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

FEB 11 1985

MEMORANDUM FOR: William J. Dircks
Executive Director for Operations

FROM: Robert B. Minogue, Director
Office of Nuclear Regulatory Research

SUBJECT: CONTROL OF NRC RULEMAKING: RES INDEPENDENT REVIEW OF ONGOING RULEMAKING SPONSORED BY NMSS

Based on our independent review of the proposed rulemaking, sponsored by NMSS, to modify §35.14(b)(7) of 10 CFR Part 35, "Human Uses of Byproduct Material," to add six new methods of use and the appropriate radiopharmaceuticals, RES agrees with the recommendation of the Director, NMSS, that this rulemaking effort should continue.

The basis for our recommendation is as follows:

- This is a minor rulemaking implementing a policy, set out in a final rulemaking notice published February 4, 1983 (48 FR 5217) to add a new 10 CFR 35.14(b)(7), that the NRC would amend the specified paragraph to allow NRC-licensed physicians and hospitals to use radiopharmaceuticals for newly developed methods of use (that are not listed on their respective FDA-approved package labels), without applying to the NRC for a license amendment.

- The proposed rule would modify 10 CFR 35.14(b)(7) to add six new methods of use and the appropriate technetium-99 radiopharmaceuticals for each method of use. With assistance from its Advisory Committee on the Medical Uses of Isotopes, NRC staff has determined that the proposed clinical procedures involving oral administration or injection of the radiopharmaceuticals can be conducted with no unjustified radiation dose to the patient and with a demonstration of adequate occupational radiation protection measures.

The complete RES independent review package has been sent to OEDO (Attention: DEDROGR) and to the Director, NMSS.

Robert B. Minogue

Robert B. Minogue, Director
Office of Nuclear Regulatory Research

Enclosure:
As stated

RES INDEPENDENT REVIEW PACKAGE

ROUTING AND TRANSMITTAL SLIP Date JAN 8 1985

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. O. E. Bassett, Member, RIRB		
2. K. R. Goller, Member, RIRB		
3. G. A. Arlotto, Member, RIRB		
4.		
5.		

X	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS "Use of Certain Radiopharmaceuticals for Procedures not Listed on FDA-Approved Label"

We are at step III.C.2, "RIRB deliberations," of the RES independent review procedures for the attached specific ongoing rulemaking sponsored by

Please evaluate the attached draft independent review package and provide RAMRB with your voting sheet indicating your position on the rulemaking.

Your response by c.o.b. JAN 16 1985 will assist in RES' making independent recommendations to the EDO in a timely manner.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
RAMRB staff	Phone No. 443-7885

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