



*Department of Human Resources*  
**HEALTH DIVISION**

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October 3, 1983

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

Mr. Nussbaumer:

Enclosed are comments on the 10 CFR Part 35 Concept forwarded to this office on September 12, 1983. The attached comments do not reflect all comments that have been made or which could be made but are our real concerns regarding this specific document and concept.

Thank you for providing us with the opportunity to comment on the proposed concept.

Sincerely,

*Mary L. Blazek*  
Mary L. Blazek  
Radiation Specialist  
Radiation Control Section

MLB:mas

Enclosure

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Comments on 10 CFR Part 35 Revision Concept

Dated September 12, 1983

Following the April 19, 1983, Commission Meeting on the revision of 10 CFR Part 35, the Commission directed the NRC staff to continue the pre-licensing review of physicians' qualifications, continue the prelicensing review of applicants' operating procedures and clarify how the staff will implement the proposed requirements regarding license amendments.

The proposed concept clearly does not meet the directive underlined above.

"Operating procedure changes which do not alter the commitments made in the plan may be made by licensee without pre-approval by NRC." Subjective language of the concept has been commented on multiple times in the past. Our complaint continues to be that the licensee may make changes which (they feel) do not alter the "plan" only to be cited by an inspector for having inadequate procedures, perhaps several years after the fact. In addition, in order to continue adequate procedure reviews, inspectors must become "field license reviewers" when evaluating radiation safety procedures for adequacy; however, it has never been the intent for NRC inspectors to review procedures in detail on-site. Since the inspector will not have a copy of the procedures prior to inspection, not only will inspections be more complex but the quality of the review would be questionable. The question of inconsistency in interpretation due to the increased number of reviewers/inspectors and to increased pressure during inspections also remains.

The impact of added costs to licensees due to increased inspection time, increased fines due to inadequate procedures or increased time in

resolving items of noncompliance, i.e., writing supplemental procedures to correct deficiencies remains to be addressed.

Radiological Safety Plan:

"The applicant has established and agrees to implement written procedures..." Although multiple documents of this nature would provide needed guidance for licensees, it is uncertain that the guidance will prevent inadequate procedures from being implemented. The licensee will be expected to "include site specific information and other steps that the licensee believes are essential for the safe use of byproduct material in his program" in these unsubmitted procedures. It appears that such essential procedures should be approved prior to licensure; otherwise, procedures "essential for the safe use of byproduct material" may never be reviewed for adequacy. This approach certainly cannot be construed to meet the Commissioners' April 19, 1983, directive.