Cardiologists, Technologists Singled Out

NRC GIVES ADVANCE NOTICE OF PROPOSED TRAINING RULES

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The Nuclear Regulatory Commission (NRC) has issued a long-awaited Advance Notice of Proposed Rulemaking on training and experience criteria for those involved in the medical use of byproduct material. The notice suggests for the first time specific guidelines for the training of cardiologists and technologists, as well as for brachytherapy and teletherapy physicists and dosimetrists. It also seeks input on continuing education guidelines and possible modifications of training criteria for nuclear medicine physicians in general.

This latest notice, published in the May 25 issue of the Federal Register (pp. 18845-18854), has no regulatory force, but instead communicates the NRC's desire for public comment before taking action. While this Advance Notice of Proposed Rulemaking is unusual in that it suggests specific language that could be employed in eventual regulations, in general an Advance Notice can be viewed as a mechanism for raising topics for discussion. The comment period is set to expire August 24, 1988.

For nuclear medicine generalists who perform procedures on a variety of organ systems, the NRC suggests training criteria that differ little from the final rule it set down in 1986 as part of a complete overhaul of its medical use regulations. That overhaul did not include any modifications in physician training (see the Federal Register, Thursday, Oct 16, 1986, pp. 36932-36968).

The notable exception in the new notice, however, concerns the time period requirements. In its recent notice the NRC does not specify 500 hours of supervised handling experience in radioactive materials as it did in 1986, nor does it specify a six-month training program in nuclear medicine, approved by the Accreditation Council for Graduate Medical Education. Instead, the NRC is "purposely vague" and seeks comment on the subject of time period for supervised clinical experience, and deletes mention of an approved training program while adding the requirement that training include "personally performing 10 cases."

For board-certified cardiologists, the NRC now suggests that the physician meet essentially the same training and experience requirements as a general nuclear medicine physician, with two exceptions. One is that the NRC suggests two weeks of supervised handling experience of radioactive materials for cardiologists, while not specifying any particular time period for nuclear medicine generalists. The other is that the NRC would expect a cardiologist to have "personal participation in cardiovascular clinical procedures for 50 complete cases and personal performance of 10 of those cases," while generalists would be expected to personally perform 10 cases.

Technologist Criteria

For nuclear medicine technologists, the NRC would recognize certification by either the American Registry of Radiologic Technologists or the Nuclear Medicine Technology Certification Board. In lieu of board certification, 200 hours of classroom and laboratory training, and an unspecified amount of supervised handling and clinical experience, would be acceptable.

The Commission also raises the issue of continuing education by asking a series of questions: Should the NRC require continuing education? Should it consist of a review of new developments, the basics, or some combination? How should the NRC monitor its quality? And who should provide such education?

The issue of physician certification (continued on page 1160)
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has had a tempestuous history. In the brief account given in the Advance Notice, the NRC said it increased the amount of time required for physician training in 1982 in response to testimony before the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). The notice explains that during those meetings several medical experts suggested that, because of the increased complexity of the interpretation of nuclear medicine studies, the time devoted to basic classroom and laboratory training and supervised handling experience of byproduct materials had decreased.

One year later, the American College of Cardiology, Bethesda, Maryland, proposed alternative criteria for physicians who perform only cardiovascular imaging procedures. Representatives of other interested organizations, including the Society of Nuclear Medicine (SNM), met in June 1984 to discuss the proposal. The NRC also held a meeting of the ACMUI.

While there was general agreement on what topics to include in basic classroom teaching, work experience and clinical experience, there was a difference of opinion concerning the minimum acceptable duration of an integrated training program and on "the operational wording of the handling and clinical experience criteria," according to the NRC. The agency received more than 200 comments letters, and about 20 individuals spoke at the ACMUI meeting.

The issue galvanized the SNM membership as well (see Newsline, Nov. 1984, pp. 1, 4-5; Mar. 1985, pp. 220-223; June 1985, pp. 557-558; May 1986, p. 590). Some urged that nuclear medicine training periods be reduced, while others felt that even existing criteria were insufficient. Ultimately the SNM Board of Trustees voted in March 1986 to recommend that "a well-defined training program of four months be required for licensing physicians wishing to limit their nuclear medicine practice to a single organ, and that the current requirement for a six-month training program be maintained for all others."

Comments Summarized

The NRC summarized the most important comments it received in 1984 in its Advance Notice of May 25:

• There is no safety reason to apply different training program duration criteria to applicants from different medical specialties, as the radiation safety problems and procedures are similar in all cases.
• Radiation safety cannot be completely separated from the quality of clinical practice. For example, misinterpretation of images, performing procedures of no clinical value, and doing procedures so poorly that they must be repeated all lead to unproductive patient exposure.
• The length of training is not so important as the quality of training, provided essential topics are covered.
• The trend toward performing nuclear medicine procedures in private offices and clinics means less opportunity for peer review than in hospitals.
• Some individuals may support longer training program duration criteria in order to disenfranchise others for economic reasons rather than for public health and safety reasons.

