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FINAL REPLY:

William R. Hendee
Medical College of Wisconsin

TO:

Chairman Meserve

FOR SIGNATURE OF :

** PRI **

CRC NO: 01-0196

Chairman

DESC:

Proposed Revisions to 10 CFR 35, "Medical Use of
Byproduct Material"

ROUTING:

Travers
Paperiello
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Reiter
Craig
Burns/Cyr

DATE: 04/06/01

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Date Printed: Apr 06, 2001 08:30

PAPER NUMBER: LTR-01-0196 **LOGGING DATE:** 04/05/2001
ACTION OFFICE: EDO

AUTHOR: WILLIAM HENDEE
AFFILIATION:
ADDRESSEE: RICHARD MESERVE
SUBJECT: QUESTIONS RE PROPOSED REVISIONS IN 10 CFR 35--BYPRODUCT MATERIALS

ACTION: Signature of Chairman
DISTRIBUTION: CHAIRMAN, COMRS, OGC, SECY TO ACK

LETTER DATE: 03/26/2001
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FILE LOCATION: ADAMS
DATE DUE: 04/19/2001 **DATE SIGNED:**

EDO --G20010133



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March 26, 2001

Richard A. Meserve
 Chairman
 Nuclear Regulatory Commission
 11555 Rockville Pike
 Rockville, MD 20852

Dear Dick:

I hope you will recall our work together on the advisory board for the CASE (Court-Appointed Scientific Experts) project of the American Association for the Advancement of Science. You will be pleased to know that the project has evolved nicely, although we miss your input to the advisory board.

I am writing you to see if you can help the American Board of Radiology obtain answers to questions it has asked about proposed revisions in 10 CFR 35 "Medical Use of Byproduct Material." I am enclosing letters from Dr. Capp (Executive Director of the American Board of Radiology) and myself (Vice President of the American Board of Radiology). These letters, addressed to Mr. Cool of the Commission on September 15, 2000 and December 26, 2000, raise questions about the interpretation of 10 CFR 35. These questions affect how the Board responds to the Commission's inquiry of whether the certification process of the American Board of Radiology satisfies the Commission's education and training requirements.

We have not heard from Mr. Cool in response to either of our letters. Hence, the issues we have raised remain unanswered, and we remain uncertain about certain aspects of our answers to the Commission's inquiry. Would you be able to help us acquire answers to our questions?

Best regards – and please extend my greetings to Greta Dicus on the Commission.

Sincerely,

Bill

William R. Hendee, Ph.D.
 Senior Associate Dean and Vice President

Cc: M. Paul Capp, M.D.
 Robert R. Hattery, Jr. M.D.
 Philip O. Alderson, M.D.
 Guy H. Simmons, Ph.D.
 Lawrence W. Davis, M.D.
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September 15, 2000

Donald A. Cool
Director, Division of Industrial and Medical Nuclear Safety
Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Cool:

I am writing in response to your letter of June 22, 2000 to Dr. Paul Capp of the American Board of Radiology (ABR). Your letter, and the Draft Final Regulatory Text: Training and Experience Criteria, were the subject of intense discussion among trustees of the ABR at our meeting in Santa Fe on September 8-10, 2000. This discussion yielded two questions that must be answered before the ABR can completely address the issues raised in your letter. These two questions are:

35.50: Training for Radiation Safety Officer

Medical physicists frequently serve as Radiation Safety Officers in healthcare institutions. To be eligible for ABR certification in Medical Nuclear Physics, a physicist must have a graduate degree in medical physics or related discipline, and 3 years of clinical experience. The educational requirements for certification include all of the items in (b.1.i), and the three years of clinical experience include all of the items in (b.1.ii.A-G). The three years of clinical experience are obtained under the supervision of a Radiation Safety Officer. However, the experience is usually embedded within a set of clinical responsibilities that extend beyond the specific duties of a Radiation Safety Officer. Strict interpretation of Section 35.50 could imply that such individuals would not satisfy the requirement of one year of full-time radiation safety experience. We wish to know whether the educational and clinical experience of a physicist eligible for certification in Medical Nuclear Physics will be interpreted by the Nuclear Regulatory Commission as satisfying the requirement of one year of full-time radiation safety experience.

