

Donald A. Podoloff, M.D., President
American College of Nuclear Physicians
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. Podoloff:

I am responding to the petition for rulemaking (PRM), dated January 3, 2001, jointly filed by you, on behalf of the American College of Nuclear Physicians (ACNP) and Jonathan M. Links, PhD, on behalf of the Society of Nuclear Medicine (SNM). 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 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

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