ASTRO
TARGETING CANCER CARE

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April 25, 2019

Kristine L. Svinicki, Chairman
Nuclear Regulatory Commission
Mail Stop O-4F00
Washington, DC 20555-0001

Dear Chairman Svinicki –

On behalf of the American Society for Radiation Oncology (ASTRO)[1], we would like to reaffirm our important working relationship with the Nuclear Regulatory Commission on issues related to the security of radioactive materials used in the treatment of cancer. We are sorry that we were unable to schedule a meeting with you in May. We appreciate your consideration of our meeting request and understand that schedules don't always align. Below are brief descriptions of the items we had hoped to discuss.

Government Accountability Office (GAO) Report, "Combating Nuclear Terrorism: NRC Needs to Take Additional Actions to Ensure the Security of High-Risk Radioactive Material", published March 14, 2019

ASTRO followed the development of this report very closely and has serious concerns about the recommendations offered by GAO. As you know, ASTRO is committed to ensuring the safe use and availability of radioactive materials to treat cancer, and if these recommendations are followed, patients might lose access to life-saving treatments. Our specific comments on the three recommendations are below.

1. *The Chairman of NRC should direct NRC staff to consider socioeconomic consequences and fatalities from evacuations in the criteria for determining what security measures should be required for radioactive materials that could be used in an RDD.*

   Including socioeconomic consequences and fatalities from evacuations into the decision-making process will shift NRC considerations away from measuring the risks and benefits of radioactive materials using science, and could end up restricting access to life-saving radioactive materials. We agree with the NRC's assessment that the current Part 37 regulations are sufficient to protect the health and safety of the public.

2. *The Chairman of NRC should require additional security measures for high-risk quantities of certain category 3 radioactive material, and assess whether other category 3 materials should also be safeguarded with additional security measures.*

[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.

Without knowing which category 3 radioactive materials the GAO is referencing, it is hard for us to comment on this recommendation with any specificity. While the materials used in radiation oncology are generally category 2 or 4, without a specific definition of "quantity of category 3" material, there is a possibility that certain amounts of some category 4 materials could fall under this definition.

3. *The Chairman of NRC should require all licensees to implement additional security measures when they have multiple quantities of category 3 americium-241 at a single facility that in total reach a category 1 or 2 quantity of material.*

   While this recommendation does not affect ASTRO members on the surface, we are concerned that the NRC could be forced to broaden the recommendation to include other radioactive materials, adversely affecting patients' access to life-saving treatments.

We would like to offer our expertise to the NRC to help in any decision making resulting from the GAO report, and we hope that as you work through a plan of action you avoid changes to current regulations that would unnecessarily restrict patient access to life-saving treatments.

Training and Experience Requirements for Radiopharmaceuticals

We appreciate the NRC doing its due diligence in reviewing current training and experience (T&E) requirements. As we have mentioned in previous statements and comment letters, ASTRO supports periodic review of the requirements and supports the work being done by the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI), as well as by the NRC staff, to thoroughly review the data and engage stakeholders in this process. We continue to believe that the excellent safety record for radiopharmaceuticals can be attributed to the required training and experience for authorized users, and therefore should not be changed.

Further, we are pleased that in February, the ACMUI validated ASTRO's position that the current Authorized User (AU) pathways found under 10 CFR 35.300, *Use of unsealed byproduct material for which a written directive is required,* are sufficient, and that there is no objective data to confirm an AU shortage. ASTRO supports the ACMUI's position that a limited-scope AU pathway is not necessary, something that the NRC sought comments on in its request for information.

Physical Presence Requirements for Gamma Knife Perfexion or Icon

We appreciate the work that the Commission has done on revising the current physical presence requirements for Gamma Knife. The most recent guidance document reads:

Therefore, Perfexion™ or Icon™ unit licensees should confirm they are meeting the requirements in 35.615(f)(3) or the following:

1) *An authorized user and an authorized medical physicist will be physically present during the initiation of all patient treatments involving the Perfexion™ or Icon™ unit;*

2) *An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the Perfexion™ or Icon™ unit; and*
3) *An authorized user will return to the Perfexion™ or Icon™ unit console if there is an interruption of treatment to evaluate the patient, to review any information related to an abnormal situation, and to ensure that the treatment is being delivered in accordance with the treatment plan and written directive prior to re-initiation of the treatment.*

We are pleased that this guidance document strikes the appropriate balance between safety and efficient medical practice, and is in line with ASTRO's position on physical presence requirements for Gamma Knife.

We look forward to continuing to work with the NRC on this and other issues affecting the practice of radiation oncology, and hope that we can coordinate our schedules to meet soon. Should you have any questions, please contact Cindy Tomlinson, Senior Manager for Patient Safety and Regulatory Affairs, at 703-839-7366 or cindy.tomlinson@astro.org.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

CHAIRMAN Resource

From: Cindy Tomlinson <cindy.tomlinson@astro.org>
Sent: Thursday, April 25, 2019 9:44 AM
To: CHAIRMAN Resource
Subject: [External_Sender] Letter from ASTRO
Attachments: Svinicki Letter 4.25.19.pdf

Please find attached a letter from the American Society for Radiation Oncology (ASTRO). Should you have any questions, please do not hesitate to contact me.

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