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PDR  
M. 24

OCT 15 1984

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

FROM: Richard E. Cunningham, Director  
Division of Fuel Cycle and Material Safety

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35

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. Written concurrences have been received from the Office of Inspection and Enforcement, the Office of Nuclear Regulatory Research, the Office of Administration, Region I, Region II, Region IV, and Region V. The Office of the Executive Legal Director has no legal objection.

The Office of State Programs and Region III do not concur with the proposal, and the Agreement States object, because contrary to current practice, it would allow licensees to make minor radiation safety program changes without agency review and approval. They raise two principal objections:

1. Radiation safety program changes.

Comment: Most licensees do not have the expertise to make an adequate health and safety review of changes.

Staff response: The essential elements of a medical radiation safety program are clearly stated in the proposed regulation. The agency would continue to review licensees' major changes listed in the regulation. Minor elements that could be changed are not of significant health and safety concern.

2. Inspection burden.

Comment: Under the proposal, inspectors would have to review procedure changes during field inspections. The inspector will be under pressure from the licensee to finish, and will not have reference works or management guidance available. A field review of written procedures is also more expensive than an office review.

Staff response: Field inspectors should not review written procedures; they should watch workers working. What workers do is more relevant to radiation safety than reading about what they are supposed to do. If an unsafe practice is observed, a citation would be issued pursuant to the regulations.

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The staff notes another possible criticism that has not yet been raised.

Comment: You have compared this internal review mechanism to that used for power reactors. Note what happened at TMI under that kind of regulatory regime.

Staff response: The proposed regulation and NMSS internal operating procedures include many of the licensee and agency administrative oversight procedures recommended in the Rogovin report.

In order to bring the differences of opinion to the attention of the Commissioners, the staff has prepared Enclosure 8, "Analysis of Unresolved Comments," and Enclosure 10, "Analysis of Alternatives."

Because of the controversial history of this proposed rule and the developments at the October 3, 1984 EDO meeting, we will contact your secretary to set up a detailed briefing on this package.

Original Signed by  
Richard E. Cunningham

Richard E. Cunningham, Director  
Division of Fuel Cycle and  
Material Safety

Enclosure:  
Proposed Rule Paper  
for Part 35

DISTRIBUTION:

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\*See previous concurrence

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DATE	9/26/84	9/27/84	10/10/84	10/15/84		