UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
631 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

W. Walker

JUN 24 1982

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

FROM: Thomas T. Martin, Director, Division of Engineering and Technical Programs

SUBJECT: REGION I COMMENTS ON PROPOSED REVISION OF 10 CFR PART 35 DATED MAY 5, 1982

This memorandum incorporates comments from the Region I Materials Program Sections, No. 1 and No. 2. My staff and I are pleased with the concepts set forth in the Proposed Revision of 10 CFR Part 35 and look forward to further participation in the review and implementation of Part 35, as necessary. Three general comments are discussed below. Additionally, specific comments are contained in the enclosure.

1. Although Part 35 is intended to cover all human use of byproduct material, neither the current nor the proposed version of Part 35 give definitive guidance on use of byproduct material for human medical research. Part 35 should provide that authorization for human medical research will be granted only if the applicant meets the requirements of 10 CFR 33.13 and has an FDA-approved Radioactive Drug Research Committee. In addition, "human medical research" should be defined. For example: "'Human Medical Research' means the internal or external administration of byproduct material, or radiation therefrom, to human beings for the evaluation of new drugs and procedures, including studies of metabolism, safety, and effectiveness. 'Human Medical Research' as used in this part does not include the administration of byproduct material or radiation therefrom to human beings for instructional purposes only."

2. There is a need for a requirement to maintain records of physician qualifications. Otherwise the NRC could be required to prove a physician's qualifications, if allegations are made.

3. With regard to procedures: a) licensees are required to have procedures, but no standards for required procedures are established, b) the proposed revision appears to abandon all the work which has gone into some excellent Appendices in Regulatory Guide 10.8 (i.e., G, K, & L); c) we suggest a requirement that the Radiation Safety Committee document their justification for deleting "model" Regulatory Guide procedures.

Please contact John Kinneman (488-1252) if additional information concerning our comments is required.

Thomas T. Martin, Director
Division of Engineering and
Technical Programs

Enclosures: As Stated

JUN 2 4 1982

Enclosure

35.1 Based on our general comment regarding "Human Medical Research", the scope should include: "The requirements and provisions of Parts 19, 20, 21, 30,33 and 170 of the chapter ..."

35.15 Under definitions, add the following:

Human Medical Research: as defined in our general comment.

Vial Shield: define by performance (i.e., provides x half-valve layers)

Syringe Shield: define by performance (i.e., provides x half-valve layers)

Qualitative instrument: Any survey meter which is used primarily to detect the presence or absence of radiation or radioactive material.

Quantitative instrument: Any survey meter or measuring instrument calibrated against a certified standard source of radiation which reads out in mR/hr, R/hr or cpm with known efficiency.

Low level survey meter: define by performance (range)

35.16 (a) Change to: "If the applicant is a Federal agency, if the applicant is an agency of the District of Columbia ..."

(b) Change to: "If the applicant is not a federal agency or an agency of the District of Columbia and is located in Connecticut, the District of Columbia, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, or Vermont, and ... Region I, Materials Program Section No. 2, 631 Park Avenue ...."

35.17(f) Does this refer to changes in the "procedures" of the licensed program which could result in a reduction of radiation safety or to something else?

35.30(c) How often is periodic? Should be more specific.

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

35.50(a)(2) Activity of standards is too low; six millicuries of activity per source is permitted. Radionuclides used for calibration should represent gamma energies of commonly-used nuclides.

35.50(b) Define "appropriate checks" (i.e., "Perform the required linearity, accuracy, and constancy checks and tests following adjustment or repair of dose calibrator.")

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

35.51(a)(1) Change to: "Calibrate 'Quantitative' survey instruments," definition provided in comments for 35.15.

35.51(a)(2) Change to: "Calibrate 'Qualitative' survey instruments," definition provided in comments for 35.15.

35.51(d) What if survey instrument fails test?

35.58 Add "... and are obtained from a manufacturer licensed in accordance with 32.74."

35.59(a) "A licensee .... shall not use the source contrary to the instructions" - rather than present wording "shall use the source not contrary".

35.59 Second (b), should it be (c)? If so, all other lower case letters following need to be revised.

35.60 Syringe shields should be defined by performance in 35.15. When is the use of a syringe shield contraindicated? Who decides?

Most of the hand dose in nuclear medicine is received during kit preparation and dose preparation (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", through there is some controversy over whether this reduces dose. 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 (Regulatory Guide 10.8) requirements are not addressed.

