



CHAIRMAN

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

December 10, 2019

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 November 6, 2019, letter expressing concern about the NRC's policy of excluding infiltrations – inadvertent injections of radiopharmaceuticals into tissue surrounding a vein or artery – from the reporting requirements for medical events. In your letter, you asked the NRC to change its position that infiltrations are not medical events and thus not subject to the agency's reporting requirements, and to therefore reject the Advisory Committee on the Medical Uses of Isotopes' (ACMUI) September 10, 2019, recommendations related to the appropriateness of this approach.

As you noted in your letter, advances in technology, medical approaches, and quality improvements to nuclear medicine procedures have made it easier to detect and minimize infiltrations of radiopharmaceuticals. The NRC staff will evaluate these advancements and the ACMUI's recommendation in the context of the agency's approach to infiltrations and its "Medical Use of Byproduct Material" policy statement, which addresses regulating radiation safety of workers and the public, as well as patient safety in a manner that minimizes intrusion on the practice of medicine. The staff plans to complete these evaluations and provide the resulting information to the Commission in the spring of 2020.

We appreciate your interest in these matters. 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 blue ink, appearing to read "Kristine L. Svinicki".

Kristine L. Svinicki