NRC's ACMUI Meets for First Time in Two Years

The Nuclear Regulatory Commission (NRC) convened a meeting of its Advisory Committee on the Medical Uses of Isotopes (ACMUI) on July 10, 1990, in order to provide the Committee with status reports on medical use rulemakings and to collect ACMUI advice on certain regulatory and administrative matters. The meeting, which was held in Rockville, Maryland, was attended by various NRC officials.

Petition for Rulemaking Change

One of the major discussions during the meeting centered around a 1989 petition filed by The Society of Nuclear Medicine (SNM) and The American College of Nuclear Physicians (ACNP) dealing with the preparation and administration of radiopharmaceuticals. SNM and ACNP submitted the petition requesting that the NRC revise its regulations to allow nuclear physicians and nuclear pharmacists to reconstitute non-radioactive kits differently from the methods recommended by the manufacturers and to allow them to prepare radiopharmaceuticals whose manufacture and distribution are not regulated by the Food and Drug Administration (FDA) (see *Newsline*, August 1989, p. 1296).

The petition is currently under consideration by the NRC, and a decision is scheduled to be made in two years. According to Larry W. Camper, chief of the medical and academic use section in the NRC's office of nuclear material safety and safeguards (NMSS), the Commission has received nearly 500 comment letters on the petition, nearly all of them in full support of it.

The primary issues identified in the petition were:

- use of byproduct material in research using human subjects.
- departure by medical use licensees (and nuclear pharmacists) from the manufacturer's instructions for eluting generators and preparing reagent kits.
- departure from the package inserts for unlisted indications and routes of radionuclide administration.

Witnesses appeared at the meeting to support the rulemaking petition. Speaking on behalf of the American Pharmaceutical Association (APHA) at the ACMUI meeting, Clyde Cole — chairman of the regulatory affairs committee of APHA's nuclear pharmacy group, academy of practice and management, section of specialized pharmaceutical services — delineated his organization's support for the petition. "Today, a pharmacist can be fined by the NRC for using his professional judgment in the preparation and dispensing of a radiopharmaceutical that is inconsistent with current NRC guidelines but consistent with the pharmacist's responsibility to preserve the patient's health," he told the Committee. "Existing NRC regulations do not allow for the extemporaneous compounding of a bona fide radiopharmaceutical prescription pursuant to a physician's order."

Mr. Cole — who is the vice-president of Cadema Medical Products, Inc., Middletown, New York — further emphasized that pharmacists are allowed to compound and dispense prescriptions and medications, including radiopharmaceuticals, by permission from the FDA and state boards of pharmacy. He told the Committee that "the NRC's position conflicts with the states' authority to regulate the practice of radiopharmacy," since NRC regulations prescribe that the compounding and dispensation of radiopharmaceuticals must fall within the limits of package inserts.

"Package inserts are generally understood to be recommendations and reflections of known drug information only at the time of FDA approval of an original new drug application," explained Mr. Cole. "Any departure is, therefore, based on the judgment of the nuclear pharmacists utilizing the most current technical information available."

Mr. Cole also underscored that the NRC's "overly restrictive" approach to compounding radiopharmaceuticals can compromise patient care and safety. He pointed out that package inserts often don't take into consideration dosage variations that are necessary, for instance, for pediatric patients or patients with certain physiologic conditions.

President of the ACNP, Robert E. Henkin, MD, bolstered Mr. Cole's contentions. "Can a doctor write a prescription for a radiopharmaceutical the way he can write a prescription for any other drug in this country?" he asked the Committee rhetorically. "The answer at the moment is no." Dr. Henkin continued, "the incidence of injury from radiopharmaceuticals is essentially nil, yet we're not permitted to use them in the most effective fashion in our professional judgment for a given patient." Dr. Henkin then added that the practice of radiopharmacy is too often constrained by inflexible package insert directions, some of which are ten or more years old.

QA Controversy

Attendees at the ACMUI meeting vociferously debated the NRC's proposed basic quality assurance (QA)

rule for medical use (see *Newsline*, April 1990, p. 22A). The NRC had published proposed amendments to 10 CFR Part 35 that would require medical use licensees to establish and implement a basic QA program. The NRC also proposed modifications to the definition of the term "misadministration."

