NRC Responds to SNM Queries on Radiopharmacy Petition

ON SEPTEMBER 21, 1990, The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) sent a letter to John E. Glenn, chief, office of nuclear material safety and safeguards, Nuclear Regulatory Commission (NRC), requesting clarification of the NRC's interim final rule on when physicians may deviate from a radiopharmaceutical manufacturer's insert instructions (see *Newsline*, March 1991, p.21N and November 1990, p. 20A). The interim rule was published after the NRC had received an SNM/ACNP petition requesting that physicians be allowed to deviate from the manufacturer's insert instructions. Mr. Glenn responded to the SNM/ACNP request for clarification on the issue in a letter dated January 9, 1991. The text of the letter sent to the NRC by SNM President Naomi P. Alazraki, MD, and ACNP President Robert E. Henkin, MD, on behalf of their respective organizations, follows.

SNM/ACNP Letter

We are writing with regard to the recently published interim final rule Fed. Reg. Vol. 55 No. 164 page 34513 in response to the Petition for Rulemaking filed by the American College of Nuclear Physicians (ACNP) and The Society of Nuclear Medicine (SNM). We appreciate the efforts that the NRC has made in response to the petition. In general, the items covered in the Federal Register notice represent a positive response to the petition. We note, as we had learned from a number of private discussions with NRC personnel, that there are significant items in the petition that would not be responded to at the present time. We look forward to that response in the future.

There is, however, some confusion that has resulted from the wording of the interim final rule. As worded, an "authorized user physician" may direct a "specific departure for a particular patient, or patients, or for a radiopharmaceutical" if he "includes the specific nature of the departure, a precise description of the departure, and a brief statement of the reasons why the departure from the manufacturer's instructions for preparing the radiopharmaceutical would obtain medical results not otherwise obtainable, or would reduce medical risk to particular patients because of their medical condition. If the authorized user physician determines that a delay in preparing the radiopharmaceutical in order to make a written directive would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the radiopharmaceutical may be prepared first without making a written directive."

In the discussions held between the nuclear medicine community and the NRC, the nuclear medicine community understood that the criteria for deviation from package insert during the three years of this trial period, would be solely physician judgement. The physician would only be required to simply note the reason for his deviation. The wording that is cited above is considerably more restrictive, in our opinion, than our discussions led us to anticipate.

The rule could be construed to say that the only justification for going outside the package insert would be:

1. To obtain medical results not otherwise obtainable.
2. Reduce risks to a particular patient.

We believe this to be too restrictive and subsequent discussions with you have indicated that it was not NRC's intent to be this restrictive.

Since there appears to be wording that could be interpreted as restrictive, we request information on what enforcement actions would be associated with physicians who used a radiopharmaceutical other than as described in the package insert and did not satisfy the NRC criteria as listed above. Without going into detail, there are a number of clinical situations in which departure from the package insert would occur and might be difficult to fit into one of the two clinical categories. For that reason we would hope that a prescription would serve as adequate documentation of the deviation and that physician judgement would be sufficient justification.

We agree with and understand the data gathering aims of the U.S.N.R.C., however, in order that our membership be able to properly comply with the rule while exercising their best medical judgement, some clarification is required as to how this rule is interpreted by NRC. If, in fact, the physician involved believes for reasons that he cannot define well, that his deviation from the package insert is in his patient's best interest, what would NRC's response be to this? Likewise, we hope that NRC will not consider the outcome of a procedure, if it did not benefit the patient, as a lack of justification for having done it in the first place. Physicians are often forced to make judgements based on their best estimation and unable to predict the outcome. If an outcome is not more beneficial than the standard method, it should still be acceptable.

These are very important issues in instructing our membership how they must comply with the interim final rule and what is and is not appropriate under that rule. We look forward to your response at the earliest possible date.

