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

NOV 21 1983

MEMORANDUM FOR: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

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

SUBJECT: REVISION OF PART 35

In response to the Commission's instructions, the staff is preparing a revision of Part 35 proposed rulemaking. The following three milestones have been established:

Distribute the regulation, the preamble, and Regulatory Guide 10.8 for review	*February 28, 1984
Comments due	April 30, 1984
Forward the complete package to Director/NMSS for transmittal to EDO	June 30, 1984

*Addenda such as environmental impact, regulatory analysis, and paperwork reduction will be prepared while this material is out for comment.

The Commission instruction and the staff plan for responding to the Commission's instructions are attached for your review.

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

Enclosures:
1. Draft plan for Revising Part 35
2. SECY-83-62 (10 CFR Part 35)

DRAFT PLAN FOR REVISING PART 35

The Commissioners unanimously directed the staff to revise SECY-83-62 in accordance with four directives. The directives and the planned responses follow.

1. "The Commission approves the consolidation of the essential safety elements . . . into a Part 35 rule." Except as noted below, the regulation the staff will only make editorial and other non-substantive changes such as adding recently approved drugs and a recently approved sealed source device, adding definitions for podiatrists and dentists, and updating the regionalization information.

2. "The Commission has decided to continue the pre-licensing review of physicians' qualifications . . ." The proposed regulations will require specific training and experience for the use of material in any particular use group. The regulation and licensing method will be revised to require each proposed authorized user (AU) physician, and Radiation Safety Officer (RSO) and Qualified Teletherapy Calibration Expert (QTCE), to submit summaries of their training and experience on a form similar to 313M Supplements A and B. The staff will review those individuals' training and experience before authorizing them to work as an AU, RSO, or QTCE. Use, or supervision of use, of material without the specified training and experience would be a violation of the regulations which would subject the user to an enforcement action.

3. "The Commission has decided to continue the pre-licensing review of applicants' operating procedures . . . " The staff will continue to review procedures submitted in support of an application in order to determine whether they are sufficient to meet the requirements of the regulations, and will issue a deficiency letter if procedures are incomplete or inadequate. (Consistent with current practice, applicants will be allowed to simply certify that they will follow the model procedure supplied in Regulatory Guide 10.8, or they will be allowed to submit their own alternative procedures for review.) A licensee will be cited for failure to have the written procedures required by the regulations, failure to follow those procedures, failure to have the records required by the regulations, failure to follow technically valid procedures, or failure to meet the requirements of the regulations or license conditions (which would list, for example, authorized users, locations of use, authorized methods of use, authorized byproduct material and inventory limits, and other site-specific limitations). However, to allow each licensee to make prompt use of new safety methods and to adjust procedures to meet new needs caused by changes in need for patient care services or patient load, licensee's will be free to modify their procedures without NRC review or approval. At an institution, the Radiation Safety Committee must review and approve a modified procedure before it may be implemented. At non-institution facilities, the RSO and management must review and approve modifications.

4. "The staff should clarify how it will implement the proposed requirements regarding license amendments . . ." The staff foresees four types of amendments.

   a. New users. The staff will review the training and experience of each proposed AU, RSO, and QTCE as described in item 2. above.

   b. New type of use. Amendment requests to add a type of use will be handled as a new application. The AU's training and experience will be reviewed for adequacy with respect to the new type of use, and procedures which must be submitted in support of the request will be reviewed for completeness and adequacy with respect to the new type of use before the amendment is issued.

   c. New method of use. Two types of amendment may be needed:

      i. If a new radioactive material (RAM) becomes available, and the procedures needed for its safe use are identical to the procedures already established for an already established and authorized use (for example, a new imaging agent administered by injection), the new RAM will be added by rulemaking to the list of materials in the appropriate use group specified in the regulations. The NRC will mail to licensees who are authorized to use material in that use group a letter that says they may begin using the new RAM on the effective date of the final rule that adds the new RAM. No individual licensing action will be taken.

      ii. If a new RAM becomes available but its safe use depends on following a new procedure that current licensees have not submitted and NRC has not reviewed, two actions will be taken.

         1. The new RAM will be added by rulemaking to the appropriate use group in the regulations but authorization to use it will be limited to persons licensed after it was added to the use group. These persons, when applying for amendment, would submit the new RAM procedure for review.

