UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CALIFORNIA 94596

McElroy
rec'd 04/9/84

APR 6 1984

MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Fuel Cycle and Materials Safety, NMSS

FROM: Ross A. Scarano, Director
Division of Radiological Safety and Safeguards Programs

SUBJECT: REQUEST FOR REVIEW OF DRAFT 10 CFR PART 35 AND DRAFT REVISION OF REGULATORY GUIDE 10.8, GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL PROGRAMS

We appreciated the opportunity to review and discuss our concerns related to the revised Part 35 and Regulatory Guide with Mr. Norman McEloy on March 22, 1984. As a result of our review, we submit the following comments for consideration:

(a) General Comment - There should be uniformity between the proposed Part 35 and Regulatory Guide 10.8. For example:

0 (1) Section 35.31 should indicate a quarterly summary report or audit as referred to in Appendix C of R.G. 10.8. see 35.3265

✓ (2) Section 35.70 addresses a low range survey meter, and Appendix G refers to a low range, thin-end-window GM survey meter. Where surveys involve beta emitters or iodine-125, the guidance in R.G. 10.8 is more appropriate.

0 (3) Section 35.53 indicates that patient doses will be assayed if the dosage is more than 10 microcuries. Appendix E, R.G. 10.8, Model Rule 14, states that each patient dose will be assayed and will not be administered if it is more than 10% off from the prescribed dose. revised RG

(b) Specific Comments -

✓ (1) It appears that the retention period of two years for records is not in the best interest of inspection and enforcement. Many licensees are inspected only every three years. In order for an inspector to do a complete program review or develop an enforcement action, the records would not be available.

✓ (2) Small research programs at group medical facilities have not been addressed in this Part 35 or R.G. 10.8. Section 1.4.2 "Specific Licenses" of R.G. 10.8 should be changed to reference these programs and to provide more guidance on how the research program should be described in the application.

(3) Although syringe and vial shields are addressed in the regulation, the use of remote handling devices for brachytherapy sources was not addressed.

(4) Page 11 of Draft Proposed Rule, under the paragraph "Enforcement" states that, "Under this regulatory scheme, a licensee will be cited for failure to....follow the procedures on hand..." We do not believe that the proposed Part 35 provides for a clear cut citation for failure to follow procedures. Section 35.31 "Radiation Safety Officer" does define a responsibility of the RSO to ensure that radiation safety activities are being correctly performed in accordance with approved procedures. In the absence of a license "tie-down" condition relative to the approved procedures, these words do not provide for a clear cut enforcement action when a licensee is found to not be adhering to procedures. We believe the proposed Part 35 should have a direct statement that licensee personnel shall adhere to approved procedures.

(5) Section 35.620 should specify that both types of survey instruments should be available to the teletherapy licensee.

(6) Section 35.622 should include a sentence in effect that patient treatment will be terminated if the viewing system becomes inoperable.

(7) Section 35.632. The procedures referenced at the top of Page 127 are out-of-date. They have been replaced by, "A protocol for the determination of absorbed dose from high-energy photon and electron beams," Medical Physics November/December 1983, Vol. 10, No. 6.

(8) Appendix Q, R.G. 10.8 refers to measuring Xenon concentrations with a film badge or a TLD. This is questionable as an acceptable monitoring procedure.

Again, we appreciate the opportunity to comment on the draft Part 35 and R.G. 10.8.

Ross A. Scarano, Director
Division of Radiological Safety and
Safeguards Programs

RESPONSES TO COMMENTS ON THE 12/07/83 DRAFT
THAT WERE RECEIVED FROM REGIONS I, II, AND III

Glenn memorandum, January 20, 1984

GS 1. A contamination control sentence has been added to a new Section 35.315 safety precautions for radiopharmaceutical therapy.

