UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 13, 2001

OFFICE OF THE
SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-01-0050

TITLE: DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN COLLEGE OF NUCLEAR PHYSICIANS/SOCIETY OF NUCLEAR MEDICINE

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 13, 2001.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

SECY NOTE: THIS PAPER WILL BE RELEASED 5 WORKING DAYS AFTER THE LETTERS ARE SENT TO THE PETITIONERS.

VOTING SUMMARY - SECY-01-0050

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	4/5/01
COMR. DICUS	X					4/5/01
COMR. DIAZ	X					4/6/01
COMR. McGAFFIGAN	X				X	3/26/01
COMR. MERRIFIELD	X					3/30/01

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and some provided additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on April 13, 2001.

Commissioner Comments on SECY-01-0050

Chairman Meserve

I approve the staff recommendations, listed below:

1. Approve the denial of the petition for rulemaking and publication of the *Federal Register* notice announcing the denial;

2. Inform appropriate Congressional Committee; and

3. Send the two letters which are attached for the Secretary's signature (Attachment 2), informing the petitioners of the Commission's decision to deny their petition.

I note the following items in the attached pages of the draft Federal Register notice for PRM-35-16 need modification prior to publication. Additionally, the two letters should be modified, as noted, before they are released.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN MESERVE

SUBJECT: **SECY-01-0050 -- DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN COLLEGE OF NUCLEAR PHYSICIANS/SOCIETY OF NUCLEAR MEDICINE**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

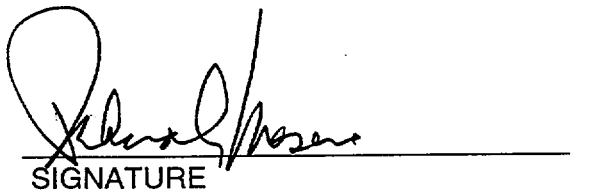
I approve the staff recommendations, listed below:

1. Approve the denial of the petition for rulemaking and publication of the *Federal Register* notice announcing the denial;

2. Inform appropriate Congressional Committees; and

3. Send the two letters which are attached for the Secretary's signature (Attachment 2), informing the petitioners of the Commission's decision to deny their petition.

I note the following items in the attached pages of the draft Federal Register notice for PRM-35-16 need modification prior to publication. Additionally, the two letters should be modified, as noted, before they are released.



SIGNATURE

April 5, 2001

DATE

Entered on "STARS" Yes X No_____

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-16]

American College of Nuclear Physicians and the Society of Nuclear Medicine;

Denial of a petition for rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of a petition for rulemaking.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking submitted by the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) (PRM-35-16). The petitioners request that the Commission: rescind its approval of the NRC staff's draft final revision of the regulations at 10 CFR Part 35 "Medical Use of Byproduct Material", which was approved by the Commission in a Staff Requirements Memorandum dated October 23, 2000; revoke all of Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the discipline's safety record. The NRC is denying the petition because: the Commission approved the final rule ~~after~~ using an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation; the Commission believes that the ACNP/SNM had ~~every~~ many ~~opportunity~~ opportunities to present ~~all of~~ their concerns and suggestions as part of that process; and the

Conclusion

The petitioners believe that the requested changes would benefit the public in two ways. First, substantial requirements for physicians' education, training, and experience, and appropriate evidence of mastery by testing would improve the knowledge and abilities of physicians offering diagnostic nuclear medicine. Second, costs to the health care system would decrease without any decrease in safety.

Reason for Denial

NRC is denying the petition because:

(1) The Commission approved the final rule addressing the issues raised in the petition after an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation;

(2) The Commission believes that the ACNP/SNM had ~~every opportunity~~ many opportunities to present ~~all of~~ their concerns and suggestions as part of that process and did so; and

(3) The petition does not appear to present any significantly new information or recommendations that the Commission has not already considered.

