



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

Miller/McElroy

Ref: SA/LAB

DEC 14 1984

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

FROM: G. Wayne Kerr, Director
Office of State Programs

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35

On December 3, 1984 Vandy Miller provided us for review and comment a copy of the most recent version of the Part 35 proposal. In responding to his request, we are providing both the position of this Office and that of the Agreement States as we understand it.

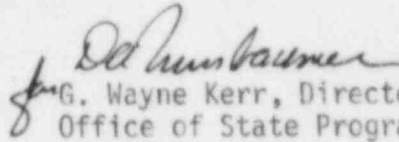
The Office of State Programs is prepared to concur on the Commission paper regarding publication of the Part 35 proposal furnished us on December 3, 1984 as a proposed rule for public comment. The change in our position as expressed in our memorandum of April 26, 1984, is based on modifications to an earlier proposal which strengthens the requirements for making changes in radiation safety procedures. These are:

- 1) The institutional radiation safety committee will review, on the basis of safety, and approve with advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes.
- 2) The licensee must retain for the duration of the license a record of each change. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, equipment descriptions, or area floor plans, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

While we believe that this approach will provide adequate safety control for the larger institutions, we have reservations concerning its suitability for small nuclear medicine programs which do not have a radiation safety committee. We suggest some thought be given to restricting the latitude for changes which may be made in such programs without agency approval.

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The Agreement State representatives who reviewed the current draft have again expressed their opposition to this latest Part 35 proposal. Basically, they do not accept what they view as a relaxation of regulatory control. They disagree with the proposition that licensees, within stated guidelines, should be allowed to change procedures, equipment, rooms of use and other aspects of their program without prior agency review and approval. The Agreement States continue to believe that review of modifications to equipment and facilities and safety procedures and changes thereto by the regulatory agency are necessary to achieve a proper level of radiation safety. They also believe that shifting the determination of the adequacy of changes made to procedures from the licensing staff to the inspectors at the licensee site is inappropriate. As noted previously the Agreement States have asked for the opportunity to have a representative address the Commission on this matter. Please note the attached memo sent to Tom Rehm on October 15, 1984.


G. Wayne Kerr, Director
Office of State Programs

Enclosure:
As stated