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Docket: NRC-2020-0141
Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2020-0141-0004
Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

Document: NRC-2020-0141-DRAFT-0444
Comment on FR Doc # 2020-19903

Submitter Information

Name: Anonymous Anonymous
Submitter's Representative: Carmine M Plott
Organization: North Carolina Radiation Protection Commission

General Comment

Dear Sir or Madam:

On behalf of the North Carolina Radiation Protection Section, I respectfully submit for your consideration the attached letter regarding the petition for rulemaking related to reporting nuclear medicine extravasations as medical events.

Thank you for your assistance.

Sincerely,
Carmine M Plott, Chair
North Carolina Radiation Protection Commission

Attachments

Docket ID NRC-2020-0141 Response from NC Radiation Protection Commission 11-30-20

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

November 30, 2020

The Honorable Kristine L. Svinicki
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Docket ID NRC-2020-0141

Dear Chairman Svinicki:

The Radiation Protection Act (G.S. 104E) established the North Carolina Radiation Protection Commission with the power to adopt, develop, amend, and repeal rules, regulations, and standards relative to radioactive material. Consisting of 11 voting public members and 10 nonvoting ex officio members, the current voting members appointed by the Governor include nuclear medicine physicians, health physicists certified by the American Board of Health Physics, medical physicists certified by the American Board of Radiology, medical health physicists certified by the American Board of Medical Physics, and Radiation Safety Officers for broad scope and specific licensees. This letter is in response to the NRC request for comments related to Docket ID NRC-2020-0141.

After reviewing the petition for rulemaking dated May 18, 2020 from Ronald Lattanze on behalf of Lucerno Dynamics as well as relevant literature, the Radiation Protection Commission met on October 16, 2020 to discuss in detail whether federal regulations should be changed to require reporting of some extravasations of diagnostic radiopharmaceuticals as medical events. After every Commission member was given the opportunity to speak on this issue and after several members of the general public also provided comments, ***the Commission voted unanimously to oppose Mr. Lattanze's petition.*** The Commission contends that current regulations are adequate and offers the following for consideration:

- **The current regulatory framework already encompasses extravasations for both diagnostic and therapeutic radiopharmaceutical administrations.**

  §35.3045(ii) requires a licensee to report as a medical event the extravasation of a diagnostic radiopharmaceutical (not resulting from patient intervention) if the wrong radiopharmaceutical was administered or the wrong patient or human research subject received the dosage and the resulting dose to tissue is greater than 0.5 Sv (50 rem) or the shallow dose equivalent to the skin is greater than 0.5 Sv (50 rem).

§35.3045(a)(1)(B) requires a licensee to report as a medical event the extravasation of a therapeutic radiopharmaceutical (except for an event resulting from patient intervention) if the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range. Furthermore, if the extravasation of a therapeutic radiopharmaceutical is the result of patient or human research subject intervention, §35.3045(b)(1) requires the licensee to report the event if it results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

- **Not all extravasations are preventable or the result of error.**

  Patients (particularly pediatric, geriatric, and chemotherapy patients) often present with compromised vascularity, making it difficult to obtain access for intravenous (IV) administrations. Even the petitioner does not suggest or reference an attainable extravasation rate of 0%.

- **Although significant extravasations may affect the calculation of the standard uptake value (SUV) in PET/CT, response to such incidents are best addressed at the institution level and based upon guidance from peer-reviewed articles published in medical journals or from professional medical organizations.**

  Oncology patients undergo multiple PET/CT exams during their course of care as this modality is invaluable for the initial assessment of metastatic disease as well as the assessment of tumor response to therapy. While extravasations of PET radiopharmaceuticals may result in erroneous SUV calculations, the potential exam misinterpretations noted by the petitioner are related to the practice of medicine and are therefore beyond the scope of the radiation protection regulatory agency. Nevertheless, requiring the reporting of such an extravasation as a medical event based upon the resultant dose to the tissue or skin would have no positive impact on a patient's care, especially if the root cause was the patient's own vascularity.

- **A standardized methodology to assess extravasation dose to tissue has not yet been defined. Furthermore, there is no skin dosimetry model that allows comparison with the organ dose thresholds specified in the medical event definition.**

  Radiation dose is equal to energy absorbed per unit mass of tissue where energy absorbed is directly proportional to the radioactivity of the radionuclide. The challenge to assess dose from a radiopharmaceutical extravasation is two-fold: determining the amount of activity at the site of infiltration and estimating the mass of the tissue impacted by the infiltration.

