UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 22, 2000

The American Board of Radiology
ATTN: Dr. M. Paul Capp
Executive Director
5255 E. Williams Circle, Suite 3200
Tucson, AZ 85711-7409

SUBJECT: RECOGNITION OF BOARDS

Dear Dr. Capp:

As you know, the Nuclear Regulatory Commission (NRC) is revising its medical use regulations in 10 CFR Part 35, "Medical Use of Byproduct Material." I anticipate the Commission will publish the final rule in the Federal Register in 2000, with an effective date 6 months after publication. As part of this revision, the regulatory text will no longer incorporate a listing of the specific boards whose diplomates automatically fulfill the training and experience requirements for an authorized medical physicist, authorized nuclear pharmacist, authorized user, or Radiation Safety Officer. Rather, the NRC will recognize certification boards that require individuals to complete the training and experience requirements specified in the regulatory text. Once recognized, the board's name will be placed on the list of recognized boards maintained on the NRC website. This change is being made to eliminate the need for a rulemaking each time a board is added or deleted.

I am writing to notify you of our intent to initiate the recognition process immediately. Other specialty boards whose diplomates are likely to seek authorization are being similarly notified. If you are interested in having your board recognized by the NRC, please submit a letter to me listing each training and experience section of the rule for which you believe your Board's diplomates should be deemed to have met the requirements. Enclosures 1 and 2 should assist you in preparing your letter. Enclosure 1 lists all areas where NRC plans to recognize boards. Enclosure 2 is a copy of the draft final regulatory text that lists the training and experience criteria for authorized medical physicists, authorized nuclear pharmacists, authorized users, and Radiation Safety Officers.

Your letter should clearly state that an individual must have completed the training and experience required by a particular section prior to receiving board certification. For example, if your board would like to be recognized under 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required," the letter should state:
(the name of your organization) 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."

The letter should be dated and signed by the chief executive of your board. If you have any questions or comments, please contact Ms. Catherine Haney of my staff (301-415-6825 or E-mail at cxh@nrc.gov) .

Sincerely,

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety

Enclosures:
1. Areas where NRC plans to recognize boards
2. Draft Final Regulatory Text - Training and Experience Criteria

The American Board of Radiology

Diagnostic Radiology Radiation Oncology Radiologic Physics

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

December 26, 2000

Note to requester: This letter is part of the document containing additional letters, that is publicly available at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML010960517

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

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ML010050221

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.

<u>Certification in Radiologic Physics</u>:

- 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,

M. Paul Capp, M. D.

MPC/sd

enclosures

October 3, 2000

Dr. Sam Jones
Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Dr. Jones:

This letter is in response to your request that I send you a list of my concerns regarding the proposed revisions in the NRC medical use regulation 10 CFR part 35. I should point out that I did not originally call you to express concerns. I called you for clarification regarding the wording so that I could determine whether I do have any concerns about the proposed revisions. I was specifically calling for clarification regarding how specific the work experience hour requirements would be. I am speaking as a private radiation oncologist, not as a training director, chair of a training program, member of ASTRO, or trustee of the American Board of Radiology.

I believe that the following sections of 35 apply to radiation oncology training programs: Paragraph 35.390, "Training for use of unsealed byproduct material for which a written directive is required; 35.392, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries; 35.394, "training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries; 35.490, "training for use of manual brachytherapy sources; 35.491, "training for opthalmic use of strontium-90; 35.690, "training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

In most of these sections, a specific number of hours of training is required, (usually 700 hours, of which 200 hours must be spent in the classroom, and 500 hours may be spent as work experience under the supervision of an authorized user). I do not personally perceive the classroom hours to be a problem, although other radiation oncology training directors may. The question I have relates to how specific the work experience must be. I would have concerns if this document intends that authorized users must have the following: 500 hours of work experience specifically in the use of unsealed by-product material for which a written directive is required, plus significant experience specifically in the oral administration of sodium iodide in quantities less than 33 millicuries, plus experience specifically relating to the administration of I-131 in quantities greater than 33 millicuries, plus 500 hours work experience specifically in manual

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brachytherapy sources, plus 500 hours of work experience specifically in the use of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units. I believe that many radiation oncology residency programs would not be able to meet these requirements if the work experience requirements for each section is specific to the procedure under consideration.

