

# Congress of the United States

## Washington, DC 20515

June 18, 2020

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

Dear Chairman Svinicki,

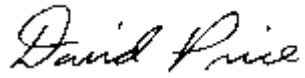
We are writing to respectfully urge the Nuclear Regulatory Commission (NRC) to expeditiously grant the petition for rulemaking Docket No. PRM-35-22 filed by Lucerno Dynamics, LLC. This petition would require licensees to report infiltrations – in which an injected radiopharmaceutical partially misses a vein and the dose is injected into a patient’s soft tissue – that exceed existing medical event criteria to the NRC. There is concern amongst 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 exceeds threshold reporting requirements. Since that time, we understand that new evidence provided to the NRC demonstrates that infiltrations can result in 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.

Since 1980, NRC’s outside Advisory Committee on the Medical Uses of Isotopes has recommended maintaining the infiltration reporting exemption, citing concerns about administrative and reporting mechanisms while discounting evidence of patient safety implications. While we are sensitive to the administrative burdens facing providers who regularly infiltrate patients, such concerns are resolvable and cannot eclipse the need to protect patients and ensure the delivery of safe, high-quality health care services. We urge the NRC to prioritize patient safety.

We call on the NRC to grant the petition for rulemaking [docket number]. Infiltrations are avoidable and reporting of these events to the NRC will improve the safety and quality of diagnostic and therapeutic nuclear medicine procedures. Thank you for your attention to this matter.

Sincerely,



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David Price  
Member of Congress



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George Holding  
Member of Congress



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G. K. Butterfield  
Member of Congress