PATIENTS
FOR SAFER NUCLEAR MEDICINE

June 24, 2024

Re: ACMUI's draft subcommittee report on the NRC staff's draft proposed rule and associated draft implementation guidance for reporting nuclear medicine injection extravasations as medical events

Dear Dr. Jadvar, Dr. Katie Tapp, and Daniel DiMarco,

Members of the Patients for Safer Nuclear Medicine coalition reviewed the June 17th ACMUI teleconference meeting materials, including the NRC staff's draft proposed rule and associated draft implementation guidance for reporting nuclear medicine injection extravasations as medical events. We would like to share some initial observations.

We applaud the NRC medical staff for drafting proposed language to limit the burden that would be placed on patients to identify and report their own extravasations and/or radiation injuries. But we want to reiterate that using injury as a criterion is not appropriate or ideal. In our experience, most patients do not truly understand that they are being injected with radioactive drugs. Furthermore, if they are not told they have been extravasated, few if any will ever connect the dots and seek medical attention for discomfort or pain in their arm when there are no visible signs of injury on the skin. This is especially true with the latent effects of ionizing radiation injuries. Instead of waiting for patients to suffer harm and for injuries to manifest long after the procedure, the NRC correctly asserts that nuclear medicine providers, due to their knowledge and experience, are better suited to identify extravasations as they occur. This allows for timely mitigation and assessment of the procedure's effects.

We are also pleased that NRC is proposing to include potential radiation injury as a threshold for reporting as opposed to visible injury only. As explained in the supplementary information, inclusion of extravasations that have the potential to cause injury "reduces reliance on patient involvement in the identification of a reportable extravasation" and will help to ensure that licensees "detect and assess extravasations while the patient is still in the care of the licensee." These points are important to patients and their care.

However, we believe the proposed rule and regulatory guidance could result in subjective assessment of extravasations, which is not in patients' best interest—a lesson the NRC has previously learned. In the Federal Records from 1980 the Commission already discussed why having a subjective criterion is not ideal. When determining whether an extravasation has the potential to result in radiation injury, different physicians may undoubtedly arrive at different conclusions. After reviewing hundreds of public comments to NRC and statements from professional organizations, it appears that many in the nuclear medicine community have a cavalier attitude toward injecting radiation into healthy tissue. This is disconcerting to say the least and gives patients little confidence that extravasations will be reported similarly across centers. Please remember, a large extravasation can affect both radiation protection and the images that affect the quality of patient care.

In the draft rule's supplementary materials, NRC says, "…a reporting criterion for nuclear medicine injection extravasations that does not rely on a dose differential strikes the appropriate balance between the dosimetry required to properly characterize an extravasation and the potential for a radiation effect on a patient…". However, the proposed criterion of potential radiation injury, as determined by a physician raises the question: What information does a physician need to know to make that determination? We believe physicians will want to know the absorbed dose to the patient's tissue before making an injury determination so they could then compare the dose to levels at which deterministic effects are expected to occur.

We agree that the methods a physician uses to determine whether radiation injury is possible would fall under the practice of medicine, but the methods used to perform dosimetry prior to medical event reporting are clearly within the NRC's purview. Without any defined criteria, dosimetry will be implemented differently, and possibly

inaccurately, by different licensees. We recommend that NRC define appropriate criteria for dosimetry of extravasations so that assessments and reports from all licensees can be compared. Furthermore, to remove any ambiguity, NRC could state a threshold that is known to result in tissue damage or preferably use the existing threshold that indicates a licensee may have potential issues in the way they handle these radioactive drugs. We also strongly recommend that NRC require that records of extravasation assessments and the methods used be saved in the patient's medical record. From our experience, patients who are extravasated once can be extravasated again. Clinical staff must be aware of a patient's prior extravasation and document their cumulative dose accurately.

During the teleconference meeting, the subcommittee initially suggested they were pleased with the proposed rule. And after approximately an hour of circular discussion regarding informed consent, ACMUI members had already begun voting to approve the report when Dr. Wallner, a representative of the American College of Radiology (ACR), recommended that all references to extravasations with the ***potential*** to result in injury should be removed. Some members of the ACMUI then immediately agreed and began recommending its removal too. After comments from NRC medical staff, the ACMUI members finally decided to recommend a weakening of the language instead of its removal, but the interaction between the ACR representative and the ACMUI members was concerning given the published Special Investigation findings from the OIG. It is clear to patients that a web of conflicted relationships exists between medical societies with agendas of self-interest and advisers who are members or even leaders in these same societies but also are paid by taxpayers to protect patients. We reiterate our previously documented concerns regarding the conflicted relationships between ACMUI members and industry representatives, as well as the overall expertise of ACMUI members on this topic.

It is disconcerting for patients to hear NRC advisers make statements in a public meeting that show they do not understand the topic. The patient advocate, Mr. Mailman, continues to suggest that a clinical study be conducted to grasp the frequency of these events. That comment suggests he does not understand that extravasation rates vary by center, technologist, and over time, as evidenced by the multicenter study on radiopharmaceutical extravasations. Furthermore, the radiation safety officer's claim of never witnessing a patient injury from extravasations is disingenuous and does not reflect the latent nature of these effects. Additionally, how is it possible that no one with vascular access training seems to be involved in the ACMUI or NRC on this topic? These examples, along with the OIG findings of federal ethics violations, and our own observations, give patients little confidence that the ACMUI is adequately representing our interests, highlighting the need for improvement going forward.

We thank the NRC for their work to ensure that rulemaking considers the priorities of nuclear medicine patients and their care. We ask that you please remove subjectivity from criteria going forward. Finally, we encourage the NRC to take steps to ensure that ACMUI members provide advice that prioritizes patient radiation protection over industry interests.

Thank you,
Members of the Patients for Safer Nuclear Medicine Coalition
Cervivor
Chicago Hispanic Health Coalition
New Day Foundation for Families
Teen Cancer America
The Leapfrog Group
TOUCH, The Black Breast Cancer Alliance
Young Survival Coalition
Stephen Harris CRNI, VA-BC
Pam Kohl, Patient