On the other hand, I would have no concerns if the work experience for each section were broader in scope, and allowed experiences such as that described in paragraph (b) (2) of section 35.490, which states: "has obtained three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in paragraph 35.490 or equivalent agreeing with state requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the ACGME or the Committee on Post-doctoral Training of the American Osteopathic Association."

As I mentioned to you in a previous call, several other radiation oncologists have expressed concerns about training program graduates meeting the requirement 35.690 relating to gamma knives if they trained in a radiation oncology program whose stereotactic radiosurgery program is linear accelerator based. However, this is not as great a concern as the work experience hour requirements.

Thank you for your attention.

Sincerely,

David H. Hussey M. D.

DHH:sd

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 8, 2001

M. Paul Capp, M.D., Executive Director
American Board of Science in Nuclear Medicine
1850 Samuel Morse Drive
Reston, VA 22090-5316

Dear Dr. Capp:

This letter acknowledges our receipt of the letter you sent, on behalf of the American Board of Radiology (ABR), to Donald A. Cool requesting formal recognition by the Nuclear Regulatory Commission of ABR's certification process in Diagnostic Radiology, Radiation Oncology, and Radiologic Physics.

Your letter will be reviewed by my staff. NRC expects to begin listing the names of recognized boards on an NRC website prior to the effective date of the final rule. I anticipate the Commission will publish the final rule in the Federal Register by June 2001, with an effective date 6 months after publication.

If you have any questions, please contact Robert L. Ayres of my staff (301-415-5746 or e-mail RXA1@nrc.gov).

Sincerely,

John W. N. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 3, 2002

The American Board of Radiology
ATTN: M. Paul Capp, M.D., Executive Director
P.O. Box 1502
Galesburg, Illinois 61402-1502

Dear Dr. Capp:

I am responding to your letter of December 26, 2000, to Dr. Donald A. Cool, regarding Nuclear Regulatory Commission (NRC) recognition of American Board of Radiology (ABR) certification under the new 10 CFR Part 35, "Medical Use of Byproduct Material". In a previous letter to Dr. William Hendee, dated May 3, 2001, Chairman Meserve provided responses to some of the issues you raised that were also in letters from Dr. William Hendee dated September 15, 2000, and from Dr. David Hussey dated October 3, 2000. (See Enclosures 1 - 5).

Please note that the revised Part 35 was issued on April 24, 2002. You may view either the full text of the rulemaking (in PDF format) on our web site at http://ruleforum.llnl.gov/cgi-bin/downloader/final_lib/280-0156.pdf, or just the rule itself at http://ruleforum.llnl.gov/cgi-bin/downloader/final_lib/280-0161.pdf. The effective date of the new rule is October 24, 2002, but there is a 2-year transition period for the new training and experience requirements, so the previous recognition of the ABR certifications in 10 CFR 35.900-961 will remain in effect for 2 years from the effective date of the new rule. During this transition period, the NRC staff will continue working with the medical community to resolve any concerns with implementing the training and experience requirements. We are pleased that you and Dr. Hendee was able to speak on this issue at the June 21, 2002, Subcommittee Meeting of the NRC Advisory Committee on the Medical Use of Isotopes.

With respect to NRC recognition of ABR certification under Subparts D, E, F, G, and H of the new Part 35, we have identified several issues which would have to be resolved before the ABR certification process could be recognized. These issues are summarized below:

1. Written Preceptor Certifications

The new Part 35 requires as a condition for NRC recognition that the board certification process must include a requirement that the candidate obtain a written preceptor statement. The preceptor must meet certain qualifications (e.g., 35.50(a) and (b)(2), 35.51(a) and (b)(2), 35.690(a) and (b)(3)).

a. The ABR does not appear to require as part of its certification process that a candidate must obtain a written certification from a qualified preceptor as specified in 10 CFR Part 35.

