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

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MAR 28 1984

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

FROM: Patricia G. Norry, Director
Office of Administration

SUBJECT: REVIEW OF PROPOSED REVISIONS OF 10 CFR PART 35 AND REGULATORY GUIDE 10.8

The Office of Administration has reviewed the draft Commission paper containing proposed revisions for 10 CFR Part 35 and Regulatory Guide 10.8. Enclosed is a marked-up copy of the package that sets out our specific comments.

Page 13 of the Commission paper and page 2 of Enclosure 1 specify a 60 day comment period. Because this draft proposed rule is a significant expansion over the previous draft both in terms of size and the specificity of requirements, we believe a comment period of 90-120 days is necessary to allow affected licensees to effectively analyze and respond to the proposed rule.

On page 2 of the Commission paper, pages 5 and 6 of Enclosure 1, and page 1 of Enclosure 7, data from 1981 is used to describe licensees and licensing actions. Because the passage of time may have made this data obsolete, we suggest that 1983 data be used for the number of licensees and licensing actions.

Pages 32, 35, 39, and 55 of Enclosure 1 contain a statement that the NRC is not soliciting comment concerning all or specified portions of "recently completed" rulemaking actions. Because of the length of time that will have passed between the completion of these actions and the publication of the proposed rule, we believe that the NRC should be open to a discussion of any new developments, considerations, or information that commenters may bring to these areas. The rulemaking actions in question and their completion dates are as follows:

1. The Radiation Safety Committee (September 13, 1982; 47 FR 40149).

2. Records and reports of misadministrations (May 14, 1980; 45 FR 31701).

3. Measurement of radiopharmaceutical dosages (September 1, 1981; 46 FR 43840 - proposed rule).

4. Teletherapy monitoring and servicing (January 18, 1983; 48 FR 2116).

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The tables in the regulatory analysis that present the estimated cost of each section of the proposed regulation and the total burden for each of the hypothetical licensees are well conceived and executed. This thorough, detailed approach provides a sound basis for agency management and affected licensees to examine the cost impact of the proposed rule. However, two additional figures must be added to the description of impact on each of the hypothetical licenses used as illustrations in the Regulatory Analysis on page 16 of Enclosure 4. The first figure should estimate the gross annual receipts that each hypothetical licensee could expect to earn. The second figure should estimate the "new" regulatory burden that would be imposed on each of the hypothetical licensees. For purposes of analysis under the Regulatory Flexibility Act a new regulatory burden is that which is imposed on licensees for the first time by regulation. These two figures are necessary to adequately support the certification, made under the Regulatory Flexibility Act, that the proposed rule will not have a significant economic impact on small entities.

On page 72, of Enclosure 1, the Regulatory Flexibility Certification statement has been amended to reflect the new size standards set out by the Small Business Administration on February 9, 1984 (49 FR 5037). Please verify that, under the new criteria, a substantial number of medical licensees would be considered small entities.

If you have any questions or comments on any of the above matters, please contact John Philips, Chief, Rules and Procedures Branch on extension 27086 or Michael Lesar of his staff on extension 27758.

The License Fee Management Branch, in a memorandum from William O. Miller to John Philips (copy enclosed), made two comments on the proposed revision. First, LFMB indicated that the Commission's licensing policy has been updated several times since 1971. Second, LFMB believes that in the transition from a general to a specific license for certain physicians an "across the board" waiver of fees for amendments and renewals, etc., would be inconsistent with the intent of Congress and Commission fee policy. If you have any questions concerning these comments, please contact William O. Miller, Chief, License Fee Management Branch on extension 27225.

Pages 106 (§35.70(b)) and 107 (§35.80(f)) of Enclosure 1 specify a one year retention period for certain records. This matter is also discussed on pages 18 and 19 of Enclosure 1. However, we note that the NRC is in the process of establishing a uniform record retention policy that would establish retention periods of two, five, or ten years, or life of the facility or license. If the reasons for establishing a one year retention period for these records are significant and it is necessary to deviate from the standard record retention periods under consideration, please contact Brenda Shelton, Chief, Document Management Branch, on extension 28132.

On page 71 of Enclosure 1, the Paperwork Reduction Act Statement has been modified to reflect the current standard statement. On page 81 of Enclosure 1, the text of §35.8 has been changed to reflect the new standard language for this section. Please note that the package requesting OMB review and approval of the new or amended information collection requirements must be transmitted to OMB before the proposed rule may be submitted for signature and publication in the Federal Register. For questions or assistance in matters pertaining to the Paperwork Reduction Act, please contact Brenda Shelton, Chief, Document Management Branch on extension 28132.

Patricia G. Norry, Director
Office of Administration

Enclosures: As stated