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May 11, 2021

Christopher Hanson, Chairman
Nuclear Regulatory Commission
Mail Stop O-16 B33
Washington, DC 20555-0001

Dear Chairman Hanson,

I am writing on behalf of the American Society for Radiation Oncology (ASTRO) to express concern over the staff's recommendation to initiate rulemaking to establish requirements for rubidium-82 (Rb-82) generators and emerging medical technologies (EMTs), dated February 9, 2021.

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.

The rulemaking plan outlined in the proposal would revise outdated, prescriptive quality assurance regulations with risk-informed, performance-based quality assurance programs, improving the overall flexibility of the NRC's medical regulations in 10 CFR Part 35, *Medical use of byproduct material* and better accommodating of future EMTs.

The staff outlined the following three rulemaking options:

1. Address Rb-82 generators only.
2. Address Rb-82 generators along with a subset of current, well-established emerging medical technologies (such as gamma stereotactic radiosurgery (GSR) and Y-90 microspheres).
3. Address Rb-82 generators along with all current, well-established emerging medical technologies, plus create added flexibility throughout 10 CFR Part 35 to accommodate future emerging medical technologies, such as "radiotheranostics" and novel designs within manual brachytherapy, such as Radiogel and AlphaDaRt seeds.

The staff is recommending Option 3. ASTRO has no position on adding requirements to address calibration and dosage measurement for Rb-82 generators. However, while we agree that it is time to update 10 CFR Part 35 to take into consideration those technologies currently licensed under 10 CFR 35.1000, *Other Medical Uses of Byproduct Material or Radiation from Byproduct Material*, and the need for flexibility in regulating future EMTs, we are concerned about the implementation of the staff's recommendation.

Implementing either Option 2 or Option 3 would allow the NRC to move current licensing guidance into the regulations, either by making changes to current requirements, or adding new sections to the rule. In either case, care must be taken to ensure that the fundamental requirements found in current licensing guidance documents are maintained. This will avoid licensee confusion and aid in the implementation of the revised regulations.

We caution the Commission that opening rulemaking on all of Part 35 to add flexibilities for EMTs (Option 3) could result in unintended consequences, such as weaking of training and experience requirements (T&E) for radiopharmaceuticals. As you are aware, ASTRO opposes the staff's recommendations to make changes to the current T&E requirements[1]. If the Commission were to deny that request, but approve this request, we are concerned that this could lead to unnecessary changes to current T&E requirements, especially if "radiotheranostics" are included as EMTs. As described in *A Framework for Patient-Centered Pathways of Care for Radiopharmaceutical Therapy: An ASTRO Consensus Document*[2]*:*

> "(T)heranostics is an innovative and rapidly evolving type of [radiopharmaceutical therapy] RPT that most commonly merges a molecularly targeted diagnostic radiopharmaceutical with an RPT. The term *theranostics* is most broadly applied as linking a diagnostic and therapeutic process, including diagnostic laboratory tests and a therapeutic agent, neither necessarily radioactive. The term *radiotheranostics* can be applied for greater specificity."

We recognize the increased number of "radiotheranostic" agents coming to market; however, the fundamental planning, prescribing, and administering of these agents is no different than the administration of a diagnostic or therapeutic radiopharmaceutical delivered separately, rather than in tandem, and we question the inclusion of these agents in the rulemaking plan.

Therefore, we recommend that if Option 3 is approved, the Commission issue strict guidelines for the implementation. This will ensure that the rulemaking is focused on true emerging medical technologies and important patient safety provisions, and not changes to already existing provisions.

For the reasons discussed above, we recommend the Commission direct staff to exclude radiotheranostics from the proposed rulemaking plan.

In addition, we recommend that the Commission direct staff to incorporate current licensing guidance for Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™[3],

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[1] Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35). SECY-20-0005. January 13, 2020.
[2] JM Buatti, DA Pryma, AP Kiess, et al. "A Framework for Patient-Centered Pathways of Care for Radiopharmaceutical Therapy: An ASTRO Consensus Document." *International Journal of Radiation Oncology Biology Physics* (2021), vol. 109, issue 4, P913-922.
[3] Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon, Licensing Guidance, January 10, 2019, Revision 1.

ViewRay™ System for Radiation Therapy[4], and Xcision® GammaPod™[5] into 10 CFR 35.600, *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit*, or into a new section of Part 35 if 10 CFR 35.600 is deemed inappropriate. We also recommend that the Commission direct staff to add new sections within Part 35 for yttrium-90 (Y-90) microspheres, and not try to incorporate the licensing guidance for these into existing sections of Part 35. We further recommend that those sections of current licensing guidance documents pertaining to patient safety be incorporated into the regulations without substantive changes. This will ensure that current patient safety protections, such as physical presence requirements for gamma stereotactic radiosurgery, are maintained.

In summary, while we generally support the staff's recommendation, we urge caution to ensure current patient safety, and other important requirements are maintained during the rulemaking process.

We appreciate the opportunity to work with the NRC on this important issue. Should you have any questions, please contact Cindy Tomlinson, Senior Patient Safety and Regulatory Affairs Manager at cindy.tomlinson@astro.org or 703.839.7366.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

CC: Commissioner Jeff Baran
Commissioner Annie Caputo
Commissioner David Wright

[4] ViewRay System for Radiation Therapy, Licensing Guidance, July 24, 2013.
[5] Xcision GammaPod, Licensing Guidance, January 22, 2020.