August 27, 2021

Attn: Kellee Jamerson
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: (ML21223A085) NRC Staff Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing over 40,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to provide feedback to the Nuclear Regulatory Commission (NRC) and the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) regarding extravasation and medical event (ME) reporting. The following comments address the NRC staff's preliminary evaluation report and corresponding ACMUI Subcommittee on Extravasation recommendations packaged in ML21223A085. As of this writing, the publicly accessible documentation does not include the NRC staff recommendations.

In general, the ACR appreciates the NRC's consideration of qualitative options to focus ME reporting on rare, clinically significant extravasations of byproduct material resulting in deterministic radiation harms. The NRC should not require licensees to purchase novel monitoring products or use nonstandard dosimetry based on assumptions that are essentially universally contested by national medical physics and health physics organizations. Arbitrary quantification in the manner described in PRM-35-22 would not demonstrate that any radiation harms or preventable errors occurred, nor would using exotic monitoring products prevent small volume extravasations from occurring. A quantitative ME reporting mandate would, however, result in clinical, professional, financial, and medicolegal impositions on health care providers with negative impacts on patient access, cost, comfort, and safety. These impacts were discussed in the ACR's comments on PRM-35-22.

The ACR continues to recommend "Option 6." Option 6 would require ME reporting of extravasations determined by a physician to meet the significant harm standard of §35.3045(b). The ACMUI Subcommittee on Extravasation is currently recommending "Option 4." Option 4 would require reporting if "*a patient requires medical attention due to skin damage near the administration site, and the damage is determined to be caused by radiation.*" Option 4 is preferable to the identified quantitative reporting options; however, the ACR has the following concerns regarding this option:

1. **"Medical attention" is ambiguous.** Taken to an unintended extreme, "medical attention" could be interpreted by NRC or Agreement State agencies as including basic care for transient erythema, mild discomfort, or swelling at the injection site. The ACMUI must clearly define the manner and intensity of the "medical attention" that should or should not trigger ME reporting requirements.

2. **Injury assessments and attribution to radiation should be done by physicians with expertise.** Option 6 would require a physician-level determination that the harm standard of §35.3045(b) has been met. Conversely, the descriptions of Option 4 in the documentation did not specify the qualifications of individuals making harm determinations and attributing cause. Ideally, an Authorized User (AU) or AU-eligible physician is best capable to differentiate "radiation-caused damage" from transient reactions to the pharmaceutical component of the radiopharmaceutical or other reactions to any nonradioactive drugs/materials administered during treatment.

3. **Option 4 would require rulemaking to create a new Medical Event type.** Depending on the position of NRC's Office of General Counsel, the essential approach of Option 6 could possibly be implementable via subregulatory policy without modifying the CFR by following ACMUI's previous recommendations on extravasation and patient intervention.

Moving forward, the ACR recommends that ACMUI reaffirm its previous position (Option 6), which is less susceptible to downstream misinterpretation than the current iteration of Option 4. Should the ACMUI wish to endorse Option 4, committee members must amend the subcommittee report to resolve concerns #1 and 2 prior to approval.

The ACR appreciates the NRC and ACMUI's consideration of this statement. Please contact Gloria R. Romanelli, JD, ACR Senior Director of Legislative and Regulatory Relations, at gromanelli@acr.org, and Michael Peters, ACR Government Affairs Director, at mpeters@acr.org or (202) 223-1670 with questions or concerns.

Sincerely,

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