



August 27, 2021

To Whom It May Concern:

We contact you on behalf of nuclear medicine patients across the United States to respectfully ask the Nuclear Regulatory Commission to adopt the recommendations made in the petition in Docket: NRC-2020-0141. We believe that patients, their physicians, and the NRC should all be made aware of radiopharmaceutical extravasations that exceed the medical event reporting limit.

The Patients for Safer Nuclear Medicine Coalition is comprised of numerous advocacy organizations, across several therapeutic areas, representing thousands of patients across the US. We are dedicated to ensuring the safety of nuclear medicine procedures, which are commonly used to support cardiology, neurology, cancer, and many other types of patients.

Radiopharmaceutical extravasations can inadvertently irradiate patient tissues with doses that far exceed the reporting limit (0.5 Sv) and the threshold that the nuclear medicine community says will lead to adverse tissue reactions (1.0 Sv). We also know that these significant extravasations that exceed the reporting limit happen far more often than they should, even though they are preventable.

In addition to contributing to injury, significant extravasations can also lead to misdiagnosis and incorrect course of treatment for patients. When it comes to cancer, for example, a significant extravasation can compromise diagnostic images, leading to a misdiagnosis that can take a patient down the wrong treatment path. Similarly, when it comes to cardiology and neurology patients, a significant extravasation can lead to doctors making decisions for treatment based on inaccurate images. The idea that information regarding a significant extravasation should continue to be kept from the patient and their physician is simply unacceptable.

We further believe the NRC should be aware of significant extravasations. The agency is responsible for protecting patients during procedures involving the use of isotopes. Unfortunately, the current problem is compounded by a lack of reporting. There is no way to address this serious issue when information is incomplete or unavailable in the first place. Patients have the right to know which nuclear medicine centers have issues in the proper administration of medical isotopes.

By adopting the recommendations included in the petition in Docket: NRC-2020-0141, we can begin to tackle this serious problem while continuing to make strides forward in the diagnosis and treatment of patients. On behalf nuclear medicine patients, we thank you for considering our request.

Sincerely,

The Patients for Safer Nuclear Medicine Coalition