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JUN 22 1984

MEMORANDUM FOR: James C. Malaro, Chief
Regulatory Analysis and Materials
Risk Branch
Division of Risk Analysis and Operations, RES

FROM: Karl R. Goller, Director
Division of Radiation Programs
and Earth Sciences, RES

SUBJECT: RES INDEPENDENT REVIEW OF ONGOING RULEMAKING

As requested by your June 8, 1984 memorandum, the NMSS package, "Human Uses of Byproduct Material" Revision to 10 CFR 35, was assigned to the Health Effects Branch for review.

The draft staff recommendation is that NRC should proceed with the specific ongoing rulemaking. One item, involving addition of materials not yet approved for licensing, is suggested for further consideration.

Enclosed is our draft independent review package. The RES task leader is Judith D. Foulke, x74563.

Karl R. Goller, Director
Division of Radiation Programs
and Earth Sciences, RES

Enclosures:
A. Rulemaking review package
received from NMSS
B. Draft staff recommendations
C. Results of RES staff review

cc: R. Cunningham, NMSS

(See attached list for distribution)

OFC:	HEB	HEB	DRPES:DD	DRPES:D			
NAME:	JFoulke:dm	WAMills	PComella	KGoller			
DATE:	6/22/84	6/22/84	6/ /84	6/22/84			

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: Disgnostic 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 restict 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.