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DIRECTOR

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Donald A. Nussbaumer  
Assistant Director for State  
Agreements Program  
Office of State Programs  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

Dear Mr. Nussbaumer:

Thank you for the opportunity to review and comment on the proposed revision of 10 CFR Part 35, as described in your letter of September 12, 1983. This Department has some concern over the concept of licensing medical facilities by the procedures described in the enclosure to your letter.

Our main concern is that this approach appears to offer only a "blanket" radiation safety plan. There was no indication that differences in the size of programs would give rise to differences in the required plan. This seems to be inconsistent with NUREG-0267, where the guidelines for ALARA at medical facilities account for different categories of medical programs.

In addition, there is some question as to why only medical programs are included in this approach to licensing. The experience with Arkansas Radioactive Material Licensees does not show that medical licensees have a better compliance history than other, non-medical licensees. Based on the compliance history, there does not seem to be justification for licensing medical facilities under more lenient requirements than other programs.

There are also some specific concerns with the radiation safety plan described. These comments are not directed at the "concept" as requested in your letter, but rather at specific points of the model radiation safety plan.

The chart titled "Proposed Implementation of 10 CFR Part 35" contains the statement, "Operating procedures which do not alter the commitments made in the plan may be made by licensee without pre approval by NRC." This provision could lead to problems in enforcement. By allowing changes in the plan to be made without review by the NRC, instances which would constitute an item of non-compliance are not as well defined. This may lead to disputes over items of non-compliance discovered during inspections, causing a particular problem where fines or civil penalties are involved.

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In the example area survey plan, the licensee would be required to investigate and correct immediately any survey readings which are "higher than normal". In the absence of further definition or clarification, this action level presents problems in implementation. Statistical deviations in radiation decay and in survey instruments usually cause a given location to read slightly higher at one particular time than at another. With a sensitive survey meter, the licensee would be required to investigate normal fluctuations in background readings.

Again we thank you for the opportunity to review the proposed changes and hope that our comments prove useful.

Sincerely,

*E. F. Wilson by gdn*

E. F. Wilson, Director  
Division of Radiation Control and  
Emergency Management Programs

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