



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

MAY 9 1984

MEMORANDUM FOR: William J. Dircks
Executive Director for Operations

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

SUBJECT: CONTROL OF NRC RULEMAKING - EDO INITIAL REVIEW

In response to your memorandum of February 13, 1984, and in accordance with instructions provided in subsequent memoranda from the Office of Nuclear Regulatory Research (RES), the Office of Nuclear Material Safety and Safeguards has reviewed the on-going rulemaking activities listed below. On the basis of our review, we recommend the approval of continued activity on these rules.

REVIEWED BY NMSS FOR EDO INITIAL REVIEW



- A. "Human Uses of Byproduct Material - revisions to 10 CFR Part 35"
- B. "Radon and Technetium Estimates for Table S-3"
- C. "Reporting Requirements for Safeguards Events"
- D. "Physical Protection Requirements for Independent Spent Fuel Storage Installations"
- E. "Material Control and Accounting Requirements for Low Enriched Uranium Facilities"
- F. "Clarification of General Physical Protection Requirements"

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

Enclosures:
Review Packages for the above
listed rulemaking activities

cc w/encl: RES
RM

DIVISION OF FUEL CYCLE AND MATERIAL SAFETY

"Human Uses of Byproduct Material - 10 CFR Part 35"

Division Contact: Norman McElroy
x74052

TITLE:

Human Uses of Byproduct Material

CFR CITATION:

10 CFR 35

ABSTRACT:

The present regulation is incomplete and hard to interpret; it needs a thorough revision and reorganization. The proposed rule would also revise certain requirements and procedures that apply to the use of byproduct material for patient care. For example, NRC's approximately 2500 specific medical licenses now contain a license condition requiring measurement of the activity of radiopharmaceutical dosages before administering them to patients. The proposed rule would replace this condition in all specific medical licenses with a regulation requiring measurement of activity in the radiopharmaceutical and recording of the patient dosage.

Since the current regulation needs extensive reorganization and rewriting, the NRC did not consider any alternative other than a complete revision. The proposed rule will maintain the current level of radiation protection for medical workers, patients, and the public. Based on a cost analysis of the regulation as it would apply to representative medical licensees, the NRC does not expect any significant savings or additional expenses for affected persons. This cost analysis will be made available to the public.

TIMETABLE:

NPRM 08/31/84

LEGAL AUTHORITY:

42 USC 2111; 42 USC 2201; 42 USC 2232; 42 USC 2233

EFFECTS ON SMALL BUSINESS AND OTHER ENTITIES: Yes

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OFFICE FINDINGS ON PROPOSED RULEMAKING

10 CFR PART 35

1. Issue

The current regulation covering "Medical Licenses for Human Uses of Byproduct Material" is incomplete and hard to read. The purpose of the proposed rulemaking is to codify all medical license requirements in the regulations. The principle issue is the need for regulatory control by license condition in addition to control by regulation.

2. Need

The need for the proposed rulemaking is based on the fact that the current regulatory system is not clear to licensees and is time-consuming for both licensees and NRC licensing and inspection staff. The urgency is based on the fact that the Commissioners are expecting a submission.

3. Alternatives

Since the current regulation is incomplete and hard to read, the staff did not consider any alternative other than a complete revision.

4. Proposed Action

There is almost unanimous consensus, and therefore no "issue," that the regulation needs to be revised. Concerning the licensing issue the staff is proposing that any regulatory controls in the license be licensee specific and that all generic controls be in the regulation.

5. Effects of Proposed Action

The benefit to all will be an easy-to-read, complete standard. Since the rulemaking is essentially codifying current practice, the staff does not foresee any change in worker or public exposure, or any change in licensee costs. There might be a small savings of NRC licensing and inspection time.

6. Resources and Schedule

NRC resources: 1.5 staff years

Planned schedule of rulemaking steps:

Distribute SECY paper and Regulatory Guide 10.8 for NRC and Agreement State comment	2/28/84
Comment period closes	4/30/84
Distribute paper and Regulatory Guide for Concurrence	6/15/84
Concurrence/non-concurrence due	6/30/84
Forward paper and Regulatory Guide to EDO	7/15/84

ENCLOSURE B

Draft Staff Recommendations

DRAFT STAFF RECOMMENDATIONS

Based on the staff review, DRPES finds that the proposed rulemaking should continue on the schedule adopted by NMSS.

One item was noted that should be brought to NMSS' attention. Section 35.400, Use of Sources for Brachytherapy, of the proposed rule lists iridium-192 as wire in (d) and tantalum-182 as wire in (g). The iridium-192 wire is currently the subject of a petition for rulemaking. We are not aware of any action regarding addition of tantalum-182 to the list. Therefore, it may be necessary to delete these before the NPRM is published.

ENCLOSURE C

Results of RES Staff Review

RESULTS OF RES STAFF REVIEW

I. Introduction

The subject rulemaking is a proposed revision of 10 CFR 35, "Human Use of Byproduct Material." NMSS prepared an earlier proposal which was described in SECY-83-62 and presented to the Commission. The present version reflects guidance from the Commission to the staff on that earlier proposal, as well as additional comments from headquarters and regional staff and from the Agreement States. Comments by the Division of Radiation Programs and Earth Sciences on the latest version were provided in a May 10, 1984 memorandum. Norman McElroy, the NMSS contact, has discussed our comments in detail and resolved them to our satisfaction.

