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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-0063
Comment on FR Doc # 2023-08418

Submitter Information

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General Comment

I am Amol M. Takalkar, MD, MS, MBA, FACNM, a Board-certified Nuclear Medicine physician practicing all aspects of Nuclear Medicine, Molecular Imaging, and Theranostics for the past 20 years. I did my Nuclear Medicine training at the Hospital of University of Pennsylvania and have a Masters in Biomedical Engineering from University of Virginia along with an Executive MBA from Louisiana State University Shreveport. Currently I am Professor of Radiology & Imaging Sciences at Emory University School of Medicine and also serve as the Associate Program Director for the Nuclear Medicine Residency Program and the Associate Director of Nuclear Medicine at Grady Memorial Hospital (GMH), a large and the only community hospital in Metro Atlanta focused on providing health care to underserved patients.

I am writing to document my strong concerns about the proposed revisions for patient release criteria by the NRC. Radio-iodine therapy with NaI-131 has been safely practiced since the 1940s and even after treating millions of patients with thyroid cancer and hyperthyroidism, there have been no definite documented episodes of significant public harm due to release of these patients after treatment with appropriate instructions to isolate and minimize exposure to their family members and the general community. With the proposed revision, we seem to be regressing to the past, when we used to admit anyone receiving more than 30 mCi of I-131, a practice still prevalent in some other countries. However, the US Health care delivery systems and the housing situation of the general US population is very different than what it used to be or currently is internationally. Increasing the occupancy factor arbitrarily from 0.25 to 1.00 without any scientific justification is counter-intuitive to science.

In this era of personalized and individualized care, enforcing an arbitrary occupancy factor of 1.00 on every patient getting radionuclide therapy is extremely unscientific. Most centers offering radionuclide therapy calculate the occupancy factor and determine the dose that can be safely given on an outpatient basis based on that. Rather than mandating a high occupancy factor of 1.00 for all, the US population will be better served by strengthening the existing safety measures in place like:

• Enforcing adequate radiation safety training for all involved in the delivery of such therapies.
• Ensuring that AU's document the occupancy factor.
• Performing an office consult visit and counseling each patient scheduled for radionuclide therapies about minimizing radiation exposure to their family members, near and dear ones, and the general community they live in.
• Hospitalizing patients that cannot be safely discharged due to their unique home situation.
• Requiring adequate training in novel radionuclide therapies as they become FDA approved and deployed in their practice.

Increasing the occupancy factor to 1.00 from the current one of 0.25 will have significant negative effects on the field of theranostics in the US and add substantial hurdles for US patients to get these life-saving therapies. The US health care reimbursement system is unique and already quite challenging. At present, the US is lagging in the adoption and offering of these life-saving therapies to the US population. Several patients have had to travel abroad to receive these therapies. Just when things are starting to improve in the US, this new, arbitrary, and unscientific revision will further put us back as the rest of the world strides ahead of us. It is very likely that the new revision will require a lot of patients to be hospitalized to receive the treatment and given reimbursement challenges in the in-patient setting, this will further increase the disparities in health care delivery in the USA by disproportionately affecting the poor and the middle class who may not even be offered these therapies due to the fiscal environment of the current US health care system.

It would be a disservice to the US population to revisit past failed policies or blindly follow some other countries. Instead of enforcing a one-size fits all rule, the US patients and general population will be better served by allowing for personalized, predictive, participatory, and preventive (P4) medicine based on the unique social conditions in the US population and the special financial situation in the US healthcare delivery system.

Amol Takalkar, MD, MS, MBA, FACNM
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Emory University, Atlanta, GA
President, Indo-American Society of Nuclear Medicine (IASNM)

See attached file(s)

Attachments

NRC_Comment_Takalkar

August 20, 2023

Office of Administration
ATTN: Program Management, Announcemnets 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

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