UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

JUN 17 1985

MEMORANDUM FOR: Vandy L. Miller, Chief
Materials Licensing Branch

FROM: J. R. Miller
Technical Inspection Branch
Region III

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35,
"HUMAN USES OF BYPRODUCT MATERIAL"

The following are comments on the proposed rule from the materials and inspection staff of Region III:

General

We are in support of the idea of consolidating criteria used to review applications for new licenses, renewals, and amendments into one part of the regulations instead of several parts and regulatory guides. However, there is concern that the revised Part 35 transfers the burden of review of licensee procedures from the NRC licensing to the inspection staff and there may be no mechanism for inspectors to correct improper procedures in the field.

Specific

(Itemized according to pertinent section of revised Part 35).

1. Section 35.16, Page 38

   This section states that applications for teletherapy licenses should be sent to the Washington, D.C. office. Perhaps this should be changed, since teletherapy licensees will eventually be reviewed by the Regions.

2. Section 35.16, page 39.

   The address for Region III should read:

   USNRC, Region III, Materials Licensing Section,
   799 Roosevelt Road, Glen Ellyn, Illinois 60137

3. Section 35.17, page 39

Perhaps there should be a section (g) added for amendments for changes in location.

4. Section 35.30, page 40

It is not clear whether or not there will be an ALARA Program for "Private Practice" type licensees, since this section only refers to "Institutional" type licensees.

In addition, you may want to specify a review period instead of "periodic" for private practice licenses, since there is no committee involved and no specified period for reviews as in Section 35.31.

5. Section 35.50, page 48

In paragraph (c) you may want to insert some statement about mathematically correcting readings after taking decay into account.

6. Section 35.51, page 49

The calibrations do not appear to cover GM survey meters since paragraph (a)(1) only addresses ionization chamber type meters. It is understood that only ionization chambers can truly be calibrated in air, however, the GM survey meter is the most commonly used meter in Nuclear Medicine programs and some calibration should be performed at least annually.

7. Section 35.53, page 50

Paragraph (b) should include an action level of $\pm$ 10% for all doses assayed in the range indicated.

8. Section 35.70, page 54

It appears that there is no wipe test survey on a weekly or monthly basis. We feel this section should include a wipe test, since many times contamination is often "missed" by a low level GM survey.

9. Section 35.70, page 55

The record keeping requirement of 1 year in paragraph (e) may be in conflict with requirements in 10 CFR Part 20.

10. Section 35.92, page 55

In paragraph (a)(2), "low-range survey meter" should be expanded to state "low-range survey meter (except in the case of iodine-125 where an appropriate survey meter should be used)." This change is necessary since a large portion of human use waste is in the form of iodine-125 which cannot be measured with most low-range survey meters.

11. Section 35.500, page 62

There may be a gadolinium-153 source that has been approved in a device by the Materials Certification and Procedures Branch for diagnostic use in humans. The source is manufactured by Gulf Nuclear, Inc. in Houston, Texas.

12. Section 35.90, page 74

It appears that an individual may serve as the Radiation Safety Officer (RSO) at a medical facility based only upon certification by one or more of the boards listed without experience. This should be changed to state that the RSO must fulfill paragraphs (c), (d) and (e), since some of the boards listed (i.e. ASCPNM ARRT, etc.) require little to no training in the kind of health physics procedures needed as part of an RSO's training/experience in order to successfully direct the Radiation Safety Program at many medical institutions.

13. Appendix A, Form 313MH, page 86

a. It is not readily apparent that the information requested in Items 5 through 16 is relevant to the health and safety review of an application.

b. The information requested in Item 22 appears to be of no value if the flow rates of the ventilation system and volume of use for xenon-133 are not included with the application.

c. In Item 23, there appears to be no mechanism for maintaining records of qualified users in Part 35. If these records are not maintained, it will be difficult for the inspection and enforcement staff to verify that a user is qualified.

J. R. Miller, Chief
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