AA73-1
PDR
M. 22

JUL 13 1984

MEMORANDUM FOR: Those on Attached List

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

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

The attached Commission paper contains a proposed revision of 10 CFR Part 35 to be published in the Federal Register for comment. This proposed revision was prepared in response to a memorandum to Mr. Dircks from Mr. Chilk (see enclosure 2 of the Commission paper). An earlier draft was distributed for comment on February 13, 1984.

Comments were received from 26 NRC offices and Agreement States comprising 105 pages. A summary comment analysis appears as enclosure 8. Due to the number of changes made, text changes have not been highlighted in the attachment. The following significant changes have been made.

1. The draft memorandum from Mr. Davis to Mr. Dircks has been revised in its entirety.

2. The comparison of the proposed regulatory regime to NRC's regulatory regime for reactors that appears in the staff paper has been expanded.

3. In the regulation:

   a. The draft title has been changed from "Human Uses..." to "Medical Uses...."

   b. The term "area of use" was defined in §35.15.

   c. The duties of the Radiation Safety Officer (RSO) listed in §35.31(b)(1) were expanded.

   d. The Radiation Safety Committee, in §35.32(b)(2), must review proposed authorized user credentials with regard to Subpart J standards.

   e. The visiting authorized user permission, in §35.34, is limited to 60 days each year.

OFFICE ▶						
SURNAME ▶						
DATE ▶						

f. Mobile nuclear medicine services, in §35.35(a), are restricted to unlicensed clients.

g. A new §35.36, "Radiation safety program changes," has been added.

h. In §35.60, syringe shields are required for mixing kits but not for drawing dosages.

i. In §35.100 and §35.200, the permission to use materials authorized by a Radioactive Drug Research Committee has been withdrawn.

j. In §35.200, Tin/Indium generators have been removed.

k. §35.205, "Control of aerosols and gases," has been expanded.

l. In §35.315(g), the licensee must measure the thyroid burden of individuals who administer therapeutic iodine dosages.

m. Tantalum wire has been removed from §35.400.

n. §35.404(a) has been clarified to require a radiation survey of implant patients immediately after the sources have been removed.

o. §35.406(c) has been added to require a survey immediately after making an implant to assure that no sources have been misplaced.

p. §35.606 no longer requires authorization before removing a teletherapy unit.

q. Safety instructions in §35.610(a)(1) have been expanded.

r. In §35.632(d), an alternative teletherapy calibration procedure is authorized.

s. §35.910(b) has been expanded for clarity.

t. §35.940(b) requires active practice of therapeutic radiology and has been expanded for clarity.

u. §35.941 requires active practice in therapeutic radiology or ophthalmology.

v. §35.90 requires active practice in therapeutic radiology and has been expanded for clarity.

OFFICE ▶							
SURNAME ▶							
DATE ▶							

4. The Regulatory Analysis, Enclosure 4, has been revised to indicate the number of licensees affected by the revision, the impact on NRC operations, and the impact of alternatives 1 and 3.

5. The comment analysis, Enclosure 8, is provided for your information. It will be removed from the final paper.

6. The Appendices of the draft regulatory guide that support Sections 35.36 and 35.205 have been revised to reflect the content of those sections and are attached. Otherwise, only a few clarifying editorial changes were made to the draft guide.

If you have any questions about the attached material, please contact Norman McElroy at (301) 427-4108.

Please provide your concurrence by memorandum to me by JUL 27 1984.

Original Signed by
Richard E. Cunningham

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

Enclosure: As stated

DISTRIBUTION:
NLMcElroy
VLMiller
DRChapell
RECunningham
NMSS r/f
FCML r/f
FC Central File
ABentley (NMSS 83-985 PARTIAL)
BCLAUSSER

OFFICE	FCML	FCML	FC	FC			
SURNAME	NLMcElroy:ht	VLMiller	DRChapell	RECunningham			
DATE	7/17/84	7/17/84	7/ /84	7/23/84			

NRC FORM 318 (10-80) NRCM 0240

OFFICIAL RECORD COPY

Addressees - Memorandum dated JUL 13 1984

Office Directors:	Your cognizant individual is:
Patricia G. Norry, ADM	Michael Lesar
Guy H. Cunningham, ELD	Tom Dorian
Robert B. Minogue, RES	Judy Foulke
Richard C. DeYoung, IE	Harriet Karagiannis
G. Wayne Kerr, SP	Lloyd Bolling
Thomas E. Murley, RI	John Glenn
James P. O'Reilly, RII	Phillip Chambless
James G. Keppler, RIII	Bruce Mallett
John T. Collins, RIV	Jerry Everett
John B. Martin, RV	R. D. Thomas

