UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
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MEMORANDUM FOR: John E. Glenn, Ph.D., Chief
Materials Program Section No. 2, RI

FROM: Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section, RIII

SUBJECT: REVISION OF 10 CFR PART 35

In response to a December 14, 1983 memorandum from Norman L. McElroy to me, Region III has the following comments on the proposed revision of 10 CFR Part 35 for consideration by the task force:

General - The Draft Plan

Not all of the Region III licensing, inspection, and management staff agree with the approach suggested in Item 3 of the draft plan. (i.e., allowing licensees freedom to modify operating procedures without NRC review following a pre-licensing review). Some of the arguments against the plan are as follows:

1. The plan, in effect, transfers the burden of evaluating licensee's operating procedures to the inspection staff. To do an adequate evaluation, the onsite time for inspection of medical licensees will be increased significantly over the time spent with the current system. In order to inspect a significant number of medical licensees, inspectors may not look at procedures. Consequently, it is possible that neither the licensing or inspection staff of the NRC will review medical licensee procedures under the new system. However, the inspection module can be changed to redirect inspection efforts toward selected procedure review.

2. It appears that the plan depends upon the Radiation Safety Officer or Radiation Safety Committee to review and approve modified procedures. This could cause some health and safety problems in some institutions where past enforcement history supports the fact that committees are "in name only" and do not have the expertise nor desire to review modifications.

3. The plan eliminates a "safety valve" in the current system (i.e., licensing reviews certain aspects of licensee's operating procedures to peruse for health and safety problems prior to modifications instead of relying solely on inspection, who corrects health and safety problems in operating procedures only after they have occurred).

4. There is no basis established for the individual inspector to determine the adequacy of procedures in the field. This may be alleviated by developing criteria to follow for evaluating changes. As a minimum, Item 3 of the plan and page 7 of the proposed rule should be modified to read:

> "However, to allow each licensee to make prompt use of new safety methods,... the licensee will be allowed to modify their procedures with NRC review or approval only if such changes do not decrease the effectiveness of their program, as changed from a health and safety perspective and continue to meet the standards of 10 CFR Parts 20 and 35."

There is no need for renewal of licenses at 5 year intervals under the plan other than to verify active status. Consequently, renewal of licenses should be defined to only encompass a report of status (i.e., active or inactive).

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

1. Section 35.2:

As stated in our September 24, 1982, memorandum to Richard E. Cunningham (enclosed), the current section 35.14(c) of 10 CFR Part 35 provides for the use of byproduct material under the general license in 10 CFR 31.11 for in vitro uses without the filing of Form NRC-483. The proposed Part 35, however, does not include such a provision. Consequently, we recommend the following addition be made to Section 35.2:

"(c) Any licensee who is licensed pursuant to paragraph (a) of this section also is authorized to use byproduct material under the general license in 31.11 of this chapter for the specified in vitro uses without filing Form NRC-483 as required by 31.11(b); provided, that the licensee is subject to the other provisions of 31.11."

Justification:

Change has been made in Section 31.11 to allow for this; however, it is not as clear as placing text in Part 35.

2. Section 35.15:

Change definition of management to read:

"Management means the chief executive officer or designee."

3. Section 35.16:

Change (b) to read: "An application.....Form-313, "Application for Materials License" or in letter form for amendments".

Justification:

Requests for changes to licenses are often more readily understood in letter format.

4. Section 35.17:

Change text in (c) to read:

"Before making any changes in operating procedures where the potential for radiation exposure to workers or the general public is not increased over the procedures previously submitted.

5. Section 35.18:

This section should be deleted since it is a reiteration of 35.17(a).

6. Section 35.30:

Subsection (3) should be deleted since it is reiterated in subsection (4).

7. Section 35.31:

The duties of the Radiation Safety Officer (RSO) in subsection (b) should be expanded to include a statement about the availability of the RSO during emergencies and day-to-day basis (e.g., pager system). The text could read like subsections (3) and (4) of Section 35.38 for authorized users.

8. Section 35.32:

Clarification: are clinics required to have radiation safety committee.

