

AMERICAN SOCIETY OF
NUCLEAR CARDIOLOGY

DPR 35
(76FR29171)

8

September 15, 2011

DOCKETED
USNRC

September 16, 2011 (11:00 am)

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

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

VIA ELECTRONIC SUBMISSION

Re: Docket ID NRC-2008-0175; Proposed Draft Modifications to 10 CFR Part 35 Medical Use Regulations

Dear Dr. Jackzo:

The American Society of Nuclear Cardiology (ASNC) is pleased to provide comments on the Nuclear Regulatory Commission's (NRC) proposed amendments to 10 CFR Part 35 Medical Use Regulation.

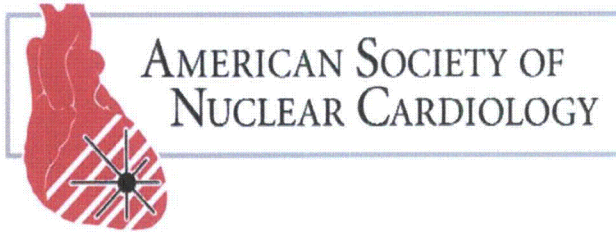
ASNC is a 4,700 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

As the professional society whose members are most involved in the delivery of nuclear cardiology imaging services to Medicare beneficiaries, ASNC is extremely interested in the NRC's proposed changes to 10 CFR Part 35. Overall, ASNC supports the proposed changes put forth by the NRC in its May 16, 2011 Draft Proposed Preliminary Language Document which the NRC developed in collaboration with the Advisory Committee on the Medical Use of Isotopes (ACMUI). There are, however, some areas where we request clarification on some of the NRC's proposed language and those areas are discussed in detail below.

Are comments on proposed changes to 10 CFR Part 35 are as follows:

35.65: Authorization for Calibration, Transmission, and Reference Sources.

- A. ASNC appreciates the NRC's recognition that transmission sources are used regularly in myocardial perfusion imaging studies such as SPECT and PET and must be available under the supervision of 35.290 trained Authorized User (AU).



- B. *We also support the proposed changes to move transmission sources that are used with patients or human research projects to Subpart G; see suggested language below.*

§ 35.590 Training for use of sealed sources and medical devices for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who-

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page); ~~or~~

(b) *Is an authorized user under §§ 35.290, 35.390, or equivalent Agreement State requirements; or*

(bc) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include-

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and

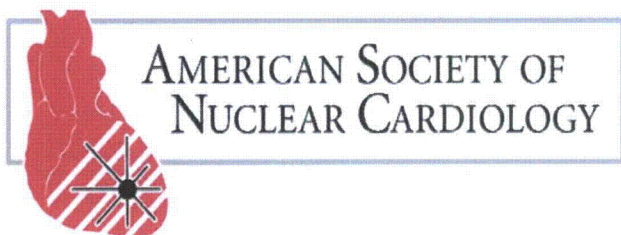
(cd) Has completed training in the use of the device for the uses requested.

- C. ASNC is concerned that the proposed language aimed at clarifying that individual sources may not be combined to create an activity greater than the nominal activity of any single source may actually be confusing and could create problems for providers of SPECT and PET scanners. These scanners may have multiple gadolinium (typically two in SPECT work) or germanium (PET work) sources. Further, aggregate sources are important when "old" and "new" sources are on site during an end of life trade out. *Therefore, ASNC urges that additional language be adopted which recognizes these issues.*

35.290: Training for Imaging and Localization Studies.

- A. ASNC strongly supports the proposed amendment to 35.290 which would allow an authorized nuclear pharmacist who meets the requirements in 35.55 or 35.57 to supervise the work experience for paragraph (c)(1)(ii)(G) of 35.290.

In regards the other proposed amendments published in the May 20, 2011 Federal register and discussed at the NRC Public Workshops held in New York and Texas in June and August 2011, ASNC offers the following comments and observations:



A. Amending Preceptor Attestation Requirements.

We offer the following comments, however in all cases where a previous requirement is kept, ASNC strongly supports the revision to the current attestation text that has been advocated by the ACMUI. Therefore, we support a modification of the current attestation text from “the individual has achieved a level of competence to function independently” to “*the individual has achieved the requisite training and experience in order to fulfill the radiation safety related duties required under a license.*”

Our more specific comments include the following:

- a. ASNC *supports* modified language that eliminates the formal attestation requirement for recognized boards, so long as boards are permitted to enact more rigorous criteria should they so elect to do so.
- b. ASNC *supports* language that would eliminate the requirement for individuals certified by a recognized board to submit a preceptor attestation.
- c. ASNC *opposes* relaxing the requirement of providing an attestation for individuals applying for AU status through the alternate pathway.
- d. ASNC understands the efficiency of allowing residency/fellowship program directors, representing the consensus of program faculty, to attest for applicants. However, we believe going forward it would be preferable to have a formal written statement included in the trainees’ folder, or submitted to the program director, from the supervising program faculty AU indicating the applicant has completed their training.
- e. ASNC sympathizes with the physics community challenges and *supports* a revision that would allow relaxation of the preceptor attestation statement for individuals grandfathered under the Ritenour Petition.
- f. Finally, ASNC *opposes* a national radiation safety exam. ASNC firmly believes that the existing processes of certification by recognized boards (such as the Certification Board of Nuclear Cardiology (CBNC)) are adequate and appropriate to ensure public safety.

B. Revise Part 35 To Allow Assistant/Associate Radiation Safety Officer’s to Be Listed on the License

- a. ASNC *supports* an amendment that would allow assistant/associate radiation safety officers (RSO’s) to be listed on a license.



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- b. Also, ASNC strongly *supports* allowing AUs to serve as RSO on a license for modalities in which they are trained. We believe this modification will help relieve the shortage of RSOs and will permit the listing of individuals with expertise in certain uses of isotopes.

C. Requiring Molybdenum Breakthrough Tests after Each Elution and Require Reporting of Failed Molybdenum Breakthrough tests.

- a. ASNC *supports* a revision that includes language to require licensees to follow manufacturer recommendations for all radiopharmaceutical generators' elution processes approved by the United States Food and Drug Administration (FDA). As this applies to Molybdenum, it would mean measuring Molybdenum breakthrough of each generator elution. This has been a requirement in the past and we do not have any concerns with this portion of the revised Part 35 language.
- b. ASNC is less convinced of the need to report failed breakthrough test to NRC. Specifically, we believe that generator performance is a manufacturer parameter and feel that the current requirement which mandates reporting to the manufacturer, who must subsequently report the breakthrough to the FDA, is sufficient.

ASNC appreciates the opportunity to provide comment on these key issues. Should you have any questions, please feel free to contact Jenna Wilkes, ASNC Director of Health Policy, at 301-215-7575 x207 or email at jwilkes@asnc.org. Thank you.

Sincerely,

Leslee J. Shaw, PhD, FASNC
President
American Society of Nuclear Cardiology

PUBLIC SUBMISSION

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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-0013

Comment on FR Doc # N/A

Submitter Information

Name: Jenna Wilkes

Organization: American Society of Nuclear Cardiology

General Comment

Please accept these comments on behalf of the American Society of Nuclear Cardiology regarding the Part 35 Preliminary Draft Proposed Rule Language.

Attachments

ASNC comments on 10 CFR Part 35 9.2011

Rulemaking Comments

From: Gallagher, Carol
Sent: Friday, September 16, 2011 10:28 AM
To: Rulemaking Comments
Subject: Comment on Part 35 Draft Rule Language
Attachments: NRC-2008-0175-DRAFT-0013.pdf

Van,

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

Thanks,
Carol