NRC Staff Requirements Memorandum Sets Process Forward For Medical Reform

The Nuclear Regulatory Commission (NRC) Commissioners, weighing all the comments received on reform of its medical program, have directed the NRC staff to submit a plan by June 6, 1997, for revising 10 CFR Part 35, and associated guidance documents, as well as the Commission's 1979 Medical Policy Statement. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation to be implemented by June 30, 1999.

The Commission also laid out the following points for the staff to consider when developing the plan:

- Focusing Part 35 on those procedures that pose the highest risk.
- For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.
- The staff should address how best to capture not only relevant safety-significant events, but also precursor events.
- Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.
- Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.
- The quality management program should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.
- The staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC needs.
- The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The Commission has set this issue as a high priority, making available additional resources as necessary.

ACNP/SNM Leadership meet with NRC Chairman and Two Commissioners

On March 27 and 28, 1997 Michael D. Devous, PhD, and Robert F. Carretta, MD, met with Chairman Shirley Jackson, as well as Commissioners Kenneth Rogers and Greta Dicus. The purpose of the meeting was to further discuss the NRC strategic assessment process and the impact that it would have on regulatory reform for nuclear medicine.

The leadership clarified that the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) have not withdrawn support for many of the conclusions reached in a 1995 National Academy of Science-Institute of Medicine report on regulatory reform. The ACNP and SNM, however, are attempting to work the with NRC in a partnership to seek compromise in addressing some of the regulatory problems facing the specialty. Devous and Carretta also stated that the ACNP and SNM are not in favor of the NRC increasing its regulatory authority to cover accelerator produced material, as indicated in an NRC staff report on the strategic assessment process. The position of the two groups on this issue clearly states that "while we are in favor of uniform radiation safety standards for all radioactive material, the implementation of these standards for accelerator produced material should remain with the states."

Devous and Carretta also emphasized that ACNP and SNM wished to be involved, to the extent allowed by law, at every step of the process for NRC's regulatory reform. It was pointed out that the two organizations had already submitted proposals for the regulation of diagnostic and therapeutic nuclear medicine. Now that the NRC staff is beginning to formulate a process for identifying those issues that should be changed, as well as new language for those sections, ACNP and SNM would like to be involved in shaping the information gathering process to ensure maximum input from all medical specialty societies.

—David Nichols is the associate director of the ACNP/SNM government relations office

Legislative Update

H.R. 1060, "The Pharmacy Compounding Act" has been introduced in the House of Representatives. This legislation would ensure that physicians and pharmacists have the right to compound under state pharmacy law and not under the Food and Drug Administration (see *Newsline J Nucl Med* 1997;38:23N.). For a copy of the legislation and a draft letter to send to your member of Congress please contact Leonard Getzin in the ACNP/SNM Government Relations Office at 703-708-9773.