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

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MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

FROM: William J. Olmstead
Director and Chief Counsel
Regulations Division
Office of the Executive Legal Director

SUBJECT: Proposed Revision of 10 CFR Part 35

We cannot concur, or nonconcur as yet, on the subject paper; it is not ready to be sent to the Commission. Aside from the extensive comments, concerns, questions, and editorial changes marked directly on the enclosed paper, our major comments are listed below in order of appearance and not in order of importance. Most of these comments are not new and have been provided to your staff on several occasions on previous drafts (see enclosed notes from Klucsik to Cook).

COMMISSION PAPER

1. Staff's Focus of Attention and Post-Evaluation Versus Pre-Evaluation. The paper stresses throughout that the reduced workload will allow the staff to focus its attention and resources on important safety issues and allow NMSS personnel to make on-site visits after issuing new licenses. (See page 2 of Commission Paper and pages 1 and 3 of Enclosure 3). Nowhere is there a discussion of what the staff has in mind and nowhere is there an explanation of the important change in practice from pre-evaluation to post-evaluation of licensees. Nor is there any explanation of how this will fit the evolving regionalization movement, and the roles the various regional and headquarters offices will play.

2. Compatibility. If the two standards listed on page 8 of the Commission Paper are used exclusively to judge whether the rule is a matter of compatibility, then the rule seems to meet both standards -- contrary to the assertion on that page -- and should be adopted by Agreement States. Are there some criteria or is there some past history which would cut against the plain meaning of the two standards?

3. Economic Impact. How can it be stated on page 10 of the Commission Paper that the rule will not have a significant impact on a substantial number of small entities when it is argued on page 9 of Enclosure 1 that the rule will have beneficial impact on these entities? We suggest that an appropriate analysis is indeed warranted.

STATEMENT OF CONSIDERATIONS

4. Scope of the Changes. The weakest part of the paper -- from a legal standpoint -- involves the section dealing with the substantive changes to Part 35. Not one of the major proposed changes to NRC's general administrative requirements (see pages 17 to 22 of Enclosure 1) is explained adequately.

(a) For example, the only basis given for the requirement on Mobile Service (pages 17 and 19) is a reference to a Material Licensing Branch Policy Outline. The explanations of other substantive requirements (such as those concerning syringe shields and vial shields (pages 18 and 19), or dosimetry equipment and the Radiation Safety Officer (page 20), provide even less information regarding their technical basis. Connecticut Light & Power Co. v. NRC, in the Court of Appeals for the District of Columbia Circuit (No. 81-1050, March 16, 1982), suggests that an agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule sufficient to allow meaningful public comment. The decision further suggests that mere reference to a branch technical position is an inadequate exposition of the technical basis for a rule. See, attached Note of April 21, 1982, to Cook from Klucsik.

(b) Other examples concern incorporation of previously-proposed rules into the present rulemaking. The statement on the Radiation Safety Committee Rule (page 17) is inadequate to accomplish incorporation of the rulemaking initiated on April 9, 1979 (44 FR 21,023). Without notice of such incorporation, the Radiation Safety Committee rulemaking must proceed independently of the Part 35 rulemaking, with separate resolution of comments and publication of a final Radiation Safety Committee Rule. There is no legal bar to parallel rulemakings, and we understand that this is what your office intends to do. However, this intention should be clearly explained. If, nevertheless, the Part 35 rulemaking is intended to incorporate and conclude earlier rulemakings still in progress, a clear statement of that intent is required. Otherwise, (1) the public will not have sufficient notice of the scope of the Part 35 rulemaking -- notice which is required by the Administrative Procedure Act -- and (2) NRC's duties with respect to earlier rulemakings (e.g., response to public comment) will persist notwithstanding the Part 35 rulemaking. For recommended language to accomplish incorporation of the earlier rulemaking, see Attachment B of attached Note of April 14, 1982 to Cook from Klucsik. Please note, by the way, that in the final rule all comments will have to be discussed, including the comments in the previous rulemakings.

