



Advancing Molecular Imaging and Therapy

DPR 35
(76FR29171)

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September 15, 2011

September 22, 2011 (3:18 pm)

U.S. Nuclear Regulatory Commission
Gregory B. Jackzo, Commissioner
Washington, DC 20555-0001

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

VIA ELECTRONIC SUBMISSION

Re: Nuclear Regulatory Commission: 10 CFR Part 35 [NRC-2008-071 and NRC-2008-0175]; Medical Use Regulations

Dear Dr. Jackzo:

The Society of Nuclear Medicine appreciates the opportunity to respond to the Commission's request for comments as posted in the *Federal Register* notice on May 20, 2011. The Society of Nuclear Medicine's (SNM) 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. SNM is pleased to offer comments on specific topics detailed below.

Amending Preceptor Attestation Requirements

Currently, there are three pathways for an individual to meet requirements in order to be approved as a Radiation Safety Officer (RSO), authorized user (AU), authorized medical physicist (AMP), or authorized nuclear pharmacist (ANP). The SNM supports the recommendation to eliminate attestation for those pursuing the grandfathering pathway if the applicant is currently an AU. For other individuals, the preceptor attestation should be required because there are no rules or guidelines regarding continuing education or Maintenance of Certification specifically regarding radiation safety. The Society also 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 the quality of training meets NRC regulations for patient and public safety.

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

Currently, 10 CFR Part 35 restricts licensees to a single RSO. SNM supports amending the regulations to allow the addition of named assistant/associate RSOs to a license. This will facilitate approval of such individuals serving as RSO on another institution's license and thereby expand the pool of qualified candidates and ease the shortage of RSOs. The qualifications for the assistant/associate RSO should be relaxed to allow individuals on-the-job training while serving in the assistant/associate capacity. Additionally, SNM recommends NRC allow AUs, ANPs, or AMPs to serve as RSOs on individual licenses for private practices (i.e. non-hospital sites).

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

10 CFR 35.204(b) currently requires a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical to measure the molybdenum-99

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concentration ("moly breakthrough") of the first elution only. Prior to 2002, however, licensees were required to test the molybdenum-99 concentration in each elution. NRC is now considering reverting to the pre-2002 requirement for testing each elute for molybdenum-99 breakthrough. Current standards of practice as well as manufacturers recommendations already include testing of every generator elution. Therefore, the Society endorses this recommendation, and recognizes that codifying it into regulation would not impose any additional burden on licensees.

The Society, however, does not support the proposal to require licensees to report out-of-tolerance tests to the NRC. Failed generators are immediately reported back to the manufacturer in order to obtain a replacement and the burden of reporting of out-of-tolerance tests to the FDA and NRC should remain the responsibility of the generator manufacturers.

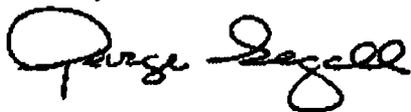
Additional Items Under Consideration for Rulemaking

NRC issued the Part 35 Preliminary Draft Proposed Rule Language in which changes are made to Part 35.65. NRC is considering placing the transmission/sources used in SPECT and PET imaging devices (Gd-158 and Ge-68) in 35.500. In addition to moving the sources to 35.500, the Society suggests including language similar to that in 35.290(b): "...is an authorized user under § 35.290 or equivalent Agreement State requirements." Without this additional language, there may result the unintended consequence of requiring an additional 8 hours of training for 35.200 users.

NRC, in its draft language, also proposes changes to 35.390: Training for use of unsealed byproduct material for which a written directive is required. Specifically, in Section (G)(3), distinct training specifically for users of alpha emitters is proposed. The Society feels that such parsing of training requirements by emission properties is ill-advised and unnecessary, as the broad training and experience of AUs that is already required is translatable among radioisotopes regardless of their specific emission properties. The proposed change thus introduces regulatory complexity without any demonstrable benefit.

The SNM is pleased to provide comments to the NRC on proposed revisions to 10 CFR Part 35. Should you have any questions, please contact Sue Bunning, Director of Health Policy and Regulatory Affairs, sbunning@snm.org or (703) 326-1182.

Sincerely,



George Segall, MD
President

CC: Fred Fahey, DSc
Gary Dillehay, MD
Munir Ghesani, MD

PUBLIC SUBMISSION

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Docket: NRC-2008-0175
Training Requirements for Experienced Radiation Safety Officers and Authorized Medical Physicists

Comment On: NRC-2008-0175-0004
Part 35 Preliminary Draft Proposed Rule Language

Document: NRC-2008-0175-DRAFT-0010
Comment on FR Doc # N/A

Submitter Information

Name: George Segall
Submitter's Representative: Janette Merrill
Organization: Society of Nuclear Medicine

General Comment

See attached file submitted on behalf of the Society of Nuclear Medicine (SNM).

Attachments

SNM Comments on Revisions to Part 35_09.15.2011

Rulemaking Comments

From: Gallagher, Carol
Sent: Thursday, September 22, 2011 2:43 PM
To: Rulemaking Comments
Subject: Comment on Part 35 Draft Rule Language
Attachments: NRC-2008-0175-DRAFT-0010.pdf

Van,

Attached for docketing is a comment from George Segall on the Part 35 draft rule language (76 FR 29171) published on May 20, 2011.

Thanks,
Carol