Advisory Committee on the Medical Uses of Isotopes

NRC Advisory Committee Calls for Narrowed QA Rule and Better-Defined Response to the Radiopharmacy Petition

THE NUCLEAR REGULATORY Commission's (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) spent the bulk of its recent two-day meeting dicussing the NRC's quality assurance (QA) rule and the Commission's interim response to the petition put forth by The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) to change 10 CFR Part 35, "Medical Use of Byproduct Material." During the meeting, which was held January 14 and 15, the Committee recommended that the NRC focus the diagnostic component of the QA rule on eliminating iodine-131 misadministrations and clarify the interim response to the Part 35 petition.

Quality Assurance Rule

The first item on the Committee's agenda was the NRC's QA rule, published in the January 16, 1990 *Federal Register* (see *Newsline*, April 1990, p.22A). During the meeting, the NRC staff reviewed the extensive information gathering that had occurred since publication of the rule. This included the pilot QA program, workshops with pilot program participants, meetings with several professional organizations, including SNM, and meetings with representatives of Agreement States. Based on this information and the original written comments provided in response to the January 1990 QA rule, the NRC staff prepared a draft revision of the rule. It was this revision that the ACMUI reviewed in detail.

Regarding the Committee's discussions of the QA rule, ACMUI Chairman Barry A. Siegel, MD, professor of radiology and medicine, director of the division of nuclear medicine, Mallinckrodt Institute of Radiology, Washington University School of Medicine, St. Louis, Missouri, says, the Committee "made an important recommendation that the QA rule be altered so as to delete any requirements relating to the diagnostic uses of byproduct material, except for those that involve more than 30 microCurie of iodine-131 (^{131}I) or iodine-125, as sodium iodide."

ACMUI member Capt. William H. Briner (USPHS, ret.) associate professor of radiology, director of the radiopharmacy and nuclear medicine laboratory, Duke University Medical Center, Durham, North Carolina, says, "The advisory committee unanimously voted that NRC should forget about quality assurance in diagnostic uses," reasoning that other entities, such as the Joint Commission on Accreditation of Healthcare Organizations, "are doing that very well."

Dr. Siegel notes that "since the dismantling of the diagnostic component of the quality assurance rule as currently written would have some impact on other parts of the rule. . .the Committee recommended that requirements for diagnostic misadministrations. . .keep essentially the same definitions, but that the reporting threshold be tied to some radiation dose, such as an effective dose equivalent of 5 Rems." The advisory group suggested that the threshold be based on National Council on Radiation Protection (NCRP) recommendations that are expected to be released in March.

The aim of the ACMUI's recommendations, according to Dr. Siegel, is to reduce the number of reportable events, so that attention can be focused on events that are "potentially more serious." Rather than get bogged down in QA requirements for routine studies, "the NRC should put their money and the focus of the rule where it is really needed."

He added, "The large paperwork burden that would be associated with the diagnostic component [as currently written] is not likely to have any beneficial effect, would not likely alter practice patterns to any significant degree, and, more importantly, it would dilute people's attention from situations where misadministrations can really do harm." By suggesting these changes, says Dr. Siegel, the Committee "is supporting the NRC's attempt to get down to zero events with ^{131}I. Those circumstances in which a thyroid scan with iodine-123 was intended and the patient incorrectly receives a 5 milliCurie dose of iodine-131 are the ones we want to prevent from ever happening again."

The Committee recommended only minor changes in the therapeutic component of the QA rule. Dr. Siegel noted that the Committee considered the requirement for a written directive from an authorized user physician for ^{131}I in therapeutic and large diagnostic doses to be "appropriate."

The last recommendation relating to the QA rule called for the deletion of the requirement (introduced into the draft revision by the NRC staff) for pregnancy and lactation evaluation of

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all women of childbearing age. Dr. Siegel noted at the meeting that such a requirement would be a *de facto* mandate for routine pregnancy testing, would cost greater than $100 million to implement, and would create a new standard in the practice of medicine.

Response to Part 35 Petition

During the Meeting, the Committee and attendees spent much time attempting to clarify the wording of the NRC's interim final response to the Part 35 petition for rulemaking change. SNM and ACNP requested clarification of the interim final rule in a September 21, 1990 letter to John H. Glenn, Jr., PhD, chief of the NRC's medical, academic and commercial use safety branch, (see *Newsline*, November 1990, p.20A), but his January 9 letter of response leaves many questions unanswered. In the letter, Mr. Glenn maintained the position from the interim final response that a departure would be permitted if it were necessary "to obtain medical results otherwise unobtainable [or] to reduce risk to a particular patient."

Dr. Siegel says the Committee considered this "current wording of the rule to be too restrictive in terms of the necessity to be capable of defining an expected benefit or a reduced risk for each deviation." The NRC, adds Dr. Siegel, "should allow physicians to be the arbiters of what are medical decisions."

