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General Comment

See attached file(s)

Attachments

MITA Comments to NRC on Patient Release Criteria - NRC-2023-0086

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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

MITA is a Division of the National Electrical Manufacturers Association (NEMA) and is the leading organization and collective voice of medical imaging equipment, radiopharmaceutical manufacturing, innovators, and developers. MITA represents companies whose sales make up 90 percent of the global market for medical imaging technologies. MITA priorities include adopting uniform standards for medical imaging service providers, ensuring patient access to medical imaging, developing standards to ensure patient safety and timely access to the market, and improving the regulatory environment to promote growth and innovation.

Comments on Draft Regulatory Guide (DG), DG-8061

While we applaud the efforts of the Nuclear Regulatory Commission (NRC) to consider updated patient release protocols, the proposal in DG-8061 to update Regulatory Guide 8.39 contains problematic provisions that could create the unintended consequence of limiting patient access to critical nuclear medicine procedures. Assumptions made in the updated guidance will be difficult to operationalize in a healthcare setting and will have a specifically detrimental impact on community hospitals and other facilities that may not have the staffing necessary to comply with the overly burdensome proposed process in DG-8061.

First Tier Approach - Impractical Occupancy Factor Adjustment

According to NRC regulations, a licensee should not authorize the release of a patient who has received treatment with a radiopharmaceutical drug unless the total effective dose equivalent (TEDE) to any other individual is not likely to exceed the current 5 millisievert (mSv) standard. DG-8061 provides a two-tiered approach to demonstrate that the expected exposure to a bystander is not likely to exceed this threshold.

The first tier provides basic activity and dose rate thresholds for licensees to use in the absence of detailed knowledge of patient-specific considerations, including the expected behavior of the patient following release.

Licensees using the approach in the first tier may demonstrate compliance with the patient release dose criteria if the administered activity is not greater than the basic activity threshold listed in Table 1 and the metered dose rate from the patient is no greater than the value in listed in Table 2 of DG-8061. However, the proposed calculations in Tables 1 and 2 apply a default occupancy factor of 1, which unrealistically assumes that a bystander would remain at a distance of 1 meter from the patient 100% of the time. This flawed assumption causes a quadruplicate increase from the occupancy factor of 0.25, which was the standard that was applied in the previous revision to Regulatory Guide 8.39. The previously applied occupancy factor of 0.25 corresponds to approximately six hours of contact per day with a patient, which is sufficient to account for contact a patient is likely to have with any one individual under most circumstances. Further, the NRC provides no data to explain why a more conservative approach to the occupancy factor calculation is necessary to protect the public health.

The Advisory Committee on the Medical Use of Isotopes (ACMUI) was established to advise the NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy.[1] The ACMUI membership includes health care professionals from various disciplines who have an operational understanding of the use of radiopharmaceuticals, and patient representatives who work to ensure the best possible outcome and experience for patients who are treated with them.

In recommendations to the NRC related to the proposed revisions of DG-8061, the ACMUI stated:

> An occupancy factor of 1.0 is unrealistic and cannot be justified for routine application, even for radionuclides with a physical half-life less than one day. The corresponding activity and dose rate values are extremely conservative, and a factor of four lower than what is currently in RG 8.39 Revision 1. This will result in an increased need for licensees to perform patient specific dose calculations and provide patient instructions at activity levels much lower than previously required. This guidance is also not consistent with the record keeping requirement in 10 CFR 35.2075(a), which only requires a record of the release if using an occupancy factor less than 0.25 at 1 meter. <u>It is recommended that the activity and dose rate values in Tables 1 and 2 be calculated with an occupancy factor of 0.25 at 1 meter, to be more realistic and compatible with 10 CFR 35.2075(a).</u>[2]

Because the revised calculation is neither practical nor demonstrated to be in the interest of public health, MITA requests the NRC revert to applying 0.25 at 1 meter for the occupancy factor default value in Tables 1 and 2.

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[1] Nuclear Regulatory Comm'n, Advisory Committee on The Medical Uses Of Isotopes, https://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html.