b. The ABR does not appear to require a preceptor statement which specifies that the the individual has completed the applicable requirements and is qualified to function independently in the applicable position; (e.g., authorized user, radiation safety officer, or authorized medical physicist).

c. For their Radiation Oncology diplomates, the ABR requests NRC recognition for six separate medical use modalities. Does the ABR require a preceptor statement that certifies that the individual has completed the applicable requirements and is qualified to function independently in each of the six separate modalities (as listed in our item 2b) for which recognition is requested? This would require either separate preceptor certifications (covering each modality requested) or a single global certification statement that the individual has achieved a level of competency sufficient to function independently as an authorized user in each of the six requested modalities. Furthermore, the required preceptor statement for §35.690 authorization requires the corresponding preceptor statement to certify competency to function independently as an authorized user of each type of medical unit for which your board is requesting NRC recognition.

2. Requirements for Authorized Users

a. You request that NRC grant recognition of your ABR certification process in Diagnostic Radiology as meeting of the requirements in the following subsections of the new 10 CFR Part 35:

§35.190	Training for uptake, dilution, and excretion studies;
§35.290	Training for imaging and localization studies; and,
§35.390[except (G)(2)]	Training for use of unsealed byproduct material for which a written directive is required.

We have reviewed this request, based on the information provided in your letter and the application requirements listed on your website for certification in Diagnostic Radiology, and find that there is insufficient information regarding whether the ABR's certification process meets the training and experience requirements set forth in the new Part 35 for each of the requested modalities. Therefore, we request that you submit information showing that ABR's certification process meets the applicable training and experience requirements set forth in the new Part 35 for each of the requested modalities.

Note that under the new Part 35, authorized users qualified under §35.390 are also deemed qualified under both §35.190 and §35.290. Thus, you may wish to consider revising your request for all three modalities and apply only for recognition under §35.390[except (G)(2)].

b. You request that NRC grant recognition of your ABR certification process in Radiation Oncology as meeting all of the requirements of the following subsections of the new 10 CFR Part 35:

§35.390	Training for use of unsealed byproduct material for which a written directive is required;
§35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries);

§35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than1.22 Gigabecquerels (33 millicuries);
§35.490	Training for use of manual brachytherapy sources;
§35.491	Training for ophthalmic use of strontium-90; and,
§35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

We have reviewed this request, based on the information provided in your letter and the application requirements listed on your website for certification in Radiation Oncology, and believe that you board's certification process complies with the training and experience requirements set forth for both §35.490 and §35.491 recognitions.

However, we have identified several concerns about the adequacy of training requirements for the four remaining modalities, as follows:

(1) For ABR's requested §35.390 through §35.394 recognitions, we can find no evidence that your board certification process requires essential specific training and experience requirements, as set forth in §35.390(b)(1)(i)(D) and (ii)(B through G). Please provide information which addresses your board's certification requirements as they pertain to these cited training and experience requirement concerns.

(2) §35.690(b)(3) requires preceptor certification that an individual ".....has achieved a level of competency sufficient to function independently as an authorized user of **each type of medical unit** for which the individual is requesting authorized user status." Does ABR certification in Radiation Oncology document this level of competency for one or more of the medical units (remote afterloader, teletherapy, and stereotactic radiosurgery) listed in Subpart H of the new rule? And, if so, which ones?

3. Requirements for Authorized Medical Physicists

10 CFR 35.51(a) establishes the requirements for the recognition of a medical physics specialty board to be a board whose certification includes all of the training and experience (T&E) requirements contained in section 35.51(b), and whose certification has been recognized by the Commission or an Agreement State. These requirements includes tasks involving sealed sources and brachytherapy sources, teletherapy units, remote afterloading units, and gamma stereotactic radiosurgery units (GSUs).

