SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

ACNM

September 26, 2019

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Office of Administration
Mail Stop: TWFN-7A06
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Program Management, Announcements and Editing Staff

Re: (Docket ID-NRC-2019-0154) Release of Patients Administered Radioactive Material

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) and American College of Nuclear Medicine (ACNM) offer the following collective comments on the Nuclear Regulatory Commission (NRC) Federal Register Notice "Draft Regulatory Guide DG-8057, Release of Patients Administered Radioactive Material."

By way of background, the SNMMI has more than 15,000 members, including physicians, technologists, scientists, physicists, chemists and pharmacists, all participating in the field of nuclear medicine and molecular imaging. These members set the standard for nuclear medicine practice by creating clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging, therapy, research and the practice of Nuclear Medicine.

For more than 50 years, SNMMI members have developed—and continue to explore—innovations in medical imaging and radionuclide therapy leading to improved noninvasive diagnosis, patient management, and treatment of diseases, with benefit to numerous generations of patients.

The Society includes a Technologist Section, which has a membership of 11,000 professional nuclear medicine technologists. Under the supervision of an Authorized User (AU), nuclear medicine technologists mix, prepare and administer imaging and therapeutic radiopharmaceuticals and operate and monitor the equipment used to image the movement and distribution of these radiopharmaceuticals within the body. Nuclear Medicine technologists are integral in delivering high quality patient care in hospitals, universities, medical clinics and research centers across the United States and abroad. They are particularly essential in the delivery of radiopharmaceutical therapy by providing radiation safety education and protection

to the patient and the public during and after the therapy administration. They administer the therapy dose under the personalized supervision of the AU. Technologists' unique training and education provide a necessary component in the safe treatment of patients and helps assure a successful clinical outcome.

The ACNM is a professional organization that directly represents the interests of Nuclear Medicine physicians before legislative and regulatory bodies, other medical organizations, the media and public. The College comprises physicians and scientists dedicated to enhancing the practice of Nuclear Medicine through the study, education and improvement of clinical practice. The goal of ACNM is to assure a legislative, legal, regulatory and economic framework that encourages and makes practicable the safe, appropriate use of nuclear medicine procedures to improve the quality of health care service available to patients. ACNM, alongside SNMMI, is pleased to offer comments on specific topics detailed below.

Specific Comments

Page 6, bullet 7: For radionuclides with a half-life that is less than or equal to one day, it is easier to justify an occupancy factor of 0.25 as the patient is in the nuclear medicine clinic and their contacts can be controlled.

Page 8, section 1.1: The requested calculations are often obtained by using the RADAR interactive dose calculator; keeping a record of the actual calculations may be difficult for some labs.

Page 11, table 2: Please consider adding F-18, N-13, O-15, Ga-68, Lu-177, I-124 and Ra-223 to the table as these are more commonly used. Ag-111, Au-198, I-125, Re-186, Re-188, Sc-47, Se-75, Sn-117m, or Yb-169 are not commonly used in practice.

Page 12, paragraph 1: The guidance is confusing as the regulatory limit is 500 mrem, not 100 mrem.

Page 12 and 13, table 3: Some of the breastfeeding interruption limits should be revisited. For example, I-123 MIBG should not be 24 hours. It should be "no interruption". The guidance document could also notate the pharmaceutical attached to Ga-68 and Zr-89. It appears there may be confusion regarding Lu-177, a beta-emitting radionuclide which is used as a therapeutic agent.

Please include the 500 mrem calculations.

Page 13, Footnote b, at the end, the NRC states, "For Tc-99m radiopharmaceuticals, rather than a radiopharmaceutical-specific interruption period, a single 24-hour interruption period is recommended. Although this time interval may be longer than necessary for some Tc-99m labeled radiopharmaceuticals, it is compliant with the 0.1-rad dose limit and simplifies the

guidance, thereby avoiding confusion and reducing the likelihood of error." This is confusing as the limit is 0.5 rad, not 0.1 rad. While it may be easier for people to remember, providing a table to facilitate informed discussion in more detail may be useful for patients who want to resume breastfeeding sooner if possible.

Page 16 (1): Children and pregnant women may receive up to 500 mrem just like other adults, and in almost all cases may remain at home. If the child is very young and requires a great deal of care, then another caregiver needs to be present, however, they can be in the same household.

Page 16 (2): It might not be practical to try to stop the patient from cooking for others. If the patient is making food for others, discontinuing cooking would be preferred, however if the patients wash their hands well or use disposable gloves, that could mitigate exposure to others who might eat the food.

P.18 2.4: The Authorized User (AU) Physician should be handling this, rather than the RSO (who is often another physician). Autopsies are very rarely done on these patients.

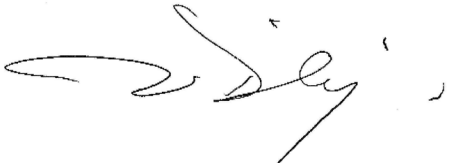
P.19 2.5: We are not aware of any long-lived contaminant in any therapeutic radiopharmaceutical that is present in high enough concentration to be an actual hazard. If NRC has no actual examples, this paragraph should be removed.

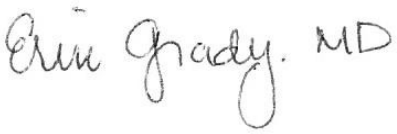
P.20 3.1: Please clarify the following: NRC states that the record should include the patient's identifier. However, at the end of section 3.1 NRC states that the records should not contain the patient's name or any other information that could identify the patient.

Appendix B, Page B-5, Table B-1: The NRC calculates an effective half-life of 5.2 days for the thyroid fraction of a hyperthyroid patient with 80% uptake. The NRC states that it used data from a paper by Stabin MG, et al. However, in looking at the data in that paper, the biological half-life of the thyroidal fraction in a patient with 80% thyroidal uptake did not average 15 days, as NRC states, but averaged 10 days, and the effective half-life is not 5.2 days, as NRC states, but 4.4 days.

SNMMI and ACNM are ready to discuss any of their comments with the NRC. In this regard, please contact Caitlin Kubler, Associate Director, Health Policy and Regulatory Affairs, by email at ckubler@snmmi.org or by phone at 703-326-1190.

Sincerely,





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