

## SNM and ACNP Presidents Meet with NRC Chairman

On March 25, SNM President Peter T. Kirchner, MD and ACNP President David R. Brill, MD met with Shirley Ann Jackson, Chairman of the Nuclear Regulatory Commission (NRC) and Commissioner Greta Joy Dicus at the NRC headquarters in Rockville, MD to discuss the Commissions' future role in regulating the medical use of radionuclides. The meeting was in response to a ground breaking report, which came out last December, from the National Academy of Sciences-Institute of Medicine (IOM) which concluded that regulatory authority should be transferred from the NRC to all 50 states.

During the meeting, Jackson stayed clearly focused on the fact that the NRC is concerned with the IOM report's results, according to David Nichols, associate director of the ACNP/SNM Government Relations Office, who attended the meeting. The NRC is planning to distribute a draft paper on the IOM report for public comment sometime this summer. Both Kirchner and Brill emphasized their desire to contribute comments to NRC's written review of the report.

The SNM and ACNP have taken the position that the IOM report presents a better alternative to the NRC's current regulation of medical isotopes produced in nuclear reactors. The report suggests that Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses. As the rule stands now, any state that is not part of the agreement state program must abide by most of the regulations set forth by the NRC concerning the medical use of radionuclides produced in a reactor. In short, Part 20 lists radiation protection standards that apply to nuclear medicine as well as other uses of radioactive material, whereas Part 35 gives requirements solely for the medical use of radionuclides.

At a February briefing held between the Institute and the Commission, the NRC's three current Commissioners outlined some of their shortfalls with the report. For example, the Commissioners expressed concern that if the states assume regulatory authority, nonagreement states will assume an unfair proportion of the costs of developing guidelines and implementation plans.

### SNM Member Testifies Before House Subcommittee

While awaiting the NRC's response to the IOM report, the Government Relations Office is going to Congress in an attempt to get the Institute's recommendations directly implemented (see February 1996 *Sourceline*, page 23N). On behalf of the SNM and ACNP, Robert W. Atcher, PhD, a faculty member at the University of Alabama at Birmingham, whose research focuses on the medical applications of radionuclides, testified before the House of Representatives Energy and Water Appropriations Subcommittee on February 29.

Atcher voiced his concern over the government's regulation of nuclear medicine. He testified that nuclear medicine faces three major problems that are under the direction of the Energy and Water Appropriations Subcommittee. They include: the

need for the NRC to withdraw from the regulation of medical activities; the need for enhanced support for research in nuclear medicine; and the supply shortage of radioisotopes and enriched stable isotopes for clinical practice and continued research. "All of these problems are critical to the current and future practices of nuclear medicine," Atcher said. The Government Relations Office is urging SNM and ACNP members to make their opinions known to Congress concerning the IOM report. You can obtain a sample letter that can be sent to your representatives and senators by contacting Heather McGavin at (703) 708-9773 or e-mail her at [hmcgavin@snm.org](mailto:hmcgavin@snm.org)

### Removing Radiopharmaceuticals from FDA Regulations

For months, the ACNP/SNM Government Relations Office in conjunction with the Council on Radionuclides and Radiopharmaceuticals (CORAR) has been providing written comments and background information to Congress on FDA reform. Their efforts seem to be paying off: Legislation was recently introduced in both the Senate and the House of Representatives that if passed could speed the approval of new radiopharmaceuticals by the FDA.

On March 27, the Senate Labor Committee passed an FDA reform bill and it will now go to the Senate floor for debate. The house bill has been referred to the House Commerce Committee. Additionally, a few months ago on behalf of the Society and the College, SNM President Peter T. Kirchner, MD, attended an FDA advisory group to draft a document that will provide guidance to manufacturers and researchers who develop radiopharmaceuticals.

The FDA reform legislation includes an amendment that will force the FDA to distinguish between radiopharmaceuticals and conventional pharmaceuticals, such as antibiotics. CORAR and SNM were instrumentive in getting the amendment inserted into the reform bill. Part of the amendment states: "the safety and effectiveness of a radiopharmaceutical are to be determined, weighing the probable benefit to health from the use of the radiopharmaceutical against any probable risk to injury or illness." It will also enable radiopharmaceuticals to be approved for diagnosing multiple diseases or approved for specific processes such as biochemical, physiological or anatomical.

Nuclear medicine leaders have for years been arguing that unlike ordinary drugs, which treat specific diseases or conditions, radiopharmaceuticals are generally used as a tool by a physician in conjunction with other diagnostic and clinical information to aid in diagnostic workups.

If the FDA reform legislation is passed by Congress and signed by the President, it could have the following impact on the approval of new radiopharmaceuticals: It will decrease the amount of time it takes the FDA to approve a new radiopharmaceutical from the current average time of 36 months.

