October 18, 1990

POLICY ISSUE
(Notation Vote)

SECY-90-356

For: The Commissioners

From: James M. Taylor
Executive Director
for Operations

Subject: SECY-90-117/SECY-89-263 - ROTATION OF MEMBERSHIP, ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)

Purpose: To respond to the Commissioners' request, in a Staff Requirements Memorandum (SRM) dated April 23, 1990, that the staff expand the representation on the ACMUI and have the ACMUI meet more frequently as a group. A draft Federal Register Notice calling for nominations for new members to the ACMUI is enclosed.

Background: The Commissioners asked the staff to expand representation on the ACMUI to ensure that the committee provides the staff with a balanced view on the policy and technical issues associated with medical uses of byproduct material. The Commissioners specifically asked for the addition of members representing patients' rights and care, the U.S. Public Health Service (USPHS), the Food and Drug Administration (FDA), and the States. Furthermore, the Commission asked that the committee meet more frequently as a group.

Discussion: Current Composition. The current ACMUI committee consists of seven physicians, two medical physicists, one nuclear pharmacist, and one nuclear medicine technologist. The physicians have three primary specialties: four specialize in nuclear medicine, two in radiation oncology, i.e., teletherapy, and one in cardiology.

ACMUI Input. During the July 10, 1990, ACMUI meeting, the ACMUI members discussed committee expansion and types of additional members, as specified by the Commission. Certain committee members were concerned that medical guidance to the committee might be diluted and the committee, then, would no longer provide the U.S. Nuclear Regulatory Commission (NRC) with the same quality of medical advice. However, the

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

CONTACT:
Donna-Beth Howe, NMSS
492-0636

committee recognized the need for expansion to ensure balanced guidance as required by the Federal Advisory Committee Act. The committee also recommended that two additional medical specialties, i.e., brachytherapy and monoclonal antibody therapy use, be added to increase the scope and depth of medical coverage, and increased efforts be made to ensure balanced representation among State licensees, small practices, and large institutions. The staff also believes that a hospital administrator would be a useful addition to the committee. The last request for nominations included this specialty; however, no nominations were received.

The ACMUI discussed the appropriate length of service for committee members, at the July 10, 1990, ACMUI meeting. The primary proposal discussed was a 5-year limited appointment, with no sequential appointment. There was no opposition to this proposal. The committee also discussed its meeting frequency and agreed to increase the frequency to biannually, preferrably in the spring and the autumn. In addition, the next meeting of the ACMUI is anticipated to be in January 1991, to coincide with completion of the quality assurance pilot program and final quality assurance rulemaking.

The FDA Representation. The staff proposes to request FDA to nominate one FDA employee with expertise in biologics, drugs, and medical devices.* According to discussions with a member of the Office of the General Counsel, Department of Health and Human Services (HHS), Food and Drug Division, an FDA employee could serve on the ACMUI. The views and opinions expressed by the employee would be those of the employee and could not be represented as those of the FDA Commissioner or the FDA. According to the member of the HHS Office of the General Counsel, the "official" FDA position on an issue is the written response to a formal request for FDA's position. This might also be the case for the USPHS representative and the State representative.

* The FDA has three distinct Centers that handle biologics, drugs, and medical devices. Therefore, it might not be practical to have only one FDA representative. The staff does not believe there is a need for three FDA employees to attend each ACMUI meeting; therefore, the staff will discuss with FDA the possibility of FDA nominating a single representative with alternates. The FDA designated representative would be the primary point of contact for ACMUI matters, and would be a voting member of the ACMUI. An alternate may vote in the place of the designated representative. The designated FDA representative, as well as the alternates, would need to undergo the same NRC conflict of interest review as the other appointed members of the ACMUI. The agenda for a particular meeting would be the basis for FDA determining which employee is most appropriate to provide insight on the issues to be considered at that meeting.

The USPHS Representation. The USPHS consists of physicians, dentists, scientists, engineers, pharmacists, and other professionals who belong to the USPHS Commissioned Corps. Its members are dispersed among many government agencies within HHS and other independent agencies, such as the Environmental Protection Agency. USPHS will be requested to nominate a physician or non-physician, having expertise in medical policy, who is willing to become a member of the ACMUI.

The States' Representation. The staff will solicit nominations of a physician or non-physician having expertise in State programs which are involved in the regulation of medicine, who is willing to become a member of the ACMUI. Organizations such as state medical licensing boards, the Conference on Radiation Control Program Directors, Inc. (CRCPD), etc., will be sent copies of the Federal Register Notice.

