State of Alabama

DEPARTMENT OF PUBLIC HEALTH

State Office Building
Montgomery, Alabama 36130

IRA L. MYERS, M.D.
STATE HEALTH OFFICER

March 3, 1982

Mr. Lloyd Bolling
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Bolling:

Enclosed are a few comments in the proposed revision of 10 CFR 35.

It was my interpretation that one purpose of the change was to provide clearer guidance to the applicant and licensee as to the requirements of Part 35. I think that the proposed change incorporates many items that should be incorporated in the regulations and not in license conditions and guides. However, I hope that Reg Guide 10.8 is not to be abandoned because it certainly provides much more needed guidance than the proposed change. One of the basic problems has always been, "What constitutes an adequate program to comply with requirements of the regs?" Reg Guide 10.8 provided assistance. In my opinion, the proposed change provides minimal assistance.

Let me say, however, that whether or not the new concept is adopted, I feel that the proposed changes to Part 35 are needed. I offer my comments in that respect and not as being supportive of the proposal to "general license" all medical users.

I would appreciate receiving comments from the Part 35 Revision Taskforce regarding my comments as attached.

Again, the attached comments are those of the writer and are not intended to be representative of other individuals, agencies, or organizations.

Sincerely,

Kirksey E. Whatley

Kirksey E. Whatley
Radiation Physicist
Division of Radiological Health
Environmental Health Administration

KEW:mpw

Enclosure

cc: Mary L. Blazek
Carol Connell
Diane Tefft

Comments on Proposed Changes to 10 CFR 35

1. 35.33 Records retention.

This section states that "records shall be maintained for two years unless otherwise stated in the requirement." Since no time limit is given for retention of training records required by 35.31(h), does this mean that after two years such records can be disposed? As a suggestion, perhaps it would be helpful to identify which records are required to be maintained.

2. 35.35 Mobile departments.

Paragraph (c) of this section appears to permit the transportation and use of generators and kits in mobile vans. It also authorizes the use of gaseous IND radiopharmaceuticals. NRC letter dated April 21, 1977, to all Agreement States, outlined licensing requirements for mobile nuclear medicine laboratories. Gaseous radiopharmaceuticals, generators, and kits were excluded from authorized use in mobile vans. In addition, radiopharmaceuticals were to be "transported only in the form of individual doses or multidose vials." This represents a significant change from "current" requirements. This is offered only as a comment and not as an opinion as to whether-or-not the change should be made.

3. 35.53 Assay of radiopharmaceutical dose.

This section requires doses to be assayed immediately prior to administration. How would this section apply to licensees who obtain radiopharmaceuticals from radiopharmacies in unit dose vials and may not possess dose calibrators? How would this apply to mobile van users?

4. 35.69 Requirements for possession of sealed sources.

As written, paragraph (a) of this section states that the leak test shall be capable of detecting the presence of 0.005 microcuries of removable contamination. It appears that this section would also apply to teletherapy sources. Under current cr'teria a leak test for teletherapy sources is required to detect only 0.05 microcuries of removable contamination. While I do not disagree with the proposed change (applying criteria to teletherapy sources), I am of the opinion that the proposed change should be noted and justified, not in the changes but in supportive criteria if not already done so.

5. Section 35.70 Surveys.....rate.

(a) This section appears to be very weak in providing guidance and instruction for performance of surveys. Specifically the section requires surveys be performed "to assure that

all by-product material has been properly secured." I realize that the term "ambient" is in the title of this section. However, it appears to be the only section relating to survey requirements. What about other survey requirements (restricted and unrestricted areas, etc.)? Why single this requirement out?

(b) Paragraph (a) of this section states why a survey is to be performed in areas where radiopharmaceuticals are prepared for human use or administered to humans. However, in reading paragraph (b) of this section, one might ask the question, why. I suggest the addition of a phrase to (b) such as "....survey meter to assure.... (whatever)....

6. 35.80 Mobile departments.

