



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

September 8, 2022

CHAIRMAN

The Honorable Ron Wyden
United States Senate
Washington, DC 20510

Dear Senator Wyden:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated July 25, 2022, requesting that the Commission make publicly available the staff's evaluation of classifying radiopharmaceutical extravasations as medical events reportable to the NRC. The Commission is reviewing a staff paper with recommendations on the reporting of extravasations that includes a petition for rulemaking.

In accordance with the NRC's procedures for preparation and review of petitions for rulemaking, the final staff evaluation on classifying radiopharmaceutical extravasations as medical events reportable to the NRC has not yet been publicly released. Those procedures reflect the agency's policy to make petition closure documents publicly available after the Commission has issued a final decision and the petitioner has been informed of that decision.

To ensure full consideration of the impacts of extravasation on patients and the medical community, NRC staff requested input from the public, medical professional societies, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), and the Agreement States. In August 2021, the NRC staff publicly released its preliminary evaluation, which summarized the various considerations and potential options. The ACMUI held a public meeting to discuss the staff's preliminary evaluation, and ACMUI issued a final report in September 2021. The Agreement States also commented on the draft of the staff's petition evaluation in the fall of 2021. Information used to inform the staff's evaluation is publicly available at www.regulations.gov (docket ID NRC-2020-0141). The docket is continuously updated and contains the petition, additional information submitted by the petitioner throughout the petition review process, public comments on the petition, and ACMUI deliberations.

I want to assure you that while the Commission 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,

A handwritten signature in black ink, appearing to read "C. T. Hanson".

Christopher T. Hanson