

November 18, 2014

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

Re: Nuclear Regulatory Commission: 10 CFR Part 35 [NRC-2008-0175]; Medical Use of Byproduct Material

Dear Chairman Macfarlane:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) appreciates the opportunity to respond to the Commission's request for comments regarding the possible amendment of regulations related to the medical use of byproduct material. SNMMI's more than 18,000 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.

Revise Part 35 to Allow Assistant/Associate RSOs on a License

The proposed rule would change the training and experience (T&E) requirements for authorized users, medical physicists, Radiation Safety Officers, and nuclear pharmacists. Licensees would now be allowed to appoint a qualified individual with expertise in certain uses of byproduct material to be named on a license to serve as an Associate Radiation Safety Officer (ARSO). These changes would make it easier for an individual to become a Radiation Safety Officer (RSO) on other medical licenses and would increase the number of individuals who would be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs. SNMMI supports relaxing the qualifications for the assistant/associate RSOs to allow on-the-job training while serving in the assistant/associate capacity. Additionally, SNMMI recommends that NRC allow authorized users (AU), authorized nuclear pharmacists (ANP), or authorized medical physicists (AMP) to serve as RSOs on individual licenses for private practices (i.e. non-hospital sites).

Exception of Board Certified Individuals from T&E Requirement

The proposed changes to NRC 10 CFR part 35 would also amend training and experience requirements in multiple sections to remove the need to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. It is the NRC's belief that certification by a specialty board, coupled with meeting the current training requirements, is sufficient to demonstrate that an individual seeking authorization on a license has met the T&E requirements and has the necessary knowledge.

SNMMI endorses retaining the attestation requirement for those individuals pursuing initial board certification and alternate pathways, with attestation provided by preceptors with similar status (AUs, RSOs, AMPs and ANPs) with whom the individual trained. Retaining the preceptor attestation helps ensure accountability and credibility by

clearly identifying an authorized user who can attest that the individual has satisfactorily completed the required NRC training.

Molybdenum Breakthrough Tests After Each Elution and Required Reporting of Failed Molybdenum Breakthrough Tests

Finally, the proposed rule would change the requirements for measuring the Molybdenum-99 (Mo-99) concentration for elutions of Mo-99m/technetium (Tc) generators as well as adding reporting requirements for failed Mo-99/Tc-99m and strontium-82 (Sr-82)/rubidium-82 (Rb-82) generators. The current requirement to measure the Mo-99 concentration after the first elution each day would be changed to require that the Mo-99 concentration be measured in each eluate because of several incidents of excessive breakthrough reported to the NRC. Current standards of practice as well as manufacturers recommendations already include breakthrough testing for every generator elution. Therefore, SNMMI endorses this recommendation, and recognizes that codifying it into regulation would not impose any additional burden on licensees.

SNMMI is pleased to provide comments to the NRC on proposed revisions to 10 CFR Part 35. As always, SNMMI is ready to discuss any of its comments with the NRC. In this regard, please contact Susan Bunning, Director of Health Policy & Government Affairs, by email at sbunning@snmmi.org or by phone at 703-326-1182.

Sincerely,



Virginia Pappas, CAE
Chief Executive Officer