



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

Ref: SA/LAB

FAX TO: R CUNNINGHAM NMES

JAN 19 1983

FR: TA Rehm

MEMORANDUM FOR: William J. Dircks  
Executive Director for Operations

Please call on  
receipt

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

TR 1/19

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35

We have reviewed the staff paper on the proposed revision of 10 CFR Part 35 which Bill Travers provided us and we have the following comments:

1. In my memo to Richard E. Cunningham dated August 31, 1982 commenting on an earlier version of this paper, we stated that we were not opposed to publication for comment but that the paper should more fully address comments by the Agreement States. We also stated that it would be useful for NMSS to prepare a summary of Agreement States' positions accepted or rejected and the related rationale that we could send to the Agreement States at the time of publication. The latter suggestion was not accepted. The concurrence page indicates that my memo recommends publication for comment which is not accurate; my memo stated no objection to publication for comment.
2. The second paragraph of page 4 of the paper does not clearly reflect the Agreement States concern with the proposal. We suggest the following paragraph be inserted in lieu of the paragraph in the paper to indicate the Agreement States' reaction to the proposal: "Most Agreement States are in favor of consolidating requirements in the regulations and support this step. The Agreement States' concern is that under the proposal, applicants (and licensees) would be required to have safety procedures but the procedures would not be submitted for review by the NRC. The applicant (or licensee) would merely certify on the application form that the procedures have been established. The adequacy of the procedures would not be determined until sometime after the license is issued. In addition, the States do not agree with the provision in the proposal which allows licensees to change safety procedures without prior review by the NRC. The NRC's frequency of inspection for medical licensees is once every 3 years although new licensees are scheduled for inspections within

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the first six months of operation. Although this regulation would not be made a matter of compatibility because it deals with licensing procedures, the States believe they will receive pressure from their licensees to adopt the NRC system with which they don't agree. The staff feels that the current effort will not decrease, but will enhance safety through three major features: (1) staff resources can be redirected from case-by-case reviews to development of guidance and integration of technical developments into licensing decisions, (2) the clear specifications of all essential safety requirements in the regulation, and (3) detailing the minimum acceptable training and experience for medical users of radioisotopes in the regulations. NRC may supplement its review with an early on-site post-licensing visit. Ability to do so is enhanced by regionalization."

3. At the annual Agreement States meeting in October, 1982 and in correspondence following the meeting the States requested that a designated representative be allowed to address the Commission when it takes up this paper. We suggest the following Note be added to the paper: "Note that the Agreement States have requested that a representative designated by them be allowed to present their views on this proposal to the Commission when the Commission meets to consider this proposal."

4. To appropriately reflect the Agreement States concern, we propose the following change to page 17 of enclosure 3:

"D. Agreement States

Many Agreement States are in favor of consolidating the various regulatory requirements and support this revision of the regulations. However, the Agreement States are concerned about the impact of the proposed licensing procedures. Agreement States regulate about 4700 medical licenses. Most feel that a prelicensing review of safety procedures is necessary to ensure safety. They believe that failure to review procedures and permitting the licensees to make program changes without prior review and approval is an unprecedented relaxation of regulatory control which could cause harm to patients and the public. Their contention is that they may be pressured by their own licensees into adopting NRC's revised procedures without the benefit of an expensive Management Information System (MIS) computer like NRC's. The NRC staff believes that, since the Agreement States are not required to maintain compatibility with NRC in the area of medical licensing, they would have the option of incorporating into their programs those features that they find desirable while rejecting those feature that they find objectionable. The Agreement States have expressed concern about the allocation of additional money and personnel to fulfill the extra inspection requirement of this revision. They have also asked about the time frame for the early on-site post-licensing

visit. In implementing the rule, the NRC staff recognizes that there may be a need for differences between NRC and Agreement State procedures. The staff feels that the current effort will not decrease, but will enhance safety through three major features: (1) redirecting staff resources from case-by-case reviews to developing guidance and integrating technical developments into licensing decision, (2) specifying all essential safety requirements in the regulation, and (3) detailing in the regulations the minimum acceptable training and experience for medical users of radioisotopes. NRC may supplement these features with an early on-site post-licensing visit."

The last sentence of the quote above indicates the NRC may take supplemental measures at the post-licensing stage but there is no firm commitment to do so; we believe such a commitment is necessary to ensure the effectiveness of this concept.

*G. Wayne Kerr*  
G. Wayne Kerr, Director  
Office of State Programs

cc: J. Davis, MSS

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