         2. NRC will mail to current licensees a letter that says they may apply for authority to use the new RAM. With that letter, NRC will supply a model procedure for the new RAM. (This would become an addition to Regulatory Guide 10.8.) Those licensees who want to use the new RAM will have to submit a request for amendment that will be reviewed for completeness and adequacy. This review will include review of procedures for the new RAM.

d. New location of use. A request to leave one location of use and begin working in a new location will have to be supported by a complete new application package. A request to add a satellite location will only have to identify the new location.

In summary, the regulatory text proposed earlier will not be substantively modified (except for subsequent rule changes that have been made to accomodate new RAM's and uses). The staff will review user training and experience and issue deficiency letters if necessary. The staff will review site-specific procedures for completeness and adequacy and issue deficiency letters if necessary but will not require licensees to follow the specific procedures that were submitted in support of the application. Amendments will generally be handled just as new applications are handled.

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DRAFT MILESTONES FOR REVISING PART 35

GOAL: Publish in the Federal Register for comments: A proposed revision of Part 35, a proposed revision of Regulatory Guide 10.8, and a proposed change in the method of regulating byproduct material for human use.

1. Prepare the plan for revising SECY-83-62 (see attachment).

   ✓a. Mr. Cunningham approves the plan.

   ✓b. NMSS staff identifies every office or group that we should coordinate with so that no one is denied the opportunity for input.

   ✓c. Mr. Cunningham decides how to deal with outside groups (informal phone calls, meetings in Washington or at their headquarters; groups to be considered are Regions, ACMUI, ABR, AAPM, ABNM, Agreement States individually or through the CRCPD, strong dissenters from the preceding proposal such as Blazek, Vaden, or Whatley).

   ✓d. Mr. Davis decides whether the package should be signed by Mr. Davis or Mr. Davis and Mr. Minogue.

2. Give a dry run presentation to critical offices (NMSS, IE, Regions) to get their input on the plan and incorporate it.
Skipped - plan was mailed, no comments need.

3. Pepare a memorandum for ~~and meet with~~ every cognizant individual (cog).

a. Clarify that cog responsiblity is to serve as a liaison between the drafting committee and their office decisionmaker (cog who must identify to us) so that all staff and management comments will be resolved before the package is mailed out for office review.

b. Describe the revision plan so that cogs can relay the plan to their managers and report back on any philosophical differences.

4. Update Rule Text

a. Lixiscope
b. Podiatrists and Dentists
c. Regionalization
d. Sulfur Colloid
e. How to handle current licensees until renewal
f. Review inspection citations to see if the regs (current Parts 19, 20, and 30 and proposed 35) are complete.
g. Review deficiency letters to see if Part 35 is complete and understandable. Skipped, but I have reviewed citations, and added a citations enclosure to CP.

5. Revise preamble

✓ a. Update Management Information System description. - deleted

✓ b. Get format of final application form.

✓ c. Describe the new licensing plan.

✓ i. Review training and experience.

✓ ii. Review procedures but no "tie-downs" as a license condition.

✓ iii. Amendments procedure.

6. Revise Regulatory Guide 10.8.

✓ a. Licensing plan.

✓ b. Instructions for application.

✓ c. Model procedures.

✓ d. Training and experience.

✓ 7. Send out preamble, rule, and 10.8 for division review.
Do not begin Regulatory Analysis, OMB paperwork statement, or Environmental Analysis until everyone concurs on regulation and model procedures. reg analysis & environmental analysis were included in the pkg. REC okd for distribution 2 10 84 @ a briefing mtg

8. Revise Regulatory Analysis.

✓ a. Describe each regulatory method that we considered.

✓ b. For each method considered, including status quo, describe:

i. Whether it meets our mandate from Congress

ii. Cost to small, medium, and large composite licensees including equipment, paperwork and time.

✓ 9. Prepare OMB paperwork statement.

✓ 10. Prepare Environmental Analysis.

✓ 11. Mark-up Commission Paper to reflect irreconcilable differences and send entire package (paper, Federal Register Notice, 10.8, supporting analyses) out for division review.

✓ no - Vandy reiterated - "take to Davis for direction."
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✓ 12. Revise package to reflect comments.

✓ 13. Circulate for office concurrence.

14. Hold private briefings with Mr. Minogue, Mr. Davis, OPE, SP and Mr. Dircks.

15. Send to Mr. Minogue and Mr. Davis.

16. Send to Mr. Dircks.

17. Send to Commission.

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