POLICY ISSUE
NOTATION VOTE

March 23, 2001 SECY-01-0050

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

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

PURPOSE:

To obtain Commission approval for denying PRM-35-16.

DISCUSSION:

By letter dated January 3, 2001, Donald A. Podoloff, M.D., of the American College of Nuclear Physicians (ACNP), and Jonathan M. Links, Ph.D., of the Society of Nuclear Medicine (SNM) submitted a petition for rulemaking (PRM-35-16) regarding the regulation of diagnostic nuclear medicine. The petitioners requested that the Commission: rescind its approval of the Nuclear Regulatory Commission (NRC) staff's draft final revision of the regulations at 10 CFR Part 35, "Medical Use of Byproduct Material," (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 staff has considered the petition and its supporting rationale. For the reasons set forth in a draft Federal Register notice addressing the petitioner's requested actions (Attachment 1),

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(301) 415-6198

the staff is recommending the denial of the petition. The staff notes that the Commission approved the final rule after an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation, in which the ACNP/SNM had every opportunity to present all of their concerns and recommendations. Also, the petition does not appear to present any significantly new information or recommendations that the Commission has not already considered.

The decision to deny the petition is consistent with NRC's performance goals. Protection of the environment and common defense and security is maintained and there is no affect on safety. Overall public confidence is not adversely affected by the decision to deny the petition. Although the petitioner may disagree with this decision, the NRC has considered the petitioners' concerns and has made its decision in a thorough, disciplined, and timely manner. In addition, the decision does not alter the effectiveness or efficiency of the regulations and is realistic, taking into account the unprecedented level of enhanced public and stakeholder participation in the Part 35 rulemaking. Lastly, the decision to deny the petition does not impose unnecessary regulatory burden on stakeholders.

COORDINATION:

The Office of the General Counsel has no legal objection to the denial of this petition.

RECOMMENDATIONS:

That the Commission:

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

/RA/

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Executive Director
for Operations

Attachments:
1. Federal Register Notice
2. Letters to the Petitioner

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Attachments:
1. Federal Register Notice
2. Letters to the Petitioner ADAMS PACKAGE ACCESSION NO. ML010730061

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