We have reviewed your request for NRC recognition for your diplomates in Therapeutic Radiologic Physics under §35.51(a). Based on the information contained in your letter and the application requirements, listed on your website for certification in Therapeutic Radiologic Physics, and find there is insufficient information to determine whether the ABR's certification process meets the requirements of §35.51(a). Therefore, we request that you provide sufficient information for us to determine whether your board certification process either meets all of the training and experience requirements set forth in §35.51(b) for full recognition or, some subset of these requirements for partial recognition.

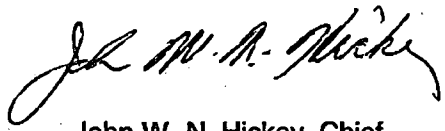
requirements in §35.50(b)(1) and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for a medical use licensee. Your current application process, which requires references certifying that the applicant is qualified to take the board examination in Radiological Physics, does not appear to satisfy the NRC requirement for a signed preceptor statement.

Note that persons already named as medical physicists on licenses are eligible to be authorized as RSOs in accordance with 35.50(c).

If any of our initial conclusions above are incorrect, or if you would like to submit additional information on the ABR certification process, you may submit additional information at any time

If you have any further questions, please contact Dr. Robert Ayres or me at 301-415-5746.

Sincerely,



John W. N. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety

cc: Dr. David H. Hussey
Dr. William R. Hendee

Enclosures:
1. Letter from M. Capp, dated 12/26/2000
2. Letter from D. Hussey, dated 10/03/2000
3. Letter from W. Hendee, dated 09/15/2000
4. Letter from W. Hendee, dated 03/26/2001
5. Letter from Chairman Meserve, dated 05/03/2001
6. Letter from J. Hickey, dated 05/31/2002

Note to requester: Enclosures 1 and 2 are included with this response. The remaining enclosures are publicly available in ADAMS (https://www.nrc.gov/reading-rm/adams.html).
Enclosures 3 and 4 are included in the document at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML010960517.
Enclosure 5 is available at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML011070073.
Enclosure 6 is part of a larger ADAMS package, at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML021510136

The American Board of Radiology

Diagnostic Radiology Radiation Oncology Radiologic Physics

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

July 16, 2002

John W.N. Hickey
Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Note to requester: This document is also publicly available in ADAMS at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML022060171

Dear Mr. Hickey:

Thank you for your recent letter of July 3, 2002, which represents a response to my letter of December 26, 2000 to Dr. Donald A. Cool regarding the Nuclear Regulatory Commission recognition of American Board of Radiology (ABR) certification under the new 10 CFR Part 35 "Medical Use of Byproduct Material." It is our understanding that your response reflects the current status of Part 35 and does not include consideration of the issues and recommended changes discussed at the Advisory Committee on Medical Uses of Isotopes (ACMUI) subcommittee meeting recently held in Washington.

As you already know, much has transpired since the December 2000 letter, particularly the recent ACMUI subcommittee meeting, in which the American Board of Radiology, in concert with several other certification boards, testified. We understand that the subcommittee report has subsequently been accepted by the full ACMUI committee. The ABR will await further developments in response to the ACMUI recommendations that address our concerns about issues in Part 35.

Thank you for your response. We await further decision by the commissioners in evaluating the ACMUI recommendations. We would appreciate any news of this progress at any time.

Many thanks.

Best regards.

Sincerely,

M. Paul Capp, M. D.

MPC/sd
cc: William R. Hendee, PhD
David H. Hussey, MD
Philip O. Alderson, MD
Robert R. Hattery, MD

Add John Hickey
NMSS 23

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON D.C 20555-0001

June 22, 2000

Note to requester: A version of this letter that also includes both of the attachments is publicly available in ADAMS at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML003725770

The American Board of Nuclear Medicine
ATTN: Dr. Ronald L. Van Heertum
Chairman
900 Veteran Avenue
Los Angeles, CA 90024-1786

SUBJECT: RECOGNITION OF BOARDS

Dear Dr. Van Heertum:

As you know, the Nuclear Regulatory Commission (NRC) is revising its medical use regulations in 10 CFR Part 35, "Medical Use of Byproduct Material." I anticipate the Commission will publish the final rule in the Federal Register in 2000, with an effective date 6 months after publication. As part of this revision, the regulatory text will no longer incorporate a listing of the specific boards whose diplomates automatically fulfill the training and experience requirements for an authorized medical physicist, authorized nuclear pharmacist, authorized user, or Radiation Safety Officer. Rather, the NRC will recognize certification boards that require individuals to complete the training and experience requirements specified in the regulatory text. Once recognized, the board's name will be placed on the list of recognized boards maintained on the NRC website. This change is being made to eliminate the need for a rulemaking each time a board is added or deleted.

