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DIVISION OF HEALTH
BUREAU OF CONSUMER HEALTH PROTECTION SERVICES

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June 8, 1982

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

Dear Mr. Nussbaumer:

I have the following comments on the proposed changes to 10CFR35:

1. In your letter to the Agreement States you noted that the proposed changes in 10CFR35 would not be considered a matter of compatibility between NRC and the Agreement States regulatory program.

Regardless of the compatibility aspect, the proposed change in the NRC regulation will have an adverse affect on an Agreement State that does not choose to make like changes in its regulations. The medical profession in our State will hear about NRC's changed regulation sooner or later, and then accuse the State regulatory personnel of being too strict in requiring documentation no longer required by NRC.

2. A back log of license applications and requests for renewal of license, or amendments to licenses, is not a logical reason for changing a regulation. That situation has nothing to do with health and safety which should be the sole concern of the regulatory agency.
3. With the "Standard License", no detailed radiation safety procedures would be submitted to NRC by the applicant. He would, however, be required by the regulation to develop written safety and technical procedures. Whether these are indeed written, and more important, adequate, cannot be determined until an inspection is performed. At the time

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June 8, 1982

of the inspection, the inspector will have to review the procedures and make a determination on adequacy. In this matter, it appears the time saved by the license reviewer in not having to review the medical safety and technical procedures will be consumed by the inspector having to review the procedures in the field.

4. Speaking of inspections, it appears that NRC licensing personnel would be used to inspect the new medical licensee at some time after issuance of the license. Presumably, the purpose of this inspection is to determine whether the licensee has the facilities, personnel, equipment, program controls he stated he would have, and is operating in a safe manner. If such is the case, then the licensing personnel will have to be trained in inspection procedures. They will have to make 75 inspections per year for the new licensees. It would appear likely that the required training and the number of inspections would cause additional delays in evaluation of requested licensing actions.
5. Enclosure 3 indicated that NRC licensing personnel take an average of 94 days to issue a license to use byproduct material, and 77 days to issue an amendment to a license. It is stated that the new licensing procedures would reduce these times to 10 days and save the medical community seven million dollars in lost revenue. How come the Agreement States can issue medical licenses and amendments to licenses so much faster than NRC? Perhaps the NRC has an inadequate staff? If this is the case, the NRC should obtain an adequate licensing staff instead of changing a regulation. It appears that NRC, similar to AEC, is still interested in promoting the use of radioisotopes, in this case in nuclear medicine, rather than considering only the safety of usage.
6. In the letter to the Commissioners, page 4, first paragraph, the statement is made that NRC has no way of knowing how many generally licensed physicians are still using the license, or have moved, etc. It is also stated that this situation makes it difficult for NRC to satisfy its inspection and enforcement responsibilities. If NRC wants to know about general licenses, they could be contacted by letter or telephone. Also, I was not aware of the fact that NRC was inspecting generally licensed physicians.
7. In the letter to the Commissioners, page 5, paragraph 2, the statement is made that detailed review of applications for medical usage of radionuclides diverted NRC resources from more important safety issues. These important safety issues should be listed for the benefit of the Agreement States personnel so they can be sure that evaluation of applications for medical licenses is not causing diversion of State resources from the same important safety issues.

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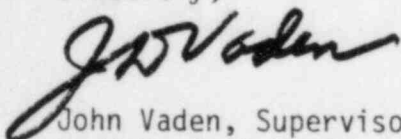
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June 8, 1982

8. In summary, NRC is apparently still trying to get out of the business of regulating doctors who use radionuclides. The next step will probably be to go to a general license for all medical usage. The rationale given for a less detailed review of applications for medical usage of radionuclides is not logically supported on the basis of health and safety. Instead, the savings in cost to the medical profession and the NRC are given as reasons. With more detailed regulations in 10CFR35, the inspector will be required to spend more time on inspections of the medical license. It appears any savings in license reviewer time will be spent in increased inspection time.

Sincerely,



John Vaden, Supervisor
Radiological Health

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