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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-0061

Comment on FR Doc # 2023-08418

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General Comment

See attached file(s)

Attachments

Dr. Halkar's comment on new proposal for release criteria

August 20, 2023

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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 - Raghuvver K Halkar MD- am a Board-certified Nuclear Medicine physician practicing and providing radio nuclide therapy since 1980. I worked in Kuwait cancer center for 8 years and then moved to USA and did Nuclear Medicine training at Emory University and has been a faculty of Emory university School of Medicine since 1994. Currently I am the director of Nuclear Medicine at Grady Memorial Hospital (GMH)Atlanta which is 1000 bed community hospital and provides health care to underserved patients.

Since iodine therapy with NaI-131 was started in 1942, millions of patients with cancer thyroid and hyperthyroidism have benefitted from the treatment. No serious adverse events to patients treated or family members or the public at large have

been reported in the last 8 decades not only from the USA but also internationally. With improved housing situations and personalized care, the existing rule of 0.25 occupancy factor has worked very well. At GMH we have treated hundreds of underserved and indigent patients with NaI-131 without any consequences with 0.25 occupancy factor. Increasing the occupancy factor to 1.0 will increase the cost of therapy significantly already strained finance of the community hospital denying the lifesaving treatments to underserved patients and further increase the disparity in health care in the USA.

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. These two treatments have proved significant improvement in survival and quality of life for patients who have no other options. Increasing occupancy factor from 0.25 to 1.0 will deprive these patients of the radionuclide therapy by making it prohibitively expensive. Only patients who are extremely wealthy will be able to afford these therapies and middleclass and financially handicapped Americans will be deprived of the benefits of radionuclide therapy. Instituting 1.0 occupancy factor will further increase in health care disparity.

Instead of changing the occupancy factor, the NRC should consider instituting a policy that only well trained (training and experience in the use of unsealed radioactive source, radiation biology, radiation safety and physics) and qualified authorized user be allowed to use radionuclide therapy after performing a

diligent pre therapy consult with the patient and family members.

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