  Traditional, simplified techniques to assess quickly potential dose will not account effectively for the removal of the radiopharmaceutical from the injection site nor the time-varying geometry of the source term. (Some imaging equipment, like the gamma cameras designed for nuclear cardiology, do not even afford whole-body imaging to review relative uptake of the radiopharmaceutical throughout the patient's body.) Such calculations would therefore over-estimate the resultant dose that would be reported unnecessarily as a medical event.

  While tomographic images acquired in PET/CT or SPECT/CT exams may be used to assess more accurately the volume of tissue impacted, multiple time points of delayed imaging would be required to assess the time-varying activity distribution. This dosimetry method would require technologist time and camera time as well as inconvenience to the patient who may be unwilling to comply with the additional time needed for additional delayed imaging – just to determine if the extravasation must be reported as a medical event. Furthermore, the patient care workflow of departments with only one gamma camera would be severely disrupted as team members assess an extravasation to determine if indeed a medical event has occurred.

- **The cost to develop and maintain an extravasation monitoring program for the purpose of medical event reporting is disproportionate to the actual risk to the patient. Accordingly, such a program would not be in keeping with the new National Materials Program "risk smart" regulatory focus.**

  Extravasation rate may be easily and appropriately addressed by the licensee's quality assurance program. However, if regulations are changed to require reporting of such incidents as medical events based on dose thresholds only, licensees will be obligated to develop and maintain a costly monitoring program that will contribute very little to the overall quality of patient care. (Every IV administration would have to be assessed to determine if an extravasation has occurred and each extravasation would have to be assessed to determine if a medical event has occurred.)

  In North Carolina, we are required to prepare a Fiscal Note to analyze the cost of any proposed rulemaking. In the Statement of Interest, the petitioner describes a detection system, the Lara® System that is commercially available from Lucerno to help characterize extravasations. In addition to the purchase price and subsequent maintenance fees of such equipment for each Injection Room, the costs of a monitoring program would include pro-rated salaries (of technologists, physicists, Radiation Safety Officers, and radiologists), camera time (for additional patient imaging), and any consultants' fees associated with the data collection and dosimetry analysis of each potential medical event.

  Nuclear medicine relies on commercial nuclear pharmacies to provide patient dosages throughout the day. Unlike computed tomography exams, nuclear medicine studies are time consuming, hence daily patient throughput is limited. Consequently, even though it is critical to comprehensive patient care, nuclear medicine is not financially lucrative. Sadly, further regulations and the associated costs to demonstrate and maintain compliance may result in fewer nuclear medicine providers.

- **Expanding the definition of medical events to require reporting of diagnostic radiopharmaceutical extravasations will not improve patient safety.**

  The petition is disingenuous. The proposed changes to the regulations will not guarantee increased patient safety but will certainly increase the sale of the petitioner's Lara® System. Furthermore, patients should not be misled to believe that federal radiation protection regulations are inadequate and that their healthcare providers are withholding safety related information because they are not required to report extravasations.

  Patient safety is improved by promoting a culture of safety. Rather than imposing the additional regulations suggested by the petitioner that are narrowly focused on extravasations, there are alternatives that would yield greater benefit in a broader sense to patient safety. Best practices such as these could be addressed in a guidance document for medical licensees:

  – All technologists who administer IV radiopharmaceuticals should be certified by the Nuclear Medicine Technology Certification Board or registered in nuclear medicine by the American Registry of Radiologic Technologists.

  – To complement §19.12, individuals who administer IV radiopharmaceuticals should complete initial and periodic training in phlebotomy.

  – Licensees should utilize catheters (rather than "direct sticks") to establish IV access and to administer radiopharmaceuticals.

- Rather than relying on decay corrections (based upon the initial assayed activity and calibration time provided by the commercial nuclear pharmacy), licensees should maintain a dose calibrator to measure the activity of each gamma-emitting radiopharmaceutical dosage prior to administering it to a patient.

- Licensees should establish a quality management program to assess extravasation rates and establish trigger levels that require corrective action.

Thank you for the opportunity to provide these comments. If you have any questions regarding the Commission or its activities, please contact us via W. Lee Cox, III, Radiation Protection Section Chief, at (919) 814-2252 or lee.cox@dhhs.nc.gov.

Respectfully,

Carmine M. Plott, PhD, CHP, DABR
Chairman
NC Radiation Protection Commission

Roger Sit, PhD, CHP
Vice-Chairman
NC Radiation Protection Commission

c: Thom Tillis, United States Senator, North Carolina
G. K. Butterfield, United States Representative, North Carolina 1st Congressional District
George Holding, United States Representative, North Carolina 2nd Congressional District
David Price, United States Representative, North Carolina 4th Congressional District
Terry Derstine, Chair, Organization of Agreement States
W. Lee Cox, III, NC DHHS Radiation Protection Section Chief