SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

January 24, 2017

Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Re: Training and Experience Requirements for Authorized Users of Alpha and Beta Emitters

Dear Chairman Burns:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) would like to provide follow-up comments from the recent Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Use of Isotopes (ACMUI) meeting on October 8-9 and teleconference on August 12, regarding the training and experience requirements for authorized users of alpha and beta emitters. SNMMI's more than 17,000 members set the standard for molecular imaging and nuclear medicine practice through the creation of clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice. SNMMI is pleased to offer comments on specific topics detailed below.

The Society of Nuclear Medicine and Molecular Imaging feels that reducing the number of hours of training requirements for parenteral radionuclide therapies to any less than 700 hours will significantly compromise the level of care for the patients receiving these treatments. As you are aware, this is a complex component of clinical nuclear medicine practice, one that requires not only deep fundamental knowledge of radiation biology and radiation safety but also of indications, contraindications and safety precautions of these treatments. In addition, the administering physician needs to be fully prepared to handle any minor or major radiation spills that may have patient and health personnel safety implications as well as major regulatory implications at the local, state and federal levels.

Decreasing the number of hours of the training requirement will make it easier for physicians without appropriate imaging and therapy training background to get trained and certified to administer radionuclide treatments, which can result in major compromise in healthcare, as explained below. While other clinicians may have a complete understanding of a patient specific condition or disease state, they lack the training and experience necessary to handle radioactive materials and safely treat patients.

We feel that a fundamental basis for the 700-hour requirement is within the context of a training program in a related field of medicine, i.e. Diagnostic Radiology, Nuclear Medicine, or Radiation Oncology. Therefore, this 700-hour requirement is not in isolation but rather over and above the thousands of hours of training spent in understanding the field of imaging and of radiation biology. This additional perspective is important because well before making a decision to treat with parenteral radionuclides one has to be able to perform comprehensive imaging review of presence and extent of disease to ensure that patients selected for the treatment are the ones most likely to benefit from these treatments. More importantly, this background imaging knowledge allows imaging physicians to appropriately exclude the patients unlikely to benefit from this treatment, or even worse, likely be harmed by this treatment. SNMMI believes that the Authorized User requirement is not for a specific therapeutic agent, however, applies to all parenterals now and in future. In summary, we are strongly opposed to reduction of hours of training and experience requirements to any less than current level of 700 hours.

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As always, SNMMI is ready to discuss any of its comments with the NRC. In this regard, please contact Caitlin Kubler, Senior Manager, Regulatory Affairs, by email at ckubler@snmmi.org or by phone at 703-326-1190.

Sincerely,

Sally Schwarz, MS, RPh, BCNP
SNMMI President