From:	Lake, Ian P.
To:	RulemakingComments Resource
Cc:	Ogretici, Akin; Campbell, Janice M.; Seitz, John
Subject:	[External_Sender] Nuclear Regulatory Commission Docket ID NRC-2022-0218 – Response Corewell Health
Date:	Monday, July 17, 2023 8:58:22 AM
Attachments:	image001.png image002.png image003.png image004.png Corewell Health Response NRC Extravasation Rulemaking Final.pdf

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Hello,

Please see attached comments to NRC-2022-0218.

Thank You,

Ian Lake

Ian Lake, MHP, CHP
He/Him/His
Radiation Safety Officer
Radiation Safety Department
Corewell Health William Beaumont University Hospital (formerly Beaumont – Royal Oak)
Corewell Health Beaumont Troy Hospital (formerly Beaumont – Troy)
Corewell Health Beaumont Grosse Pointe Hospital (formerly Beaumont – Grosse Pointe)

248.551.1086 Direct
815.600.2067 Cell
corewellhealth.org

Corewell Health™

3601 West 13 Mile Road | Mail Code: 305 ABW
Royal Oak, MI 48073

Corewell Health corewellhealth.org

Nuclear Regulatory Commission Docket ID NRC-2022-0218 – Response

July 17, 2023

Background

Beaumont Health d/b/a Corewell Health – Southeast Michigan, is responding to the Nuclear Regulatory Commission Docket ID NRC-2022-0218 request for comments on, "Reporting Nuclear Medicine Injection Extravasations as Medical Events" under 10 CFR Part 35.

The NRC is seeking feedback from the public on preliminary proposed rule language before proceeding to the development of a proposed rule. Full background on the Petition for Rulemaking (PRM-35-22) and events leading to this request can be found in 88 FR 24130. As a large academic multi-hospital medical institution with broad scope NRC license, Beaumont Health d/b/a Corewell Health – Southeast Michigan has a great deal of historical knowledge and experience regarding the use of intravenous delivery of radiopharmaceuticals for both diagnostic and therapeutic use. As such, we are providing our feedback to the Commission regarding this proposed rule.

Comments

Beaumont Health d/b/a Corewell Health – Southeast Michigan has had no reported injuries due from extravasations related to excess radiation exposure. Per our organization's internal variance reporting policy, extravasation events using radiopharmaceuticals would be deemed as radiation safety program variances. Since 2006, 209 parenteral therapeutic injections have been administered with no extravasations reported.

Beaumont Health d/b/a Corewell Health – Southeast Michigan has reviewed position statements put forth by industry organizations regarding the initial response to NRC docket 2020-0141. Those reviewed include the American College of Radiology (ACR – August 31, 2022), American Society for Radiation Oncology (ASTRO – May 19, 2022), Society of Nuclear Medicine and Molecular Imaging (SNMMI – September 29, 2020), American Association of Physicists In Medicine (AAPM – November 30, 2020), Health Physics Society (October 14, 2020), as well as the Advisory Committee on the Medical Uses of Isotopes (ACMUI – September 16, 2021)[1].

Based on a review of the initial petition, our institutional experience, and a review of leading industry organizations, it is the opinion of our organization that **the NRC's policy regarding extravasations established in May 1980 does not require additional rulemaking and that no new rules need to go into effect. Any requirement to monitor would cause unnecessary burden and increased costs. Requiring patients to follow-up when there is no medical reason increases a cancer patient's concern and difficulty, physician time, and facility resources.**

Beaumont Health d/b/a Corewell Health – Southeast Michigan recognizes that the NRC has proceeded with rulemaking and is asking for comments on preliminary proposed rule language before proceeding to the development of a proposed rule. Please see our organizational responses below:

[1] See last page for references

Specific Considerations Requested in 88 FR 24130

1. What term should the NRC use (e.g., extravasation, infiltration) when describing the leakage of radiopharmaceuticals from a blood vessel or artery into the surrounding tissue?

Answer: No comment on the proposed definition of extravasation as, "Extravasation means the leakage of a radiopharmaceutical from the blood vessel into the surrounding tissue."

2. What criteria should the NRC use to define "suspected radiation injury"?

Answer: The focus for intervention and patient safety should be on the potential tissue reaction aspects of these incidents. An authorized user should have the ability to use their judgment as to whether the injury is related to radiation or other potential tissue reaction.

