



CHAIR

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 19, 2023

Nancy Warden
Vascular Wellness
151 Quarrystone Circle
Suite 112
Cary, NC 27519

Dear Nancy Warden:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated December 9, 2022, emphasizing the need to address extravasations for all patients, especially the specific circumstances for patients of color. I appreciate the points you raised concerning underserved communities, including the higher rates of extravasation in patients of color, and the need to reduce reliance on patient self-reporting of extravasations. I also appreciate you and other members of Patients for Safer Nuclear Medicine directly sharing these views with me in a November 9, 2022, meeting.

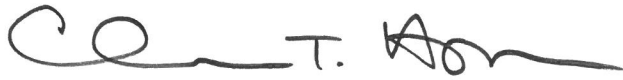
The Commission recently granted a petition for rulemaking¹ on the issue of nuclear medicine injection extravasations. As part of its review of the petition, the Commission considered extensive feedback from the public, patient advocates, the medical community, and professional societies. Given the Commission direction on this matter, the NRC staff will be conducting a rulemaking to include certain nuclear medicine injection extravasations as reportable medical events. This rulemaking would amend the NRC's regulations to mandate medical event reporting of extravasations that require medical attention for a suspected radiation injury. In addition, the Commission has directed the NRC staff to continue to explore approaches that would reduce the reliance on patient reporting. Specifically, the staff should evaluate whether the NRC should require licensees to develop, implement, and maintain written procedures to provide high confidence that radiation-safety-significant extravasations will be detected and reported.

The rulemaking process will include public outreach on the proposed regulatory requirements and guidance being developed by the NRC. We encourage you and your members to participate in this process.

¹ The NRC staff's rulemaking plan is available at [ML21268A005](#), and the Commission's direction is available at [ML22346A112](#).

If you have any questions or need additional information, please contact me or contact Kevin Williams, Director of the Division of Materials Safety, Security, State, and Tribal Programs, at (301) 415-3340.

Sincerely,

A handwritten signature in black ink, appearing to read "C. T. Hanson". The signature is written in a cursive style with a large initial "C" and a distinct "Hanson" at the end.

Christopher T. Hanson