I am writing to notify you of our intent to initiate the recognition process immediately. Other specialty boards whose diplomates are likely to seek authorization are being similarly notified. If you are interested in having your board recognized by the NRC, please submit a letter to me listing each training and experience section of the rule for which you believe your Board's diplomates should be deemed to have met the requirements. Enclosures 1 and 2 should assist you in preparing your letter. Enclosure 1 lists all areas where NRC plans to recognize boards. Enclosure 2 is a copy of the draft final regulatory text that lists the training and experience criteria for authorized medical physicists, authorized nuclear pharmacists, authorized users, and Radiation Safety Officers.

Your letter should clearly state that an individual must have completed the training and experience required by a particular section prior to receiving board certification. For example, if your board would like to be recognized under 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required," the letter should state: (the name of your organization) 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."

The letter should be dated and signed by the chief executive of your board. If you have any questions or comments, please contact Ms. Catherine Haney of my staff (301-415-6825 or E-mail at cxh@nrc.gov) .

Sincerely,

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety

Enclosures:
1. Areas where NRC plans to recognize boards
2. Draft Final Regulatory Text - Training and Experience Criteria

The American Board of Nuclear Medicine

A Member Board of the American Board of Medical Specialties

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New York, New York

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S. Ted Treves, M.D.
Boston, Massachusetts

Executive Director
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Los Angeles, California

Associate Executive Director
Heinrich R. Schelbert, M.D
Los Angeles, California

Administrator
Gloria W. Gorden, M.P.H.
Los Angeles, California

Please Address All Communication To:

900 Veteran Avenue
Los Angeles, CA 90024-1786
Telephone (310) 825-6787
Fax (310) 825-9433

July 10, 2000

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

Dear Mr. Cool:

I am responding to your letter of June 22, 2000 concerning the recognition of boards whose diplomates automatically fulfill the training and experience requirements for authorized use of byproduct materials. I am writing to you on behalf of the American Board of Nuclear Medicine (ABNM), which is a medical specialty certifying board recognized by the American Board of Medical Specialties, the American Medical Association, and the Council of Medical Specialty Societies. Since its inception in 1971, ABNM has examined and certified approximately 5000 physicians as specialists in the clinical use of byproduct materials. Certification by ABNM has been recognized in the past by the NRC as sufficient indication of competence in the safe uses of byproduct materials, and it has issued licenses to physicians certified by the ABNM for all categories of use of unsealed byproduct materials

In conjunction with the Council on Medical Education of the American Medical Association and the Society of Nuclear Medicine, the ABNM sponsors a Nuclear Medicine Residency Review Committee that establishes criteria for residency training in nuclear medicine. The Residency Review Committee currently oversees 69 nuclear medicine residency training programs. All nuclear medicine training programs are monitored and routinely audited by the Accreditation Council on Graduate Medical Education.

Nuclear Medicine programs comprise three years of training, which includes one year of preparatory clinical experience and two years of full-time nuclear medicine instruction. They are highly structured educational programs that encompass both basic science and clinical instruction. Basic science instruction includes the following areas: radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology and radiation dosimetry, and substantially exceed 200 hours of didactic instruction. In addition, residents receive

more than 700 hours of training and experience in basic radionuclide handling techniques that are applicable to the medical use of unsealed byproduct material for imaging and localization studies, and for radionuclide therapy that requires a written directive. The programs also provide training in radiation safety, including shipping, receiving, and assaying of radioactive materials and the use of instrumentation, such as survey meters and calibration meters. Instruction in the prevention of radionuclide contamination, proper decontamination procedures, and the disposal of byproduct material also are included. Upon the completion of training and to obtain certification as nuclear medicine specialist physician's must pass a rigorous eight-hour examination on all aspects of nuclear medicine.