Advisory Committee on the Medical Uses of Isotopes Members:
Vincent P. Collins, M.D., Houston Institute of Cancer
Frank H. Deland, M.D., Veterans Administration Hospital
Jack K. Goodrich, M.D., Hamot Medical Center, Radiology Associates of Erie
Melvin L. Griem, M.D., University of Chicago
B. Leonard Holman, M.D., University of Chicago
Edward W. Webster, Ph.D., Massachusetts General Hospital
David H. Woodbury, M.D., Wayne County General Hospital
Joseph B. Workman, M.D., Duke University Medical Center

Consultant:
Peter R. Almond, Ph.D., M.D. Anderson Hospital

10.m.4. Spilled Gas Clearance Time

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in section Q4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearence times according to the following procedure, you may respond to item 10.m.4. by saying, "We will calculate spilled gas clearance times according to the procedure that was published in Regulatory Guide 10.8, Revision 2, Appendix Q4, (*** insert R.G. publ date***)"

You may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §35.205. Say on your application, "We have developed a procedure for calculating spilled gas clearance times that is appended as ATT 10.m.4." and append your procedure.

Q4: Model Procedure for calculating spilled gas clearance time.

1. Collect the following data:

    a. Highest activity of gas in a single container;

    b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value);

    c. Measured airflow exhaust to each vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;

    d. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1 x 10-5 uCi/ml in restricted areas and 3 x 10-7 uCi/ml in unrestricted areas. For other gases see Appendix B to 10 CFR Part 20.

2. For each room make the following calculation:

    a. Decide whether you will control the room as a restricted or unrestricted area.

    b. Divide the largest single container activity by the total exhaust rate.

    c. Divide the quotient from step b. by the maximum permissible concentration. This is the clearance time that should be posted.

4. For protection equipment:
   a. What level of protection does it provide?
   b. What is the required level of protection?
   c. In case it fails, is back-up equipment available, and can it be repaired in a timely fashion?

Procedure changes:

1. Why is the change needed?
2. What doses or dose rates apply to the individuals affected by the change?
3. For each step in the procedure, what things are likely to go wrong either by equipment failure or human error.
4. What are the likely consequences of problems noted in question 3?
5. What steps can be taken to mitigate the consequences noted in question 4?

APPENDIX W

Considerations in Making Progam Changes
(See §35.36)

The regulations allow the licensee to make changes in radiation safety procedures, equipment that is used to meet regulatory requirements, and rooms where byproduct material is received, stored, or used. In an institution the changes must be approved by the Radiation Safety Officer, the Radiation Safety Committee, and the management representative (see §35.32). In non-institution licensees, changes must be approved by the Radiation Safety Officer and management (see §35.31).

When making changes it is the licensee's responsibility to ensure that the result will be in accord with the regulations and license conditions. Any change must be reviewed for radiation safety considerations before it is approved. Licensees should consider the following questions before making changes. Not all the questions apply to all changes. There may be other questions the licensee should consider before making changes.

Be sure proposed changes are fully explained and do not include abbreviations or undefined words. Spell out measurement units such as millicurie and microcurie; only use the abbreviations in calculations or log sheets. Identify, by name or office, who is responsible for doing each task. Do not simply assume the task will be done.

Room changes:

1. Why is the change needed?
2. Can the room be secured in case of spills?
3. Can the room surfaces be cleaned?
4. Is the room adequately ventilated?
5. Does the room provide radiation shielding?
6. What are the anticipated doses each week in the room and in surrounding areas?
7. What are surrounding areas used for? What might they be used for in the future.

Equipment changes:

1. Why is the change needed?
2. Was the equipment designed for the intended purpose?
3. For detection and measuring equipment:
   a. What is the lowest level of detection for the equipment?
   b. What is the level of detection required?
   c. Will the instrument be interfered with by ambient radiations, light, temperature, humidity, or chemicals in the area?
   d. In case it fails, is back-up equipment available, and can it be repaired in a timely fashion?