GS 2. The recommendation to use syringe shields when drawing dosages has not been included.

a. It appears all of your dose rates came from Barrall and Smith (B&S) AAPM Monograph 1, 1976. Nuclear medicine technicians do not hold syringes as in B&S Figure 1 (copy attached); common practice is to hold the back half of the barrel where there is no radioactivity; the 2 cc dosage volume they use is out of date (see HP v. 41, n. 3, p. 535, Figure 1, copy attached -- 1 cc is a more representative number).

b. For the dose per year to the tip of the finger, assuming 1 mR/mCi-min (HP p. 538, average value for unshielded index finger; cf. B&S p. 84, position 4 measure of 1,100 mR/hr for 20 mCi that is equivalent to 0.9 mR/mCi-min), average dosages of 10 mCi (New England Nuclear catalogue: MDP 10 to 20 mCi; gluceptate 10-20 mCi; MAA 1-4 mCi; pertechnetate for brain 10-20 mCi, thyroid 1-10 mCi, blood pool 10-30 mCi), 10 dosages per day (your number), 0.2 min per dosage (12 sec, you said 10 sec), and 250 days per year, the estimated fingertip dose per year due to drawing dosages is:

$$\frac{1\ \text{mR}}{\text{mCi-min}} \times \frac{10\ \text{mCi}}{\text{dosage-draw}} \times \frac{0.2\ \text{min}}{\text{draw}} \times \frac{10\ \text{dosages}}{\text{da}} \times \frac{250\ \text{da}}{\text{yr}} = \frac{5\ \text{rem}}{\text{yr}}$$

c. One may respond by saying that we can save the 5 rem per year dose with a one-time purchase of a $200 syringe shield. I disagree. The first thing the technician would do after drawing the dosage is remove it from the shield to measure it. If the dosage is high or low, the next step would be to put the syringe back in the shield to return it to the vial and adjust the volume, and then remove the syringe again to remeasure it. It appears the increased handling will consume most of the projected dose savings, rendering the expenditure unproductive.

Mallett memorandum, January 11, 1984

MG 1. Many people have said that inspectors will now have to review procedures in the field. First, there is no need to review all procedures if your initial facility walkthrough and review of dose and survey records indicates that materials are being handled safely. Under the current system you review the procedure before issuing a license and review it again before inspecting. Under the proposed plan you will only review the revised procedure once, onsite, if you think the end result is inadequate. A new section has been added to require a file that contains a record of each modification. It must be retained until the license has been renewed.

MG 2. If a modified procedure is inadequate, a citation can be issued based on reference to regulation, reference books, or technical argument that critical elements are missing or commonly proscribed steps are being taken.

MG 3. The pre-licensure review and post-licensure inspection double safety valve is expensive for the applicant who, after a few months of experience in operation or after changes in patient service needs, realizes that things can be done more safely or inexpensively in a different way.

MG 4. The suggestion to establish criteria on which to evaluate procedural changes was addressed in MG 2 above. The phrase "if the modification does not reduce the program effectiveness and meets Title 10 requirements" has been suggested before. If the licensee is doing something contrary to regulation and doesn't have an exempting license condition, he is subject to enforcement action. A notation that procedural modification must be in accord with the regulations will appear throughout the preamble. The standards are in the regulations. There will always be a difference of opinion among and between licensees and NRC staff on what is proper and reasonable. A licensee may design a very safe program that is too expensive or inflexible. He should not have to pay an amendment fee to modify his program as long as it continues to meet the regulatory standards. Your suggestion to replace renewal requirements with a status report would be a major policy change that is outside the jurisdiction of this project.

MS 1. Concerning in vitro users, see the conforming amendment to Part 31.11 in the new draft, and the discussion of Section 31.11 in the preamble. No group licensee will have to file a Form 483.

MS 2. ELD advises that "designee" is implied in legal construction. Compare the use of the word "licensee," which may be a non-living corporate entity.

MS 3. Your suggestion that amendments and renewals be allowed in letter form has been added.

MS 4. Paragraph (f) has been removed.

MS 5. Sections 35.17 and 35.18 are complementary, not reiterative. One requires approval for new key individuals, and one requires notification when key individuals depart. Both sections are retained.

MS 6. Section 35.30.c(4) does not reiterate 35.30.c(3). Section c(3) tells the RSO to "see what happened," and c(4) says "see what happened and spend some time to figure out if you can do something to prevent it."

MS 7. For the level of hazard of material licensed under this part, a paper and 1-hour response time by the RSO are not needed. The authorized user and probably a technician would be available to control material in case of an emergency.

MS 8. A clinic would not need a Radiation Safety Committee unless several medical disciplines were practiced there. See the statements of consideration for a discussion.

