UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
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Need 4 copies
Norm McElroy

March 30, 1984

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

FROM: Jack A. Hind, Director, Division of Radiological and Materials Safety Programs

SUBJECT: REVIEW OF DRAFT 10 CFR PART 35 AND DRAFT REVISION OF REGULATORY GUIDE 10.8

In response to your February 13, 1984, memorandum to Region III and our March 23, 1984, meeting with Mr. Norman McElroy of your staff, we have reviewed the draft of 10 CFR Part 35, the draft of Regulatory Guide 10.8, and the revision of the licensing program that were submitted. Our comments and/or concurrences are indicated on the attached enclosure.

We believe that the meeting on March 23, 1984, with Mr. McElroy was beneficial to us and request that this type of approach be taken in future tasks requiring the input from regional staff members.

Jack A. Hind

Jack A. Hind, Director
Division of Radiological
and Materials Safety Programs

Enclosures: As stated

cc w/encls:
J. E. Zerbe, OPE
G. H. Cunningham, ELD
R. B. Minogue, RES
R. C. DeYoung, IE
G. W. Kerr, SP
Regional Administrators

ENCLOSURE

I. Part 35 Draft (Item i of Enclosure 1)

1. Section 35.15, page 82, line 8:

✓ As stated in our January 11, 1984, memorandum to John E. Glenn (enclosed), the definition of management should be changed to read: "Management means the chief executive officer or designee."

Justification: Organizations such as medical institutions operate by delegating programs such as radiation safety to the radiation safety officer or committee. We are interfering with the way they do business and being inflexible if we do not change this definition as suggested.

2. Section 35.17, page 86, lines 3-4 (Reference Enclosure 1, page 13, line 20 and page 29, lines 3-4):

✓ These sections need to be modified to indicate that an amendment for a new location of use includes a change in room locations, as well as building location.

Justification: To ensure that the general licensing scheme in Section 30.33(a) of 10 CFR Part 30 is satisfied, a close-out survey is accomplished as required for other types of licensees, and the regulation is consistent with that for other types of licensees.

3. Section 35.31, page 89, after line 16:

✓ As stated in our January 11, 1984 memorandum, 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 on a day-to-day basis (e.g., pager system). The text could read like subsections (3) and (4) of Section 35.38, page 95, lines 9-14 for authorized users.

Justification: Part 35 licensees frequently utilize outside consultants or staff members with major commitments other than radiation safety (e.g., physicians) as RSO's. Consequently, it is necessary to require these RSO's to be immediately (within 1 hour) available during emergencies. The requirement is more appropriate for RSO's than authorized users.

4. Section 35.49, page 96, lines 7-9:

✓ Subsection (c) should be deleted as suggested in our January 11, 1984 memorandum.

Justification: Since the intent of Part 35 is to regulate the routine diagnostic and therapeutic use of radiopharmaceuticals and sealed sources, licensees should not be allowed to receive radiopharmaceuticals approved by RDRC's, which are only for research purposes.

In addition, Part 35 does not have requirements for research procedures, and there would be no review of the licensee's changes in research procedures. This is not compatible with how we license other organizations performing research.

5. Section 35.51, page 99, after line 3:

Modify to add: (4) Utilize a source whose activity the manufacturer has determined within 5 percent of its stated activity.

Justification: To ensure accuracy of test and be consistent with the requirements for sources utilized to calibrate a dose calibrator in Section 35.50, page 97, line 2.

6. Section 35.70, page 105, subsection (F), line 19:

As indicated in our January 11, 1984 memorandum, subsection (F) should be modified 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.

7. Section 35.622, page 123:

The text in this section should be strenthened to require continuous surveillance of the patient from the teletherapy unit console during irradiation.

Justification: To assure prescribed application of radiation.

8. Section 35.30, page 31, lines 21-23, page 32, lines 1-2, and page 87:

We believe it is incorrect to state that an ALARA program is not needed for programs other than institutions simply because these programs do not depend on the cooperation of individuals from several different departments. Many of these programs do have several auxiliary medical personnel who may be exposed to radiation; and therefore, should work under a program where, as a minimum, the RSO reviews occupational exposures and establishes investigational levels.

II. Regulatory Guide 10.8 Draft (Enclosure 10):

1. Section 1.4.2, page 5, lines 7-11:

The wording should be changed as follows: "Many institutional licensees also provide a means whereby physicians...obtain clinical radioisotope training and experience...."

Justification: It is not totally correct to state that institutional licenses (implying all institutional licenses) provide such training programs when many institutional licenses do not.

no it does not imply all

2. Section 4, Item 7.c, page 11, lines 8-10:

We recommend criteria similar to that presented in our October 31, 1983, memorandum to V. L. Miller (enclosed) be incorporated where the RSO is a consultant.