Paragraph (b) of this section uses the term "physical supervision." This term should be defined. Does it mean that the user must be physically present at all times when radioactive material is used? If it does mean that, then there appears to be no need for paragraph (e) since the user, who is physically present, would have 30 hours of radiation safety training.

7. 35.90 Storage of volatiles and gases.

It is recommended that the phrase "properly operating" be inserted before the word "fume" in this section. A fume hood may not be working at the time of inspection. The intent is clear, however, such an addition might avoid confusion.

8. 35.91 Storage of waste.

The phrase "securely closed" is at the mercy of the reader. If procedures are not going to be reviewed prior to issuance of license, I can see licensees having all kinds of interpretations of "securely closed." As a suggestion, it might help to state the purpose of having waste containers securely closed (ie; "....securely closed prior to storage so that.... ...and labeled....etc.).

9. 35.92 Decay in storage.

What does a licensee do with an isotope with half-life greater than 60 days (ie; Se-75)? Does this mean he cannot hold selenium 75 for decay?

10. 35.102 Authorized Use.

Paragraph (b) refers to "Taplin petition." Reference should be given where copies of, or an explanation of this "petition" can be obtained. Such would be consistent with other referenced documents (ie; procedures for calibrating teletherapy units).

11. 35.100 Group I.

There appears to be no requirements for the licensee to have written operating procedures to use radioactive material. The licensee should provide guidance for safe use in the form of written instructions to employees. It does not appear that written instructions are required by any user of radioactive material.

12. 35.200 Group II/III.

Comment as in Number 11 above applies to 35.200.

13. 35.300 Group IV/V.

Written instructions are required for all personnel caring for patients. There is no argument with this requirement, but what about written instructions for nuclear medicine personnel - placing patients in private rooms, surveys, collection of waste, notifying nurses of potential problems, etc.? These appear to be just as important as written nursing instructions. Why single out written radiation safety procedures here and not elsewhere?

14. 35.400 Group VI.

It appears that safety precautions, similar to those required for licensees performing radiopharmaceutical therapy, would also be required for licensees to perform brachytherapy treatments. Such is not included in proposed change. Comments as in Number 13 above also apply.

15. 35.630 Equipment.

Paragraph (a) states that "one survey meter" must be on hand at all times. Other sections define the survey meter needed as "low-level" or "ionization-type." Clarification would be helpful in 35.630.

16. 35.32 Radiation Safety Officer (RSO).

There are no requirements defined for minimal qualifications of the RSO. Yet, the RSO is assigned essentially the brunt of the radiation safety program. I realize that this is the case now, but at least someone reviews what the "RSO" (consultant, etc.) proposes to do. If no review of procedures is to take place prior to licensing, minimal qualifications need to be established for the individual responsible for "establishing and implementing" the radiation safety program.

17. 35.32 Radiation Safety Officer (RSO).

Perhaps I have overlooked the requirement in proposed changes, but I cannot find where a licensee is required to have written procedures for emergency action, periodic radiation surveys, inventory of licensed material, safety during use, performance checks of safety equipment, and training. Section 35.32 simply states that the RSO shall establish and implement procedures. Procedures can be established and implemented without being written.

18. General Comment.

Certain sections of the proposed changes give detailed instruction and define exactly what needs to be done (ie; misadministration requirements and teletherapy calibration). Yet, other sections simply state that the licensee shall comply with a referenced regulation. There seems to be an abundance of guidance on certain sections and practically no guidance on others. Why not just require the licensee to report misadministrations or to calibrate teletherapy equipment? That's what is done when the licensee is told to provide "adequate" surveys. What is adequate? Shouldn't the same criteria which is applied to the misadministration section be applied to all sections? Then guidance would be given.

19. General Comment.

Again, I would like to express my concern that no prelicensing review of an applicant's written operating and emergency procedures will be made under the proposed change. I feel that even if it means that the applicant simply copies something that is provided him there is value in that. At least he has a reference to go to. Under the proposed change (assuming that written procedures will be required) the licensee may not even have such a reference. It has been my experience that the licensing process, the renewal process, and inspection programs are in reality training programs and serve a very important role to the applicant and licensee.