John Telford, section leader for the rulemaking section, regulation development branch, office of research, NRC, delivered a status report on the QA program. According to Mr. Telford, in May 1990, 72 NRC and Agreement State licensees began a "pilot program" designed to evaluate different QA programs across the country, to find weaknesses and strengths, and to determine a consensus QA program that would address the minimum requirements of nuclear medicine facilities.

According to Mr. Telford, the NRC's desire to implement a standard QA protocol was also meant to decrease the incidence of misadministration of radionuclides at nuclear medicine facilities. The QA rule "is a basic effort to try to prevent misadministration," Mr. Telford told the Committee. "It doesn't say that thou shall make zero mistakes. It just says thou shall design a program to try to prevent these mistakes." John Glenn, PhD, chief, medical and commercial use safety branch, NMSS, asserted that "the purpose of the QA program is to have each licensee look at its program [and] establish a QA procedure that would guarantee that the directives of the licensed authorized users [are] carried out." Mr. Telford estimated that 80% of the misadministrations that have occurred in the past decade in nuclear medicine facilities could have been avoided if a prescriptive QA rule had been in place.

Dr. Henkin, however, argued that "you can reduce the incidence of errors to a definable point, but you can't eliminate them until you eliminate the humans from the system." Dr. Henkin went on to point out that the rate of misadministration of radionuclides in nuclear medicine is only about 6 per 100,000 procedures. Moreover, he asserted that the QA manual produced by the Joint Council on Accreditation of Health Care Organizations (JCAHO) serves as an adequate and effective model.

Based on initial comments received from the participants of the pilot study, Mr. Telford indicated that the NRC's prescriptive QA protocol involved only 10% more work from the QA programs already in place at these various facilities. To that figure, Dr. Henkin responded, "If 90% of what you propose doing is already being done, why is any regulation required at all?"

The SNM and the ACNP remain steadfast in their opposition to the QA proposal and requested that the NRC withdraw the rule — which the NRC refused to do. Dr. Henkin maintained that this rule is directed only toward the perceived problem of misadministration and not QA. SNM and ACNP "feel strongly that QA is a medical function, and not the domain of the Federal Government. Only peers can judge QA. There are too many variables between different practices such that it is difficult to mandate what quality control and quality assurance are." Joining the opposition to the QA rule was Committee member Carol S. Marcus, PhD, MD. "The manner in which professionals conduct their business is an inherent and integral part of the practice of medicine [that] many of us feel is being interrupted without any logical [or] substantial reason on the part of the NRC," she said.

Visiting Fellows Program

Concerning the NRC's recently mandated Visiting Fellows Program, ACMUI decided that candidates with expertise in the fields of diagnostic and therapeutic radiological physics and/or radiopharmacy should be considered for these posts, along with specialists in nuclear medicine and radiation oncology (see *Newsline*, August 1990, p. 31A). "We are very hopeful that this program will be well received by the medical community and that it will provide us with useful [information] that we can go about incorporating into the regulatory process," said Mr. Camper during his status report on the progress of the program.

Although the program was universally praised by ACMUI members, some Committee members expressed concern that the program would not be able to attract enough worthy candidates if the compensation paid was not substantial or at least comparable to what candidates would earn at their regular institutions of employment. When Mr. Camper suggested that the fellow's home institution might be asked to pay for part of the fellow's salary, Committee member Edward W. Webster, PhD, noted that a full-time position at the NRC would discourage the candidate's institution from putting up the bulk of his salary. ACMUI member Captain William H. Briner, (USPHS, Ret.), added that certain clinics and universities would be unwilling to let their physicians leave for a year-long sabbatical, especially in today's market in which shortages of qualified physicians and technologists abound. The issues of salary and fellowship job description are still under deliberation.

With regard to the training and experience criteria for nuclear medicine personnel, the ACMUI recommended maintaining the NRC's current requirements, which specify a six-month training program for physicians who use byproduct material for clinical procedures.

