



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 18, 2022

Mary Farrell Ajango
Young Survival Coalition
on behalf of the Patients for
Safer Nuclear Medicine Coalition
405 Lexington Avenue, 26 Fl.
New York, NY 10174

Sent via email to majango@youngsurvival.org

Dear Ms. Ajango:

I am responding to your letters dated June 2, 2022, and August 8, 2022 (Agencywide Documents Access Management System Accession Nos. ML22164A919 and ML22222A138), requesting that the U.S. Nuclear Regulatory Commission (NRC) correct a statement made in a 1980 *Federal Register* notice (45 FR 31701; May 14, 1980). In this *Federal Register* notice of the NRC's final rule on misadministrations, now referred to as medical events, the Commission states, "[e]xtravasation frequently occurs in otherwise normal intravenous or intraarterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration." You requested, based on recent studies indicating that quality improvement methodologies may reduce the occurrence of extravasation, that the NRC correct the statement that extravasation "is virtually impossible to avoid" and immediately revise NRC regulations to require medical event reporting of extravasations resulting in a localized dose equivalent exceeding 0.5 sieverts.

As cited in your letter, there is a petition for rulemaking on this subject pending before the Commission (PRM-35-22). The NRC staff has determined that the concerns in your request will be addressed in the petition for rulemaking process, and staff has added your letters to the petition docket (NRC-2020-0141 on www.Regulations.gov). As the NRC explained in the *Federal Register* notice that published the agency's Information Quality Guidelines, "interpretations of data or information" publicly disseminated after October 1, 2002, are not subject to the NRC's Information Quality Guidelines and information correction process (67 FR 61695; October 1, 2002). Rather than the NRC's information correction process, the more appropriate vehicle to seek revision of NRC regulations is a petition for rulemaking, filed in accordance with 10 CFR § 2.802.

While the Commission is considering this issue, the decision published in the 1980 *Federal Register* notice remains in effect. The information in your request, information submitted by the petitioner, public comments on the petition, published literature reviewed by NRC staff, and input from the Agreement States and NRC's Advisory Committee on the Medical Uses of Isotopes, will all help inform the Commission's evaluation of the petition for rulemaking. The Commission's decision on the petition will determine whether the NRC will pursue a rulemaking to classify certain extravasations as medical events. If there are further regulatory actions related to extravasation, there will be additional opportunities to inform the staff's implementation of the Commission's petition decision.

M. Ajango

If you have further questions or concerns, please contact me by email at Kevin.Williams@nrc.gov, or by phone at 301-415-3340.

Sincerely,



Einberg, Christian signing on behalf
of Williams, Kevin
on 08/18/22

Kevin Williams, Director
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

M. Ajango

SUBJECT: Letter to Mary Farrell Ajango From Kevin Williams Regarding June 2022
Extravasation Information Correction Request DATE: August 17, 2022

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