AA73-1
PDR
M. 13

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

AUG 26 1983

MEMORANDUM FOR: Those on Attached List

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

SUBJECT: REVISION OF 10 CFR PART 35

The purpose of this memorandum is to bring you up-to-date on the status of the revision of 10 CFR Part 35, to get your comments on the current plan to revise Part 35, and to re-convene the Task Force.

After receiving office concurrences, the Task Force presented a revision of 10 CFR Part 35 to the Commission on April 19, 1983. The proposed revision of the regulations contained those requirements that the drafting committee believed were necessary and sufficient to ensure the existence of an appropriate radiation safety program at all human use licensee facilities. The preamble described a proposed licensing system in which an applicant would assure the NRC that authorized users had met the training and experience requirements in the regulations and that procedures had been developed and implemented to ensure compliance with prescriptive requirements in the regulations.

Two groups dissented. The Agreement States believe it is necessary to review an applicant's procedures and the training and experience of the applicant's authorized users before issuing a license to ensure that the procedures are adequate to ensure safety. Two NRC staff members also expressed that opinion.

On June 23, 1983 the Commission directed the staff to re-draft the package to provide for the pre-licensing review of both physicians' qualifications and applicants' operating procedures.

The staff now proposes to continue review of the training and experience of proposed authorized users and the radiation safety officer as is currently required.

The proposal will also be revised to require that each applicant submit a description of a radiation safety plan containing those procedural elements needed to meet the requirements of the regulations. Before issuing a license, staff will review the plan. The licensing guide will describe the ~~minimum~~ acceptable plan to meet the requirements of the regulations. The

licensee will be committed to the plan description that is submitted as part of the application, and will have to incorporate the commitments made in the plan description into detailed operating procedures. These will also include site-specific information and other steps that the licensee believes are essential for the safe use of byproduct material in his program. The licensee will not be able to modify the plan without obtaining a license amendment, but could modify the operating procedures used to implement the plan as long as the modifications do not affect the procedures described in the plan to meet the requirements of the rules.

The medical licensing guide (Regulatory Guide 10.8), in addition to describing the minimum acceptable plan, will contain model procedures and a model application. It will be distributed for concurrence along with the Commission paper.

A chart describing the proposed implementation of the revision is attached.

If you have questions or comments on the plan described above, please contact me so that we may discuss them.

Please appoint a member of your staff to the Task Force. The person you designate will serve as a point of contact with the task force members revising Part 35 and should be prepared to review and comment on the package during the drafting stage. In order that we comply with the Commission's decision at the earliest possible time, please notify me of your selection by September 9, 1983.

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

Enclosures:
1. Proposed Implementation of
   10 CFR Part 35
2. The Rule
3. Radiological Safety Plan
4. Area Survey Procedures
5. Estimated Completion Schedule
   for 10 CFR Part 35

cc: Robert B. Minogue
John G. Davis
Thomas Rehm

List of Addresses

Dr. Forrest J. Remick, OPE
Guy H. Cunningham, ELD
Richard C. DeYoung, IE
G. Wayne Kerr, SP
Patricia G. Norry, ADM
Thomas E. Murley, Region I
James P. O'Reilly, Region II
James G. Keppler, Region III
John T. Collins, Region IV
John B. Martin, Region V

Enclosure 1

Proposed Implementation of 10 CFR Part 35

Rule	Radiological Safety Plan	Radiation Safety Program
Regulation 10 CFR Part 35	Regulatory Guide Regulatory Guide 10.8	Operating Procedures
Requirements determined by the NRC as essential for safety. Must be met unless given a specific exemption.	The Guide provides a detailed example of those commitments the licensing staff would expect on the application (the plan). Applicants could submit their own plan for staff review. The staff will determine whether the regulatory requirements were met. Additional commitments may be required from some applicants to cover special cases. Changes in the plan require a license amendment.	Step-by-step routines for carrying out the radiological safety plan. These will be supplemented with specific personnel assignments, location data, good practices and other such non-safety administrative routines as needed to accomplish the plan. Operating procedure changes which do not alter the commitments made in the plan may be made by licensee without preapproval by NRC.

THE RULE

An example from the proposed 10 CFR Part 35 requirements for conducting area surveys.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

a. The licensee shall survey with a low range survey meter at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. The licensee shall survey with a low range survey meter at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

c. The licensee shall survey for removable contamination once each week all area where radiopharmaceuticals are routinely prepared for use, administered, or stored.

d. The licensee shall keep a record of the surveys for one year. The record must include the date of the survey, a plan of each area that was surveyed, the measured exposure rate at several points in each area expressed in millirem per hour or disintegrations per minute, the model number of the instrument used to make the survey and/or to analyze the samples, and the initials of the individual who performed the survey.

RADIOLOGICAL SAFETY PLAN

This is an example of an acceptable Radiological Safety Plan for area surveys as it will appear in the new Medical Licensing Guide, Regulatory Guide 10.8. An applicant must submit this plan or one of his own for NRC review. This plan is also guidance for the technical reviewer who must determine adequacy of an applicant Radiological Safety Plan.

Item 17: Area Survey Plan

There is no need to submit your area survey procedures with the application. Simply confirm that you have established and agree to follow written procedures for performing routine radiation surveys and contamination monitoring and that these written procedures include as requirements the plan specified in a. through g. below.