9. Section 35.35:

a. The text in (a) should be modified to read:

"The Commission will only license mobile services in accordance with Subparts D, E, F (iodine-131 for treatment of hyperthyroidism and cardiac dysfunction on an outpatient basis only) and H of this part and 31.11 of this chapter."

Justification:

Many mobile vans currently treat patients with iodine-131 as stated above without any significant radiation safety hazard. The deletion of this authorization may jeopardize this service.

b. Need to clarify whether or not a mobile service license requires the use of a radiation safety committee as an institution.

c. Add a subsection as follows:

"(c) Mobile service licensees shall not service an institution that holds a current byproduct material license issued pursuant to 10 CFR Part 35".

Justification:

This creates problem of who is in control of material if not included.

10. Section 35.38:

Needs to be expanded to include:

a. The duties an authorized user can delegate to technicians and/or other physicians.

b. The conditions under which an authorized user can delegate (i.e., physician in an accredited training program with intent of adding to the license).

Justification:

This addition will avoid situations where the physician is operating under the supervision of an authorized user in lieu of being added to the license.

11. Section 35.49:

a. Question: Will this section cover the use of IND's?

b. Not sure why subsection (c) is included, since radiopharmaceuticals approved by RDRC's are only for research purposes and not for routine diagnostic programs. Suggest that this subsection be deleted.

12. Section 35.50:

Modify text to read:

"(2) Test each dose calibrator for accuracy... radionuclides with energy ranges equivalent to those normally encountered in clinical use whose activity the manufacturer...."

Justification:

Accuracy tests on some of the old dose calibrators used in the field will be of no value for licensees utilizing radiopharmaceuticals such as technetium-99m if checked with radium-226, which has a different energy range.

13. Section 35.51:

Modify to add:

"(F) Utilize a source whose activity the manufacturer has determined within 5 percent of its stated activity."

Justification:

To ensure accuracy of test.

14. Section 35.59:

Subsection (e)(1) should be modified to delete "repair" as an option for licensees finding "leaking" sealed sources.

Justification:

Most licensees do not have expertise for this procedure.

15. Section 35.70:

Modify subsection (f) to read:

"The licensee shall....this section and follow established procedures to prevent the spread of contamination."

Justification:

This version provides for licensee action related to the purpose of the survey rather than a notification.

16. Section 35.80:

a. Modify (a) to read:

"Transport to each location of use, syringes or vials containing unit dosages of prepared radiopharmaceuticals or vials containing multiple dosages of prepared radiopharmaceuticals."

b. Add (g):

"Utilize a dose calibrator at each location of use to assay unit dosages drawn at site as described in 35.53."

c. Modify (d) to read:

"Check survey instruments....and check all other equipment related to the radiation safety program as recommended...."

Justification:

a. and b. Many mobile service operations currently transport a multiple dosage vial of prepared radiopharmaceuticals to a location and withdraw a unit dosage. This is acceptable, from a radiation safety standpoint, as long as the unit dosage is assayed in a calibrated dose calibrator.

c. Need to only require them to check safety related equipment.

17. Section 35.92:

Modify subsection (a)(2) to read:

"(2) Monitors byproduct material at the container surface with all shielding removed prior to...."

Justification:

Erroneous results if shielding is present.

18. Section 35.10:

We agree with the comments you faxed to us on December 31, 1983. For example, a private room is necessary in keeping with the ALARA concept.

19. Section 35.62:

The description of the instruments listed in this section is confusing.

20. Section 35.205:

We agree with the comments you faxed to us on December 31, 1983.

21. Section 35.633:

The word "promptly" should be defined.

22. Section 35.900:

Should have or after subsection (1).

23. Section 35.971:

Text should read: "A physician who...not comply with the requirements of §§35.910(c) or 35.920(c)."

Bruce S. Mallett

Bruce S. Mallett, Chief
Materials Licensing Section

Enclosures:
1. December 14, 1983 Memo
2. June 17, 1982 Memo

cc w/o encls:

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V.L. Miller, NMSS
John R. Potter, RII
Robert J. Everett, RIV
Robert D. Thomas, RV
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