

Congress of the United States
House of Representatives
Washington, DC 20515-3302

July 12, 2021

Dr. Darlene Metter
Chair
Advisory Committee on the Medical Uses of Isotopes
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Kellee Jamerson
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Dr. Metter and Ms. Jamerson:

I have followed with interest the U.S. Nuclear Regulatory Commission's (NRC) evaluation of its policy on medical event reporting on extravasations. As you are aware, this 41 year-old policy exempts from medical event reporting requirements incidents in which patients are irradiated unintentionally during nuclear medicine procedures due to an injection extravasation, regardless of the severity of the irradiation.

I am concerned by scientific literature demonstrating the frequency with which extravasations occur, the high levels of radiation to which patients can be unintentionally exposed, and the potential consequences. Literature also shows that these events are largely preventable. There are compelling reasons for patients to know if they have been irradiated at high levels as a result of an extravasation during a diagnostic or therapeutic nuclear medicine procedure. NRC should take interest in these incidents in order to determine if a particular facility is having trouble safely handling radioactive materials.

As you are aware, a bipartisan group of Members of the U.S. House of Representatives and the U.S. Senate has urged NRC to update its outdated policy through public comment to petition for rulemaking PRM-35-22. Patients, patient advocacy groups, the Commission's own regulatory partner — the Organization of Agreement States (OAS), and scientific and clinical experts have also supported the petition.

I urge NRC to take this opportunity to protect patients, improve health care quality, and increase transparency. Again, extravasations can be prevented, and changing NRC's current policy would likely be beneficial for patients undergoing diagnostic and therapeutic nuclear medicine procedures.

Very truly yours,



Deborah K. Ross
Member of Congress

McCloskey, Bridin

Attachments: Ross_NRC_7.12.21.pdf

From: Paulson, Katie <Katie.Paulson@mail.house.gov>

Sent: Monday, July 12, 2021 5:23 PM

To: Jamerson, Kellee <Kellee.Jamerson@nrc.gov>

Cc: Lee, Matt <Matt.Lee@mail.house.gov>

Subject: [External_Sender] Letter from Congresswoman Ross

Dear Ms. Jamerson,

Please find attached a letter from Congresswoman Deborah Ross regarding the NRC's policy on medical event reporting on extravasations. We look forward to your response.

Sincerely,

Katie Paulson | *Legislative Assistant*
Office of Congresswoman Deborah Ross (NC-02)
1208 Longworth House Office Building
(202) 934-0652 (cell)