3. What techniques or methods should be included in the definition of "medical attention"?

Answer: No comment on the proposed definition of medical attention as, "Medical attention means any techniques used to reduce the chance, severity, or symptoms of a suspected radiation injury."

4. What steps could the licensee take to minimize the chance of a radiopharmaceutical extravasation occurring?

Answer: There are well-established medical procedures for the prevention of extravasated radiotherapeutic agents, as indicated by their infrequent occurrence. A successful injection is dependent on a combination of acquired technical skills and the ability to navigate, to the extent feasible, the patient's anatomical landscape and physiological conditions. Because of all these factors, injecting a radiopharmaceutical is truly a medical practice issue.

5. What steps should the licensee take when an extravasation is suspected or discovered?

Answer: The response from the licensee should be risk-based and dependent on the quantity and type of radiopharmaceutical administered – with particular focus or concern for therapeutic doses.

6. What techniques, technologies, or procedures (e.g., post-treatment imaging, visual observation, patient feedback) should be used to help identify an extravasation during or immediately after a radiopharmaceutical injection?

Answer: If there is a suspected extravasation event, visual observation and patient feedback would be the preferred methods.

7. What techniques, technologies, or procedures (e.g., post-treatment imaging, survey measurement) should be used to better characterize an extravasation after radiopharmaceutical treatment?

Answer: These techniques, technologies, or procedures would not be necessary. Requiring patient to follow-up when there is no medical reason increases a cancer patient's concern and difficulty, physician time and facility resources.

8. What information should licensees provide to nuclear medicine patients on how to identify an extravasation and how to follow up with their physician if they suspect a radiation injury?

Answer: Provide the patient with written instructions including physician contact information.

9. When should a reportable extravasation be counted as "discovered" for the purposes of notification (e.g., when medical attention is administered, when the physician identifies that the injury is from radiation)?

Answer: An extravasation should not be considered discovered until a physician authorized user is able to assess the patient and make the determination the injury is from radiation.

10. The NRC requires that licensees notify the referring physician and the individual who is the subject of a medical event no later than 24 hours after discovery of the medical event. When should licensees be required to provide notification of an extravasation medical event to the referring physician and the individual?

Answer: For radiation skin injuries, it may not be practical to determine if a “medical event” has occurred until an authorized user has a chance to assess the injury and make a reasonable determination that it is radiation-related. This may be particularly challenging due to the onset of injury potentially being days or weeks after an injection occurs. A licensee should not be required to report an extravasation unless permanent radiation-induced injury effects have or are likely to occur.

11. Who (e.g., patient’s primary physician, authorized user, nuclear medicine technician) should be able to identify an extravasation that could result in a “suspected radiation injury”?

Answer: Only an authorized user should be able to identify an extravasation that could result in a suspected radiation injury. Their expertise both clinically and in the use of radiopharmaceuticals make them uniquely qualified to make this determination.

12. What topics should the NRC include in guidance to assist licensees to accurately identify, characterize, and report extravasation events in a timely manner?

Answer: Clear guidance would need to be provided regarding the identification and characterization process of suspected radiation injuries. Tissue reactions may be complicated and judgement subjective.

13. What regulatory actions could help ensure that extravasations in patients affected by healthcare inequities are accurately assessed and reported?

Answer: Any requirement to monitor would cause unnecessary burden and increased costs – especially in patients with healthcare inequities. Requiring patients to follow-up when there is no medical reason increases a cancer patient’s concern and difficulty, physician time and facility resources.

14. Are vascular access tools and other technologies (e.g., ultrasound guided vein finders) likely to reduce the potential for an extravasation in all patients, particularly in patients of color?

Answer: Use of vascular access tools should remain a medical practice decision.

References

American Association of Physicists in Medicine (AAPM). (2020, November 30). *RE: Petition for Rulemaking: "Reporting Nuclear Medicine Injection Extravasations as Medical Events"*. Retrieved from https://www.regulations.gov/comment/NRC-2020-0141-0443

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American Society for Radiation Oncology (ASTRO). (2022, May 19). *ASTRO Letter to Commissioners Extravasation*. Retrieved from https://www.astro.org/ASTRO/media/ASTRO/News%20and%20Publications/PDFs/ExtravasationLtr.pdf

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