35.51: Training for an Authorized Medical Physicist

Medical physicists who are certified in Therapeutic Radiological Physics by the ABR satisfy the requirements described in (b)(1) to be authorized medical physicists for therapeutic medical units as described in (b)(2). Some physicists certified in Therapeutic Radiological Physics also meet the education and clinical experience requirements described in 35.50, with the possible exception of one year of full-time experience in radiation safety, as described in the preceding paragraph. We wish to know whether these physicists satisfy the requirements of the Nuclear Regulatory Commission to serve as an institutional Radiation Safety Officer.

We look forward to your response to these two questions.

Sincerely,

William R. Hendee, Ph.D.
Senior Associate Dean and Vice President
Vice President, ABR

cc: Philip O. Alderson, M.D.
M Paul Capp M.D.
Ms. C. Haney
Guy H. Simmons, Ph.D.

The American Board of Radiology

Diagnostic Radiology

Radiation Oncology

Radiologic Physics

M. Paul Capp, M.D., Executive Director



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December 26, 2000

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Donald A. Cool

Director of Industrial and
Medical Nuclear Safety

United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Dr. Cool:

This is an official response from the American Board of Radiology to your letter of June 22, 2000 regarding the revision of your medical use regulations in 10 CFR Part 35, "Medical Use of Byproduct Material." The American Board of Radiology grants certification in three specialties: Diagnostic Radiology, Radiation Oncology, and Radiologic Physics. Consequently, the ABR response is by each of the specific disciplines.

Certification in Diagnostic Radiology:

- The American Board of Radiology by its certification in Diagnostic Radiology has reviewed 10 CFR 35.190 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by this board
- The American Board of Radiology by its certification in Diagnostic Radiology has reviewed 10 CFR 35.290 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.
- The American Board of Radiology by its certification in Diagnostic Radiology has reviewed 10 CFR 35.390 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board. However, at the present time we would restrict 35.390 toward the "low dose" portion of this directive to not include (G) (2) "Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131.

Certification in Radiation Oncology:

- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.390 and has determined that our

Radiation Oncology

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certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.392 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.
- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.394 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.
- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.490 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.
- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.491 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.
- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.690 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

However, we have some serious concerns regarding the interpretation of the document. This regards the specific number of hours that authorized users must have received. We would have no problem in addressing (b)(2) of section 35.490. However, at the present time many radiation oncology residency programs would not be able to meet the specific requirements of (b)(1)(ii) requiring 500 hours of work experience in each of the areas listed above. I have attached a letter from David H. Hussey, MD, who is a trustee of the ABR and Chair of the Radiation Oncology Examination Committee, that was sent to Dr. Sam Jones. We would need further clarification of this problem.

Certification in Radiologic Physics:

- The American Board of Radiology by its certification in Medical Nuclear Physics has reviewed 10 CFR 35.50 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.
- The American Board of Radiology by its certification in Therapeutic Radiologic Physics has reviewed 10 CFR 35.51 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

However, a strict interpretation of 35.50 could imply that current physicists in training under the supervision of a radiation safety officer may not satisfy the requirement of one year of full-time radiation safety experience.

This could be true for physicists training in both Medical Nuclear Physics as well as Therapeutic Physics. I have included a letter from William R. Hendee, PhD, a physicist trustee of the American Board of Radiology that was sent to you dated September 15, 2000.

The American Board of Radiology has always enjoyed a good relationship with the Nuclear Regulatory Commission in abiding by NRC Guidelines. We hope this relationship continues in the future, and we look forward to hearing from you regarding the above concerns.

Best regards.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. Paul Capp". The signature is stylized with a large initial "M" and a cursive "Capp".

M. Paul Capp, M. D.

MPC/sd

enclosures