Reference: 10 CFR 20.1(c)
10 CFR 20.201
10 CFR 35.70

Licensing Plan: The applicant has established and agrees to implement written procedures for performing routine radiation surveys and contamination monitoring. As a minimum, these procedures shall require:

a. That all areas used for elution, preparation, assay, or dispensing of radioactive material be surveyed daily.

b. That all other areas where radioactive materials are used or stored be surveyed weekly.

c. That higher than normal readings for any area be investigated and corrected immediately.

d. That these surveys be performed with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

e. That a series of wipe tests be performed at least weekly in order to detect surface contamination.

f. That the method for analyzing the wipe tests be sufficiently sensitive to detect 220 dpm per 100 cm^2 for the contaminant involved.

g. That areas be covered, cleaned, or identified to employees if the contamination level exceeds 220 dpm per 100 cm^2.

h. That areas be cleaned or else posted and restricted from use if the contamination level exceeds 2,200 dpm per 100 cm^2.

i. That records of the results of all surveys and wipe tests be maintained for NRC inspection for a period of one year.

Further Guidance: The area survey procedures in Appendix I fulfill the plan established above.

AREA SURVEY PROCEDURES

This is an example of a step-by-step routine for carrying out the radiological safety plan contained in Regulatory Guide 10.8. A licensee may adopt this one, or develop his own, as long as the procedure he implements meets the commitments made in his license application. This procedure need not be submitted to NRC for prelicensing approval.

1. Area surveys will be performed by ____(insert the name of your Radiation Safety Officer or their designee).[1]

2. Survey Methods (Two types of measurements are necessary to conduct area surveys.)

   a. Monitor with a calibrated survey meter.

      (i) The survey meter used to conduct area monitoring is ____(insert the make/model number or other identification of the survey instrument you will use to conduct your surveys. Remember, the instrument should be sensitive enough to detect 0.1 mR/hr radiation levels).

      (ii) The procedure used to conduct area monitoring is ____(attach specific monitoring procedure or write your procedure here).

   b. Wipe test for removable contamination.

      (i) The instrument used to evaluate wipe test samples is ____(specify well counter or low level survey instrument used to count samples. Instrument used should be capable of detecting 220 dpm per 100 cm^2 for technetium-99m).

      (ii) Wipe tests will be performed according to the following procedures ____(attach specific wipe test procedure or write your procedure here).

3. Frequency of Surveys

   a. Survey elution, preparation, and injection areas[2] daily with the survey meter designated above.

---

[1] If more than one person will be performing the area surveys, specify each individual's name and/or survey responsibility (e.g., daily, weekly, monthly).

b. Survey waste storage areas, use areas, and adjacent unrestricted areas[2] weekly by survey meter and wipe test procedure designated above.

c. Survey area where less than 200 μCi quantities of radioactive material[2] are used monthly by survey meter and wipe test procedure designated above.

4. Action to be Taken

a. If wipe test is below action level in Figure 1 record results (see item 5 below).

b. If wipe test indicates contamination, the following actions will be taken:

1. Notify ____(insert the name of your Radiation Safety Officer)____ at ____(insert telephone number).____

2. Record initial results (see item 5 below).

3. Decontaminate area or restrict area from use ____(attach decontamination guidelines or write your procedure for decontamination or restricting areas from use).____

4. Record results of additional wipe tests and any comments concerning the decontamination action (see item 5 below)

5. Recordkeeping Requirements

A record of all surveys will be kept for one year. The record will include the following items:

a. Date

b. Name of individual conducting survey

c. Area surveyed

d. Base line exposure rates, keyed to facility diagram (attach drawing of routinely surveyed areas)

e. Surveyed levels, keyed to facility diagram

f. Corrective action taken (if required)

g. Surveyed levels after corrective action

h. Remarks

---

[2]Attach a drawing indicating the points to be surveyed within the laboratory area. This key to area surveys is for your records and should not be submitted.

FIGURE 1

Action Levels

The following action levels will be used to determine if removable contamination exists in the laboratory (from Table 2, Regulatory Guide 8.23, Radiation Safety at Medical Institutions).

Type of Surface		Beta or Gamma Ray Emitters ($\mu Ci/cm^2$)	(dpm/100 cm^2)
1.	Unrestricted areas	10^{-6}	200
2.	Restricted areas	10^{-5}	2,200
3.	Personal clothing worn outside restricted areas	10^{-6}	220
4.	Protective clothing worn only in areas	10^{-5}	2,220
5.	Skin	10^{-6}	220

Averaging over an area of up to 300 cm^2 is acceptable for floors, walls, benchtops, etc. Averaging over a 300 cm^2 area is also acceptable for skin and hands.

ESTIMATED COMPLETION SCHEDULE FOR IMPLEMENTING COMMISSION DECISIONS ON SECY-83-62 (10 CFR PART 35)

Estimated Completion Date	Task	
August 12, 1983	Develop proposed revision of procedure to implement new Part 35 IAW Commission directive	(Completed)
September 2, 1983	Contact Offices listed below for pre-coordination of proposed revisions. Follow-up with face to face meeting as necessary. Reactivate task force. OPE OGC ELD IE Region I thru V SP ADM RES	(Underway)
October 8, 1983	Time / Staff Rewrite rule — 2 wks — 2 Rewrite guide — 3 wks — 3 Rewrite paper — 2 wks — 1 This includes the time for retyping but does not include the secretarial help. *Some compression of time may be possible if three professional staff members are assigned full time.	(Underway)
November 17, 1983	Circulate the guide and paper (rule) as a package for reconcurrence (Offices listed above). Circulate concurrently to Agreement States for comments. This phase has been allotted 30 days, but past experience says replies will take up to 60 days or more.	
December 16, 1983	Resolution of comments (conflicts) and rewrites as necessary.	
January 16, 1984	Forward to Director, NMSS, for transmittal to EDO..	