7590-01

NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

PUBLIC MEETING

The Nuclear Regulatory Commission's (NRC) Advisory Committee on the Medical Uses of Isotopes will hold a public meeting at 9:00 a.m. on Monday, August 18, 1980 in Versailles IV Room, Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland.

The following agenda is scheduled:

1. Training and Experience Criteria for Physician-Users, Including Physicians Whose Use of Byproduct Material Is Limited to Nuclear Cardiology

   The Committee, which began discussion on this topic at its January 18, 1980, meeting, will continue its review of NRC's current physician-user qualification program.

   By way of background, NRC's objective is to ensure that authorized physician-users have sufficient training and experience to handle safely the radioactive material they request. The current criteria are stated in Appendix A, Regulatory Guide 10.8 for Groups I through VI (as listed in 10 CFR 35.100) and in NUREG-0339 for teletherapy.

   Evidence of adequate training and experience may be documented by using Supplements A and B of Form NRC-313M. The physician-applicant completes Items 4 and 5 of Supplement A outlining

his or her training in basic radioisotope handling techniques and his or her experience in using various types and quantities of radioactive material. The physician's preceptor completes and signs Supplement B describing the applicant's clinical experience. In lieu of documenting training and experience by submitting Supplements A and B, Form NRC-313M, a physician may submit evidence of certification by certain medical specialty boards. The current acceptable specialty board and nuclear medicine procedures are referenced in Appendix A and in NUREG-0339.

With one exception, the training and experience criteria for physicians performing only nuclear cardiology studies are the same as those for the entire spectrum of diagnostic procedures (Groups I-III). The exception is a reduction in the required number of clinical hours to 250. Individual physicians and professional societies have disagreed with these criteria.

During the January 18, 1980 meeting, the Federated Council of Nuclear Medicine Organizations requested that the Committee postpone further discussion of this topic until the Council could submit a proposal regarding training and experience criteria for physicians performing only nuclear cardiology studies. The Council agreed to provide its proposal to the Committee within

six months. The Committee agreed to continue review of its entire physician-user qualification program at its next meeting.

In its continuing review of this matter, the Advisory Committee will consider:

a. Whether to accept the Federated Council of Nuclear Medicine Organizations' proposal for physicians who are performing only nuclear cardiology studies. Alternatives will also be considered.

b. Whether NRC is meeting its objective with respect to authorized physician-users' training and experience.

c. Whether NRC's current criteria are appropriate.

d. Whether NRC should require documentation that the physician-applicant has successfully completed a course in basic radioisotope handling techniques.

e. Whether NRC should require that the preceptor certify that the physician-applicant is qualified to perform independently the clinical procedures specified on Supplement B, Form NRC-313M.

f. Whether there are medical specialty board certifications other than those currently accepted by NRC that should be considered by NRC as evidence of adequate training and experience. (For example, should certification by the American Board of

Nuclear Medicine be accepted as evidence of acceptable training and experience for Groups IV and V? Should certification by the osteopathic boards be accepted for licensing purposes in the same manner as their counterparts, the American Board of Radiology and the American Board of Nuclear Medicine?).

2. Use of Iodine-131 for Treatment of Cardiac Dysfunction

Among other procedures, Group IV of 10 CFR 35.100 currently authorizes use of iodine-131 for treatment of cardiac dysfunction. The Commission has asked for the Committee's formal recommendation and the basis for that recommendation regarding continued authorization of this procedure.

The background for the Commission's request is as follows. NRC's Medical Policy Statement indicated that NRC would restrict use of therapeutic drugs to the indicated procedures that have been approved by the Food and Drug Administration (FDA). In 1971 FDA classified use of iodine-131 for treatment of cardiac dysfunction as "possibly effective" and invited persons to submit data in support of this "possibly effective" indication. By 1976 no clinical data had been submitted and FDA reclassified the treatment of cardiac dysfunction as "lacking substantial evidence of effectiveness." (This classification does not constitute evidence of ineffectiveness).

Cardiac dysfunction is usually treated using non-radioactive drugs. However, there are physicians who believe that iodine-131 treatment may be useful in some patients. If the procedure were deleted from Group IV, physicians would be unable to use iodine-131 to treat

patients with cardiac dysfunction except in accordance with a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA (see 10 CFR 35.100(d)(4)).

The Committee will consider various alternatives for dealing with this problem. The issue to be decided is whether authorization of the use of iodine-131 for treatment of cardiac dysfunction should be continued. The Committee will also formulate a statement explaining the basis of its decision.

3. Status Report on Proposed and Final Rule Changes and Other Items Of Interest

The NRC staff will provide a report on the current status of various rule changes (e.g., misadministration reporting requirement; changes in composition and function of medical isotopes committee) and other items of interest (e.g., model program for medical licensees for keeping radiation exposures as low as reasonably achievable, rewriting of 10 CFR Part 20).

Practical considerations may dictate alteration in the above agenda.

Mr. Richard Cunningham, Director, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, will serve as Chairperson of the Advisory Committee meeting. Mr. Cunningham is empowered to conduct the meeting in a manner that, in his judgment, will facilitate the orderly conduct of business.

The following requirements shall apply to public participation in the agenda items listed above.

1. Persons wishing to submit written statements on agenda items may do so by providing a readily reproducible copy at the beginning of the meeting. Persons wishing to mail written comments may do so by sending at least one readily reproducible copy (preferably 25 copies) to Mr. Cunningham in care of NRC, Washington, D.C. 20555. Comments postmarked no later than August 11, 1980, should be received in time for consideration at the meeting. The minutes of the meeting will be kept open for 30 days for the receipt of written statements for the record.

2. Persons desiring to make oral statements should make a request to do so prior to the beginning of the meeting and should identify the agenda items they wish to discuss. To the extent that the time available for the meeting permits, the Committee will receive oral statements during a period of not more than 60 minutes at a time chosen by the Chairperson. The Chairperson shall rule on requests to make oral statements and shall apportion the available time among those he selects to make oral statements.

3. Questions may be asked only by Committee members, consultants, and staff.

4. Seating for the public will be on a first come - first served basis.

5. Rulings on requests to make oral statements and the time allotted may be obtained by prepaid telephone call to Mr. Cunningham at (301) 427-4485 between 9:00 a.m. and 5:00 p.m. EDT on August 14 or 15, 1980.

6. Other information regarding the meeting may be obtained by prepaid telephone call to Mrs. Patricia Vacca at (301) 427-4232 between 9:00 a.m. and 5:00 p.m. EDT.

7. A copy of the minutes of the meeting will be available for inspection at the NRC Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555 on or before October 10, 1980. Copies of the minutes may be obtained upon payment of required charges.

The meeting is held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a), Federal Advisory Committee Act (Pub. L. 92-46), Executive Order 11769, and the Commission's regulations in Title 10 Code of Federal Regulations, Part 7.

Dated at Washington, D.C., this 20th day of June, 1980.

John C. Hoyle
Advisory Committee Management Officer