



February 8, 2021

Christopher Hanson, Chairman  
Nuclear Regulatory Commission  
Mail Stop O-4F00  
Washington, DC 20555-0001

Dear Chairman Hanson,

The American Society for Radiation Oncology<sup>1</sup> (ASTRO), the American Association of Physicists in Medicine<sup>2</sup> (AAPM), the American College of Radiology<sup>3</sup> (ACR), and the Society of Nuclear Medicine and Molecular Imaging<sup>4</sup> (SNMMI) would like to draw your attention to [report language](#) included in the FY 2021 House Energy and Water Development and Related Agencies Appropriations Bill.

The language reads:

*The Committee encourages the Commission to ensure that patient safety is at the forefront of its examination of training and experience requirements for radiopharmaceuticals and to work with the medical community to ensure that important patient safeguards and the safety record of radiopharmaceuticals are maintained.*

We agree with Congress and believe that maintaining the status quo is appropriate and that it protects the safety of patients, the public, and practitioners. Current NRC regulations ensure that patients have access to safe and effective treatments. However, in January 2020, NRC staff sent

---

<sup>1</sup> 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.

<sup>2</sup> AAPM, the premier organization in medical physics, both in the U.S. and abroad, represents over 9,000 medical physicists. The mission of AAPM is to advance medicine through excellence in the science, education and professional practice of medical physics--a scientific and professional discipline that uses physics principles to address a wide range of biological and medical needs. Clinically, medical physicists work side by side with radiation oncologists to design treatment plans and monitor equipment and procedures to ensure that cancer patients receive the prescribed dose of radiation at the correct location. Medical physicists also contribute to the effectiveness of medical imaging by ensuring the safe and effective use of radiant energy (e.g., optical, ionizing, ultrasonic, or radiofrequency) to obtain detailed information about the form and function of the human body.

<sup>3</sup> ACR is a professional association representing more than 40,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists.

<sup>4</sup> SNMMI's more than 16,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research, and practice.

recommendations to the Commission that, if implemented, would weaken the current Training and Experience (T&E) requirements for radiopharmaceuticals. We believe that weakening the current training requirements for the safe administration of radiopharmaceuticals will put patients at risk.

The NRC's focus on patient safety and the safety of the general public as it develops training and experience requirements is appropriate. The NRC determined that the level of training required to administer these agents must include either NRC-recognized board certification or completion of specified "alternate pathway" T&E prerequisites, including 700 hours of training and experience. The 700 hours of T&E currently also serve as NRC's de facto board recognition criteria. Beyond NRC's minimum requirements, additional classroom and clinical experiences encompassed by radiation oncology, radiology, nuclear medicine, and other radiological training programs provide the appropriate level of knowledge and skill necessary to safely administer current and future radioactive agents. We believe that the necessary depth of knowledge and expertise comes with the didactic and hands-on experience of the current T&E requirements.

Reducing the current T&E requirements or changing them to encourage non-expert use could put patients and the public at risk and undermine NRC's other regulatory safeguards that rely on authorized users (AU) expertise, such as medical event recognition and reporting. The excellent safety record for radiopharmaceuticals can be attributed to the required T&E for AUs. Additionally, as noted in a presentation to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on March 20, 2020, the following events were reported to the NRC during 2019:

- 1 event using Ra-223 dichloride,
- 3 events using Lutetium-177,
- 1 event using Samarium-153, and
- 3 events using Iodine-131.

This is a very small number of events compared to CMS utilization data showing that there were approximately 9,200<sup>5</sup> therapeutic radiopharmaceutical administrations performed in 2019 (0.09%).

We would also like to draw your attention to the 2019 ACMUI "Training and Experience for All Modalities" Subcommittee [report](#) that reviewed Accreditation Council for Graduate Medical Education (ACGME) training program data, along with American Boards of Radiology (ABR), Nuclear Medicine (ABNM) and Osteopathic Radiology data. With the current pipeline of AUs in training for 10 CFR 35.390 along with currently practicing AUs and those who graduate annually, the subcommittee concluded that "there are no objective data to support an AU shortage at the present time."

Accordingly, we urge the Commission to follow the advice of its own ACMUI and [maintain the status quo](#).

---

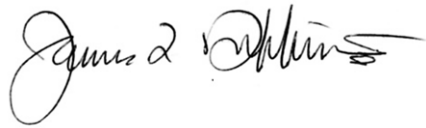
<sup>5</sup> Data obtained from the American Medical Association's RBRVS database.

We appreciate the opportunity to work with the NRC on this important issue. If you have any questions, please contact Cindy Tomlinson, Senior Manager for Patient Safety and Regulatory Affairs, ASTRO, at 703.839.7366 or [cindy.tomlinson@astro.org](mailto:cindy.tomlinson@astro.org).

Sincerely,



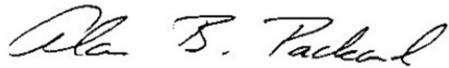
Laura I. Thevenot  
Chief Executive Officer  
American Society for Radiation Oncology



James T. Dobbins, III, PhD, FAAPM  
President  
American Association of Physicists in Medicine



Howard B. Fleishon, MD, MMM, FACR  
Chair, Board of Chancellors  
American College of Radiology



Alan B. Packard, PhD  
President  
Society of Nuclear Medicine and Molecular Imaging

CC: Commissioner Jeff Baran  
Commissioner Annie Caputo  
Commissioner David Wright