

MEMORANDUM FOR: William J. Dircks
Executive Director for Operations

FROM: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: PROPOSED REVISION OF PART 35

*Original sent to EDO w/
Part 35 on 12/28/84; RSC
to reconvene re: chg in
CP*
DEC 21 1984

The staff has prepared a proposed revision of 10 CFR Part 35, "Human Uses of Byproduct Material," (retitled "Medical Use of Byproduct Material") for public comment. The proposed revision is based on SECY-83-62 and the Commission's response to that proposal. Several Headquarters Offices, each Regional Office, and the Agreement States were asked to comment on this proposal.

The Cost Assessment Group has reviewed the Regulatory Analysis and their comments have been resolved.

Based on Enclosure 7 of the Commission paper and pursuant to 10 CFR 51.31, I have determined that this proposed rule, if adopted, will not have a significant environmental impact.

Two Agreement State individuals from the Conference of Radiation Control Program Directors' Ad Hoc Committee on Part 35 provided technical comments and the Agreement State perspective during the development of this proposal. An earlier draft proposal and draft Regulatory Guide 10.8 were sent to all Agreement States for comment.

The Agreement States would like to speak to the Commission on this matter. They generally endorse the proposed regulatory text, but do not endorse the licensing method that the staff recommends. Region III would prefer more license control. A discussion of these views is included as Enclosure 8. A range of alternatives and a discussion of each is provided as Enclosure 10.

The following offices have concurred with the proposal, indicating that they have no objection to publishing the proposed revision for comment: Office of Inspection and Enforcement, Office of Nuclear Regulatory Research, Office of Administration, Office of State Programs, Region I, Region II, Region III, Region IV, and Region V. The Office of the Executive Legal Director has no legal objection.

(Signed) John G. Davis

John G. Davis, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure: Proposed revision
of 10 CFR Part 35

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Norman L. McElroy

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TITLE OF PROPOSED PAPER

Proposed Revision of 10 CFR Part 35 "Medical Use of Byproduct Material"

PAPER TYPE

MEETING

AFFIRMATION

NOTATION

INFORMATION

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Norman L. McElroy

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OFFICE OF THE
SECRETARY

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

March 29, 1985

AA73-1
PDR
M. 27
IN RESPONSE, PLEASE
REFER TO: M850320A

ACTION - Davis
Cys: Dircks
Roe
Rehm
Stello
McElroy
GCunningham
Kerr
Taylor

MEMORANDUM FOR: William J. Dircks, Executive Director
for Operations
FROM: John C. Hoyle, Acting Secretary
SUBJECT: STAFF REQUIREMENTS - DISCUSSION OF PROPOSED
REVISIONS TO PART 35, 10:00 A.M., WEDNESDAY,
MARCH 20, 1985, COMMISSIONERS' CONFERENCE
ROOM, D.C. OFFICE (OPEN TO PUBLIC ATTENDANCE)
(SECY-84-485)

The Commission* met with staff, representatives from Agreement States, and members of the medical community to discuss proposed revisions to Part 35 of the NRC regulation entitled "Medical Use of Byproduct Materials."

Commissioner Zech requested that staff summarize in the statement of considerations to the proposed revision of Part 35 NRC's regulatory role with respect to patients receiving radiation therapy. In this connection, the Commission stated its intention to give early consideration to a review of NRC policy on the question of medical misadministration and enforcement action in misadministration cases.

(NMSS) (SECY Suspense: 4/19/85)

Commissioner Bernthal requested from staff a clearer definition of what would constitute a "minor change" in a licensee radiation safety program under the revised rule with a representative cross-section of the kinds of "minor changes" which have required license amendments in the past.

(NMSS) (SECY Suspense: 4/19/85)

Chairman Palladino requested that Commissioners address SECY-84-485 as a notation vote item and focus on issues needing modification by requesting comment rather than trying to settle every aspect of the whole rule at this time. The Chairman requested Commissioners to submit their notation votes within 10 days.

(OCM) (SECY Suspense: 4/1/85)

REC'D ON ED9
Date 4-1-85
Time 12N

* Commissioner Roberts was not present.

85 04 08 00 37 app.

cc: Chairman Palladino
Commissioner Roberts
Commissioner Asselstine
Commissioner Bernthal
Commissioner Zech
Commission Staff Offices
PDR - Advance
DCS - 016 Phillips