The Consumer Representative. The staff will solicit nominations of an individual having experience with and interest in the regulation of medicine. Organizations such as the American Association of Retired Persons, Consumers Union, etc., will be sent copies of the Federal Register Notice. The staff contacted the FDA Office of Consumer Affairs which has an extensive list of consumer groups interested in medical practice and many years of experience identifying and selecting consumer representatives for all of FDA's advisory committees. The staff will continue to consult with FDA to identify appropriate consumer groups which might nominate a consumer representative having an in depth knowledge of the medical community balanced with experience in representing consumers' interests in medical issues.

Proposed Implementation of Expansion and Rotation of the ACMUI Membership. The staff proposes to expand the ACMUI, as requested by the Commission, to include members representing patients' rights and care, the USPHS, the FDA, and the States. Other members having medical and technical expertise that ACMUI members and NRC staff believe necessary for a balanced viewpoint will be added to the committee. Such members include: a radiation oncologist having expertise in brachytherapy, a medical researcher having expertise in medical antibody use, and a hospital administrator.

The expansion of the ACMUI will be implemented in two phases, over the next 2 years. The current members of the ACMUI will be asked to remain on the committee until new members are added to replace them. The staff plan provides for the replacement of one member in 1991, one in 1992, and approximately three members each year, beginning in 1993.

The staff proposes to add four additional new committee members in 1991. Therefore, the new members will include the consumer representative, States' representative, a USPHS employee, a FDA employee, and a brachytherapy physician. The final two new members (i.e., a hospital administrator and medical researcher) would be added in 1992. All future committee members will be appointed to, and limited to, a 5-year no sequential term.

Conclusion: The staff believes the proposed plan provides for the orderly expansion of the ACMUI committee membership, a broad base of experts to provide advice to NRC on the medical use of isotopes, and implementation of 5-year appointments to the ACMUI.

Coordination: The Office of the General Counsel has reviewed this paper and has no legal objections.

Recommendations: That the Commission:

(1) Approve the letter in Enclosure B, for the Chairman's signature, for transmittal to FDA Commissioner Benson.

(2) Approve the letter in Enclosure C, for the Chairman's signature, for transmittal to the Assistant Secretary of Health.

(3) Note:

a. In accordance with the SRM dated April 23, 1990, the staff is calling for nominations for the ACMUI to include one member from FDA, one member from USPHS, a member with broad experience in medical regulation as conducted by the States, and a member representing patients' rights and care.

b. The staff is also calling for nominations for a radiation oncologist having expertise in brachytherapy.

c. The staff proposes to send the enclosed Notice calling for nominations to the Federal Register.

James M. Taylor
Executive Director
for Operations

Enclosures:
A. Draft FR Notice
B. Ltr to FDA
C. Ltr to USPHS

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Thursday, November 1, 1990.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Thursday, October 25, 1990, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ENCLOSURE A

[7590-1]

NUCLEAR REGULATORY COMMISSION

Nominations for New Members of the

Advisory Committee on the Medical Uses of Isotopes

AGENCY: Nuclear Regulatory Commission.

ACTION: Call for Nominations.

SUMMARY: The Nuclear Regulatory Commission (NRC) is increasing membership on its Advisory Committee on the Medical Uses of Isotopes (ACMUI) and is inviting nominations of qualified individuals from public interest groups representing patients' rights and care, individuals having expertise in state regulatory programs governing medicine, and individuals having expert qualifications in certain medical specialty fields.

DATES: Nominations due by _____, 1990.

ADDRESS: Submit nominations to: Secretary of the Commission, ATTN: Advisory Committee Management Officer, Nuclear Regulatory Commission, Washington, DC 20555

FOR FURTHER INFORMATION CONTACT: Larry Camper, Medical, Academic, and Commercial Use Safety Branch, MS 6-H-3, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3417.

SUPPLEMENTARY INFORMATION: The ACMUI advises the NRC staff on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. Responsibilities include providing guidance and comments on changes in NRC rules, regulations, and guides concerning medical use; evaluating certain non-routine uses of byproduct material for medical use; and providing technical assistance in licensing, inspection, and enforcement cases.

