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**Docket:** NRC-2023-0086

Draft Regulatory Guide: Release of Patients Administered Radioactive Material

**Comment On:** NRC-2023-0086-0001

Draft Regulatory Guide: Release of Patients Administered Radioactive Material; Extension of Comment Period

**Document:** NRC-2023-0086-DRAFT-0059

Comment on FR Doc # 2023-08418

## Submitter Information

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## General Comment

Decreasing the occupancy factor to 0.25 will require patients receiving more than 100 mCi of PSMA and dotatate based therapies to be admitted which will further increase hospital and healthcare costs. This may reduce the treatment availability at large and may restrict the existing treatment to the people who can afford it.

Prostate cancer is the most prevalent cancer in the world and it is of utmost importance to maintain existing treatment options for patients with increasing life expectancy.

Decreasing occupancy factor from 1.0 to 0.25 may render only people with money to avail this treatment given Medicare coverage for inpatients and will deny the benefits of radionuclide therapy to a large portion of population.

With increasing patient population requiring the PSMA and Dotatate based therapies there is in fact need of consulting patients and determining candidature for radionuclide therapies as it is clinically necessary in patients.

## Attachments

Comment

August 20, 2023

Office of Administration

ATTN: Program Management, Announcements and Editing Staff

Mail stop: TWFN -&-A60M

U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

RE: Docket ID NRC-2023-0086, Draft Regulatory guide (DG) DG-8061, Release of patients administered Radioactive Material, "Federal Register Vol 88, NO 77; April 21, 2023

I, Jitesh Dhingra MD and I am a Board-certified Nuclear Medicine physician practicing and providing radionuclide therapies in Pittsburgh. I have worked across the world in India, London, US and have completed my Nuclear Medicine training at Emory University. Currently I am employed as a specialist of Nuclear Medicine at Allegheny General Hospital in Pittsburgh which is a 576 bed community hospital and provides health care to underserved patients.

Radionuclide therapies have till date reported no significant adverse events to patients treated or family members or the public at large. The existing rule of 1.0 occupancy factor has not reported any radiation hazards till date.

Decreasing the occupancy factor to 0.25 will require patients receiving more than 100 mCi of PSMA and dotatate based therapies to be admitted which will further increase hospital and healthcare costs. This may reduce the treatment availability at large and may restrict the existing treatment to the people who can afford it.

Additionally in the last 5 years FDA has approved Lu-177 dotatate for metastatic neuroendocrine tumors and Lu-177 PSMA for castration resistant metastatic prostate cancer.

In my current practice we treat many patients of both the malignancies and have proved to demonstrate significant improvement in survival and quality of life for patients who have no other options.

Prostate cancer is the most prevalent cancer in the world and it is of utmost importance to maintain existing treatment options for patients with increasing life expectancy.

Decreasing occupancy factor from 1.0 to 0.25 may render only people with money to avail this treatment given Medicare coverage for inpatients and will deny the benefits of radionuclide therapy to a large portion of population.

With increasing patient population requiring the PSMA and Dotatate based therapies there is in fact need of consulting

patients and determining candidacy for radionuclide therapies as it is clinically necessary in patients. This should be restricted to the community of NM physicians with significant experience in the same or dedicated NM training.

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