NRC Reissues QA Rule for Medical Licensees

The Nuclear Regulatory Commission (NRC) reissued a proposed rule governing quality assurance (QA) for medical licensees in January 1990. As part of 10 CFR Part 35, currently being reviewed (see *Newsline*, September 1989, p. 1296), the proposed rule, which the NRC calls "performance-based," would require medical licensees to establish a QA program and would modify both the related reporting and record-keeping requirements and the definition of misadministration. In recent discussions with The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP), the NRC commissioners indicated that the proposed rule might conceivably be modified to account for a Joint Council on Accreditation of Healthcare Organizations (JCAHO) QA program manual, which was published in 1988.

Second Effort at QA Rule

In 1987, the NRC had proposed a prescriptive QA rule, but public comment indicated that because such specific requirements did not provide sufficient flexibility, they would interfere with the practice of medicine. The NRC says that the newly proposed amendments "would enhance patient safety while allowing the flexibility necessary for proper medical care." SNM and ACNP disagree.

SNM/ACNP Activities

The Society and the College have continued to oppose the NRC's attempts at formulating a QA rule on the grounds that medical quality assurance is not the mandate of the NRC, the occurrence of biologically-significant misadministrations is so low that any such rule is unnecessary, and the required reporting and record-keeping and the infringement into medical practice would be counterproductive. In addition, the Society and the College have pointed to the requirements of the JCAHO QA manual as effective and adequate measures that ensure quality (see *Newsline*, October 1989, p. 1584).

"The problem SNM/ACNP has with the QA rule is that, as proposed, it interferes with the practice of medicine, which is really not the purview of the NRC," says SNM President Richard A. Holmes, MD, who attended the meetings with the NRC Commissioners. While the Society and the College don't object to reviews of misadministrations, "they feel that organizations like JCAHO already assess and evaluate nuclear medicine from the standpoint of quality assurance."

Carol Marcus, PhD, MD, director of the nuclear medicine outpatient clinic at Harbor-UCLA Medical Center, who also attended the meetings, adds, "We do not accept the idea that the NRC has the right to dictate the practices of nuclear medicine and nuclear pharmacy. We believe that such action was proscribed in Section 104 of the Atomic Energy Act."

ACNP President Robert E. Henkin, MD, says, "SNM and ACNP agree with the NRC that misadministrations have to be reduced, but they don't agree that this proposed rule will do it." Dr. Henkin points to the shortage of nuclear medicine technologists as contributing to the problem and adds that by giving more work to overworked technologists, the proposal "overall would degrade the quality of patient care."

During their recent meetings, both the Society's Board of Trustees and the College's Board of Regents passed resolutions calling for the NRC to withdraw its proposed QA rule. The NRC has indicated that the request to withdraw the proposal would be considered with any other comments they receive, but that the agency does not intend to withdraw the proposal at this time.

Both Boards also resolved to request that the National Council on Radiation Protection and Measurements (NCRP) prepare a commentary on nuclear medicine misadministrations to determine their extent and health impact. SNM and ACNP are convinced that the study's results would support their contention that misadministrations have a minimal impact on patient health, particularly when weighed against the benefits to patients of nuclear medicine examinations. If the NCRP were to prepare such a commentary, it would likely take several months. The NRC told SNM/ACNP that the agency would need the NCRP commentary by December 31, 1990 to use the information in the final QA rule.

During meetings on February 13, 1990, the NRC Commissioners met with SNM/ACNP members and indicated that they wanted to develop a better understanding of the significance of nuclear medicine misadministrations. They told SNM/ACNP members that they would consult with the NRC staff in an effort to modify the proposed rule based on their new understanding. NRC staffers have since asked to meet with SNM/ACNP members to discuss the rule. Dr. Holmes told *Newsline*, "This is the first time the NRC has opened the door. . .I don't want to lose that opportunity." But rather than meet now with the NRC staff with no counteroffer to the proposal, Dr. Holmes says, he would like SNM/ACNP to develop an alternative proposal and then meet

with the NRC. "If we propose a QA rule in their language that we can agree with, then we can meet with them on reasonable ground."

The current NRC misadministration figures are skewed, according to Dr. Holmes, because "the NRC lumps brachytherapy and teletherapy with non-sealed source nuclear medicine studies. When nuclear medicine studies are separated, the numbers are much lower." Dr. Henkin cites a misadministration rate of 6 per 100,000 doses for nuclear medicine compared to 10,000 to 20,000 per 100,000 doses for the rest of medicine.

The Proposed Rule

Without modification, the proposal, issued in the January 16, 1990 *Federal Register* (*1*), would require medical licensees to have in place and use a QA program that includes annual audits that are management evaluated. The program would be required to include written policies and procedures designed to ensure that the medical use of radioactive materials is appropriate for the patient's condition, that it is in accordance with a prescription or a diagnostic referral and clinical procedures manual, that the patient's identity is verified as the individual referred, and that any unintended deviation from the prescription or referral is identified and evaluated. The verbal prescription, verbal order, or verbal deviation from the procedure manual is not to be permitted except in what are termed emergencies but are left undefined, according to Dr. Marcus. Written orders for such emergencies, she adds, would have to be in place within 24 hours.

Definition of Misadministration

The definition of a misadministration would be expanded under the proposed rules. The term misadministration would include all those events currently listed as misadministrations as well as medical use not authorized in the license, not in accordance with a prescription or a diagnostic referral, and without proper recording of the radiation dose or radiopharmaceutical dosage.

In addition, the proposed modifications relating to teletherapy events or misadministrations also include "errors in the source calibration, the time of exposure, the treatment geometry, or other errors that result in... for any treatment fraction, the administered fractional dose being greater than twice or less than one half of the prescribed fractional dose... for the fraction administered to date, the sum of the administered fractional dose differing from the sum of the prescribed fractional dose by more than 10% of the prescribed total dose."

