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.