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

McElroy
rec'd 04/09/84

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MEMORANDUM FOR: Richard E. Cunningham, Director, FCMS Division, NMSS

FROM: J. Philip Stohr, Director, EPMS Program Division

SUBJECT: COMMENTARY ON PROPOSED 10 CFR 35 AND REGULATORY GUIDE 10.8

In response to your request for review of the subject revision dated February 13, 1984, we offer comments as follows:

10 CFR 35

A. General Comments

1. We believe it is important to clarify whether it will continue to be necessary for the Regional Licensing Staff to review the applicants' operating procedures. Normally, we do not review applicant documents that will not become enforceable. If reviews are to be made, then some guidance will be necessary on what actions a license reviewer is to take if he finds the procedures inadequate to meet regulatory requirements.

B. Specific Comments

1. P. 105, §35.70(d) and (g) - Will the applicant specify the dose rate and contamination action levels in the application or can these be specified later in operating procedures?

2. P. 107, §35.90 - Will the licensee be required to initially open volatiles and gases in a fume hood?

3. P. 109, §35.120 - Suggest rewording to require possession of an "operable" portable survey meter.

4. P. 113, §35.220 - Suggest rewording as in §35.120 above.

5. P. 115, §35.320 - Suggest rewording as in §35.120 above.

6. P. 118, §35.420 - Suggest rewording as in §35.120 above.

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7. P. 122, §35.620 - The teletherapy licensee should have access to both a high and low level survey meter. The high range meter is needed for approaching a malfunctioning teletherapy unit or as substitution for a malfunctioning installed monitor. The low range meter is needed for occasional §20.105 measurements.

8. P. 95, §35.39(a)(4) Requiring the authorized user to be physically present on one hour notice should be clarified. It appears the purpose of this requirement is to provide for management of toxic shock and loss of material or contamination. We suggest rewording to extend this interval to eight hours if the institution has a full time emergency room physician and the supervised nuclear medicine technologist is on duty. If the authorized user is available by telephone he can arrange with the hospital administrator for any required support. The Nuclear Medicine technologist on duty should be able to deal with any cleanup, or isolation, or search for missing isotopes under the telephone guidance of the authorized user. The one hour rule seems unduly restrictive for most hospitals.

9. P. 9, Notes, last paragraph - most human use licensing is now handled by individuals who are in close proximity to those who inspect; however, we do not believe that most NRC license reviewers also inspect.

10. P. 84, §35.16(d)(2) - reword to include the U.S. Atlantic Ocean Commonwealth & Territory of Puerto Rico & Virgin Islands within the non-federal licensing jurisdiction of Region II, in the same manner as the U.S. island territories of the Pacific Ocean are within Region V. The Region II address is Suite 2900 rather than 3100.

11. P. 99, §35.51(b)(3) - suggest defining the term "dedicated" check source. Just a "check source" should be adequate.

Regulatory Guide 10.8

A. Specific Comments

1. P. 8, Item 5, line 7, reword as "if you plan to have an eye applicator, express its total activity (in mCi), as a separate line item."

2. P. 9, Item 7.d. requires "properly" trained paramedicals. Are licensing reviewers supposed to verify credentials of supervised individuals in the same manner as for an "authorized user?" If so, then 10 CFR 35.38 should require supervised individuals to possess such credentials.

3. P. 10, Item 7.a.(4) Can physicians not previously authorized as users, be independently approved, based on training and experience which meets the criteria in 10 CFR 35 or Regulatory Guide 8.10, without consulting the NRC ACMUI? If not, then this is a significant reversal in our licensing policy.

If you have any questions, please contact me.

/ J. Philip Stohr

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