35.61 Vial shield should be defined by performance in 35.15.

35.70 "Low range survey meter" should be defined in terms of performance in 35.15.

35.75 This should be changed to "Confinement and Release of patients". Change 35.75(a) to read: "The licensee shall confine patients undergoing treatment with byproduct materials listed in 35.300 and 35.400 in a single (private) room within a hospital or similar facility until the requirements of 35.75(b) or 35.404 are met." 35.75(b) as currently proposed for 35.75.

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

35.92(a)(2) Low level survey meter should be defined in terms of performance in 35.15.

35.92(a)(2) Does "unshielded" refer to the trash or the probe of the survey meter?

35.92(a)(4) Define "generator."

35.100(a) Should "human medical research" definition be placed here? Should this be restricted to 33.13 licensees? What about IND's and NDA's?

35.200(a) Same comment as 35.100(a).

35.204 Shouldn't Mo-99 content be checked prior to administration? What happened to five microcurie total limit?

35.304(a)(1),(2),(3),(4) What are the standards for these procedures? What can we do if they adopt inadequate procedures?

35.404 What is "confinement for medical care?" See 35.75 comments.

35.405(a)(1)(2) What are the standards for these procedures?

35.621 (1) Battery backup is unnecessary if power for monitor is independent of power for teletherapy. Reason for separate power is fact that "Emergency Bar" usually disconnects all power to unit. Teletherapy source normally returns to safe position on power failure. The probability that a mechanical source jam will occur at the same time as hospital-wide power failure is small.

(2) An audible alarm is important. There have already been instances 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.

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

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(f) 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 would not be an unreasonable burden.

35.900 What about certification by American Board of Radiology in Radiation Therapy, if license includes all groups?

35.920(b)(2)(vi) Alumina contamination assay not required by any other sections?

35.921(b) Top of Page 79. Correct to 35.920 instead of 35.921.

35.942(?) This section is refered to in 35.941. What is proper reference or is 35.942 missing?

DRAFT

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

FROM: Ronald C. Haynes, Regional Administrator, Region I

SUBJECT: REGION I COMMENTS ON PROPOSED REVISION OF 10 CFR PART 35 DATED MAY 5, 1982

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check this wlm

2. There is a need for a requirement to maintain records of physician qualifications. Otherwise the NRC could be required to prove a physician's qualifications, if allegations are made. RSO must keep these. done wlm

3. With regard to procedures: a) licensees are required to have procedures, but no standards for required procedures are established; b) the proposed revision appears to abandon all the work which has gone into some excellent Appendicies in Regulatory Guide 10.8 (i.e., G, K, & L); c) we suggest a requirement that the Radiation Safety Committee document their justification for deleting "model" Regulatory Guide procedures.

yes they are. disagree

"deliberations" clause. All inappropriate.

Please contact John Kinnerman (488-1252) if additional information concerning our comments is required.

Ronald C. Haynes
Regional Administrator

Enclosures: As stated

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35.15 Under definitions, add the following:

Human Medical Research: as defined in our general comment. consider

Vial Shield: define by performance (i.e., provides x half-valve layers) + dose curves aren't, and needn't be, circular. mem

Syringe Shield: define by performance (i.e., provides x half-valve layers)

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Low level survey meter: define by performance (range) see RG

35.16 (a) Change to: "If the applicant is a Federal agency, if the applicant is an agency of the District of Columbia ...." done

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35.17(f) Does this refer to changes in the "procedures" of the licensed program which could result in a reduction of radiation safety or to something else? anything - catchall

35.30(c) How often is periodic? Should be more specific.

35.38 Supervision should also include protection of the patient. The authorized user should select patients, prescribe dose, and interpret the results of procedures. opens a floodgate of "also's"

35.50(a)(2) Activity of standards is too low; six millicuries of activity per source is permitted. Radionuclides used for calibration should represent gamma energies of commonly-used nuclides.

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35.92(a)(2) Does "unshielded" refer to the trash or the probe of the survey meter? leave vague intrn

35.92(a)(4) Define "generator." common term.

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35.204 Shouldn't Mo-99 content be checked prior to administration? What happened to five microcurie total limit? ELD // USP

35.304(a)(1),(2),(3),(4) What are the standards for these procedures? What can we do if they adopt inadequate procedures? ELD bang on something else

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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. you are correct, but there are an infinite no. of things we could get into.

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