SNM/ACNP Consider Appealing NRC Quality Management Rule

IN RESPONSE TO THE RECENT publication of the Nuclear Regulatory Commission's final rule on quality management, The Society of Nuclear Medicine (SNM) and American College of Nuclear Physicians (ACNP) have asked a federal court to extend the September 25 deadline for appealing the rule until December 1. SNM/ACNP Director of Government Relations Kristen Morris says that the societies need the added time to work with NRC nominee Gail de Planque, PhD, who is expected to take charge of issues related to the medical use of isotopes in late September after the original deadline expires. SNM/ACNP leaders have not yet decided whether to appeal the rule.

The NRC's final rule on quality management (10 CFR Parts 2 and 35), effective on January 27, 1992, has changed significantly since it was first proposed in 1987. The revisions likely to have the most impact on the nuclear medicine community are as follows:

- The rule no longer regulates most diagnostic procedures due to the low radiation risk to patients.
- The organ radiation dose threshold for identifying misadministrations has been changed from 2 rems to 50 rems dose equivalent and the whole-body threshold has been changed from 0.5 rem to 5 rems.
- The NRC lowered the estimated $4 million annual cost to $1.4 million. The revisions affect licensees who perform teletherapy, brachytherapy, and radiopharmaceutical therapy, or who administer diagnostic doses of iodine-131 or iodine-125 sodium iodide, in quantities greater than 30 microcuries.
- Rather than prescribing quality management practices to licensees, the NRC will provide guidelines, allowing the licensee to develop a system for meeting those guidelines.

Members of the nuclear medicine community have voiced concern that the regulations will overlap existing programs, particularly those of the JCAHO. ACNP President Terence Beven, MD, says, "My primary concern is that the rule is redundant and it's going to cost many practices a great deal of paperwork."

The cost of implementing a quality management program, says Dr. Beven, may be significant in view of the NRC's recent raising of inspection fees. "With the new rule," he says, "hospitals will have to raise their fees and the costs of inspection will ultimately be covered by the patient." Small providers of healthcare may be hit especially hard with the installation of the NRC-mandated quality management program. Says Mark S. Hayward, acting chief counsel for advocacy for the Small Business Administration, in a letter to NRC: "The quality management will require numerous small providers of healthcare to provide for written directives of dosages, redundant identification of the patient, rechecking of calculations, and written explanations of deviations." He also noted that these requirements would force licensees to hire more technicians.

Some licensees believe that the revised rule will benefit their practice. ACMUI Chairman Barry Siegel, MD, director of nuclear medicine at Washington University's Mallinckrodt Institute of Radiology, St. Louis, Missouri, says, "There's something to be gained from this rule for the nuclear medicine community. First, the precautions required by the rule should be part of any good nuclear medicine practice. Second, the misadministrations that will now have to be reported are quite different from those prior to the revisions. Before, licensees had to report nearly all diagnostic misadministrations to the NRC. Now 95% of such misadministrations will be recorded on a form and reviewed by a local radiation safety committee."

Edward Silberstein, MD, an NRC consultant who handles misadministrations, and professor of radiology and medicine at University of Cincinnati Medical Center, is optimistic that the quality management rule will lower the rate of misadministrations (the NRC places the national misadministration rate at 1 in 10,000 hospital patients) by encouraging licensees to become more attentive to patient care. "If a physician is as involved in the therapeutic process as he is supposed to be so that he actually sees a request from the referring physician, examines the patient to confirm the necessity for an ^{131}I dose, and correctly identifies that patient, then any reason for a misadministration is eliminated."

The adequacy of existing quality management programs remains a topic of debate. To strengthen its supposition that a quality management rule is necessary, the NRC commissioned the National Council on Radiation Protection and Measurements (NCRP) to prepare a commentary on the radiobiological significance of nuclear medicine misadministrations, and used a draft of the commentary as a source in creating the rule. The NRC is also mailing questionnaires to approximately 2,400 nuclear medicine facilities to assess the quality assurance standards of each institution.

Although the NRC's revisions may make the quality management rule easier for institutions to adopt, there is no concrete evidence that a quality management rule will reduce misadministrations. Stanley J. Goldsmith, MD, of the Mount Sinai Medical Center in New York City and chairman of SNM/ACNP government relations says, "Since nuclear professionals are already motivated to perform at a high level I don't see how additional regulations will improve practice. Furthermore, I'm concerned that the increased costs, financial and workload, might even have an adverse effect."

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