

TO: RES INDEPENDENT REVIEW BOARD MEMBERS

FROM: RAMRB, DRAO, RES

TITLE OF RULEMAKING: "USE OF CERTAIN RADIOPHARMACEUTICALS FOR PROCEDURES
NOT LISTED ON FDA-APPROVED LABEL"

SUMMARY ANALYSIS: (NOTE: This summary sheet is provided only for the convenience of the RIRB members. It will be removed from the RES independent review package before the package is dispatched to the EDO or is distributed outside RES.)

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 RES Task Leader, J. Foulke, HEB, DRPES, agrees with the recommendation of the Director, NMSS, that this rulemaking should be initiated.

RES INDEPENDENT REVIEW BOARD

VOTING SHEET

TO: F. P. GILLESPIE, CHAIRMAN, RIRB

FROM: G. A. Arlotto, RIRB Member

TITLE OF RULEMAKING: "USE OF CERTAIN RADIOPHARMACEUTICALS FOR PROCEDURES
NOT LISTED ON FAD-APPROVED LABEL"

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AGREE WITH DRAFT RES
INDEPENDENT RECOMMENDATIONS
IN DRAFT INDEPENDENT REVIEW
PACKAGE.

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REQUEST RIRB
MEETING.

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MODIFY DRAFT RES
INDEPENDENT RECOMMENDATIONS
AS INDICATED BELOW.

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NOT PARTICIPATING.

COMMENTS AND SUGGESTIONS:

A. Arlotto
MEMBER, RIRB
1/11/85
DATE

DRAFT RES INDEPENDENT REVIEW PACKAGE