PATIENTS DEMAND NRC ACTION ON EXTRAVASATION REPORTING

Contrast media shortage drives sense of urgency to notify patients when extravasation occurs

<u>Patients for Safer Nuclear Medicine</u>, a coalition of 29 patient advocacy organizations representing thousands of patients, along with more than 600 concerned US citizens submitted an <u>Information Correction Request</u> on June 2, 2022 asking the Nuclear Regulatory Commission (NRC) to correct a 42-year-old NRC policy that exempts reporting of certain accidental patient exposures.

Radioactive drug misadministrations caused by human error, inadequate training, lack of quality procedures, and that exceed defined radiation dose thresholds are currently reportable to NRC. Extravasations, once thought to be unavoidable, occur when radioactive drugs used in nuclear medicine procedures are inadvertently injected into the patient's tissue instead of a vein.

"Significant extravasations of diagnostic radioactive drugs can compromise images used to guide patient care and can result in high doses to patient tissue and skin. In addition to the dose to tissue, skin and the patient's lymphatic system, therapeutic radioactive drug extravasation also means the therapy is not being delivered as intended" said John Witkowski, President of UPPI, which represents 80 independent and institutional radiopharmacies across the US. "It is critical to patients that radioactive drug administrations are monitored, and large extravasations are immediately identified so clinicians can begin mitigating the dose right away."

"30 million administrations of radioactive drugs occur every year in the US, but NRC has excluded extravasations from reporting, even if they cause radiation doses hundreds of times higher than other reportable events," says Patients for Safer Nuclear Medicine spokesperson Mary Ajango. "We now know that extravasations can almost be eliminated. Correcting the 1980 exemption policy will ensure that large extravasations are measured, and most importantly patients and their physicians will be informed. Patients need to know if their care is affected. The worst approach is to do nothing and wait for patients to be injured."

Extravasations are a hot topic. Last August, the International Atomic Energy Agency, an authoritative scientific body, published <u>QUANUM 3.0</u>, emphasizing the need to identify, characterize, mitigate, prevent, and report these preventable errors. Recent op-eds have also called for the NRC to corrects its outdated policy, including an article in <u>The Cancer Letter</u> and two opinion pieces published <u>by a radiation oncologist</u> and <u>the co-inventor of the PET/CT scanner</u>.

Jackson W. Kiser, MD, Chief of Molecular Imaging at Carilion Clinic, noted that the ongoing shortage of contrast media for CT scans makes the issue of extravasation even more timely.

"The contrast media shortage means some patients will shift to nuclear medicine imaging. They need confidence their radioactive drugs are being delivered ideally." Dr. Kiser notes. "NRC needs to act now, and we hope they will respond favorably to the growing chorus of expert and patient voices seeking improved patient care by requiring reporting of significant extravasations."