[2] Nuclear Regulatory Comm'n Advisory Committee on the Medical Use of Isotopes (ACMUI), Final Report (Jan. 21, 2022), ML22021B300, https://www.nrc.gov/docs/ML2202/ML22021B300.pdf (emphasis added).

Second Tier Approach – Overly Burdensome Patient Release Calculations

The NRC acknowledges that the thresholds applied in the first-tier approach include conservative estimates, so DG-8061 provides a second-tier approach whereby treating facilities may apply patient-specific modifying factors to determine whether to hold or release the patient. The NRC proposes that treating facilities must justify the specified value of each patient's modifying factors, including the occupancy factor. Unfortunately, the NRC fails to recognize the improper burden this patient-by-patient calculation will place on treating facilities. Indeed, many community hospitals and treating facilities do not currently employ on-site physics support staff, which would be needed to calculate the proposed patient-specific modifying factors under this approach.

If treating facilities are unable to provide documented support supplied by highly trained technical professionals, they will be faced with two choices: hospitalizing patients or denying them critical therapies. In fact, many treating facilities do not have the physical infrastructure nor staffing capabilities to admit patients for even one night. As proposed, DG-8061 would require those patients currently treated on an outpatient basis to potentially be hospitalized for multiple days. This places an incredible burden on patients, many of whom have late-stage cancer. Patients should not have to stay in a hospital and give up precious days with their loved ones because of overly burdensome regulations. Many radiopharmaceutical patients are already forced to travel great distances to receive life-extending care, and many current treatments are administered at four- or six-week intervals, rather than through a single dose. As revised, DG-8061 could have the effect of eliminating certain life-extending cancer therapies as viable treatment options for critically ill patients, with no countervailing discernable public health benefit.

As proposed, DG-8061 would create significant changes that hospitals and other sites of care would need to operationalize. In addition, the impact to insurers, including Medicare and Medicaid could be significant if drugs currently being reimbursed on an outpatient basis are suddenly required to become part of a more expensive inpatient stay. As noted, some therapies require multiple treatments, which would require multiple hospital stays.

The ACMUI made the following recommendations to the NRC regarding the second-tier approach:

> "The Patient-Specific Modifying Factors and Methods presented in Appendix B, and Example Calculations illustrated in Appendix C, are overly complex and require an unrealistic level of knowledge of extended patient behavior following release. While this calculational methodology is an admirable academic exercise, it is not practical for licensees to use for authorizing and documenting patient release using patient specific factors. Determining "Time Durations" for Travel, Instruction, and Afterward in units of effective half-lives, and the corresponding fraction of time a bystander spends in close contact with the patient during these periods would be unworkable. While the Geometric Modifying Factor accounts for varying bystander separation distances and source-receptor configurations, it again requires an unrealistic detailed knowledge of patient and bystander behavior following release. The Attenuation Modifying Factor tables account for photon scatter, buildup, and absorption at different patient tissue thicknesses, however, buildup is not applicable for distributed sources within the body and accurately determining the

> overlying tissue thickness would be much more challenging than simply measuring the dose rate from the patient after administration of the radiopharmaceutical. To be of practical operational value, the model needs to be simplified, such as that in the current RG 8.39 or the RADAR Patient Exposure Radiation Dose Calculator."[3]

MITA requests that the NRC consider the regulatory, operational, and financial burden that the proposed revisions to DG-8061 would place on treating facilities, and the physical, emotional and financial burdens that could be placed on patients battling life threatening illnesses and their families.

Conclusion

The NRC plays and indispensable role in protecting public health and safety. Unfortunately, the proposed revisions to DG-8061 would impose significant and unjustified regulatory burdens on both patients and providers. MITA respectfully requests the NRC consider revising its overly conservative assumptions used to calculate administered activity and dose rate values in DG-8061, and instead apply a 0.25 occupancy factor to the calculations.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging innovations. These products include magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. MITA Member company technologies are an important part of our nation's healthcare infrastructure and are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.

[3] Id. (emphasis added).