II. Quality Control Review

A check of the package submitted by NMSS against the documentation requirements specified in II.C.1. of the "Procedures for Conducting RES Independent Rule of Rulemakings," revealed that several documents were missing. Norman McElroy provided the Periodic and Systematic Review (Enclosure 3), the Regulatory Analysis (Enclosure 4), the Environmental Impact Analysis (Enclosure 7), a summary table of comments on content of SECY-83-62 regulation (Enclosure 8), and a summary table of human use licensee citations issued in 1982 (Enclosure 9); copies are attached for the RES Independent Review Board. At this stage of development it is not necessary to examine the draft public announcement or the draft congressional letter.

The Regulatory Analysis was reviewed using the criteria outlined in "Contents and Format for the Regulatory Analysis" of NUREG/BR-0058. The regulatory analysis was very well-written and addressed all six requirements in Section III.B. Especially noteworthy was the table developed to estimate the burden on six hypothetical licensees of complying with each individual section of the proposed regulation. This table with accompanying discussion contains the basic information collection burden estimates required by the Paperwork Reduction Act and the economic impacts on small entities required by the Regulatory Flexibility Act. A complete OMB Statement has been prepared in accordance with draft NRC appendix 0230; it was spot-checked and appeared comprehensive. The Cost Analysis Group (CAG) reviewed the cost analysis section of the Regulatory Analysis and provided comments in their April 6, 1984 memorandum; all comments have been resolved.

The Environmental Impact Analysis (Environmental Assessment - Finding of No Significant Impact) was reviewed using 10 CFR 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection." The specific impacts discussed were exposure of the public resulting from release of patients containing radiopharmaceuticals or permanent implants, mobile service transportation, storage of volatiles and gases, and exposure of the ecosystem. The discussion of why none of these will result in any significant impact on the environment was technically sound and well-presented.

The RES Independent Review procedures state that CRGR guidelines apply only to requirements imposed on one or more classes of power reactors. NMSS rulemaking concerning medical licensees is therefore exempt from CRGR review.

III. Evaluation of Rulemaking Proposal

a) Issue to be addressed.

NMSS is proposing a complete revision of the regulations for licensing the intentional irradiation of humans by medical practitioners. These regulations are codified in 10 CFR 35, "Human Use of Byproduct Materials."

b) Necessity and urgency for addressing the issue.

At the present time the requirements that apply to human use are dispersed throughout the existing Part 35, standard license conditions, branch policy positions, and regulatory guides. The proposed revision will codify all the requirements in one place, thus reducing confusion on the part of the licensee and promoting uniformity among the Regions in licensing and inspection. Also by codifying the requirements, it will not be necessary to tie the licensee to all statements made in his application including those not related to health and safety. This will allow greater flexibility and reduce the number of requests for amendments.

The urgency for revising Part 35 results from the fact that an earlier version was presented to the Commission in SECY-83-62. The Commission directed the staff to revise it and resubmit it for their review.

c) Alternative to rulemaking.

There is really only one alternative, and that is to do nothing. The present system, while cumbersome, is workable.

d) How the issue will be addressed through rulemaking.

As noted in (b) above, the revision will codify all the requirements for medical use in the regulation itself.

e) How the public, industry, and NRC will be affected.

Because no additional requirements will be imposed, no economic burden will be imposed on the licensee (or be passed on to the public as increased costs for medical treatment). On the contrary, the resulting flexibility will reduce licensee costs and NRC staff time for amendments.

Regarding protection of the public and worker health and safety there will be no change since the requirements will be the same as those presently imposed, but dispersed throughout various sources.

f) NRC resources and scheduling.

Most of the resources have already been expended in preparing the first version for the Commission, in incorporating the Commission's directives,

and in responding to comments from other NRC offices and licensees. NMSS hopes to issue a Notice of Proposed Rulemaking by the end of August 1984. Analysis of public comments submitted during the comment period and preparation of the final rule will require substantial staff effort.

IV. Additional Discussion Item-Mobile Nuclear Medical Services
Ref: Congressional Letter from MASI

Background: Diagnostic radiopharmaceuticals are reconstituted in multi-dose vials from which the user can draw a single dosage. Current licensing policy allows mobile nuclear medicine services to transport both unit dosages and multi-dose vials for use at client facilities.

Events: In an earlier draft the drafting committee proposed to restrict mobile services to transport of unit dosages because it was assumed that they were inherently safer in case of an accident. During the NRC and Agreement State comment period that ended March 30, several individuals pointed out that both were safe, and there had been no problem with current policy. Also, one licensee who had obtained the draft called an NRC license reviewer and said: (1) if a client has an extra patient, there would be no pharmaceutical available; and (2) if the mobile service arrived early or late, the unit dosage may be outside the prescribed dosage range due to radioactive decay.

The markup draft was changed, in response to these comments, to allow mobile services to transport multi-dose vials.