



# Government Relations Update

NEWSLINE

## Government Relations Committee Meeting Highlights

The ACNP/SNM Government Relations Committee met on January 31, 1998, in Las Vegas, NV, to review its 1997 accomplishments and discuss goals for 1998. As outlined in the 1997 Government Relations Committee annual report (available on the SNM Web site at [www.snm.org](http://www.snm.org)), the Government Relations Office either completed or made significant progress toward accomplishing each of its 1997 goals. These goals were as follows:

- Pushing for general licensure for diagnostic and therapeutic agents regulated by the Nuclear Regulatory Commission (NRC).

- Implementing "fast-track" approval from the Food and Drug Administration (FDA) for diagnostic cancer agents.
- Implementing legislation governing the approval process for radiopharmaceuticals and other issues such as pharmacy compounding and PET.
- Monitoring and disseminating information on issues pertinent to nuclear medicine.

Looking forward for 1998, the committee discussed a variety of issues affecting nuclear medicine and established new goals for the year. Following discussions

on the FDA, the NRC and the Department of Energy (DOE), the committee set the following goals for 1998:

- To continue to work with the NRC to eliminate unnecessary regulations affecting diagnostic and therapeutic nuclear medicine.
- To work with the FDA to implement the portions of the 1997 FDA reform bill affecting nuclear medicine.
- To increase nuclear medicine research funding governed by the DOE.
- To continue to monitor and disseminate information on issues pertinent to nuclear medicine.

## NRC Update

The NRC has finished receiving comments from the regulated community and other stakeholders, completing the drafting stage of the process of revising 10 CFR Part 35. As reviewed by Catherine Haney, chair of the NRC 10 CFR 35 working group, at the SNM House of Delegates Meeting February 1, 1998, the draft rulemaking contained several important changes to the current 10 CFR 35. The document was reviewed by a task force chaired by SNM president H. William Strauss, MD, to develop positions on such important issues as training and experience for authorized users. The task force, which worked right up until the March 1 deadline, concluded that the NRC should remove itself from evaluating clinical competence and focus only on radiation safety. The SNM made

three recommendations to the NRC on training and experience:

1. SNM identified 10+ topics that users should be educated in to ensure competency in radiation safety only.
2. SNM would ensure competency in these 10+ topics through an examination developed and administered by a third party. In recognition of the fact that individuals' aptitudes vary, neither a minimum nor a maximum number of hours was included for this section.
3. SNM also felt it was important to require some handling and practical experience for nuclear medicine. This could be accomplished through either an Accreditation Council for Graduate Medical Education-approved

course or a graduate-level course at an accredited institution. Once again, a specific number of hours was not prescribed; instead, the focus was on subject areas deemed important to understanding radiation safety.

The NRC working group now has approximately 2 months to collate comments and develop a proposed rule for Commission approval. It is expected that the NRC will publish an official proposed rule in the *Federal Register* in May 1998. It is likely that there will be another series of workshops over the summer, with the comment period closing in the fall. The Government Relations Office will continue to closely monitor this topic and provide regular updates through the SNM Web site ([www.snm.org](http://www.snm.org)).

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

## New Isotope Production Company (Continued from page 18N)

For now, the nuclear medicine industry will reserve judgment on International Isotopes until the company is up and running and delivers on its expectations of "being able to ship to anywhere in the U.S. within 4 hours" and meeting industry demand for a varied number of isotopes. Stockholders, however,

seem to have already placed their faith in the company. When International Isotopes went public last August, its shares were priced at \$9 per share. As of press time, the stock was trading on the NASDAQ SmallCap Market (under the symbol INIS) for \$19.25 per share.

—Deborah Kotz