MS 9a. The drafting committee purposely omitted all radiopharmaceutical therapy procedures from mobile service licenses. If there is a need, it may be licensed on a case-by-case basis if accompanied by a license condition that exempts the licensee from Section 35.35 and identifies the authorized therapy material.

MS 9b. A private practice mobile service licensee would not need a radiation safety committee. If the service were based at an institution it would need a committee.

MS 9c. Done.

MS 10. In an early SECY-83-62 draft the committee tried to list delegable duties and found that the list was more confusing than the simple direction to exercise supervision.

MS 11a. The intent was to allow use of INDs. The text has been revised.

MS 11b. Deleted.

MS 12. A requirement to use at least one calibration source whose principal energy is 100 keV to 500 keV has been added.

MS 13. Only NBS can measure to a certain accuracy level. The section has been rephrased to require the report to include the certified (undefined) exposure rates of the calibration source.

MS 14. The section had been revised to direct the licensee to withdraw the source from use and store it.

MS 15. That the licensee follow his procedures is required already in Section 35.31.b, that says the RSO must establish and implement procedures. Section 35.70 is intended only to get notice to the RSO that a problem exists.

MS 16a. Multi-dose vials have been added.

MS 16b. The licensee is required to measure each dosage.

MS 16c. The text has been revised to require that the licensee check all transported equipment for proper function before administering material.

MS 17. The phrase "with no interposed shielding" has been inserted.

MS 18. No response.

MS 19. [The comment refers to Section 35.620.] He may use either instrument. The same descriptor phrases were used in each survey instrument possession section.

MS 20. No response.

MS 21. The dictionary definition of "promptly" as "done readily or immediately" is sufficiently prescriptive to require that the licensee initiate actions to remedy the situation.

MS 22. No; defer to DRR.

MS 23. No; defer to ELD.

Potter memorandum, January 11, 1984

P 1. It appears the Commission wants to deal with misadministration as a separate issue. The current wording was purposely retained.

P 2. Puerto Rico and Virgin Islands added. The headquarters submission wording is intended to copy current policy.

P 3. The visiting authorized user time period has been extended indefinitely.

P 4. Under current policy a hospital cannot be a distributor, although specific exceptions may be granted.

P 5. The daily constancy check is based on Section 4.5.1 of the ANSI standard. Our current practice goes beyond the ANSI-recommended requirement.

P 6. A licensee may use any method for testing the dose calibrator for linearity. ANSI Section 4.2.2 says "Calibration of the equipment should cover as completely as practicable the activity ranges for which it will be used, particularly those ranges of activity of radionuclides to be administered to patients." There is no public health and safety need to check linearity from 2 curies to 10 microcuries. This may cause unnecessary worker dose.

P 7. See response GS1 above.

P 8.1. Transportation requirements are in Part 71. But note the physician exemption in Section 71.8.

P 8.2. If the mobile service is administering material, it must be licensed under Part 35. If it is transferring material to another licensee for human use, it must be licensed under Part 32. If it is doing both it must be licensed under both. ELD can advise you on applicability of State law.

P 8.3. A check of transported equipment has been added.

P 8.4. A closeout survey is required at the end of each day of use. See Section 35.70.

P 8.5. Unless based at an institution, a mobile service will not need a Radiation Safety Committee.

P 8.6. Part 35 does not dictate corporate organization.

P 9. A complete description of digital instrumentation is in the Regulatory Guide.

P 10. Paragraph b. requires that the licensee who elutes the generator must measure the Mo (see the conforming amendment to Section 30.34). The clarification you suggest is in the statement of consideration.

P 11. A biannual check has been added.

P 12. In light of the Riverside incident, it is indefensibly inconsistent to require, on the license, identification of the user and RSO but not the physicist.

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

JAN 11 1984

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:

MG 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.

MG 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.

MG 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).

MG 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).

MS 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.

MS 2. Section 35.15:

Change definition of management to read:

"Management means the chief executive officer or designee."

