UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

(3)

May 1, 1998

MEMORANDUM TO: Donald A. Cool, Director
Division of Industrial and Medical Nuclear Safety, NMSS

FROM: Cynthia D. Pederson, Director, DNMS

SUBJECT: PROPOSED RULE: MAJOR REVISION OF 10 CFR PART 35
(AITS R98-1059)

We are in receipt of the proposed rulemaking dated April 10, 1998, regarding the revisions to 10 CFR Part 35. While the Regions were not specifically requested to provide comments, as discussed between Roy Caniano and Fred Combs on April 24, 1998, we do have several comments that we are providing for your consideration.

- Page 50 of the proposed Federal Register Notice states that the definition of "medical institution" was revised to include the clause, "and provides inpatient care," yet the clause does not appear in the proposed definitions in 10 CFR 35.2 on page 211.

- The intent of 10 CFR 35.41 is unclear. It appears that any deviations from written directives would be in violation of 10 CFR 35.41. If this is the intent, then we recommend clarification in NUREG-1556, Volume 9.

- 10 CFR 35.69 should require more specific information on the labels. It appears from our review that the only requirement will be use of "Radioactive Material" labels on vials and syringes. This could cause confusion regarding the contents of vials and syringes in a busy nuclear medicine department.

- It appears that compliance with 10 CFR 35.75 requires licensee confirmation of whether or not patients are breast feeding prior to administration of licensed material. If this is the intent, then we recommend that it be stated in NUREG-1556, Volume 9.

- Item 5.1 of NUREG-1556, Volume 9 states that "committing to using the model procedures" will expedite the review, yet the applicant will not typically be requested to submit procedures for review. This may cause confusion with applicants.

- 10 CFR 35.70 and Item 8.33 of the NUREG require end-of-day surveys of patients' rooms where radiopharmaceuticals requiring a written directive were administered. In most cases, this survey would not be beneficial because the patients would still be in the room pursuant to 10 CFR 35.75. Therefore, clarification is necessary.

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- Item 1.1.2 of NUREG-1556, Volume 9 needs to include the clause, "and provides inpatient care," when referring to medical institution.

- Appendix L to NUREG-1556, Volume 9 appears to conflict with 10 CFR 20.1501. The licensee's evaluation of the need to monitor personnel exposure is based on the likelihood of the individual receiving greater than 10 percent of the dose limits. Therefore, unless the evaluated individual's normal duties involve response to accidents or emergencies, the evaluation should not consider "accident scenarios."

Your consideration of our comments would be appreciated.

cc: F. Combs, NMSS
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A. Beach, RIII
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