December 15, 2023

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemaking and Adjudications Staff
Docket ID NRC–2018–0297

RE: DOCKET ID NRC-2018-0297, "RUBIDIUM-82 GENERATORS, EMERGING TECHNOLOGIES, AND OTHER MEDICAL USE OF BYPRODUCT MATERIAL" FEDERAL REGISTER VOL.88 NO.126; JULY 3, 2023

The American Society of Nuclear Society (ASNC) is pleased to provide comment to the Nuclear Regulatory Commission (NRC) on Rubidium-82 Generators, Emerging Technologies, and other Medical Use of Byproduct Material" published by notice in the *Federal Register* on July 3, 2023.

ASNC is a greater than 4,900-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.

The Nuclear Regulatory Commission (NRC) requests feedback from stakeholders on adding requirements for calibration and dosage measurement for strontium-82/rubidium-82 generators and on establishing performance-based requirements for existing and future emerging medical technologies. In addition, the NRC solicits input from experts on training and education requirements, including whether device-specific training should be required for authorized users or whether current requirements are sufficient.

Question A.1.1: Please provide comments on the need for radiation safety officers to have specific training for all generator systems licensed under 10 CFR part 35, subpart D, "Unsealed Byproduct Material—Written Directive Not Required." If general awareness on radionuclide generators, including their functions and risks, is sufficient, explain why.

ASNC believes it is reasonable to require radiation safety officers (RSOs) to have specific training for all generator systems licensed under 10 CFR part 35, subpart D, "Unsealed Byproduct Material- Written Directive Not Required" provided such training is not overly onerous. In addition, ASNC believes such training should be vendor specific and vendor provided for any generator which their lab is actively using. ASNC believes it is important for

required training to include specifics on generator function and radionuclide characteristics, prescribing information, dosing information, and quality control protocols.

The NRC is considering amending the requirement in § 35.63, "Determination of dosages of unsealed byproduct material for medical use," to clarify that, for the incremental administration of rubidium-82, dose measurements do not have to be complete before administration when the dose is measured continuously during the infusion of Rb-82 from a generator to the patient.

ASNC agrees that the NRC should clarify that for the incremental administration of rubidium-82, dose measurements do not have to be complete before administration given that the 75 second half-life of Rb-82 makes a proper assay of the dose impossible.

Moreover, 10 CFR §35.204 (a)(2) states that licensees cannot administer a dose to a human of a radiopharmaceutical that contains "More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82." To that end, 10 CFR §35.204 (c) further requires "(c) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (a) of this section." Thus, the approved protocols of a daily Sr-82 breakthrough assay provide adequate protection.

Question A.1.3: The NRC has found that AUs authorized under § 35.290, "Training for imaging and localization studies," have sufficient understanding of radionuclide generators, and the NRC is considering revising § 35.27, Supervision," to require device-specific training requirements for supervised individuals. Please provide comments with a rationale on whether § 35.290 AUs should also be required to have device-specific training for all radionuclide generators for which they supervise the use.

ASNC agrees that AUs authorized under §35.290, "Training for imaging and localization studies," have sufficient understanding of radionuclide generators. ASNC supports requirements for §35.290 AUs to have device-specific training for all radionuclide generators for which they supervise the use provided such training is reasonable in time and scope and is not overly burdensome. Required training should include specifics on generator function and radionuclide characteristics, prescribing information, dosing information, and quality control protocols.

ASNC appreciates the opportunity to share feedback with the Nuclear Regulatory Commission and is available to provide any additional information if needed. Please contact Georgia Lawrence, Director, Regulatory Affairs at glawrence@asnc.org for any questions.

Sincerely,

Mouaz Al Mallah, MD

President,

American Society of Nuclear Cardiology