Bolling

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DEPARTMENT OF HUMAN RESOURCES

HEALTH DIVISION

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RICHARD H. BRYAN
Governor

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Director

March 13, 1984

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

Dear Mr. Nussbaumer:

I have the following comments on the proposed revision to 10 C.F.R. Part 35:

1. On Page 7 of the Draft Commission staff paper the statement is made: "All the individuals that commented on the proposed revision submitted in SECY 83-62 agreed the current Part 35 was in need of revision....." I sent comments to you on proposed changes to Part 35 on June 8, 1982, which did not contain a statement that I agreed Part 35 needed to be revised. On that same Page 7, the statement is made: "The staff is not aware of anyone who would recommend retaining the current Part 35 over the proposed revision." I wasn't aware this was a popularity contest but now that I am, I vote to retain the current Part 35.

2. On Page 12 the statement is made: "Most citations are not made for failure to follow a certain procedure....." In Enclosure 9 the number of citations for violations of statements made in the application and for violations of regulatory guides is about 41% of the total number of violations. That data supports the above statement. However, if 41% of the citations are for not following procedures that licensees said they would follow, why would it be acceptable for them to state that they will follow a procedures listed in the licensing guide?

3. On Page 13, the recommendation is made to the Commission to certify that the changes proposed to Part 35 will not have a negative economic impact on small entities. On Page 16 of Enclosure 4, there are several hypothetical licensees listed for which costs from additional work load attributed to the proposed regulatory changes have been listed. These costs run from a minimum of $1618 to a maximum of $13,018 per licensee. These costs may seem negative to the Commission but they are not negative in helping to raise the cost of medical care. Further, the cost range also indicates that from 398 to 598 additional technician hours would be needed by licensees if the proposed changes to Part 35 are approved. In our State there is a shortage of nuclear medical technicians.

4. On Pages 18 and 19 record retention is discussed. Some records are to be retained for 1 year or 2 years and this is said "to provide adequate evidence of compliance with requirements." There seems to be no point at all in keeping records for such short periods of time because the Commission inspectors will probably never inspect a private practitioner's or hospital's nuclear medical program as these types of licenses have no priority. The teletherapy programs are scheduled for inspection once every six years.

5. On Page 27, "podiatrist" is defined. NRC has informed the Agreement States that it will permit podiatrists to use byproduct material sources on humans provided the podiatrist has eight hours of training in radiation safety. It is doubtful that this training "is sufficient to ensure that they are able to understand and follow regulations for the safe use of byproduct material" which is apparently a Commission goal as noted on Page 29.

6. I see no use in a requirement that dosage measurement records include patient information as discussed on Page 38. This is already being done by recording the dosage in the patient's treatment record.

7. Request for clarification, on Page 89, Section 35.32 (a)(1), the membership of the radiation safety committee must include an authorized user for each type of use permitted. Is this per group or one for nuclear medicine, one for teletherapy?

8. On Page 90 paragraph (a)(4)(V), indicates that numerical ballots by the radiation safety committee must be included in the minutes. If such detail is warranted in the regulations perhaps then these should be a requirement for the committee to follow Robert's Rules of Order.

9. On that same Page 90, paragraph (b)(2), indicates the Committee will "review on the basis of safety and approve or disapprove any individual who is to be listed as an authorized user....." Does this mean that a person who has not caused any major spills or who has never been over exposed to radiation or in short, has a good radiation safety record, should be approved by the committee regardless of any review of his academic background or clinical experience with radionuclides?

10. I object most strenuously to the concept of "Provisional authorized user, Section 35.34, page 92. It could be as long as five years at license renewal time before the licensing agency would be informed of a provisional user. Further, with the turnover of medical staff, several provisional users could come and go and never be approved to the licensing agency. This authority should continue to be reserved for the broad medical licensee who is allowed to designate users.

11. In Paragraph 35.630, page 102, the definition of "portable low level radiation survey instrument" does not rule out a g.m. survey instrument. In Paragraph 35.631 (f), however, that g.m. survey instrument might be used by a person

entering a teletherapy room when the radiation monitor in that room is inoperative. If that person isn't looking at the GM meter constantly and the teletherapy source is exposed, the g.m. tube could saturate and the meter read zero giving the impression that it was safe to enter the room.

12. If Section 35.622 is going to require a patient viewing system, then there should also be a requirement that irradiation of patients must cease when the viewing system is inoperative.

13. On Page 131, Section 35.641 paragraph (a)(2)(i) and (ii), the term "radiation quantities" is used. Rather than Curies I suspect millirems is intended, therefore perhaps "radiation levels" is more proper.

14. It appears that the Commission staff is never going to be content until it can eliminate detailed evaluation of applications for medical use of radionuclides. That being the case, I have a few suggestions that may help stream line the licensing process.

The application forms and envelope, addressed to the program regional licensing office, should be furnished to all persons requesting a nuclear medical license. On the back of the envelope there should be printing requesting the following information:

1. Name and address of applicant.

2. Statement: "This application is for Groups I, II, III, IV, V, VI, VII or Teletherapy (mark as indicated).
Signed_____.

3. Statement: "All proposed users are qualified for the Groups or Teletherapy as marked above, in accordance with the requirements of the Regulatory Guide 10.8 dated_____.
Signed_____.

4. Statement: "Are the proper procedures selected for each Group or Teletherapy from Regulatory Guide 10.8 dated_____and will they be followed?
Answer: Yes No Maybe
(Mark as indicated) Signed_____.

When the above application is received by NRC licensing the statements on the envelope are optically scanned. If (1), (2), (3) and (4) are completed and the answer to (4) is "yes", the unopened package is routed to file and BAIL action ensues. BAIL stands for Bureaucratic Automatically Issued License. This is done by computer and the license, also signed by the computer incorporates the statements on the envelope.

However, if items (1), (2) and (3) are in order but the answer to item (4) is "No", the applicant may have made a mistake or have developed his own procedures. In case of a "No", the computer sends out a form letter stating "don't say no now, say maybe".

In the case where the applicant answers item 4 with a "maybe", a form letter goes out stating that at least 50% of people (particularly females) when they say "maybe" mean "yes". The applicant is asked to review the application and to consider a "yes" answer.

If the second application comes in with a "yes" all is well. But if the applicant insists on saying "no", a form letter is dispatched stating that the application will be considered abandoned if the answer to Item 4 remains "no". The applicant is also advised that if individual procedures have been developed for the proposed nuclear medical program then they must move to an Agreement State for licensing.

If similar forms are developed for amendments to licenses it should completely eliminate the need for NRC's nuclear medicine licensing staff.

Perhaps other information could be obtained for allowing the applicant to check one of these statements on the envelope: "I am in a hurry for his license, please assign this application to a liberal reviewer"; or, "I don't get much mail so please assign this application to a conservative reviewer".

In conclusion, I don't think Commission staff has really followed the intent of paragraph 3 in the Commission's memo on SECY 83-62 dated June 23, 1983, by allowing an applicant to choose a prescribed procedure and then to change it any time they want without NRC review.

Sincerely,

J. V. Vaden

J. V. Vaden, Supervisor
Radiological Health
Consumer Health Protection

JV:jao