Accordingly, the ABNM requests formal recognition under 10 CFR Part 35-Medical Use Of Byproduct Material. We have reviewed the area listed where NRC plans to recognize boards and have determined that the ABNM certification process requires an individual to meet all of the requirements in the following subsections of Part 35:

35.190 Training for uptake, dilution, and excretion studies.
35.290 Training for imaging and localization studies.
35.390 Training for use of unsealed byproduct material for which a written directive is required.
35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).
35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

Your favorable consideration of our request to be listed as a recognized board that provides training and experience in the above use of byproduct materials will be most sincerely appreciated.

Sincerely,

Ronald L. Van Heertum

Ronald L. Van Heertum, M.D.
Chairman
American Board of Nuclear Medicine

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 28, 2000

Ronald L. Van Heertum, M.D.
Chairman
American Board of Nuclear Medicine
900 Veteran Avenue
Los Angles, CA 90024

Dear Dr. Van Heertum:

This letter acknowledges our receipt of the letter you sent, on behalf of the American Board of Nuclear Medicine (ABNM), to Donald A. Cool requesting formal recognition by the Nuclear Regulatory Commission of the ABNM's certification process.

Your letter will be reviewed by my staff. NRC expects to begin listing the names of recognized boards on an NRC website prior to the effective date of the final rule. I anticipate the Commission will publish the final rule in the Federal Register by spring 2001, with an effective date 6 months after publication.

If you have any questions, please contact Sam Jones of my staff (301- 415-6198 or e-mail SZJ@NRC.gov).

Sincerely,

Patricia Holahan, Branch Chief
Rulemaking and Guidance Branch
Division of Industrial and
Medical and Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

The American Board of Nuclear Medicine

A Member Board of the American Board of Medical Specialties

Please Address All Communication To:

[illegible] Veteran Avenue
Los Angeles, CA 90024-1780
Telephone (310) 825-6787
Fax (310) 825-0155

November 29, 2000

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

Dear Mr. Cool:

The American Board of Nuclear Medicine (ABNM) wishes to submit an addendum to its recent letter that requested formal recognition by the Nuclear Regulatory Commission of the ABNM certification process. Since many of our diplomates are required to act as radiation safety officers in association with their clinical activities, I would like to describe the pertinent training they receive, which we believe would qualify them to act as radiation safety officers.

It is our opinion that the ACGME-approved Nuclear Medicine Residency Training Programs, as delineated in my letter of July 10, 2000, that lead to certification by the American Board of Nuclear Medicine cover the required Radiation Safety Officer training as described in 10 CFR, part 35, section 35.50. The latter section states that a Radiation Safety Officer is an individual certified by a recognized specialty board whose certification process includes all of the requirements in paragraph (b) of this section. It is our contention that ABNM Diplomates, by virtue of their two years of nuclear medicine residency training, satisfy these requirements and that they acquired a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Your favorable consideration of our request to accept the training received by diplomates of the American Board of Nuclear Medicine as satisfying the requirements for Radiation Safety Officer training would be appreciated.

Sincerely;

Ronald L. Van Heertum MD

Ronald L. Van Heertum, M.D.
Chairman, American Board of Nuclear Medicine

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 8, 2001

Ronald L. Van Heertum, M.D., Chairman
American Board of Nuclear Medicine
900 Veteran Avenue
Los Angeles, CA 90024-1786

Dear Dr. Van Heertum:

This letter acknowledges our receipt of the letter you sent, on behalf of the American Board of Nuclear Medicine (ABNM), to Donald A. Cool as an addendum requesting formal recognition by the Nuclear Regulatory Commission of ABNM's certification process for qualification under 10 CFR 35.50 for Radiation Safety Officer for a medical use licensee.

Your letter will be reviewed by my staff. NRC expects to begin listing the names of recognized boards on an NRC website prior to the effective date of the final rule. I anticipate the Commission will publish the final rule in the Federal Register by June 2001, with an effective date 6 months after publication.

