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Draft Regulatory Guide: Release of Patients Administered Radioactive Material

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Submitter Information

Email: jbellinger@snmmi.org
Organization: Society of Nuclear Medicine and Molecular Imaging

General Comment

See attached file(s)

Attachments

NRC Patient Release Comments Final

SOCIETY OF NUCLEAR MEDICINE & MOLECULAR IMAGING

August 20, 2023

Office of Administration
ATTN: Program Management, Announcements and Editing Staff
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U.S. Nuclear Regulatory Commission
Washington DC 20555-001

Docket ID NRC-2023-0086

Dear Commissioners and Staff:

We are writing to comment on **Docket ID NRC–2023–0086- Draft Regulatory Guide DG-8061, Release of Patients Administered Radioactive Materials, Federal Register VOL. 88, NO 77; April 21, 2023**. SNMMI and its more than 15,000 members set the standard for the practice of nuclear medicine and molecular imaging by creating guidelines, sharing information through journals and meetings, and advocating on key issues that affect molecular imaging and therapy, research, and practice.

There have recently been transformative advances in radiopharmaceutical therapy. We have seen increased procedures, and as new radiopharmaceuticals become more widely available, the practical implications and impact of these release guidelines will be even more significant. It would clearly be problematic if these more restrictive guidelines had the unintended consequence of limiting the availability of radiopharmaceutical therapy to patients, especially in already underserved areas.

Our primary concern with the proposed guidance is the overly conservative assumptions used in the patient release calculation. The occupancy factor of 1.0 is four times more restrictive than the previous guidance. We support and recommend keeping the current occupancy factor of 0.25 used in previous guidance. The proposed occupancy factor is unnecessary and problematic. There is no data that we're aware of that shows that public health and safety have been compromised using an occupancy factor of 0.25. Requiring patients to keep a distance of one meter for 6 hours per day until complete decay is realistic, well understood and we believe, respected by patients.

With appropriate patient care and access at the forefront of our decisions and recommendations, we would like to elaborate further on what we mean when we say access to life-saving therapy would be affected. Increased cost to patients is anticipated which is an unfortunate hurdle for many patients, even with the assistance of our social work colleagues. If patients must be kept inpatient, we have had difficulty in securing insurance coverage even for I-131 therapy in the setting of the 0.25 occupancy factor. We anticipate that this would worsen severely should the more restrictive occupancy factor of 1 be in place. Another consequence of this is that the billing of therapy as inpatient falls under the DRG for admission which limits the amount of coverage for patients based

on the admission diagnosis. We would expect that these newer and expensive therapies would then have an even higher cost to the patient as most hospitals pass on uncovered costs to patients. In addition, even the most well-developed academic center practices also only have a limited number of lead-lined rooms which would increase the already significant backlog many of us have for patients suffering from advanced prostate cancer and seeking ^{177}Lu-PSMA therapy. We also feel pressure for these rooms at our institutions where inpatient rooms are in high demand and many patients are housed longer than would be usual in the emergency rooms. We only use these rooms when absolutely necessary by the 0.25 occupancy factor. If moving to an occupancy factor of 1, these rooms will be needed more often by our practices and leaving other inpatients in the ER for longer periods where they could be better cared for on inpatient floors. We are very concerned about these unintended consequences and without data to support the need for the more restrictive occupancy factor may face many challenges with hospital administrators when trying to care for our patients when we need these rooms more frequently. When considering all these things, we foresee the creation of a cycle of delay of care (for many patients who cannot afford to wait for these life-saving therapies) and increased costs to patients.

We are also concerned with the patient-specific dose calculations, i.e., the "Second-Tier Approach," for determining individualized patient releasability. We understand that theoretically it may allow patient release at higher activities and dose rates, however it requires the treating facility to justify the specific values of the patient modifying factors, including the occupancy factor. For community hospitals and other facilities that do not have internal nuclear physics assistance this is unworkable and will result in nuclear medicine facilities not offering service and care, limiting de facto patients' access to critical and life-saving radiopharmaceutical therapies.

Our opinion and recommendation are also supported by the experts of ACMUI which, in their January 2022 report, recommended that NRC replace the overly restrictive 1.0 occupancy factor with the reasonable, but conservative 0.25 occupancy factor.

Therefore, we urge the NRC to keep an occupancy factor of 0.25 as the default value. This will prevent the limiting patients' access to critical care while continuing to protect public health and safety.

Thank you for your consideration. Please contact me if I can provide additional information or if you have questions.

Sincerely,

Helen Nadel, MD, FRCPC (Diag Rad) (Nuc Med), ABR (Ped Rad), ABNM, FACNM, FSNMMI
President, SNMMI