



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

May 16, 2022

The Honorable Thom Tillis
United States Senate
Washington, DC 20510

Dear Senator Tillis:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated April 13, 2022, regarding the NRC staff's preliminary evaluation of whether radiopharmaceutical extravasations should be classified as medical events reportable to the NRC. Extravasations occur through the inadvertent injection of some or all of a radiopharmaceutical dosage into the patient's tissue surrounding an injection site. As your letter notes, the NRC staff has been assessing this issue and looking at new information. The Commission recently received the staff's recommendations on reporting certain extravasations as medical events and for resolving the related petition for rulemaking (PRM-35-22).

I appreciate your reference to the International Atomic Energy Agency tool for auditing all aspects of nuclear medicine services and the concerns of patient advocacy groups about transparency for patients, physicians, and the NRC. The staff is aware of this tool and considered it during its assessment along with the large volume of public comments. The Commission will also consider this information during its evaluation of the staff's recommendations. While the agency is considering this issue, the NRC's current medical use regulations are protective of public health and safety.

If you have any questions or need additional information, please contact me or have your staff contact Eugene Dacus, Director of the Office of Congressional Affairs, at (301) 415-1776.

Sincerely,

Christopher T. Hanson