking, the NRC can establish clearer safety standards, increase transparency to patients, and protect the public from unintended irradiation.

In 1980, the NRC instituted a policy exempting infiltrations from medical event reporting requirements on the understanding that infiltrations occur frequently and are "virtually impossible to avoid," even if the infiltration irradiates patient tissue with doses that exceed threshold reporting requirements. Since that time, we understand that new evidence provided to the NRC demonstrates that infiltrations can result in both direct and indirect harm to patients and are avoidable through dedicated monitoring and quality improvement planning. This new evidence should be considered when updating these rules.

Requiring the medical event reporting of extravasations that exceed existing reporting criteria will improve patient radiological health and safety by encouraging licensee facilities to adopt patient safety and quality improvement measures. While this requirement would require licensee facilities to invest time and effort in quality improvement processes, these processes could enhance patient health and safety and ensure the delivery of safe, high-quality diagnostic and therapeutic health care services.

We call on the NRC to grant the petition for rulemaking Docket No. PRM-35-22. Infiltrations are avoidable and reporting of these events to NRC will improve the safety and quality of diagnostic and therapeutic nuclear medicine procedures. Thank you for your attention to this matter.

Sincerely,



David Price
Member of Congress



George Holding
Member of Congress



G.K. Butterfield
Member of Congress



Ben Cline
Member of Congress



Denver Riggleman
Member of Congress



Lucy McBath
Member of Congress