Under the proposed rule, brachytherapy administrations in which a sealed source is leaking, lost, or unrecoverable or in which errors in brachytherapy treatment planning or execution result in the prescribed dose differing from the administered dose by more than 20% of what was prescribed would be considered misadministrations.

Reporting and Record-Keeping

Under all such circumstances, Radiation Safety Officers are required to promptly investigate, and licensees would be required to submit reports and records to the NRC. The proposed rule would direct licensees to notify the referring physician and the NRC "in writing within 15 days of the discovery of a diagnostic misadministration if it involved the use of byproduct material not authorized for medical use in the license, administration of a dosage differing by at least fivefold from the prescribed dosage, or administration of the byproduct material such that the patient is likely to receive an organ dose greater than 2 Rem [0.02Sv] or a whole body dose greater than 0.5 Rem [0.005 Sv]."

In the event of a therapy misadministration, the rule would require that the licensee notify the NRC before completion of the next government working day following discovery of the misadministration. In addition, the licensee would be required to notify the referring physician as well as the affected patient or the patient's guardian within 24 hours of such a discovery, unless the referring physician agrees to notify the patient or notification is deemed potentially harmful. Licensees must also file a written report within 15 days of the telephone notification.

The new rules would still require licensees to keep a record of each misadministration for 10 years, but would also require that they keep information on all administrations of radioactive material to patients for three years whether or not an error was involved. "All records must be in a readily auditable form," says Dr. Marcus. The new rule states that it would require an estimated increase in paperwork of nine hours per year per licensee. In contrast, representatives of SNM/ACNP have calculated this to be about one day per week of physician's time. "The number of paper violations that would result would be enormous," says Dr. Marcus.

In conjunction with the final QA rulemaking, the NRC intends to modify its enforcement policy to reflect that "the Commission views... misadministrations and other reportable events as evidence of inadequate quality assurance in the medical use of byproduct material and may subject the licensees to enforcement action."

The NRC's voluntary pilot program, set up to test implementation, will run through August 1990. The program, which includes both NRC state and agreement state licensees, will be run by Brookhaven National Laboratory.

Regulatory Guide

The NRC staff has prepared a draft regulatory guide that provides general guidance for developing a QA program that meets the requirements of the pro-

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News Briefs

Utah Applies to NRC for Additional Waste Disposal Authority

The State of Utah has requested that the Nuclear Regulatory Commission (NRC) amend the state's agreement status so that it may undertake additional regulatory authority over land disposal of radioactive materials in the state.

In accordance with Section 274 of the Atomic Energy Act of 1954, which provided a mechanism for the transferal of certain regulatory powers from federal to state jurisdiction, the state would assume regulatory control over the land disposal of radioactive source, by-product, and special nuclear materials not sufficient to form critical mass. If approved, Utah will become the 28th state in the nation to govern land disposal of such radioactive materials. (Currently, 29 states have an agreement state relationship with the NRC.) Presently, the state of Utah does not plan to assume authority over uranium and thorium mills and tailings.

According to the specifications of the 1954 Act, the Commission must assess the agreement state's local radiation control programs to see if they are compatible with NRC standards and adequate to protect public health and safety. Following approval, the NRC would periodically review state protection standards, regulations, and statutes to assure compliance.

"We expect the NRC to amend the agreement in a few months," said Larry F. Anderson, MPA, director of the bureau of radiation control, Utah Department of Health, the body that will administer local regulations. "We have been building our radiation control program and it is a natural progression for us to regulate land disposal of radioactive wastes."

Mr. Anderson added that prior to the State of Utah's initial agreement with the NRC in 1984, the state's disposal regulation was handled out of an office in Arlington, Texas. "In those days, our sites were inspected only four weeks in a year, and some licensees were not even inspected at all. It is more efficient to regulate closer to home." ■

Nuclear Medicine Week Update

The fifth annual Nuclear Medicine Week (NMW) celebrations will be held July 29–August 4, 1990. Efforts have begun to make the week's activities more widely recognized and successful than ever. GE Medical Systems is again sponsoring the Media Stars contest, in which nuclear medicine departments compete on the basis of their NMW activities, such as media coverage, open houses, and slide and video shows. Posters, buttons, and stickers will be available for order beginning this month. For further information or to obtain a guidelines packet contact: Virginia Pappas, CAE, The Society of Nuclear Medicine, 136 Madison Ave., New York, NY 10016-6760; (212) 889-0717; fax: (212) 545-0221. An article in the May 1990 *Newsline* will preview this year's NMW poster and button. ■

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posal. (Copies of this guide, "Basic Quality Assurance Program for the Medical Use of Byproduct Material," document – DG-8001, can be obtained via written request to: U.S. Nuclear Regulatory Commission, Division of Information Support Services, Washington, DC 20555.) Licensees can propose an alternative QA program that is based on another guidance, but under the proposed rule, according to Dr. Marcus, any program "would have to include specific requirements that can lead to violations and enforcement actions." The NRC would review such proposed programs individually.

The NRC is accepting public comment on the proposed rule through April 12, 1990. SNM and ACNP are jointly preparing official comments to the proposed rule. Send comments to: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attn: Docketing and Service Branch. Any changes would be integrated into the final rule, which is expected to go to the Commissioners in March 1991. The rule will take effect six months after the final *Federal Register* announcement.

Sarah M. Tilyou

References

1. Basic quality asssurance program, records and reports of misadministrations or events relating to the medical use of byproduct material. *Federal Register* 1990;55(10):1439.