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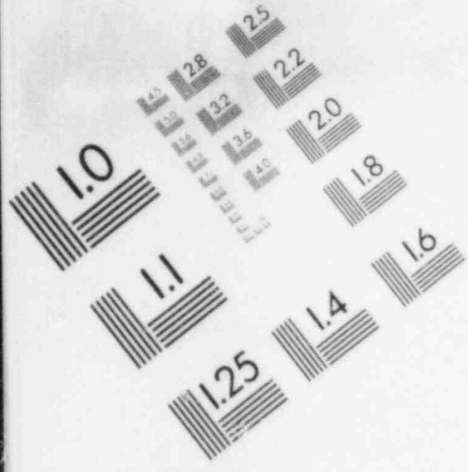

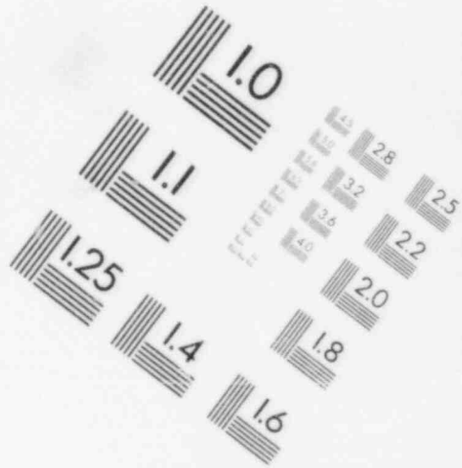

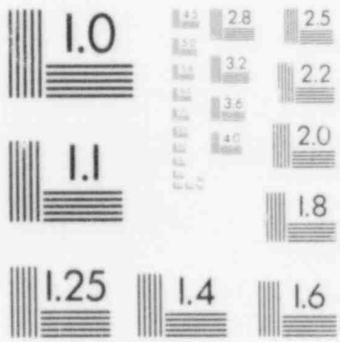

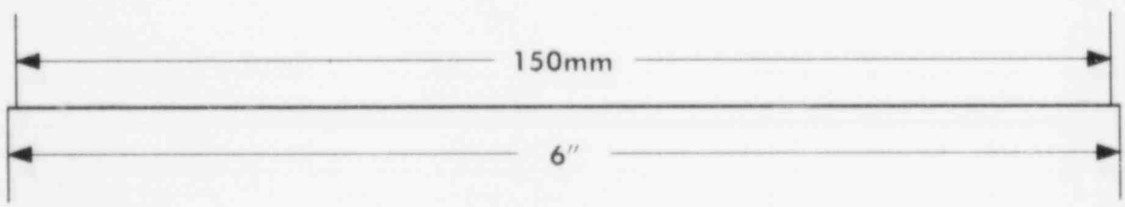

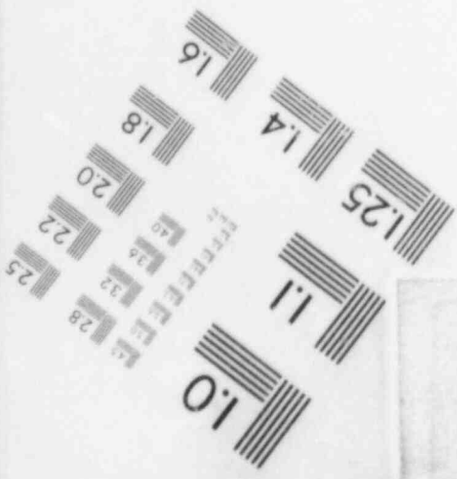

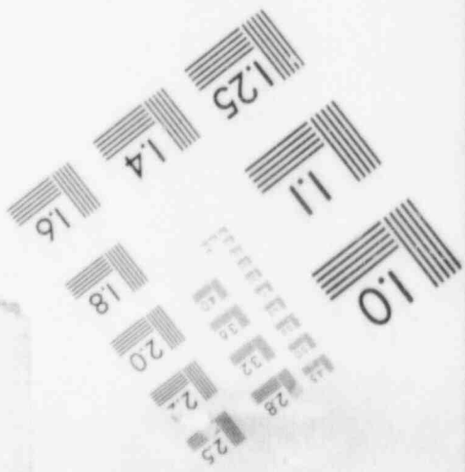

3. Section 35.16:

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 (f) 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.

MS 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.

MS 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.

MS 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.

MS 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.

MS 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.

MS 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.

MS 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.

MS 21. Section 35.633:

The word "promptly" should be defined.

MS 22. Section 35.900:

Should have or after subsection (1).

MS 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:
D. Chapell, NMSS
V.L. Miller, NMSS
John R. Potter, RII
Robert J. Everett, RIV
Robert D. Thomas, RV
All RIII Materials Inspectors
All RIII Materials Licensing Reviewers