

SNMMI Comments on NRC Part 35 and Part 20 Rules

On November 18 and 20, 2014, SNMMI submitted comments on the Nuclear Regulatory Commission (NRC) 10 CFR Part 35 Proposed Rule and Part 20 advance notice of proposed rulemaking. Part 35 changes included updates for the medical use of byproduct material, specifically, medical event definitions, training and experience, and clarifying amendments. The society's comments on Part 35 pertained to: (1) an update to allow an assistant/associate radiation safety officer (RSO) on an NRC license; (2) a new exception of board-certified individuals from certain training and experience requirements; and (3) the performance of ^{99}Mo breakthrough tests after each elution and required reporting of failed tests. Part 20 changes and comments addressed elements of radiation protection regulation. These comments are detailed here.

(1) SNMMI noted that the proposed changes would make it easier for an individual to become an RSO on other medical licenses and would increase the number of individuals available to serve as preceptors for individuals seeking to be appointed as RSOs or assistant/associate RSOs. As a result, the society expressed support for relaxing the qualifications for the assistant/associate RSOs to allow on-the-job training while serving in the assistant/associate capacity. In addition, SNMMI recommended that NRC allow authorized users (AUs), authorized nuclear pharmacists (ANPs), or authorized medical physicists (AMPs) to serve as RSOs on individual licenses for private practices (i.e., nonhospital sites).

(2) SNMMI also endorsed 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 individuals trained. SNMMI noted that "retaining the preceptor attestation helps ensure accountability and credibility by clearly identifying an AU who can attest that the individual has satisfactorily completed the required NRC training."

(3) SNMMI endorsed the recommendation to change requirements for measuring ^{99}Mo concentration for elutions of $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ generators, as well as to add reporting requirements for failed $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ and $^{82}\text{Sr}/^{82}\text{Rb}$ generators, and acknowledged that codifying these requirements into regulation would not impose additional burdens on licensees. The current requirement to measure the ^{99}Mo concentration after the first elution each day would be changed to require that the ^{99}Mo 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.

The society's comments on Part 20 addressed several issues in radiation protection, including methodology and terminology, occupational dose limit for the lens of the eye, dose limit for the embryo/fetus of a declared pregnant occupational worker, individual protection, metrication, and reporting of occupational exposure. SNMMI's comments were consistent with previous positions on these issues, with the exception of the occupational dose limit for the lens of the eye and adoption of new methodology and terminology. The society stated that the proposed decrease in occupational dose limit for the lens of the eye should likely be lowered to new standards, as proposed by the International Commission on Radiological Protection (ICRP) publication on *Tissue Reactions in Normal Tissues and Organs—Threshold Doses for Tissue Reactions in a Radiation Protection Context*. This perspective came from new information regarding the threshold for cataracts, which appears to be lower than previously believed. Despite cataracts being a surgically correctable condition (unlike most other radiation-induced morbidities), the society believes that the efforts to reduce such disease can and should be enacted in its prevention.

In addition, SNMMI recommended the adoption of the current methodology and terminology associated with effective dose (ED) and total effective dose (TED), noting that this is consistent with current publications, although some level of effort may be needed to implement these changes. To date, the NRC has utilized the methodology as described in ICRP Report 26 and the definition of effective dose equivalent and total effective dose equivalent, as opposed to ED and TED as described in ICRP Report 103.

If NRC develops draft supporting guidance for a proposed 10 CFR Part 20 rulemaking, then the public will have an opportunity to provide comments on the draft guidance. If the NRC decides not to pursue a 10 CFR Part 20 rulemaking on this topic, the NRC will publish a document in the *Federal Register* that will generally address public comments and withdraw the Advanced Notice of Proposed Rulemaking. The SNMMI comments on Part 35 are available at http://snmmi.files.cms-plus.com/docs/hpra/NRC%20-%20Part%2035%20Comments112014_FINAL.pdf. Comments on Part 20 are available at: http://snmmi.files.cms-plus.com/docs/hpra/NRC%20-%20Part%2020%20Comments_Final.pdf.

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