Misadministrations

While explaining its decision to call for public comment so early in the rulemaking process, the NRC noted the impact of misadministration reports on deliberations. "During the same time the NRC was examining the issue of physician training and experience for the diagnostic use of radiopharmaceuticals, a series of misadministrations occurred that led the Commission to believe that its public health and safety responsibilities required that rulemaking begin on quality assurance in the medical use of byproduct material," the Advance Notice states (see Newsline, Mar. 1988, pp. 283–286; May 1988, p. 592; June 1988, p. 1008). "The Commission now believes that the training of all individuals who participate in the medical use of byproduct material deserves more rigorous attention."

In asking for input from the medical community, the NRC acknowledged its debt to such contributions in the past. "The 1984 increase in duration of integrated training programs for diagnostic use of byproduct material was based almost entirely on recommendations from the ACMUI and medical specialty societies," the Notice said. "A change at this time, without a well-documented, technical basis for action and with a lack of consensus within the medical community, seems imprudent."

Preliminary reactions to the Advance Notice, which makes some-

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what unwieldy reading, have been unenthusiastic. Barry Siegel, MD, director of the nuclear medicine division of the Mallinckrodt Institute of Radiology, St. Louis, Missouri, said "the implication is that the way we're training people is incorrect. Somehow the small number of errors that occur are related to the system for developing nuclear medicine personnel, which is somehow deficient. I don't believe that. . . . On the mean it's a system that works very well."

"Big Bucks"

Dr. Siegel said that because nuclear medicine is heavily regulated, practitioners in the field may already be more attuned to minimizing errors than those in other medical specialties, and that additional paperwork would only increase costs. "It's not clear that some document is going to make our doctors better doctors or our technologists better technologists," he said. "The potential cost of the system carried to an extreme, and hidden in the NRC questions, are non-trivial. Every time you get a copy of a document, some individual—or two or three individuals—have spent 10 to 15 minutes getting it ready. Multiply that over the whole country and we're talking about big bucks."

Dr. Siegel also expressed concern that the proposed training for cardiologists is inadequate. "Fifty is an inordinately small number of cases," he said, adding that it would provide insufficient exposure to the range of clinical problems as well as to problems with instruments, computers, and other technical aspects. "That's not a training program." In contrast, he said, "our diagnostic radiology residents, who spend six months in nuclear medicine, would be exposed in reading sessions to about 1,000 to 1,500 cardiac nuclear medicine cases."

Others active in government affairs noted the uncharacteristically large number of questions posed by the NRC in this Advance Notice. "I think that it's not the usual proposed regulations," said Carol Marcus, PhD, MD, head of the Nuclear Medicine Outpatient Clinic at the Los Angeles County-Harbor/University of California at Los Angeles Medical Center. "They are really asking very broad questions, and want a lot of input from us on a diversity of issues," even to the point of seeking guidance as to where regulation should begin and end. "It's a very broad mandate for us," she said.

"They've bitten off more than I think they can chew on this one," said Capt. William H. Briner, director of radiopharmacy at Duke University Medical Center, Durham, North Carolina, and chair of the SNM Government Relations Committee. For example, he pointed to the NRC's interest in possibly monitoring continuing education. "They can't monitor it, that's the whole problem," he said. "The private sector is taking care of it, I don't know why they're even thinking about it."

After analyzing the public comments submitted in response to the Advance Notice, the NRC plans to study the adequacy of training received by authorized physician users, nuclear medicine technologists, and radiation therapy physicists, technologists and dosimetrists. "The NRC believes that a comprehensive study will likely culminate in the development of a solid technical basis from which the Commission can proceed to develop training and experience criteria for all individuals who participate in the medical use of byproduct material, if such action is necessary," the notice said.

[The Society of Nuclear Medicine (SNM), the SNM Technologist Section and the American College of Nuclear Physicians (ACNP) are preparing a joint statement in response to the NRC's notice. Written comments are welcome. Send to Melissa Brown, Director of Government Relations, ACNP/SNM, 1101 Connecticut Ave. NW, Suite 700, Washington, DC 20036.]

Karla Harby

Material Sought for Archives

Material of historical interest is being sought by the historian of the Society of Nuclear Medicine for inclusion in the permanent archives.

Relevant materials include photographs, tape recordings, notes, monographs and old advertisements, particularly those depicting obsolete equipment or radiopharmaceuticals. Old instruments are also welcomed.

The material will be indexed and filed under the direction of Frank DeLand, MD, Society historian and chief of staff at the VA Medical Center in Syracuse, New York. Those who wish to retain possession of their materials could still enrich the archives by providing a list of documents or instruments held, so that they could be accessed when needed. Any donations that are duplicates or otherwise inappropriate will be returned to the donor.

The archives are used to construct historical displays and in writings about the history of nuclear medicine.

[For further information, contact Frank DeLand, MD, Chief of Staff, VA Medical Center, 800 Irving Ave., Syracuse, NY 13210, (315) 476-7461 ext. 2226.]