(c) The statement on Measurement of Radiopharmaceutical Doses (Page 18) is inadequate for incorporation of the earlier rulemaking (46 FR 43840). See Attachment C of Note of April 14, 1982 to Cook from Klucsik for recommended language to accomplish incorporation.

(d) The statement on Exemption for Tc-99m Pentatate Sodium Aerosal (page 19) is inadequate for incorporation of the earlier rulemaking (47 FR 15798). For recommended language to accomplish incorporation, see Attachment D of Note of April 14, 1982 to Cook from Klucsik.

(e) The statement on Dosimetry Equipment (page 20) provides some, but not enough, indication that incorporation of an ongoing rulemaking is intended. It is inadequate in its presentation of a technical basis, or indeed any background. It fails to even reference a docket number to identify the petition of the American Association of Physicists in Medicine.

(f) Also, considering the vocal opposition of cardiologists to the revised Training and Experience Criteria for Nuclear Medicine Physicians (page 22) a more thorough discussion of the basis for the training and experience requirements is warranted. Mere reference to the recommending groups is unlikely to be found adequate by the courts or Congress, absent some discussion of the basis for the recommendation.

(g) Finally, the "Derivation Table" (on pages 24 to 29) makes clear that terms in the present regulation were revised, that entirely new text was added, and that material was extracted from license conditions, regulatory guides and licensing policy documents and inserted into the Part 35 revision. All the important, substantive, and major changes, additions, and deletions must be explained in the statement of considerations.

PROPOSED RULE

5. Section 35.17(f) (page 39) requires a licensee to apply for a license amendment before making any changes in the licensed program which could result in a reduction of safety. This is a critical provision. Nowhere is it explained, though, how -- i.e., using what criteria -- the licensee must make the requisite determination and how the staff will review and grant or deny the application. The same concern arises with respect to the Radiation Safety Committee's "review on the basis of safety" of authorized users and of the Radiation Safety Officer, as well as the proposed type of use of by-product material. (See § 35.31(b)(2) and (3), page 42.) What safety considerations should the Committee take into account? What will NRC do if the Committee uses other considerations? Matters like these should be explained in the statement of considerations, and key criteria should be included in the rule, or, at least, in the statement.

6. Section 35.34 (page 44) represents another type of concern, namely, the issue of choosing deadlines or dates without explaining why they were chosen. For example, why do we allow licensees to permit visiting physicians to use licensed material for only 60 days? Matters like this should be explained.

7. Section 35.38 (pages 46 and 47) revises and incorporates a provision on supervision from regulatory guide and attempts to solve several problems with the revised provision. However, the changes are not explained in the statement of considerations and raise new problems. One problem that is not solved concerns our allowing non-licensees and non-authorized users to possess and use byproduct material without an NRC license. This should be explained; in any case, these users should be exempted. On the other hand, if this section is intended to authorize possession or use of byproduct material by persons not licensed to engage in such possession or use, it is inadequate to do so. As written, it merely permits an authorized user to supervise others who must be authorized users or licensees by operation of § 35.2. Finally, this section appears to be unnecessary, since there is no legal bar to such supervision.

8. The two sections involving release of patients (§§ 35.75 and 35.404 -- pages 54 and 61 -- both confusingly using the same heading) raise an important constitutional issue. Requiring the licensee to confine a patient (possibly against his will) may be an unconstitutional deprivation of the patient's liberty. Whether this deprivation can be justified by a compelling state interest in protecting the public health and safety is uncertain. To decide this issue, we need to review whatever health and safety justification you can provide. As yet, we have seen none.

9. Paragraphs (a)(8) and (a)(15) of §§ 35.100 (page 56) and 35.200 (page 58), respectively, must contain appropriate incorporation by reference language when discussing FDA's rules.

10. The recordkeeping requirements of many of the sections seem unenforceably vague. See, for instance, §§ 35.304(b), 35.404, 35.405(b), 35.621(d), and 35.642(c). For example, requiring the licensee to "maintain records to show compliance" may be unenforceably vague. If the retention of the written radiation safety instruction is all that is intended, § 35.304(b) could read, "the licensee shall retain for the duration of the license a copy of the radiation safety instructions required by paragraph (a)." Note though that OMB frowns on such indefinite deadlines.

