American College of Radiology™

October 3, 2024

The Honorable Christopher T. Hanson
Chairman, U.S. Nuclear Regulatory Commission
U.S. Nuclear Regulatory Commission
Mail Stop O-16 B33
Washington, DC 20555-0001

Dear Chairman Hanson:

The American College of Radiology (ACR)—a professional association representing more than 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine (NM) physicians, and medical physicists—appreciates the opportunity to discuss concerns regarding the NRCs draft Notice of Proposed Rulemaking (NPRM), "Reporting NM Injection Extravasations as Medical Events" (SECY-24-0067; ML24016A292). The potential for extravasation is routinely weighed in medical decision-making with all risks and benefits of the imaging/therapy agent, vascular access procedures, catheter sizes/types, and alternatives. The goal of the practice of medicine is to obtain the best patient care outcome while minimizing risks to the patient. While we do not see a safety need for revising NRC's prior policy, the ACR generally supports the Dec. 2022 Commissioners' decision on SECY-22-0043 to mandate Medical Event (ME) reporting of rare extravasations "that require medical attention for a suspected radiation injury" (ML22346A115).

We understand that the purpose of 10 CFR 35.3045, "*Report and notification of a Medical Event,"* is for NRC and Agreement State programs to receive ME reports and analyze concerns about handling/use errors (§35.3045(a)) or major radiation harms (§35.3045(b)), and to share actionable lessons with licensees and regulators. ME reports are not medical communications; however, they involve disruptively rapid processes and deadlines in clinical settings and influence healthcare facilities. Therefore, it is important for NRC to scope the new §35.3045(a)(3) ME definition pursuant to the urgency, actionability, and intended use of this data by NRC.

While supportive of the Commissioners' Dec. 2022 decision, the ACR is concerned that the draft NPRM appears to unintentionally deviate from the directive on a few key proposals. If left uncorrected in future rulemaking, these deviations would likely lead to misidentified §35.3045(a)(3) MEs, patient care impositions, and added costs to patients, providers, and regulators. We respectfully request that the Commissioners provide additional direction to staff to ensure an implementable and sustainable rulemaking outcome.

NPRM Concerns (ML24016A292)

- The NPRM deviates from the Commissioners' directive to mandate ME reporting of cases *requiring medical attention*. The NPRM proposes Common Terminology Criteria for Adverse Events (CTCAE) V5.0, Grade 2 as the targeted level of interest for NRC MEs. By CTCAE definition, Grade 2 events are "moderate; minimal," and may receive routine monitoring, self-care, or local noninvasive alleviations; examples of the latter include application of a warm/cold compress and/or elevation of the affected limb to increase circulation and expedite imaging/therapy site uptake. The ACR continues to recommend that NRC use CTCAE Grade 3 and above to define MEs of interest to the agency. Grade 3 adverse events

are defined as "severe or medically significant" and indicate a necessary medical intervention, such as a surgical treatment, which is an unambiguous and auditable outcome for determining NRC ME reportability.

- The NPRM uses the speculative language "*can be* attributed to radiation" for the "radiation injury" definition under §35.2. The symptom commonly used as an example in the NPRM preamble is CTCAE Grade 2, or "moderate; minimal," erythema. Erythema is defined by the National Cancer Institute (NCI) as "redness of the skin," and is a symptom of 17 distinct CTCAE adverse event categories. Interpreted literally, the proposed §35.2 language includes non-radiation causes of minimal erythema frequently seen during and after many vascular access procedures, such as skin sensitivity to the puncture or to the adhesive used in a bandage. We recommend that NRC's §35.2 definition of "radiation injury" be narrowly scoped to effects *caused by, or most likely to be caused by*, byproduct material.

- The NPRM proposes to define a §35.3045(a)(3) ME when an extravasation "*has the potential to* result in a radiation injury." Read literally, this would mandate speculation in the absence of any deterministic health effect. Bearing in mind the minimal, inclusive definition for "radiation injury" under §35.2, we recommend against requiring prediction-based reporting. NRC should instead enable voluntary reporting by the licensee if, for example, a §35.300 material extravasation is asymptomatic but severe in the AU's professional judgment.

- The NPRM proposes to enable any physician to determine a §35.3045(a)(3) ME. The physician does not need to be an Authorized User (AU) or have relevant expertise or background about the event or byproduct materials. Their claim would trigger the processes and deadlines of §35.3045(c) through (g), without time or opportunity for validation or authentication by the licensee. It would fall upon the regulator to medically validate the claim. Instead, we recommend that NRC limit MEs to claims validated by the AU or an AU-eligible physician.

Costs/Benefits and Concerns Raised by the Regulatory Analysis (ML24016A293)

- We applaud the NRC rulemaking staff for their regulatory analysis discussion of the alarming impacts on cancer care providers and patients of the 50-rem "Alternative 3," which would cost healthcare providers *billions* of dollars. As devastating as this financial cost would be for cancer care, current real-world costs extrapolated to 5,332 licensees suggest a conservative underestimation in the year one "method acquisition" and per-year "method upkeep" line items for Alternative 3. Nonetheless, such costs are plainly untenable.

- While the Alternatives 2 and 3 "qualitative benefits" are overstated and based on questionable assumptions, the negatives in the analysis do not include the public health impacts of an inevitable decline in numbers of providers able to offer NM imaging and/or therapies from Alternative 3. Qualitative costs would include severe patient access limitations (particularly impacting small/rural centers, community hospitals, and critical access hospitals), out-of-pocket expenses for patients, escalation of patients most likely to have vascular function irregularities to complex/higher risk access procedures (e.g., central venous access), and delayed cancer diagnoses and treatments.

- The NPRM/analysis package includes references to an NRC contractor-devised extravasation dosimetry model, which we understand to be a VARSKIN+ module scheduled for release in 2025. VARSKIN+ is currently a reactor/industry tool for occupational dose to skin from external particles/contamination. We have concerns about such a model being referenced in a rule preamble—particularly at this early stage, prior to model accessibility and review. Importantly, any extravasation evaluation tool referenced by rules or guidance, even if intended by NRC to be optional, could cause future misinformation and confusion for authorized personnel, licensed facilities, and regulators. Moreover, the cost analysis for Alternative 2 does not include implementation of novel extravasation dosimetry methods.

Thank you for your consideration of these concerns. We also appreciate the NRC staff's difficult task on this medically complex topic. As always, the ACR invites any questions or discussion with the Commissioners and/or NRC staff about these concerns. Please contact Michael Peters, ACR Senior Director, Government Relations, at mpeters@acr.org.

Sincerely,

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Chief Executive Officer
American College of Radiology