UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30303

c January 11 1984

MEMORANDUM FOR: John Glenn, Chief, MRP Section, RI

FROM: John Potter, Chief, MRP Section, RII

SUBJECT: DRAFT RECODIFICATION OF 10 CFR 35
(YOUR FAX TO J. POTTER, 12/21/83)

Pursuant to your request, as the NRC regional coordinator, we offer comments on the subject draft as indicated in the enclosure. Phil Chambless is our Task Group Representative and was the principal author of these comments.

John Potter

ENCLOSURE

Comments

1. Page 53 "Misadministration"

   Comment - Eliminate #5

   Reason-Therapeutic Misadministrations can occur because of human error such as an addition or subtraction error (and actually has in RII). The Commission should only be concerned in those misadministrations that occur because of errors in source calibration, time of exposure, etc. since these could (1) Be an actual violation of a license condition or regulation (misadministrations per se are not) or, (2) Be an issue of generic interest to other licensees.

   Note-All of the licencee's I have spoken with agree with this point of view.

2. Page 55 Paragraph (d)(2)

   - Need to include Puerto Rico and the U. S. Virgin Islands.

   - Why send licensing materials to headquarters as indicated in Paragraph(e)?

3. Page 61 - 35.34 Visiting Authorized User

   - Should extend the period of temporary use to perhaps 90 days or longer. There is no rationale for limiting it to 60 days since the licensee reviews the qualifications of the visiting user and not the NRC.

4. 35.49 - Suppliers

   - Can a hospital be a "supplier" to other hospitals of unit dosages without being licensed to do so as a "Nuclear Pharmacy"?

5. Page 64 - 35.50

   Para (b)(1) is quite a divergence from current philosophy in Reg. Guide 10 8

   - Do we still want daily checks using low, medium and high energy sources? If so, say so. As written, a licensee could do daily checks w/ Ra^{226} only; and if he chose the 50uCi of any other γ-emitting nuclide, why couldn't he use Co^{60} (an energy totally inappropriate).

6. Page 64 para (b)(3) -

- Linearity

1. "Highest dosage that will be administered" might be as low as 20 mCi and yet an elution from their generator might be as high as 400 mCi which is used as the "stock" $Tc^{99}m$ elution. The rule should reflect the current accepted practice in R.G 10.8.

2. The assumption here is that the licensee can use any method they choose for performing linearity. (i.e. the "old" method, cali-check or lineator, etc.).

7. Page 70 - 35.60

- Should include "... who administers or draws a radio pharmaceutical ..."

Exposure to the fingers can be higher drawing a dosage than administering a dosage.

8. Page 72 - 35.80 "Mobile Sevice"

1. Should be a statement that licensees operating a mobile service should comply with Part 71 as far as their transportation of RAM.

2. When does a mobile service become a nuclear pharmacy and thus be licensed in accordance w/10CFR 32.72 and 73, and thus either be excepted by FDA or have a State Pharmacy License? How many hospitals can they service without requiring a State Pharmacy License?

3. There are generally two types of mobile services: (1) pharmaceuticals carried to facilities who own their own equipment; or (2) equipment and pharmaceuticals carried to the facilities

- In the second case, QA checks should be required on the equipment before it is put into use since transporting the devices can change their calibrations or affect operation of the PM tubes.

4. There should also be a requirement to perform vehicle surveys in the second case above since doses will be administered in the vehicle itself.

5. Special provisions should be included for the membership of the Rad. Safety Committee for a mobile service because of several different administrations, nursing staffs, etc. involved (i.e. Representation from each institution served since their facilities are likely to be used).

6. Should the mobile service licensee management have to include the authorited physician users as officers of the company in order to insure appropriate management control?

9. Page 74 - 35.120

- What about digital auto-ranging protable survey meters? This statement as written simply wouldn't apply to these type meters.

- Should read instead "... not more than 1 mr/hr or digital survey meter capable of reading in tenths of a mr/hr.

10. Page 76 - 35.204

- Should include a statement to the effect that for a licensee using a nuclear pharmacy for individual doses, in lieu of performing their own moly-breakthru, they only need a statement from the Pharmacy that these tests are done on each elution.

11. Page 76 - 35.205

- Should include provisions for testing ventilation rates in rooms if this is the preferred method for controlling airborne contamination; preferably every 6 months or after each change in the facility which would affect air flow in the Nuc. Med. Department.

12. Page 81 - 35.60

- Why must the qualified expert be specifically listed on the license? It is sufficient to require the licensee to use a qualified expert for the required tests on their unit, but a small hospital might need to use several different physicist in the course of five years. What are we gaining by having them amend their license for a new physicist when the licensee reviews the qualifications and not the NRC?

- This should be deleted and the definition of the qualified expert should be amended to delete the implication that the person is actually listed on the license.