3. Section 4, Items 8-11, page 11, lines 28-30:

We suggest that items such as the scale and the direction for room drawings be deleted since they do not relate to radiation safety.

4. Section 4, Items 8-11, page 15, lines 3-4:

We suggest modifying to read: If the application is for an institution or medical center, it must be signed by the director, chief executive officer or his/her designee.

Justification: See our comments on Section 35.15 of the Part 35 draft.

5. Supplement A, Exhibit 2:

Item 1. of the form should be clarified to indicate that the training and experience is for the authorized user or RSO applying for authorization.

Justification: Many applications to add a physician as an authorized user enclose a Supplement A with the RSO's training instead of the physician's. the RG instructions are clear

III. Revision of the Licensing Program (Commission paper and Items a-h of Enclosure 1):

1. Region III concurs with the selection of Alternative 3 as specified on page 6 of the Commission paper and has no objection to publishing the proposed Part 35 as submitted to us for review and revised by our enclosed comments.

2. Region III does not concur with the new licensing method proposed in Alternative 2. If would be acceptable if:

   a. The Commission paper, Proposed Rule, and Part 35 in Enclosure 1 are modified to include regulations/statements indicating that the licensee is free to modify only procedures for which requirements are specified in Part 35 (e.g., dose calibrator, calibration tests). The licensee must obtain an amendment for any procedures not specified in Part 35 and the application/letters submitted will be "tied down" by a license condition.

   b. Certain sections of the Commission paper and Enclosure 1 are modified as follows to reflect data/experience generated by Region III.

1). Commission paper, page 9, line 10:

As indicated in our January 11, 1984 memorandum, the plan, in effect, transfers the burden of evaluating licensee's operating procedures to the inspection staff. This will increase the onsite inspection time for Region III inspectors over the time spent with the current system; this is in contrast to the statement made on page 9, line 10 of the Commission paper. For example, a recent procedure utilizing various concentric, lead shields was submitted to the Commission for authorization as a method for testing the linearity of the dose calibrator. Region III licensing staff spent at least 8 staff hours evaluating and approving the method. Under the new proposed plan, these staff hours would have been added to the onsite inspection time. In addition, it will be difficult for the individual inspector to determine the adequacy of procedures in the field in cases such as described above when the review may require input from several different experts in the NRC and the knowledge of several reference documents.

2). Commission paper, page 10, after line 5:

Need to add a statement that the plan eliminates a "safety valve" in the current system (i.e., licensing reviews certain aspects of licensees' operating procedures 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).

3). Commission paper, page 9, lines 20-27:

Under the decentralization program, 53 percent of human use licensing is handled by staff in Region III, who do not routinely conduct inspections. Accordingly, lines 20 and 21 on page 9 are incorrect.

It is misleading to indicate that material inspections are solely "based on compliance." Inspections consist of verification and validation of the licensee's radiation safety program. Procedures are not simply examined to see if they exist. Rather, procedures are verified for adequacy by direct observation. The current statement on page 11 under Alternative 3 could lead one to conclude that inspectors are "bean counting."

4). Commission paper, page 10, lines 24-27:

It is inaccurate to state that the staff does not foresee any

significant changes in the day-to-day operations within the NRC as a result of the new licensing method. As indicated in lines 20-27, page 9, the new plan will transfer the burden of review from licensing to inspection staff.

5). Commission paper, page 11, lines 30-31:

It is inaccurate to state that, under Alternative 3, the licensee cannot replace any equipment without requesting a license amendment. Currently, Region III does not require licensees to specify manufacturers' names of equipment; the only requirement is to specify the type and range of equipment as specified in the proposed Part 35. Under this method, which can be utilized under Alternative 3, the licensee can replace equipment without an amendment.

6). Enclosure 1, page 36, lines 19-22:

The review criteria established by the FDA and followed by the RDRC's does not include the review of licensees' equipment and procedures for radiation health and safety. Therefore, the statement that this review is sufficient to assure the health and safety of the public or workers is not substantiated by current practice.

7). Enclosure 1, page 43, section 35.80, lines 1-5:

There is a need for the use of bulk radiopharmaceuticals in the form of multi-dose vials, since many mobile nuclear medicine services in Region III currently transport multi-dose vials to each place of use. In addition, the use of these may be "safer" than unit doses in accident conditions due to the use of vials instead of syringes. In review of these statements, the text in lines 1-5 needs to be modified.

8). Commission paper, pages 9 and 10, opponents section:

Need to include a statement 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 expertize nor desire to review modifications.