



Government Relations Update

ACNP/SNM Government Relations Office Update

Nuclear Regulatory Commission (NRC)

The NRC published a proposed rulemaking for the rewrite of 10 CFR 35 at the end of June 1998 and accepted comments through the fall. This rulemaking is the result of several years of negotiation with the agency through written comments and public meetings. The ACNP and SNM have participated in four workshops with the NRC on this topic since November 1997, and several of our comments have been included in the proposed rule. Key areas ACNP/SNM should still focus on are training and experience, radiation protection programs and the policies and procedures associated with a written directive.

The NRC is shifting its focus to a performance-based rule which relies on an agency requirement that licensees develop procedures to implement parts of the rule but does not inform the licensee about the type of procedure which may be appropriate. In the past, NRC would review necessary procedures prior to granting a license, but now inspectors on routine inspections would only verify that such procedures existed. Since the release of the NRC initial draft "strawman" proposal, ACNP and SNM were successful in eliminating the requirements for precursor event notification and have participated in two public workshops discussing various aspects of the rulemaking.

Members are encouraged to visit the government relations section of the SNM web site to view the proposed rule and other documents. ACNP and SNM submitted comments to the agency, and we are monitoring the development of the final rule.

Food and Drug Administration (FDA)

The FDA has been working on two provisions that comply with the FDA reform act passed by Congress last year. The

first provision relates to the approval process for radiopharmaceuticals. ACNP/SNM have been working with the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) to develop a system that classifies radiopharmaceuticals by associated risk. With support of ACNP/SNM, CORAR has submitted a proposal about this approval process, and the FDA is considering the comments. A final rule and associated guidance are expected by May 1999. ACNP/SNM believe that these improvements will lead to a faster approval time for radiopharmaceutical agents and allow more agents to enter the marketplace.

The other provision that responds to the 1997 reform act concerns the development of regulations governing production and distribution of positron emission tomography (PET) radiopharmaceuticals, particularly taking into consideration the inherent differences between commercial manufacturers and nonprofit institutions. The ACNP/SNM and the Institute for Clinical PET have proposed to the agency that it use updated U.S. Pharmacopeia (USP) guidelines and an approval structure for nonprofits less restrictive than manufacturer's requirements. The PET community is also working on an agreement between manufacturers and academic facilities on one set of CGMP guidelines for both types of facilities.

The FDA held an initial public meeting, the first in a series, to discuss some of the issues in the proposal relating to chemistry, manufacturing and control and will be moving in the direction of a proposed rule by the middle of 1999.

Department of Energy (DOE)

Since June, the ACNP/SNM Government Relations Office has mounted several efforts connected with the DOE. The main focus has been on the FY99 Energy

and Water Appropriations bill, for which ACNP/SNM have tried to win House and Senate agreement on a \$22.5 million budget for isotope production. Based in large part on the lobbying efforts of ACNP/SNM and other groups, Congress agreed on \$21.5 million, up \$7 million from the original House figure. This will allow for the DOE to come near completion with its Mo-99 project; allow labs to maintain isotope-producing facilities; and provide funds for the construction of a beam spur at Los Alamos to replace the existing accelerator. This beam spur would increase the DOE's capability to meet the demand for research isotopes.

We have also worked to establish an advisory committee at the DOE for isotope production issues and have succeeded in placing three members of the nuclear community on the Nuclear Energy Research Advisory Committee (Richard Reba, MD, Linda Knight, PhD, and Daniel Sullivan, MD).

The focus will now turn to the FY00 budget, for which we are seeking an additional \$5 million for the Advanced Nuclear Medicine Initiative, which would fund production of peer-review-selected isotopes. We have had several meetings with DOE officials and Office of Management and Budget staff and will be participating in several workshops with DOE between now and the end of March.

For more information about ACNP/SNM Government Relations Office activities, please contact David Nichols, the office's director, at 703-708-9773, or visit the government relations portion of the SNM web site (www.snm.org/gov.html).

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