In general, the proposed rule amendments, comments, and supporting information presented by the petitioners were previously submitted by the ACNP/SNM in the following documents that provided comments on the rulemaking to revise Part 35.

specific provisions in Part 35 in SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments., **Part II - General Issues,** A. Risk.,Issue 4, as follows:

> The final rule includes requirements that are needed to protect occupationally exposed individuals, patients, and the public. Certain radiation protection-related requirements unique to medical use are needed in Part 35 because of their contribution to risk reduction. For example, the final rule retains requirements to calibrate instrumentation used to measure the radioactivity of patient dosages before they are administered (§ 35.60). For this reason and because the NRC believes that these requirements are essential to the safe handling of byproduct material, ... "

The NRC staff has already responded to Requested Actions 2-4 regarding training and experience requirements for the medical use and possession of byproduct material. See SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues,** ~~A. Risk.~~ E. Training and Experience, Issue 7 , as follows:

> The NRC believes that the training and experience requirements in the final rule for authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), authorized users (AU), and Radiation Safety Officers (RSO) are sufficient to assure that the radiation safety of the public, patients, human research subjects, and workers is maintained. Therefore, we deleted the requirement for an examination from all the training and experience sections. Instead of an examination, we will rely on the preceptor's certification that an individual has completed the required training and experience and has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO.

Further, under the revised 10 CFR Part 35, NRC will continue to rely on health care professionals who are required to meet certain NRC training and experience criteria to protect the health and safety of the public and patients.

The NRC staff has already responded to Requested Action 5 regarding the structure of regulations for the medical use of byproduct material in nuclear medicine (i.e., there are

specific provisions in Part 35 in SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments., **Part II - General Issues,** A. Risk.,Issue 4, as follows:

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The NRC staff has already responded to Requested Actions 2-4 regarding training and experience requirements for the medical use and possession of byproduct material. See SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues**, A. Risk., Issue 7 , as follows:

> The NRC believes that the training and experience requirements in the final rule for authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), authorized users (AU), and Radiation Safety Officers (RSO) are sufficient to assure that the radiation safety of the public, patients, human research subjects, and workers is maintained. Therefore, we deleted the requirement for an examination from all the training and experience sections. Instead of an examination, we will rely on the preceptor's certification that an individual has completed the required training and experience and has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO.

Further, under the revised 10 CFR Part 35, NRC will continue to rely on health care professionals who are required to meet certain NRC training and experience criteria to protect the health and safety of the public and patients.

The NRC staff has already responded to Requested Action 5 regarding the structure of regulations for the medical use of byproduct material in nuclear medicine (i.e., there are

different requirements for training of AU's under §§35.100, 35.200 and 35.300) in SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues,** E. Training and experience., 2. Training and experience - unsealed byproduct material., Issue 5, as follows:

> The NRC recognizes that there is a certain degree of basic radiation safety knowledge that is common among all the types of use, e.g., use of the decay formula and decontamination techniques. However, we also believe that there are some basic differences between the uses of byproduct material under §§ 35.100, 35.200, and 35.300 that warrant additional training and experience, e.g., increased potential for exposures in excess of Part 20 limits and the potential for adverse biological effects. For example, AUs [authorized users] handling byproduct material for imaging and localization studies, as compared to uptake, dilution, and excretion studies, are generally handling larger quantities and many different radionuclides. Also, AUs meeting the training and experience requirements in § 35.190 are not authorized to prepare radioactive drugs using generators and reagent kits, but AUs under § 35.290 are authorized to prepare drugs using generators and reagent kits. Finally, AUs under § 35.390 are handling material in quantities that can cause deterministic effects.

The NRC staff has already addressed the cost figures (i.e., over $100,000,000/ year to $1 billion/year) presented by the petitioners in SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues,** G. Costs of the revision, Issue 5, as follows:

> In evaluating the costs of regulatory compliance and implementation, the NRC has used detailed information whenever it is available. We have sought data from a number of sources, including medical speciality groups, manufacturers, members of the ACMUI, the National Institutes of Health, and various published sources. However, certain necessary data are treated as proprietary. Other data are not collected or are available only in a disaggregated form. Many of the compliance costs will vary substantially from licensee to licensee, depending on the number and type of modalities and procedures that they use and perform. Other compliance costs will be dependent on numerous interrelated variables. We believe that an effort to collect the necessary data and/or develop necessary models to provide substitutes for missing or unavailable data would require very considerable time and expense. We are concerned that at the conclusion of such an effort, because of many remaining gaps and uncertainties in the underlying data, an estimate of the total cost of the regulations would still fall within such broad confidence bounds that it would be fundamentally flawed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

Jonathan M. Links, Ph.D., President
Society of Nuclear Medicine
Government Relations Office
1850 Samuel Morse Drive
Reston, VA 20190-5316

SUBJECT: DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN COLLEGE OF NUCLEAR PHYSICIANS / SOCIETY OF NUCLEAR MEDICINE

Dear Dr. Links:

I am responding to the petition for rulemaking (PRM), dated January 3, 2001, jointly filed by you, on behalf of the Society of Nuclear Medicine (SNM) and Donald A. Podoloff, M.D., on behalf of the American College of Nuclear Physicians (ACNP). The petition has been docketed as PRM-35-16.