11. Training and Experience Requirements (pages 73 et seq.).

(a) The provision that certain persons are "prima facie determined to have met the training requirements" suggests the existence of other requirements not identified in the regulations which will conclusively determine compliance. Please note that any such additional standards are unenforceable for lack of notice. In any event, there should be an explanation of why and how the prima facie factors were chosen.

(b) Additionally, what is meant by the vague term "continuing involvement" which appears in §§ 35.900(c) (page 74) and 35.910(b)(6) (page 76)?

(c) Finally, the statement of considerations should explain the exemptions in §§ 35.911 and 35.921 (pages 76 and 78).

VALUE IMPACT

12. It is stated that one of the disadvantages of a general licensing scheme for the revised Part 35 is that such a scheme cannot assure public health and safety for the entire gamut of uses for byproduct material under Part 35. The so-called standard licensing scheme -- using a standardized specific license and post-licensing evaluations -- comes very close to the general licensing concept. The only difference is that specific licensing would involve a computerized application for a license while the general licensing scheme could involve some sort of reporting requirement. It should be made clear that both schemes can assure the public health and safety, and that specific licensing was chosen for other reasons, which should be explained.

13. The value-impact statement points out that there is evidence that a substantial number of license applicants employ professional consultants to write their procedures. (See page 8). If this is so, the paper should explain what guarantees NRC will have that licensees will be aware of, understand, and adhere to NRC's requirements.

14. It is stated that the proposed regulations would allow flexibility in the selection of cost-effective means of meeting regulatory requirements. (See page 8.) Nowhere is it explained why this would be so. In fact, rather than attempting to set broad performance standards, the rule goes into great detail on such matters as "on-off" switches and calibration measurements and spends 13 pages on training and experience requirements. We suggest that flexibility is not a strong argument.

15. The value-impact statement is unclear about costs and revenues comes up with some strange numbers. (See pages 10 to 13; see also page 9 of the Commission Paper). For example, it states that, based on 75 new applications per year, lost revenues for all applicants would be approximately $4,725,000 per year -- presumably, if the revised procedures are not implemented. It derives this figure from the following facts: (1) an average of 94 days is required by NRC to review and issue a new byproduct license; (2) this processing time could be reduced to 10 days; and (3) a typical new nuclear medicine department performs about 15 procedures per day at a "cost" of about $100 each. Before analyzing the approach, a quick review of the paper's calculations shows that they are wrong:

(a) 15 procedures per applicant per day x $100 = $1,500 per applicant per day.

(b) 94 days for NRC processing per applicant - 10 days processing = 84 days processing per applicant.

(c) $1,500 x 84 = $126,000 lost per applicant.

(d) $126,000 x 75 applicants = $9,450,000.

How was $4,500,000 derived? Under the revised system, using the previous calculations, applicants would still lose $1,125,000 as follows:

(a) $ 1,500 x 10 = $ 15,000.
(b) $15,000 x 75 = $1,125,000.

Obviously, the paper incorrectly equates $100 of costs--it does not specify whose: the licensee's, the patient's, or NRC's, or what--with $100 of lost revenues. The entire approach, aside from the calculation, is way off base.

The same problem can be found in the calculations on license amendments. We suggest that some better dollar measure, -- perhaps lost profits -- be found to equate the present and proposed systems.

16. Finally, four key, interrelated issues are not covered:

(a) What will be NRC's costs for implementing the new procedures, including the cost of the computer and computer personnel?

(b) How does the staff intend to convert from the present procedures to the new procedures? In what time-frame does the staff intend to move from the present system to the proposed system? And, if the staff intends to move slowly and carefully, does this not skew the so-called cost calculations?

(c) How much money will licensees have to spend in order to become part of the new computerized system? And, if they spend no money because NRC will absorb the cost of converting the files to the computerized system, how much of NRC's money, time, and effort will this entail?

(d) What will be the impact on NRC and on licensees of the conversion while it is taking place?

If you have any questions about these comments or those on the enclosed paper, please feel free to call me (492-7203) or Tom Dorian (492-8690) of my staff.

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Enclosures:
As stated

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