UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I

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MEMORANDUM FOR: Vandy Miller, Chief, Material Licensing Branch

FROM: J. H. Joyner, Chief, Technical Inspection Branch, Region I

SUBJECT: REGION I COMMENTS ON DRAFT REVISION OF PART 35 (DATED FEBRUARY 26, 1982)

This memorandum incorporates comments from the Region I Materials Radiological Protection Section and the Region I Licensing Section. My staff and I are pleased with the concepts set forth in the Draft Revision of 10 CFR Part 35 and look forward to further participation in the review and implementation of Part 35. A general comment is discussed below. Additional, specific comments are enclosed.

It appears that the qualifications of physicians using licensed material will no longer be reviewed during the licensing process. This is acceptable, provided the inspector is not expected to review the qualifications of physicians, or the validity of the certification submitted with the application on a routine basis. The reasons:

1. This would not be an efficient use of inspector time. One physician may practice at several institutions and will change institutions over a period of time. It is not appropriate to have his qualifications reviewed repeatedly.

2. It is unreasonable to expect an inspector to address the complexities of physician qualification during an inspection. This may well cause disputes during inspections and adversely effect the review of the radiation protection program.

We will be happy to discuss our comments with you or your staff, if you desire.

for John D. Kinneman

James H. Joyner, Chief
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Enclosure: As stated

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Comments on February 26, Draft - Part 35

General Comments, Comments on Application Form and Ommissions

1. The February 26 draft of Part 35 and the application form do not refer to the Regional Offices. The appropriate revisions should be made to indicate which applications should be addressed to the Regional Office, rather than to NMSS.

2. 10 CFR 35.14 currently requires that group licensees receive only materials manufactured and distributed by specific licensees (Part 32). This requirement appears to have been dropped. We believe this requirement is fundamental to the Group Licensing concept.

3. All references to General Licenses (current 10 CFR 35.11 and 10 CFR 35. 31) have been dropped from the draft. Is this intentional?

4. By combining Groups IV and V, it appears that private practice licensees may be authorized to perform therapy procedures normally requiring hospitalization. Is this intentional?

5. The form does not appear to provide for a physician wanting to use Group II only or strontium-90 eye applicators from Group VI only. If a physician certifies that he is qualified to use Group VI based on the criteria in 10 CFR 35.941, how will a licensing reviewer know that he is not indicating that he meets the criteria of 10 CFR 35.940.

6. In part III of the application form under "Qualified Expert", certification line should read, "ABHP", not "HPS".

7. What provisions need to be made to keep licenses issued in accordance with the present 10 CFR 35 valid when the new 10 CFR 35 is adopted?

8. There seems to be shifts between "must" and "shall"; is there a difference?

9. The word, "demonstrate" would be bettwe than "prove" in a number of places.

10. One year record retention is not sufficient; two is more appropriate.

Specific Comments on Paragraphs

§35.15 "Authorized user" - physicians practicing under an institutional license are not "licensed by the Commissioner".

"Transfer" - must include DOE and other competent authorities, like NRC.

§35.30(c)(3) Investigation of "known instances" is insufficient. RSO must conduct an ongoing audit program to discover and correct deviations from good practice (also §35.32).

§35.31(h) It seems that requirements like this should be on the licensee, not the RSO.

§35.32(f) Appears to supercede record retention requirements in other parts. Also, same comment as 35.31(h).

§35.38 Supervision should also include protection of the patient. The authorized user should select patients, prescribe dose, and interpret the results of procedures.

§35.50(a) Radionuclides used for calibration should represent gamma energies of commonly-used nuclides. Linearity check only to highest does administered is good.

§35.50(c) Shouldn't the instrument be adjusted/repaired?

§35.51 Term, "ionization survey instrument" is vague. All detectors of ionizing radiation rely on ionization in some material (gas, scintillator, semi-conductor) for the detection mechanism. If "ionization chamber type" or "cutie-pie" is meant, it should be so stated. Calibration frequency should be based on function, not instrument type.

§35.53 No assay required for phophorus-32?

§35.58 Any byproduct material?

§35.59(a)(1) The term, "not contrary to" should be changed to, "in accordance with".

§35.59(d)(2) Does the Director of Inspection and Enforcement still want copies of this report?

§35.60 Most of the hand dose in nuclear medicine is received during kit preparation and dose preparation. (cf. J. E. Burr + R. Berg, JNMT 5, 158 (1977)). Syringe shields should be required during all manipulations of radioactive materials in syringes. In difficult injections, syringe shield may still be used, if puncture is made with a "butterfly". No mention is made of the use of waterproof gloves or tongs to reduce hand contamination and exposure. Surveys of hand and clothing, prohibition of food with radioactive material, prohibition of mouth pipetting, and other Appendix G (Reg. Guide 10.8) requirements are not addressed.

§35.70 Should define a "low range survey meter".

§35.75 The blanket prohibition of release of patients with body burden of iodine-131 above 30 millicuries (mCi) is not sufficient. A patient who received a dose of 200 mCi will excrete a large part of it in the first two days and will have a body burden of approximately 50 mCi after 2 days, very little of which will be excreted. A patient receiving 29 mCi of iodine-131, particularly one with little or no thyroid function due to surgery or prior radioiodine therapy, may, nevertheless, be released, even though most of the dose will be excreted during the first day or two, possibly in a public lavatory on the way home from the hospital.

§35.80(c) Make clear equipment must be checked after each transport, but prior to use.

§35.90 The regulation as written may prevent releases to restricted areas. How about the environment?

§35.200 Xenon-133 does not appear in any of the proposed Groups. Since 10 CFR 35.205 refers to gases and aerosols, it appears that xenon-133 should be added to Groups II/III.

§35.204 This is quite a change from current requirements. Suggest a special notice be given of change.

§35.303 How does one measure whether procedures are adequate; no criteria are given?

§35.621 (1) Battery backup is unnecessary if power for monitor is independent of power for teletherapy. Teletherapy source normally returns to safe position or power failure automatically. The probability that mechanical source jam will occur at the same time as hospital-wide power failure is small.

(2) An audible alarm is imperative. Region III has already had one instance of a technologist ignoring the flashing light. Wording in 10 CFR 34.29(b) requiring audible alarm only if entry is attempted while source is on is appropriate. (Alarm will not normally sound during treatment). Monitors now in use (generally Nuclear Associates Primalert 10 or Eberline SPI-2) can be easily retrofitted with a door-cancellable audible alarm for no more cost than original installation with audible alarm.

§35.630 Meaning of "have available" is unclear. Must instrument be present in hospital or is a consultant on call with instrument sufficient?

§35.630(a) This form is excellent.

§35.632(c) AAPM has new protocol in preparation under Task Group-21 (TG-21) chaired by R. J. Schulz, Ph. D. Preliminary document presented at AAPM meeting, August, 1981, Boston, probably out this year.

§35.633(b)(5) Spot check measurement should be compared with value used for treatment. A comparison with an ad hoc calculation of dose rate by decay from primary calibration value does not provide a check on value used for treatment.

§35.633(e) ANSI N449-1974 recommends these functions be checked daily. Regulation should require that these be checked each day unit is used. Since all checks require only cursory observation or a few seconds, and consequences of failure could be serious, requirement is not an unreasonable burden.

§35.641(1) and (ii) Make "radiation levels" and "quantities of radiation" read the same.