Capt. Briner says, "the impact of the interim final rule is still an unknown quantity. The NRC hasn't explained to the whole country how it's going to implement the interim rule."

The Committee and attendees expressed concern about the potential restrictiveness of the ruling and its vague language, but the NRC indicated that the rule would not be narrowly interpreted. From the standpoint of enforcement, says Dr. Siegel, "the NRC indicated that they're not going to second-guess physicians' directives. During the interim final rule, they're more interested in looking to see that the record-keeping is done." In fact, in his letter of response, Mr. Glenn wrote that the two criteria for departure are to be interpreted broadly, allowing for "a great deal of latitude in the best interest of the patient." The letter goes on to state, however, that either a false departure statement or a failure to record reasons for the deviation "would be subject to enforcement action."

To provide the NRC with the data they are attempting to collect through the rule's record-keeping requirements, the Committee recommended that SNM and ACNP independently undertake a project to collect data on the type and frequency of deviations from manufacturer's instructions over a six-month interval, sampling a broadly representative group of licensees.

Expressing skepticism about the value of such data, Committee member Carol S. Marcus, PhD, MD, associate professor of radiological sciences, University of California, Los Angeles (UCLA), director of the nuclear medicine outpatient clinic, Harbor-UCLA Medical Center, says that the numbers would be skewed because, currently, departures and the reporting of departures are at an inappropriately low level, due to fear of NRC enforcement actions.

SNM President Naomi P. Alazraki, MD, co-director of the division of nuclear medicine, Emory University Hospital, chief of nuclear medicine, VA Medical Center, Atlanta, Georgia, said at the meeting that SNM would undertake such a project, pending receipt of details from the NRC or the ACMUI specifying the nature of data, the timing, and other goals to be achieved.

It is unclear whether the NRC will accept any or all of the ACMUI's recommendations regarding the QA rule and the interim final response to the Part 35 petition. The NRC staff has indicated that it will attempt to present a final QA rule to the Commission by April 1991, but no timetable has been put forward for resolution of the

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petition and interim response.

In other presentations during the ACMUI meeting, the NRC announced that Myron Pollycove, MD, professor of laboratory medicine and radiology, director of the nuclear medicine department, of the San Francisco General Hospital, California, and Mark H. Rotman, MS, PharmD, BCNP, chief of the radiolabeling unit, monoclonal antibody section, department of nuclear medicine, National Institutes of Health, Bethesda, Maryland, have been "selected, pending final negotiations" into the agency's Medical Visiting Fellows Program. Larry W. Camper, section leader of the NRC's medical and academic section, says that fellowships are expected to last "at least one year and possibly two years." According to Mr. Camper, projects for physician fellows might include: assisting the NRC in establishing "what constitutes an adequate preceptorship" and taking a "further look at misadministrations." Projects for radiopharmacist fellows might include: assisting the NRC with "potential regulatory changes relative to some of the emerging radiopharmaceuticals," such as radiolabeled biologics, and providing "input as the Commission works to resolve the remaining issues in the radiopharmacy petition submitted by the SNM and the ACNP." Mr. Camper noted that "one of the primary objectives" of the fellows program is "to develop a cadre of individuals that the Commission could turn to in the future," when it is presented with "complex regulatory issues impacting on the practice of nuclear medicine." Dr. Siegel says, "The most important reason to have such experienced nuclear medicine professionals within the NRC is to establish a readily available link to the reality of how nuclear medicine is practiced."

According to Mr. Camper, "There will be further *Federal Register* notices calling for additional applicants to the Program. Such notices will be timed to coincide with the agency's need and the terms of the existing fellowships."

The NRC renewed its call for additional ACMUI members during the meeting. According to Dr. Siegel, the NRC has asked the Secretary of Health and Human Services and the Food and Drug Administration Commissioner to nominate Public Health Service and FDA representatives. The NRC is also seeking "an expert in brachytherapy, someone who can represent the interests of the states, and a consumer representative," says Dr. Siegel.

During the ACMUI meeting, Dr. Alazraki, Robert E. Henkin, MD, immediate past president of ACNP, and Sharon A. Surrel, CNMT, Chairwoman of the SNM Technologist Section Government Relations Committee, made statements relating to the issues before the Committee.

The next ACMUI Meeting is scheduled for May 1991.

Sarah M. Tilyou

ACMUI Members

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

Chernobyl

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carry out two missions. One, requested by the U.S., is scientific — to collect data on the effects of radiation. The other, requested by the Soviet Union, is to address the medical, psychological, and economic needs of the population living in the contaminated areas of the Soviet Union." The tragic accident at Chernobyl has ironically provided scientists with a wealth of data and an excellent opportunity to study the health effects of radiation. The knowledge gained may be used by medical practitioners and review bodies faced with the need to establish and review new procedures and guidelines involving human radiation exposures. At the same time, physicians and governments must grapple with how to handle the immense medical needs, both physical and psychological, of the massive numbers of people who were affected by the fallout from Chernobyl.

Joan Hiam