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December 15, 2023

Secretary

US Nuclear Regulatory Commission

Washington, DC 20555-0001

Attn: Rulemakings and Adjudications Staff

Re: Rubidium-82 Generators, Emerging Technologies, and Other
Medical Use of Byproduct Material [Docket No. NRC-2018-
0297] Regulatory Basis

To whom it may concern:

The American Society for Radiation Oncology¹ (ASTRO) appreciates the opportunity to comment on the Nuclear Regulatory Commission's (NRC) Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material Regulatory Basis. The regulatory basis serves as a precursor to the proposed rule, providing background, proposed policy, and technical changes to current regulations, and identifies different approaches to addressing regulatory issues. The rulemaking will focus on two areas: Rubidium-82 generators and moving technologies (such as Gamma Knife and Y-90 microspheres) from 10 CFR 35.1000 into the regulations. Currently, these and other technologies are regulated by guidance.

ASTRO believes that care must be taken to ensure that the fundamental requirements found in current licensing guidance documents are maintained. We recommend that those sections of current licensing guidance documents pertaining to patient safety be incorporated into the regulations without substantive changes, ensuring that these protections, such as physical presence requirements for gamma stereotactic radiosurgery, are maintained. This will avoid licensee confusion and aid in the implementation of the revised regulations. We also caution the NRC against adding additional regulatory burdens for licensees.

Below, please find our responses to selected questions asked in the Regulatory Basis.

¹ ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

Question A.6.1: Please provide comments on the need for model-specific training for radiation safety officers for certain 10 CFR part 35, subpart H devices. If model-specific training is needed, how should the NRC determine which devices would require such training?

ASTRO Response: If the Food and Drug Administration, during its evaluation of a new or modified device, determines that significant alterations in hardware or software have occurred, the manufacturer must certify the device. When this occurs, authorized users and radiation safety officers should undergo training after FDA approval of the device, prior to use. For novel injected unsealed sources, vendor specific information should be provided to the radiation safety officer, but novel source training should only be required if it is substantially different from existing unsealed sources, and if the decay is not alpha or beta emitting (i.e., higher energy photon decay), or if the method of injection is substantially different (i.e., not a liquid injectable substance).

Question A.7.3: As the complexity of the medical use of byproduct material increases, use of teams in medical care is becoming more common. Please provide comments on the fundamental elements of a successful team-approach program.

ASTRO Response: Cancer care is multidisciplinary and often involves radiation oncologists, surgeons, medical oncologists, diagnostic radiologists, pathologists, internists (e.g., gastroenterology, pulmonary, neurology), social works and others. Communication between disciplines is challenging but exceedingly important as treatment approaches involve multiple disciplines. The table below describes interdisciplinary and multidisciplinary approaches to quality in cancer care delivery.²

Radiation Oncology	Analogous Multidisciplinary
Pretreatment clinical team discussion	Tumor board
Daily morning huddle	Regular multidisciplinary meetings to review patients under treatment
Determining unambiguous methods of communication between clinical staff in the oncology information system	Determining unambiguous methods of communication between multidisciplinary care providers in an oncology-specific or health system-wide electronic health record
Safety rounds within radiation oncology	Safety rounds within the health system
Safety culture amongst radiation oncology staff	Safety culture within the health system
Discipline-specific training	Team training

Clear communication among team members is vital. Well-defined roles and responsibilities are essential within the team, preventing ambiguity and reducing the risk of errors. Each team member should understand their scope of practice and the

² American Society for Radiation Oncology. *Safety is No Accident: A Framework for Quality Radiation Oncology Care*. 2019 Edition. Available at: https://www.astro.org/ASTRO/media/ASTRO/Patient%20Care%20and%20Research/PDFs/Safety_is_No_Accident.pdf, accessed December 11, 2023.

limits of their authority. Continual education and training are indispensable in the ever-evolving field of medicine, where technology advances regularly. Staying updated on the latest advancements in their respective areas is vital and team members must stay updated on the latest advancements in their respective areas to provide the safe and effective care. Quality assurance and safety measures must be integrated into the team's approach, encompassing regular safety checks, adherence to regulations, and proactive risk identification and mitigation. Patient-centered care should be at the forefront, tailoring individualized treatment plans. Teams should regularly review outcomes and performance metrics, allowing for ongoing enhancement of protocols and procedures.

Once it is decided that a novel unsealed source is the proper clinical course of action, a team is needed for the successful and safe administration of the unsealed source. This team is led by the Physician Authorized User. Each team member has a specific role depending on the phase of treatment (preparation of the room, patient preparation, verification of dose, administration of the radiotherapeutic, post-injection monitoring, recording of dose administration, assay and release of the patient, and release of the room). As well, the details of administration may vary depending on the specific radiotherapeutic injected, but generally, the team will involve, at minimum, the physician, oncologist, nurse, and radiation safety officer (who could also be the physicist or oncologist, depending on the institution).

Question A.8.4: Due to the increased number and complexity of EMTs, please comment on why the NRC should or should not require continuing education for AUs. If continuing education should be required, what should it entail, at what frequency should it be acquired, and how should knowledge topics be acquired?

ASTRO Response: Radiation oncologists are already required, through maintenance of certification (MOC) requirements, to complete 75 hours of continuing medical education hours, and a practice quality improvement project every three years. Radiation oncologists must maintain their state licensure, which may have additional requirements. Radiation oncologists must also participate in the Online Longitudinal Assessment (OLA) which measures their knowledge, judgement, and skills on a weekly basis. This is a continuous certification and radiation oncologists are assessed every three years to make sure they are compliant with all MOC requirements.

Requiring additional continuing education will add additional burdens and will take away physician autonomy to direct their own education. Further, ASTRO questions whether the NRC, and the Agreement States, have the resources to track compliance with such a requirement.

Question A.8.6: Please comment and provide a rationale for whether physicians authorized for full use under § 35.300 need additional T&E to fulfill their radiation safety-related duties and supervision roles because of expected emerging therapeutic radiopharmaceuticals. Please comment on why additional training is or is not needed on regulatory requirements for emerging therapeutic radiopharmaceuticals. If needed, what topics should the T&E include?

What specific training should these AUs be required to have (*e.g.*, vendor training on clinical use and safety procedures) prior to first-time use, if any? Why should they be required or not required to have continuing education?

ASTRO Response: ASTRO believes that current training and experience requirements for radiopharmaceuticals are sufficient and should be maintained. Radiation Oncologists are uniquely qualified to administer radiopharmaceuticals and welcome vendor training on clinical delivery and safety procedures when there are variations in administration. However, we caution the NRC about imposing additional regulatory burden when this training is already built into the process of radiopharmaceutical delivery.

ASTRO thanks the NRC for the opportunity to provide comments on the regulatory basis. We look forward to continuing to work with the Commission on this and other important issues. Should you have any questions, please do not hesitate to contact Cindy Tomlinson, ASTRO's Senior Manager for Patient Safety and Regulatory Affairs at cindy.tomlinson@astro.org or 703.839.7366.

Sincerely,

A handwritten signature in cursive script that reads "Laura Thevenot".

Laura I. Thevenot
Chief Executive Officer