NRC Response

The text of John Glenn's letter on

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News Briefs

Henry N. Wagner, Jr., Receives AMA's Scientific Achievement Award

The American Medical Association (AMA) has selected Henry N. Wagner, Jr., MD, department of radiological sciences, The Johns Hopkins Medical Institutions, Baltimore, Maryland, as the 1991 recipient of its Scientific Achievement Award. The AMA established this award "to recognize individuals for outstanding scientific work," said James S. Todd, MD, executive vice-president of the AMA. According to William R. Hendee, PhD, vice-president for science and technology, AMA, "Dr. Wagner is the first nuclear medicine physician to be so honored. The award is an acknowledgement of the high quality of scientific work that Dr. Wagner has produced throughout his long, illustrious career and the many contributions he has made to medicine, and the impact he has had on other individuals' work."

The Award, which consists of a $2,500 stipend and a medallion, will be presented to Dr. Wagner during the opening ceremonies of the AMA's Annual Meeting of the House of Delegates at the Chicago Hilton and Towers Hotel, at 2:00 P.M. on Sunday, June 23. ■

Nuclear Medicine Week

Nuclear Medicine Week will run from **July 28 to August 3, 1991.** Posters, buttons, and stickers promoting Nuclear Medicine Week will be available for purchase. To see the poster turn to p. 57A. For further information or to obtain The Society of Nuclear Medicine's *Nuclear Medicine Week Guidelines* packet, contact: Virginia Pappas, CAE, The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760; 212-889-0717. ■

Radiopharmacy Petition

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behalf of the NRC, directed to Drs. Alazraki and Henkin follows.

This is in response to your September 21, 1990 letter requesting clarification of how the Nuclear Regulatory Commission (NRC) interprets the interim final rule published August 23, 1990 in the *Federal Register* (55 FR 34513).

The NRC intended the interim rule to permit departures that are both physician driven and in the patient's best interest. The NRC considers the two criteria for making the departure, i.e., to "obtain medical results not otherwise obtainable" and to "reduce risk to particular patient," to be very broad categories encompassing many different specific reasons. They are intended to recognize the need for the authorized user physician to exercise a great deal of latitude in the best interest of the patient.

The NRC expects the authorized user physician to articulate the reason why the departure is appropriate for the particular patient, type of procedure or radiopharmaceutical. The NRC believes that the rule relaxes requirements to permit needed departures to benefit patients. A licensee's failure to articulate that reason is a failure to meet the minimum requirements established to permit the departure. (Of course, a false statement of reasons for the departure would also be subject to enforcement action.) The NRC recognizes the final outcome is uncertain and did not use patient outcome as a regulatory criterion for determining compliance with the interim final rule, i.e., a departure may be in full compliance with the rule not withstanding that in the particular case the desired medical results were in fact not obtained.

With respect to your questions regarding inspection and enforcement actions, NRC plans to direct its inspectors to check for completeness of required documents and to avoid questioning the medical basis or practice regarding the departures. In general, a licensee's failure to have the documents required under the interim rule or the presence of incomplete documents would be considered a record keeping violation and a severity level V violation. For violations that are willful or signify management break down, the NRC could take appropriate escalated enforcement action consistent with current enforcement policy described in 10 CFR Part 2.

Although not raised in your letter, there are issues related to the manufacturer's instructions which may be causing confusion about the interim final rule. The interim final rule neither addresses nor changes the regulations regarding departures from the indications for use, dosages or route of administration as currently addressed in the manufacturer's instructions for diagnostic radiopharmaceuticals. The NRC dropped those restrictions from 10 CFR Part 35 in the major revision of Part 35 which became effective in 1987. Further, the interim final rule neither addresses nor changes the use of radiopharmaceuticals in "any form" as authorized on a license of broad scope for "medical diagnosis, therapy or research."

I trust our explanations will help your membership in understanding the interim rule. I am also forwarding your letter to the NRC Office of Nuclear Regulatory Research so that it may be added to the public comments on the interim rule.

ACMUI

The interim final rule will be a topic at a meeting of the NRC's Advisory Council on Medical Uses of Isotopes (ACMUI) on May 9-10.