The petition requests that the Commission: rescind its approval of the U.S. Nuclear Regulatory Commission (NRC) staff's draft final revision of the regulations at 10 CFR Part 35, "Medical Use of Byproduct Material," which was approved by the Commission in a Staff Requirements Memorandum dated October 23, 2000; revoke all of 10 CFR Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material, in diagnostic nuclear medicine, that reflects the discipline's safety record.

The NRC has considered the petition and the supporting rationale. For the reasons provided in the enclosed Federal Register notice, your petition is denied. In summary, the petition is being denied because the Commission approved the final rule after an extensive rulemaking process that provided an unprecedented level of enhanced public participation; the Commission believes that the ACNP/SNM had ~~every opportunity~~ many opportunities to present ~~all of~~ their concerns and suggestions as part of that process; and the petition does not appear to present any significantly new information or recommendations that the Commission has not already considered.

The Federal Register notice denying the petition is being transmitted to the Office of the Federal Register for publication.

Sincerely,

Annette Vietti-Cook
Secretary of the Commission

Enclosure: Federal Register notice

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-01-0050 - DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN COLLEGE OF NUCLEAR PHYSICIANS/SOCIETY OF NUCLEAR MEDICINE**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

none

Greta Joy Dicus
SIGNATURE

April 5, 2001
DATE

Entered on "STARS" Yes x No ____

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-01-0050 - DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN COLLEGE OF NUCLEAR PHYSICIANS/SOCIETY OF NUCLEAR MEDICINE**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

No comments

SIGNATURE

Apr 6, 01

DATE

Entered on "STARS" Yes ✓ No ____

--REC'D BY NUD--

26 MAR 01 9:15

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-01-0050 - DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN COLLEGE OF NUCLEAR PHYSICIANS/SOCIETY OF NUCLEAR MEDICINE**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: See minor edits attached.

Edward McGaffigan Jr.
SIGNATURE

March 26, 2001
DATE

Entered on "STARS" Yes X No ____

Conclusion

The petitioners believe that the requested changes would benefit the public in two ways. First, substantial requirements for physicians' education, training, and experience, and appropriate evidence of mastery by testing would improve the knowledge and abilities of physicians offering diagnostic nuclear medicine. Second, costs to the health care system would decrease without any decrease in safety.

Reason for Denial

NRC is denying the petition because:

(1) The Commission approved the final rule addressing the issues raised in the petition after an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation;

(2) The Commission believes that the ACNP/SNM had every opportunity to present all of their concerns and suggestions as part of that process and did so; and

(3) The petition does not appear to present any significant new information or recommendations that the Commission has not already considered.

In general, the proposed rule amendments, comments, and supporting information presented by the petitioners were previously submitted by the ACNP/SNM in the following documents that provided comments on the rulemaking to revise Part 35.

petition does not appear to present any significant new information or recommendations that the Commission has not already considered.

ADDRESSES: Copies of the petition for rulemaking and the NRC's letters to the petitioners are available for public inspection or copying in the NRC Public Document Room, 11555 Rockville Pike, Room 01-D23, Rockville, Maryland.

FOR FURTHER INFORMATION CONTACT: Samuel Z. Jones, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6198, e-mail: szj@nrc.gov.

The Petition

On January 11, 2001, the NRC docketed a January 3, 2001, letter from Donald A. Podoloff, MD, of the American College of Nuclear Physicians, and Jonathan M. Links, PhD, of the Society of Nuclear Medicine, to the Office of the Secretary, as a petition for rulemaking under 10 CFR 2.802 (PRM-35-16). The petitioners request that the Commission: rescind its approval of the NRC staff's proposed revision to 10 CFR Part 35, "Medical Use of Byproduct Material," which was approved by the Commission in a Staff Requirements Memorandum dated October 23, 2000; revoke all of 10 CFR Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the discipline's "unparalleled and undisputed safety record."

The petitioners provide a history of the Commission's statutory authority and nuclear medicine regulation from their perspective. The petitioners state that the NRC regulates the

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-01-0050 - DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN COLLEGE OF NUCLEAR PHYSICIANS/SOCIETY OF NUCLEAR MEDICINE**

Approved ✓ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: No additional comments.

SIGNATURE

3/30/01

DATE

Entered on "STARS" Yes ✓ No ____