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

Norm McElroy
mailed 8/8/84
phone

AUG 03 1984

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

FROM: J. A. Hind, Director
Division of Radiation Safety
and Safeguards

SUBJECT: REQUEST FOR CONCURRENCE ON PROPOSED REVISION
OF 10 CFR PART 35

In response to your July 13, 1984 memorandum to Region III, we concur with recommending that the Commission publish for public comment a proposed revision of Part 35 as specified in Alternative 3 on page 5 of the Commission paper as submitted to us for review. We do not agree with recommending that the Commission consider publishing Alternative 2, which includes a new method for licensing the medical use of byproduct material. The basis for our decision is summarized in the attached enclosure.

We recommend the staff consider three modifications to Part 35 as suggested in our March 30, 1984, memorandum to you, since the summary account, Enclosure 8 to your memorandum, does not address our concerns. Based upon our experience with licensees in Region III, these modifications are necessary to alleviate a potential for increased external and/or internal exposure to radiation to workers and the public.

In view of recent events in Region III with "breakthrough" of molybdenum-99 into generator eluates, we recommend that Section 35.204 of Part 35 be modified to include a reporting requirement as outlined in the attached enclosure.

C. J. Paperiello
for J. A. Hind, Director
Division of Radiation Safety
and Safeguards

cc: P. G. Norry, ADM
G. H. Cunningham, ELD
R. B. Minogue, RES
R. C. DeYoung, IE
G. W. Kerr, SP
Regional Administrators, RI, RII, RIV, RV

ENCLOSURE

Basis For Not Selecting Alternative 2

Most escalated enforcement with medical licensees in Region III is the result of lack of management control and Alternative 2 places more control for radiation safety judgement in the hands of these managers.

Alternative 2 will definitely change day-to-day operations within NRC, contrary to lines 29-31, page 8 of the Commission paper, by transferring the burden of evaluating licensee's operating procedures from licensing to inspection staff. An extensive training program would be necessary for all the inspectors.

The new method will eliminate NRC's ability to examine changes in facilities and procedures proposed by licensees for which criteria are not addressed in the proposed Part 35. Experience in Region III has shown that health and safety problems with a particular modification have been circumvented by a review prior to licensee initiation. This is one of the major benefits as a result of regionalization.

The new licensing method depends upon the Radiation Safety Officer (RSO) or Radiation Safety Committee to review and approve modified procedures. This may cause health and safety program degradation in some medical institutions where past inspection history supports the fact that authorized users functioning as RSO's or committees do not have adequate expertise nor desire to review modifications.

Alternative 2 will eliminate NRC's ability to review inspector concerns with a particular licensee during the next license amendment request. This has been an effective means of correcting potential health and safety problems in Region III.

Modifications To Part 35

1. Section 35.30, Page 70 of Enclosure 1

   Modify to include minimum criteria for an ALARA program for all medical programs and not medical institutions, exclusively.

   Justification:

   We understand that the ALARA program elements in Section 35.30 are written to ensure information flow between managers with overlapping responsibilities; however, they also include commitments to keep doses as low as reasonably achievable, a review of personnel exposures, and establishment of investigational levels. We believe these commitments are necessary for all medical programs.

2. Section 35.19, Page 69 of Enclosure 1

Modify to include requirements to amend license for any room relocation, as well as, building location.

Justification:

Part 35 does not include criteria for medical licensees to utilize for performing close-out surveys prior to release of rooms and/or areas for unrestricted use.

3. Section 35.31, Page 71, and Section 35.38, Page 77 of Enclosure 1

Modify Section 35.31 to include a statement of availability of the RSO for emergencies and routine day-to-day operations. Delete this same statement for an authorized user in Section 35.38

Justification:

Since the radiation safety program and actions proposed by Part 35 revolve around the RSO and not the authorized user, it is more prudent to require the RSO to be available than the user.

4. Section 35.204, Page 89-90 Enclosure 1

Modify to include a reporting requirement as follows:

(d) The licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D, of Part 20 of this Chapter and any affected medical facilities of the results of any tests where the molybdenum-99 concentration exceeds that specified in (a) above. These notifications must be made within 24 hours after the licensee discovers the result.

Justification:

Recent events in Region III where licensees were not required to report the results of "high breakthrough" of molybdenum-99 in generator eluates have led to unnecessary misadministrations. Notification may alleviate future problems by making licensees and the NRC aware prior to distribution of such eluates for medical use in humans.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
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ATLANTA, GEORGIA 30303

AUG 7 1984

McElroy need 2 w/ att memo

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

FROM: J. Philip Stohr, Director
Division of Radiation Safety and Safeguards

SUBJECT: CONCURRENCE ON PROPOSED REVISION OF 10 CFR PART 35
(YOUR MEMO, JULY 13, 1984)

This office has completed its review of the Proposed Revision of 10 CFR Part 35, and along with our previous verbal and written comments, we concur subject to the following additional comment:

10 CFR 35.35(a) limits the availability of mobile nuclear medicine services to just unlicensed clients. We believe this is unnecessarily restrictive since licensed hospitals may have an equipment failure and need a mobile service, rather than transfer an ill patient. This consideration should prevail over the unlikely problem of determining fault between two licensees.

In the past, where a service licensee performs for a facility licensee, the NRC has generally held the facility licensee responsible for the conduct of activities even though the service licensee may have been an independent contractor, rather than an agent. In some cases both parties have been held in violation. Also, a simple condition in the mobile service license could define the responsibilities of the parties involved (e.g., the mobile service licensee is subject to the radiation safety procedures of the client licensee upon entry onto their premises), and similar language could be placed in the client license.

In summary, we believe the potential benefit of permitting mobile services at licensed hospitals far outweighs the risks. Please advise me of any questions or problems.

J. Philip Stohr

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