



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

February 4, 2020

The Honorable David Price
United States House of Representatives
Washington, DC 20515

Dear Congressman Price:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your December 19, 2019, letter concerning the NRC staff's review of the agency's policy to exclude infiltrations or extravasations—inadvertent injections of radiopharmaceuticals into tissues surrounding injection sites—from the NRC's reporting requirements for medical events. Specifically, you urged the NRC and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) to carefully consider all evidence related to infiltrations before making a final decision on this matter.

The NRC staff is currently conducting an independent evaluation of whether the agency should require infiltrations or extravasations to be reported as medical events. As you acknowledged, there have been advances in nuclear medicine that can detect, minimize, and prevent infiltrations. These advances, stakeholder input, and ACMUI's recommendations, will be among the staff's considerations during its review. As indicated in the House and Senate Reports accompanying the Further Consolidated Appropriations Act, 2020, the Commission will provide a report to Congress in March 2020 on updates to injection quality monitoring, classification, and reporting requirements regarding extravasations.

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,

Kristine L. Svinicki