

MEDICAL/DENNIS

*recd 3/15/84*  
3-13-84

MEMORANDUM FOR: Richard E. Cunningham

FROM: Clyde Jupiter

SUBJECT: COMMENTS ON DRAFT 10 CFR PART 35 AND DRAFT REVISION OF  
REGULATORY GUIDE 10.8, GUIDE FOR THE PREPARATION OF  
APPLICATIONS FOR MEDICAL PROGRAMS

In response to your request of February 3, 1984, the draft Part 35 and draft Reg. Guide 10.8 have been reviewed. These documents have been greatly improved by the recent work on them and they appear generally to be in good form. However, there are at least two substantive issues to be addressed. They are related to: (1) conflicting statements concerning the use of a general license; and (2) the question of how one assures that physicians' training is adequate when it involves private tutoring. These and other less substantive issues are discussed in the attachment.

I hope you will find these comments useful.

Attachment:

As Stated

cc: J. E. Zerbe  
D. Rathbun  
H. McElroy

*p. 61 in soft  
✓ clarify depth of review of  
training listing (313A6B)*

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PDR PR  
35 50FR30616 PDR

ATTACHMENT

COMMENTS ON DRAFT 10 CFR PART 35 AND DRAFT  
REVISION OF REG. GUIDE 10.8

1. p. 5 of "Review of Part 35" document (Notes of General Interest and Clarification for Reviewers): *resolved over phone*

*in 20*

Item 3 states that the patient excreta exemption that is in the current Part 20 has not been included because it will require an extensive environmental impact analysis, and that it will be handled at a later date. However, the exemption is noted in the draft revision of Reg. Guide 10.8 (item 1, p. 55). The language in the proposed draft Reg. Guide 10.8 should be consistent with the proposed draft Part 35. Is an EIA required if the issue of patient excreta exemption has already been resolved in Part 20?

2. Enclosure 1, p. 10, top line:

*can't find*

Insert the words "after completing the review" following the word "application". *resolved over phone*

3. Enclosure 1, p. 23, 2nd § *resolved over phone*

*fixed*  
*different General Lic.*

This section appears to state that new general licenses will no longer be granted, but current general licenses will be grandfathered. If this is indeed the case, it would be useful to state it more clearly. Note however, the conflict with the text on p. 4 §1.4.1 of Reg. Guide 10.8, which states that "...an applicant may request a general license... on Form NRC-313 when applying for a human use license." That statement in the Reg. Guide also conflicts with the statement beginning on the last line of p. 24, Enclosure 1, "The commission uses the specific licensing

process to limit the use of byproduct material to persons who have the equipment, ...needed to ensure its safe use."

4. Enclosure 1, p. 61, middle § *see note p 61*

*noted in Encl. Comment*

The statement is made that training (of physicians) may be received as private tutored instruction, or elsewhere. There is no assurance that the instructor is qualified or that the course is adequate. The classroom and laboratory training requirements given on pp. 134, 137, 139, 141, 142, 143 and 144 do not provide assurances of training adequacy. As a possible fix, the regulation might be revised to indicate that physicians must pass a test administered by NRC instead of completing those training courses; or perhaps the training could be endorsed or verified by a licensed physician. The latter option would still not provide complete assurance of adequacy of training, but would raise the level of confidence that the training was adequate by involving someone other than the applicant in the training verification.

5. Enclosure 1, p. 115, item (f): *discussed. "minor point"*

*not discussed in Encl.*

It may be noted that a contamination level of 200 d.p.s./100 cm<sup>2</sup>-sec. does not provide information regarding the type of radiation or its energy, and could represent a widely-varying dose hazard.

6. Enclosure 1, p. 136, last line of item (b): *minor, skip it*

Insert the word "licensed" before the word "nuclear".

7. Enclosure 1, p. 137, last line of item (b):

no Add the words "...both supervised by a licensed practitioner" at the end of the sentence. *"ignore this then"*

8. Encl. 1, pp. 140, 142, 143, and 144, first line of item (b):

no Add the words "from a licensed practitioner" after the word "instruction". *"withdrawn"*

Proposed Revision 2 to Reg. Guide 10.8

1. p. 3, line 15:

done Add the words "under his direction" after the word "individuals". *done*

2. p. 4, Section 1.4.1.

no The use of general licenses conflicts with pp. 5 and 23 of Part 35. *comment withdrawn*

3. p. 10, Item 7.b:

no Provisions here for non-human use of byproduct materials are not consistent with the purpose of the Guide stated in Section 1.1.1., page 2. *comment withdrawn*

Additionally, minor corrections are offered in the mark-up of pps. 16, 20, 50, 51, 55, 63, 86, 93, 104, 105 and 133 of Enclosure 1.