August 18, 2023

Office of Administration
ATTN: Program Management, Announcements and Editing Staff
Mail Stop: TWFN-7-A60M
U.S Nuclear Regulatory Commission
Washington, DC 20555

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

On behalf of the American Society of Nuclear Cardiology (ASNC), I am pleased to provide comments on Draft Regulatory Guide (DG), DG-8061, Release of Patients Administered Radioactive Material," Federal Register Vol. 88, No. 77; April 2023.

ASNC is a greater than 4,700-member professional medical society, which provides a variety of continuing medical education programs related to the role of nuclear cardiology in patient-centered cardiovascular imaging, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology.

Current regulations in 10 CFR Part 25 "Medical Use of Byproduct Material" provides requirements for the radiation safety of workers, the public, patients and human research subjects. 10 CFR 35.75(a) further provides that a licensee can authorize the release of any individual from its control who has been administered unsealed byproduct material or implants containing byproduct material if the total effect dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (mSv)(0.5 rem). The 5mSv release limit applies per administration to the patient and is not an annual limit. [1]

In April 2023, NRC released the second phase of the update to Regulatory Guide 8.39 and confirmed the 5(mSv)(.5rem) total effect dose equivalent. However, this revision contained patient release at activity and dose level rates that were significantly more restrictive than those provided in Revision 1 of Regulatory Guide 8.39.

We are concerned with the application of the highly conservative assumptions used to calculate patient release calculations (particularly the occupancy factor of 1.0) in Revision 2 of Regulatory

[1] Regulatory Guide 8.39, Release of Patients Administered Radioactive Materials. (nrc.gov)

Guide 8.39. ASNC members use radiopharmaceuticals (Tc-99m, N-13, and Rb-82) several of which are radionuclides that would not have activity thresholds that apply because of the minimal exposures to bystanders resulting from dosages normally administered for diagnostic purposes. However, we are concerned with the prospect of more conservative assumptions used in patient release thresholds given that future research could yield radionuclides where activity thresholds would apply. We are also generally concerned that more restrictive assumptions result in regulatory requirements that will result in costly and complex reactive management including additional staff time, inconvenience to patients, and more documentation requirements. Where more conservative assumptions are warranted by scientific data, ASNC would be fully supportive of more stringent assumptions.

ASNC supports the recommendation of the Advisory Council on the Medical Use of Isotopes (ACMUI) and asks the NRC to replace the 1.0 occupancy factor used in calculations in DG-8061 with the reasonable assumption of a .25 occupancy factor.

Sincerely,

Mouaz Al- Mallah, MD

President,

American Society of Nuclear Cardiology