Bollinger

State of Alabama

DEPARTMENT OF PUBLIC HEALTH

State Office Building
Montgomery, Alabama 36130

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

May 25, 1983

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

Dear Mr. Nussbaumer:

Enclosed are several comments on the proposed changes to 10 CFR 35. The attached comments in no way reflect all comments which could be made on the proposed changes. The comments attached simply indicate that in this writer's viewpoint significant problems are prevalent with the document as submitted to the Commission.

As indicated previously to members of your Staff, these comments were available at the hearing on April 19, 1983. I did not include the attached list in Bill Spell's letter of thanks to the Commission due to the fact that the proposed changes had been sent back to the Staff for review and I saw no need to add fuel to a seemingly warm fire already. However, the attached comments are submitted after further consideration of the matter.

Sincerely,

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

KEW:mpw

Attachment

General Comments on 10 CFR 35 Proposed Revision as Submitted by Kirksey E. Whatley - Agreement States Taskforce Member Reviewing Proposed Changes

1. The Agreement States have not been provided copies of the Commission version of the proposed change to Part 35. The statement in the value/impact statement that the Agreement States support this version of the regulations is in error.

2. Although the specific changes to 10 CFR 35 will not be made an item of compatibility, for many NRC regulations, although not considered items of compatibility are "strongly recommended" to the Agreement States. Such "strongly recommended" items have the impact of compatibility and, therefore, impact on Agreement State Programs. The Agreement States, therefore, do have an interest in the proposed changes.

3. It is the duty and responsibility of each licensing agency to reasonably determine that an applicant can protect the health and safety of his employees, his patients, and related personnel. It is impossible to make such a determination under the proposed method of implementation where an applicant simply signs a statement that he has procedures. To the applicant this may be a true statement; however, the procedures may be totally inadequate as reviewed by a license writer or inspector. The licensing agency must issue a license only after reasonable assurance of safety can be demonstrated. The proposed method of implementation cannot provide such assurance.

4. The value/impact statement does not properly discuss the probability of added cost to licensees due to increased inspection time, increased fines due to inadequate procedures and the cost of shutdown due to following inadequate procedures.

5. The value/impact statement does not address the added cost to the Office of Inspection and Enforcement due to reviews of procedures and reviews of physician qualifications at licensee facilities. If it takes an experienced license writer ten hours to review an application in his office, how much longer will it take the inspector in the field? This ties up not only the inspector but representatives of the licensee as well.

6. The value/impact statement does not address the cost to patients being diagnosed and/or treated by unqualified physicians.

7. The value/impact statement does not address the cost to licensees for increased time in resolving items of noncompliance, writing supplemental procedures to correct deficiencies, etc. It appears that the 40 percent application deficiency letters will simply shift to I & E and become deficiency letters subject to fines.

8. The value/impact statement erroneously implies a savings to applicants in developing required procedures. The proposed revision requires that the applicant develop procedures. The only difference is not having to submit them for review. The savings amounts to cost of postage on the part of the applicant.

9. Currently, as stated in the proposed rule, "40 percent of all applicants receive either a deficiency letter or phone call for additional information." Such a high percentage of inadequate applications should not be used to justify the elimination of reviews. Granted many deficiency letters probably relate to rather insignificant items. However, it is important to remember that many deficiency letters also relate to significant health and safety issues. Such issues would not be resolved under the proposed change prior to inspection of the licensee.

10. Numerous items and statements in the proposed changes relate directly to radiation safety, and in the writer's view are worthy of re-examination. Several of these are as follows:

    a. The proposed change permits "licensees to modify procedures to meet NRC requirements without obtaining a license amendment." Since 40 percent of applications are now deficient, such a proposal cannot be justified without specifically detailing the types of amendments which can be made.

    b. The proposed change requires a licensee to notify the Commission within thirty days when a radiation safety officer is no longer affiliated with the program. The notification is all that is required. What about a replacement?

    c. Section 35.38 of the proposed change does not clearly define who the "supervisor" shall be. It simply requires that an "authorized user" be present or within "one hour" notice. Being present or within "one hour" notice does not mean supervision. Currently this is a major problem in medical licensing. A clear definition and distinction should be made as to the meaning of supervision.

