

PUBLIC SUBMISSION

As of: 7/19/23, 12:48 PM
Received: July 18, 2023
Status: Pending Post
Tracking No. lk8-diox-tz8i
Comments Due: July 18, 2023
Submission Type: Web

Docket: NRC-2022-0218
Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2022-0218-0004
Reporting Nuclear Medicine Injection Extravasations as Medical Events

Document: NRC-2022-0218-DRAFT-0055
Comment on FR Doc # 2023-08238

Submitter Information

Email: anthony.curry@aah.org
Organization: Advocate Health

General Comment

See attached file(s)

Attachments

Advocate Health Comments Docket ID 2022-0218

July 18, 2023

The Honorable Christopher T. Hanson
Chairman
U.S. Nuclear Regulatory Commission
Mail Stop O-16 C12
Washington, DC 20555-0001

RE: Nuclear Regulatory Commission Docket ID 2022–0218: Reporting Nuclear Medicine Injection Extravasations as Medical Events

Dear Chairman Hanson:

Advocate Health appreciates the opportunity to provide comments to the Nuclear Regulatory Commission (NRC) regarding proposed rules for reporting some nuclear medicine extravasations as medical events.

Advocate Health Overview

Advocate Health is a leading nonprofit integrated health system in the United States providing care under the names Advocate Health Care in Illinois, Atrium Health in the Carolinas, Georgia and Alabama, and Aurora Health Care in Wisconsin. We are a national leader in clinical innovation, health outcomes, consumer experience and value-based care, with Wake Forest University School of Medicine serving as the academic core of the enterprise. Headquartered in Charlotte, North Carolina, Advocate Health serves nearly 6 million patients and is engaged in hundreds of clinical trials and research studies. It is nationally recognized for its expertise in cardiology, neurosciences, oncology, pediatrics and rehabilitation, as well as organ transplants, burn treatments and specialized musculoskeletal programs. Advocate Health employs nearly 150,000 team members across 67 hospitals and over 1,000 care locations and offers one of the nation's largest graduate medical education programs with over 2,000 residents and fellows across more than 200 programs. Committed to equitable care for all, Advocate Health provides nearly \$5 billion in annual community benefits.

We appreciate your consideration of the comments that follow below.

Advocate Health supports the official joint position statement adopted by the Society of Nuclear Medicine and Molecular Imaging, the American College of Nuclear Medicine and the American Society of Nuclear Cardiology published in September 2020 that extravasations of

radiopharmaceuticals are a practice-of-medicine issue which should be managed at the institutional level and at the discretion of the authorized health care professionals.¹

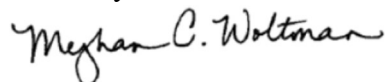
Advocate Health believes it is our collective responsibility to ensure patient safety and reduce harm when providing care to the individuals, families, and communities we serve. As such, we have worked tirelessly over the last several years to achieve this important goal. We currently have internal standard policies and practices in place which achieve the same objectives proposed in this docket and recommend that NRC does not impose any additional unnecessary regulatory and operational burdens on hospitals and providers at a time when we are facing unprecedented workforce and staffing challenges. Additionally, there are internal procedures within Advocate Health that address the management of extravasated radiotherapeutic agents similar to those in place for extravasated chemotherapy agents.

Furthermore, there is currently no clinical data supporting the claim that extravasation of radiopharmaceuticals pose a patient safety issue. For these reasons we support the stance taken by prominent organizations in the Nuclear Medicine community mentioned above to not impose any additional regulations on hospitals and providers.

Conclusion

Thank you for the opportunity to provide our feedback to the NRC regarding the commission's regulatory oversight of nuclear medicine. Please do not hesitate to contact me (Meghan.Woltman@aah.org) should you have any questions or if we can be of any assistance.

Sincerely,



Meghan Woltman
SVP, Chief Government Affairs Officer

¹ [SNMMI statement final signed w letterhead 9-29-20.pdf](#)