



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

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OCT 15 1984

RADIATION CONTROL SECTION  
OREGON STATE HEALTH DIVISION

OCT 10 1984

Mary L. Blazek  
Radiation Control Section  
Health Division  
1400 S.W. 5th Avenue  
Portland, Oregon 97201

Dear <sup>Ms.</sup>~~Miss~~ Blazek:

Thank you for taking time to review and comment on the draft revision of the Nuclear Regulatory Commission (NRC) medical use regulations and licensing policy. In your letter of August 16, 1984, you outlined several concerns that lead you to the conclusion that the proposal is unacceptable. I would like to respond to those concerns.

As you note, there is an additional cost to licensees because the draft imposes some new technical requirements; there is also some anticipated savings to NRC because we believe inspectors would spend less time preparing for inspections. However, there was never any suggestion that the agency's savings justify the industry's added burden.

You note that an agency review of radiation safety program changes is needed to ensure a proper degree of safety. With the current regulatory smorgasbord of regulations, regulatory guides, NUREG reports, standard license conditions, and licensing branch policy, I agree with you. However, the draft regulation comprises a readable codification of essential medical radiation safety standards. It provides both a legal basis for control of licensees and a convenient checklist that may be used when planning or modifying a day-to-day operating procedure. With the checklist in hand, the licensee would be able to make the safety review now made by the agency.

You note that the current inspection frequency is too low to provide an assurance of safety under the proposed system because procedures might be changed between inspections. This implies to me that the procedures are intricate mechanical procedures that if not followed with meticulous attention to detail and sequence will result in an unsafe situation. The procedures that NRC reviews are generally better characterized as program management guidance comprised of groups of individual actions that do not have to be taken in any particular order as long as all are completed. This is also a proper characterization of the few technical procedures that NRC reviews.

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You note that the responsibility to review changes in day-to-day operating procedures will now fall on the shoulders of the field inspector, who is already pressed for time. Your comment assumes that an official of the state must make a safety review of each procedure change. We disagree; with the codified checklist, the licensee is capable of making this review. Never-the-less, for those inspectors who are concerned about changes, the regulation requires a clear and complete record of each change. The inspector would be able to review the procedure as implemented in the field setting. Alternatively, an inspector could simply watch employees at work and review the required records to determine whether a licensee is in compliance with the regulations.

You note that the proposal would put more responsibility on the shoulders of licensees, while Agreement State enforcement actions are frequently precipitated by lack of licensee management control. NRC's first enforcement action above a simple notice of violation is a conference with licensee management; for its 2500 licensees, NRC initiates only about five medical conferences each year. To require all licensees to work under stringent regulatory controls because of the non-compliance of a small minority is unnecessarily burdensome for licensees and NRC.

Finally, you ask why the staff has not considered revising the regulation and continuing to require licensees to use materials in accordance with the statements and representations in the application. The staff does not consider this an advisable alternative because it affords at best only a small additional public health and safety benefit, yet:

- (1) It results in a different set of requirements for each licensee because control is based on the licensee's application;
- (2) It increases licensee and agency paperwork burden because minor program changes must be submitted to the agency, reviewed, authorized, and filed;
- (3) It increases the burden on inspectors because they must review each application in order to make a thorough inspection of a licensee's program; and
- (4) It ties up agency staff who could be assigned to work on problems that have a greater impact on worker and public health and safety.

Mary L. Blazek

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After working on the project three years, we have not received any comments that lead us to believe the draft regulation and licensing policy might be unsound. The Agreement States' concern about the wisdom of the proposal appears to be based on the belief that it would provide an unwarranted amount of regulatory relaxation. The staff believes the level of control in the draft is appropriate and therefore has recommended the proposed change in licensing policy.

Once again, thank you for taking time to review and comment on the drafts.

Sincerely,



Norman L. McElroy  
Material Licensing Branch  
Division of Fuel Cycle and  
Material Safety