    d. Section 35.80 under Subpart A, Page 23, indicates that a mobile nuclear medicine service could not have a restricted area in client facilities. Does this mean that a mobile nuclear medicine licensee could not control an area for purposes of protection of individuals from radiation or radioactive materials? If a licensee cannot control his radiation area to protect individuals, his license should be withdrawn or never issued. That is basic to regulatory responsibility.

e. Section 35.80 also states that a mobile nuclear medicine licensee "must carry a calibrated survey meter to monitor exposure and contamination in case of a traffic or other accident that may result in the release of by-product material." Should not surveys at the place of use be required following operations? The requirement is to survey the "ambient exposure rate." "Ambient exposure rate" needs to be defined.

f. Section 35.90 allows radioactive gases to be stored and used in systems not previously reviewed for adequacy to protect public health and safety. All systems involving the use of radioactive gases are worthy of prelicensing reviews.

g. Section 35.51 permits a licensee to calibrate survey meters. The only requirement regarding the type of source, size of source, and activity of the source is that the licensee must keep "a description of the source radionuclide used and its estimated activity." Should not survey meters be calibrated using sources of known, traceable activity?

h. Further explanation is needed in Section 35.59 regarding taking of leak test samples. For instance, what is a test sample? How does one take a test sample from a cobalt 60 teletherapy unit? Under the proposed change determination of an acceptable leak test method is left up to the applicant or licensee.

i. Section 35.59(c)(2) requires that a test sample be taken from a teletherapy source in the "off" position. How does one take a "sample" from a source in the "off position?" A statement that the sample should be taken from the nearest accessible surface would add clarity to this regulation and provide necessary guidance. Having to go to a revised Reg. Guide 10.8 to find proper guidance defeats one of the stated purposes of the revision.

j. Section 35.59 does not require the use of proper instrumentation for performing analysis of leak test samples. Should the licensee use his 1R survey meter which has been calibrated to an accuracy of 10% with a source of estimated activity or some other instrument? Is it necessary for the licensee to use reference sources to determine efficiency of instrumentation? The problem with the concept is that the licensee may or may not know how to perform leak tests! He may develop beautiful procedures, but the procedures may be totally inadequate. A review should be made by a licensing authority to assure that procedures are adequate.

k. Section 35.59 requires a licensee to decontaminate, repair, or dispose of leaking sources. Licensees should not be allowed to perform such activities until specifically authorized.

l. Section 35.59(h) requires that each licensee survey with a low range survey meter quarterly all areas where sealed sources are stored.

What is the purpose of this survey? What constitutes an adequate survey? What is the licensee looking for?

m. Section 35.90 should require a minimum face velocity and require that the fume hood be operable.

n. Section 35.630 and several other sections require that the licensee have a calibrated dosimetry system available for use. The term "available for use" needs clarification. Does this require that each licensee maintain such a system?

o. Section 35.641(a)(2) should define "phantom." Is the reference to a phone book or a standard water phantom? If such a determination is totally left to a licensee, clarification is needed.

p. Section 35.960 discusses training requirements for teletherapy. A licensee can spot-check his teletherapy equipment but no requirements exist in this training section for calibration procedures or for performing spot checks. If the licensee is authorized to perform such checks he should know how to do them.

11. To quote from Section 35.28 under Subpart A, Page 15, "the staff must be assured ..... that the applicant has established procedures adequate to assure the safe use of by-product material."

A signature on a piece of paper stating that the applicant has adequate procedures does not provide the assurance needed for licensing personnel to issue a license. Nor does it assure the license reviewer that a physician has proper training.

The applicant may in good faith sign such an application, but due to his lack of understanding, he may have totally inadequate procedures and qualifications to use radioactive material. Such relates directly to health and safety.

12. The strongest support for continuing a procedure/physician qualification review prior to issuing a license is stated in the proposed change. That being that 40 percent of current applications are deficient. Although some deficiencies may be minor problems, many may be significant and this fact alone warrents continued review. Such reviews in the long run are not a deterent to the practice of nuclear medicine but rather are supportive of good practice in nuclear medicine.