Following suggestions from the NRC that the ACMUI's membership should be as broad as possible — representing perhaps public interest

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groups, the United States Public Health Service, the FDA, state regulatory agencies, and other individuals experienced in medical issues — the Committee will consider widening its scope and balancing its viewpoints. Chairman Siegel presented a rough proposal for the Committee's future composition. Dr. Siegel stated that the Committee body should consist of two or three nuclear medicine technologists and nuclear medicine physicians (from both university programs and the clinical practice arenas), two radiation oncologists, one radiation physicist, one radiopharmacist with expertise in human radiobiology, representatives from the FDA and consumer groups, and academics involved in medical policy-making issues.

After receiving further suggested additions to the Committee body (including possible representation from the cardiovascular community and practitioners of teletherapy and brachytherapy), Committee members voiced the concern that so many potential candidates would make the ACMUI too unwieldy and too broad-based. They also expressed their fear that too many non-physicians in the mix would dilute the medical input into the advisory group and, thus, decimate the original intent of the Committee. In response, Dr. Siegel noted, "Since we are talking about advising the NRC with respect to regulatory efforts that affect a broad slice of medical practice, including both physicians and ancillary personnel, getting representation of more than one viewpoint is essential."

The Committee will also consider decreasing the term of appointment for members (currently six years) and agreed to increase the frequency of meetings to a minimum of two a year. Dr. Siegel proposed a five-year term with no sequential reappointments. "It is important for advisory committees to turn over, to [bring] new opinions and new blood [into the advisory process]."

Dr. Siegel also proposed that the name of the Committee be changed since the acronym "ACMUI" is difficult to pronounce and sounds odd. Alternatives that surfaced at the meeting included "Medical Uses Advisory Committee" (MUAC) and "Advisory Committee on Radioisotopes in Medicine" (ACRIM). These issues will be discussed in greater detail at the next ACMUI meeting, scheduled to be held in January 1991.

Palash R. Ghosh

Members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Barry A. Siegel, MD *(Chairman)*
Peter R. Almond, PhD
Capt. William H. Briner, (USPHS, Ret.)
Vincent P. Collins, MD
Jack K. Goodrich, MD
Melvin L. Griem, MD
Nilo E. Herrera, MD
Carol S. Marcus, PhD, MD
Joan A. McKeown
Gerald M. Pohost, MD
Edward W. Webster, PhD

1990 Scientific Exhibit Prizes

The Scientific Exhibits Subcommittee of the Scientific Program Committee awarded the following prizes during The Society of Nuclear Medicine's 37th Annual Meeting last June.

FIRST PRIZE:

Development of a High Current Electrostatic Accelerator and Targetry for the Production of Radionuclides for PET. Robert E. Klinkowstein, Ruth E. Shefer, Jonah H. Jacob, Michael J. Welch, James W. Brodack. *Science Research Laboratory, Inc., Somerville, Massachusetts and Washington University, St. Louis, Missouri.*

SECOND PRIZE: (two)

Accuracy of Bone Scintigraphy for Detection of Osseous Spinal Metastasis Correlated with Primary Tumor Histology. Kirkman G. Baxter, Diane E. Engelbrecht, Louis H. Wetzel, Ralph G. Robinson, David F. Preston. *University of Kansas Medical Center, Kansas City, Kansas.*

Definition of Myocardial Viability in the Rabbit Heart. Jay A. Bianco, Ramiah Subramanian, Linda Sebree, Robert Pyzalski. *University of Wisconsin Medical School and VA Medical Center, Madison, Wisconsin.*

THIRD PRIZE:

A Diagnostic Algorithm for the Systematic Evaluation of Suspected Osteomyelitis. Robert D. Katz, Randall A. Hawkins. *Kaiser Permanente and University of California, Los Angeles, California.*

FOURTH PRIZE:

The Duke Experience — 1,000 Clinical PET Studies. John M. Hoffman, Michael W. Hanson, C. Craig Harris, John L. Need, Sharon M. Hamblen, David M. Coates, Thomas C. Hawk, Vernon D. Dew, Michael F. Dailey, R. Edward Coleman. *Duke University Medical Center, Durham, North Carolina.*