## The American Board of Science in Nuclear Medicine Celebrates 20th Anniversary

The American Board of Science in Nuclear Medicine (ABSNM) will celebrate its 20th anniversary at the Society of Nuclear Medicine's (SNM) Annual Meeting this June in Denver, CO. A dinner reception will take place on Monday June 3, 1996 from 5pm-7pm. Invited guests include ABSNM diplomats, current and past Board members and those taking this year's certification exam at the SNM meeting. The activities of the ABSNM are administered through the services of the Society, and the certification examinations have been given at the SNM Annual Meetings since 1979.

### Requirements for ABSNM Certification

To sit for the ABSNM exam, applicants need to demonstrate that they have met the following standards: (1) a minimum of a



D.H. Lawrence Ranch in Albuquerque, NM.

Master's Degree with a major in a field of physical, pharmaceutical, biological or engineering science; (2) for the Master's Level, applicants must satisfactorily complete a two-year documented

formal training program in a nuclear medicine science or have five years experience in nuclear medicine; and (3) applicants must have a membership in an appropriate professional organization related to activities in the field of nuclear medicine.

The six-hour long written exam consists of two parts: a section that assesses knowledge of basic aspects of nuclear medicine science and a section that tests candidates' knowledge of a predetermined subspecialty area of their choice, including nuclear medicine physics and instrumentation, nuclear pharmaceutical science and radiochemistry, or radiation protection. "To me, the certification reassured confidence in myself and in my work. Additionally, it gave me confidence and trust in my colleagues," B. Wally Ahluwalia, PhD, current ABSNM secretary/treasurer who works in the radiological sciences department at the University of Oklahoma Health Science, Oklahoma City, OK said. Ahluwalia took the second ABSNM examination in 1980 in Detroit, MI. The ABSNM board is currently working on an oral part of the exam and hopes to incorporate the oral section soon.

### Twenty Years Ago . . .

ABSNM was established on September 9, 1976 with the sponsorship of the SNM, the American College of Nuclear Physicians (ACNP) and the American College of Nuclear Medicine (ACNM) to develop procedures and standards for certifying nuclear physicians and scientists who satisfy the requirements established by the ABSNM board. "Nuclear medicine scientists were not getting the recognition they deserved in the 1970s. Sci-

ence is a big part of nuclear medicine, thus the founders of the ABSNM unanimously felt there was a need to create a certification board specifically for nuclear medicine scientists," said Ahluwalia.

The ABSNM exam differs from the American Board of Nuclear Medicine's (ABNM) certifying exam in that it focuses on the science aspect of nuclear medicine. Although physicians do not need to take the ABSNM exam to practice nuclear medicine, Ahluwalia said ABSNM certification gives physicians further recognition from regulatory agencies. (Coincidentally, the ABNM is celebrating its 25th anniversary this year as well.)

The ABSNM exam covers nuclear medicine physics and instrumentation, which is a branch of nuclear medicine science that deals with diagnostic and therapeutic applications of radionuclides and equipment associated with their production and use. It also covers nuclear pharmaceutical science, radiochemistry and radiation protection. "The ABSNM exam covers [subject matters such as] camera assessment, radiopharmaceutical clearances in humans, and instrument evaluation and the performance of the camera," Ahluwalia said.

### Creating the First Exam at the D.H. Lawrence Ranch

As the first President of the ABSNM, SNM Past-President John Hidalgo, MS, a consulting physicist along with the first ABSNM Vice-President Buck Rhodes, PhD, now a consultant for RhoMed, Inc. in Albuquerque, NM recruited 20 "top" scientists in the field of nuclear medicine science to contribute their time to develop the exam. "This was a huge event. I petitioned all three organizations [SNM, ACNP, ACNM] to get approval to create the exam and then pushed for enough funding to begin working," Hidalgo said. Participants spent four days at the D.H. Lawrence Ranch in Albuquerque, NM. At the end of the retreat, they had completed the first ABSNM certification exam, totaling 300-400 questions. "It was not an easy task," Hidalgo said, "but 20 years later it seems to have been worth it"

The original board of the ABSNM included: John U. Hidalgo, President; Buck A. Rhodes, Vice-President; Thomas P. Haynie, Secretary; Howard J. Glenn, Treasurer; C. Craig Harris; Jack M. Morgan; Harold A. O'Brien; Robert E. O'Hara; Ralph E. Robinson; Gopal Subramanian; Eugene J. Vineguerra; and Richard L. Witcofski. "Having a mixed board [of scientists and physicians] was a stroke of genius," Hidalgo said. "Nuclear medicine is a function of many professional disciplines; it took all of those dedicated professionals to create what the ABSNM stands for today."

Ahluwalia said that the ABSNM certification enhances the role of nuclear science in nuclear medicine, provides recognition for scientists and provides experts in the fields of nuclear medicine radiation safety as well as radiopharmacy. This year's 1996 certification examination will be given Saturday, June 2, 1996 in Denver, CO, in conjunction with the 43rd SNM Annual Meeting. For more information contact Joanna Wilson at: [jwilson@snm.org](mailto:jwilson@snm.org).

—Stacey Silver