Committee members possess the medical and technical specialty skills needed to address evolving issues. The ACMUI currently consists of two physician specialists in therapeutic radiology; four physician specialists in nuclear medicine, with backgrounds in pathology, radiology, internal medicine, and nuclear cardiology; one nuclear medicine technologist; a radiopharmacist; and two specialists in medical physics. Because NRC is now examining issues such as quality assurance, and training and experience criteria, it is appropriate to expand the ACMUI's experience base to include new members who not only are technically qualified, but also can represent patients' interests or have experience from the perspective of the States on the regulation of radioactive material for medical use.

NRC is soliciting nominations of persons to fill the following three openings on the ACMUI; an individual qualified to address patients' rights and care, a person with broad experience in medical regulation as conducted by the individual States, and a brachytherapy physician. Persons who can provide perspectives from organizations on patients' rights and care, or regulatory agencies of States, as well as physicians having expertise in brachytherapy are encouraged to apply.

Committee members will serve and be limited to a 5-year appointment.

Nominations must include a resume describing the educational and professional qualifications of the nominee, and provide the nominee's current address and telephone number.

Nominees must be U.S. citizens and be able to devote approximately 80 hours per year to committee business. Members will be compensated and reimbursed for travel (including per diem in lieu of subsistence), secretarial, and correspondence expenses.

Dated at Washington, DC, this _____ day of _____ 1990.

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

John C. Hoyle
Advisory Committee
Management Officer

ENCLOSURE B

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

CHAIRMAN

Mr. James S. Benson
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Benson:

The U.S. Nuclear Regulatory Commission (NRC) requests your assistance in having a U.S. Food and Drug Administration (FDA) employee with expertise in biologics, drugs, and medical devices to act as a member of NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI). NRC regulates the medical use of byproduct material (radioisotopes), which includes the manufacture, distribution, use, and disposal of drugs, biologics and medical devices that contain byproduct material. These products are also regulated by FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH).

The ACMUI advises the NRC staff on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. Responsibilities include providing guidance and comments on changes in NRC rules, regulations, and guides concerning medical use; evaluating certain non-routine uses of byproduct material for medical use; and providing technical assistance in licensing, inspection, and enforcement cases. Because of the important interface of NRC and FDA regulatory responsibilities governing the medical use of byproduct material, we believe a member of the FDA staff would be a very useful addition to our ACMUI as it develops recommendations on NRC regulatory policy and guidance. The ACMUI will meet approximately twice a year in the Washington metropolitan area.

NRC recognizes that the FDA employee you may nominate might only present their individual views based on personal knowledge and experience and not necessarily the views of the FDA. NRC will continue to work directly with the FDA to obtain the FDA's official position on issues common to both agencies.

The NRC also recognizes FDA has three distinct Centers that handle biologics, drugs, and medical devices, and it may not be practical to have only one FDA representative. Therefore, the FDA may want to nominate a single representative from one of the centers, and alternates from the other two centers. The FDA may want its designated representative to be the primary point of contact with NRC. The designated representative would be a voting member of the ACMUI, and an

alternate could vote in place of the designated representative. The designated FDA representative as well as the alternates would be considered members of the ACMUI for the NRC's conflict of interest review.

Thank you for your assistance on this matter. If you have any questions, contact Richard E. Cunningham of my staff at 492-3426.

Sincerely,

Kenneth M. Carr

ENCLOSURE C

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

CHAIRMAN

James O. Mason, M.D.
Assistant Secretary of Health
U.S. Public Health Service
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Mason:

The U.S. Nuclear Regulatory Commission (NRC) requests your assistance in having a U.S. Public Health Service (USPHS) employee with expertise in medical policy issues to act as a member of NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI). NRC regulates the manufacture, distribution, use and waste disposal of byproduct material (radioisotopes), for medical use.

The ACMUI advises the NRC staff on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. Responsibilities include providing guidance and comments on changes in NRC rules, regulations, and guides concerning medical use; evaluating certain non-routine uses of byproduct material for medical use; and providing technical assistance in licensing, inspection, and enforcement cases. We believe a member of USPHS with broad knowledge of national medical policy issues would be a very useful addition to our ACMUI as it develops recommendations on regulatory policy and guidance. The ACMUI will meet approximately twice a year in the Washington metropolitan area.

NRC understands that the USPHS employee you nominate may present their individual views and not necessarily the views of the USPHS.

Thank you for your assistance in this matter. If you have any questions, contact Richard E. Cunningham of my staff at 492-3426.

Sincerely,

Kenneth M. Carr