

May 3, 2001

William R. Hendee, Ph.D
Senior Associate Dean and Vice President
Office of Research, Technology and Informatics
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, Wisconsin 53226

Dear Dr. Hendee:

I am responding to your letter of March 26, 2001, requesting answers to questions previously raised about the upcoming revision to 10 CFR Part 35, "Medical Use of Byproduct Material." It is my understanding that in response to a previous letter from you to Dr. Donald Cool, dated September 15, 2000, and a letter from Dr. M. Paul Capp, dated December 26, 2000, acknowledgment letters with interim replies were sent on October 27, 2000, and March 8, 2001. Delays in responding fully to your questions were a result, in part, of the staff's desire to complete the final rulemaking package prior to responding.

The Part 35 rulemaking package was submitted to the Office of Management and Budget (OMB) on March 16, 2001, for review of recordkeeping and reporting requirements. The staff has prepared the enclosed answers to your questions based on the rule text currently under review by OMB.

I appreciate your efforts to bring these questions to our attention. During this rulemaking process, the Commission has placed a high priority on obtaining input from the medical community and other stakeholders, and this process has been helpful and constructive.

If you have any further questions, please contact me.

Sincerely,

/RA/

Richard A. Meserve

Enclosure: Staff Responses to
Questions on Part 35

cc: Dr. M. Paul Capp, ABR

STAFF RESPONSES TO QUESTIONS FROM THE AMERICAN BOARD OF RADIOLOGY ON THE UPCOMING REVISION OF 10 CFR PART 35, BASED ON THE RULE TEXT PROVIDED TO THE OFFICE OF MANAGEMENT AND BUDGET FOR REVIEW ON MARCH 16, 2001

Question 1: For American Board of Radiology (ABR) certification in Medical Nuclear Physics, would the three years of clinical experience obtained under the supervision of a Radiation Safety Officer (RSO) satisfy the requirement for one year of full-time radiation safety experience specified in § 35.50(b)(1)(ii)?

Response 1: Yes, under certain conditions. The ABR needs to make a determination whether all candidates who meet the three-year clinical experience requirement also meet the one-year radiation safety experience requirement, and whether the associated preceptor statement certifies that the one-year requirement has been met. In this regard, we would accept an ABR finding that the *radiation safety experience* obtained over three years of clinical experience will in all cases be equivalent to one-year of full-time radiation safety experience.

Question 2: For ABR certification in Therapeutic Radiological Physics, does a medical physicist who meets the requirements in 10 CFR 35.51(b) also meet the requirements in § 35.50(b) for an RSO?

Response 2: Yes, in some cases. According to the description provided by ABR, only some physicists who meet § 35.51 also meet § 35.50. Therefore, certification under §35.51 would not necessarily ensure qualification as an RSO under § 35.50. However, note that 10 CFR 35.50(c) allows an authorized medical physicist, who is both identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material, to be appointed as an RSO.

Question 3: For ABR certification in Radiation Oncology under 10 CFR 35.390, 35.392, 35.394, 35.490, 35.491, and 35.690, does a candidate have to obtain the specified hours of work experience separately for each category? For example, to meet the qualifications for both §§ 35.490 and 35.690, does a candidate have to obtain 1000 hours of work experience?

Response 3: No. The hours of work experience do not have to be obtained separately for each modality of medical use in the regulations cited. A candidate could qualify under both §§ 35.490 and 35.690, if: (1) he or she has at least 500 hours of work experience which includes all the topics listed under paragraph (b)(1)(ii) of each section; (2) the work experience is obtained under the supervision of an authorized user who meets the requirements in each section; and (3) the appropriate written preceptor certifications are obtained from preceptors who meet the requirements for an authorized user for each type of use for which the candidate is requesting authorized user status.