If you have any questions, please contact Robert L. Ayres of my staff (301-415-5746 or e-mail RXA1@nrc.gov).

Sincerely,

John W. N. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 29, 2001

The American Board of Nuclear Medicine
ATTN: Dr. Ronald L. Van Heertum, Chairman
900 Veteran Avenue
Los Angeles, CA 90024-1786

Dear Dr. Van Heertum:

I am replying to your letters dated July 10, 2000, and November 29, 2000, to Donald Cool, requesting formal recognition, under the new 10 CFR Part 35, "Medical Use of Byproduct Material", for American Board of Nuclear Medicine (ABNM) diplomates.

In your letter of July 10, 2000, you stated that the ABNM certification process meets all of the requirements of the following subsections of new 10 CFR Part 35:

§35.190	Training for uptake, dilution, and excretion studies;
§35.290	Training for imaging and localization studies;
§35.390	Training for use of unsealed byproduct material for which a written directive is required;
§35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabaecquerels (33 millicuries); and,
§35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than1.22 gigabaecquerels (33 millicuries).

We have reviewed your request, and concluded that the ABNM certification process, as described in your letter and your board's application requirements, does meet the new requirements for each of the requested subsections listed above for which you are requesting recognition. In particular, your required "Evaluation of Clinical Competence" certification requirement would appear to meet the individual subsection requirements for written certification, signed by a preceptor authorized user, that the diplomate has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses defined in the five subsections for which you have applied for recognition. After Part 35 is issued in final form, we plan to list on our web site the boards which have been recognized. We will include ABNM on that list.

In your letter of November 29, 2000, you also requested Commission recognition of ABNM diplomates under 10 CFR 35.50(a) for Radiation Safety Officer (RSO), which requires the board certification process to include all of the requirements in §35.50(b). Our review of this request, along with your board's certification process, does not show that your process includes either: (1) the requirement for one year of full-time radiation safety experience under the supervision of

an RSO; or, (2) written certification, signed by a preceptor RSO that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for a medical use licensee. Thus, at this time, your board certification process does not meet the requirements of 10 CFR 35.50(a) for an RSO.

However, since your board diplomates are recognized by the Commission to be authorized users, they can be appointed RSO's under §35.50(c) if they are identified on a medical use license and have radiation safety experience with similar types of use of byproduct materials for which the individual has radiation safety responsibilities. Also, an ABNM certified individual can still be authorized as an RSO at a medical use licensee facility, if: (1) the licensee submits a license amendment request which demonstrates that the person meets the criteria specified in the new §35.50(b); or (2) the person is currently listed as an RSO at a medical use licensee facility as specified in the new §35.57(a).

If you have any questions, please contact Dr. Robert Ayres at 301-415-5746 or e-mail at rxa1@nrc.gov .

Sincerely,

John W. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety

ML021500449

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 30, 2002

The American Board of Nuclear Medicine
ATTN: Dr. Ronald L.Van Heertum, Chairman
900 Veteran Avenue
Los Angeles, CA 90024-1786

Dear Dr. Van Heertum:

This is a follow-up to our letter to you, dated June 29, 2001, which concluded that the ABNM certification process meets the requirements for recognition under the new 10 CFR Part 35, Medical Use of Byproduct Material.

Following inquiries from other parties regarding the requirements for preceptor statements, we have determined that we need additional information regarding the ABNM certification process.

The new Part 35 requires, as a condition for NRC recognition, that the board certification process must include a requirement that the candidate obtain a written preceptor statement. Both the preceptor and the applicant must meet certain qualifications (see for example, §35.190(c)(2) and §35.290(c)(2)). We request that ABNM respond to the following questions:

1. Does the ABNM require as part of its certification process that a candidate must obtain a written certification from a qualified preceptor authorized user?

2. If a preceptor statement is required, does ABNM specify that the statement must certify that the candidate has completed the applicable requirements and it qualified to function independently for the medical use authorization(s) requested?

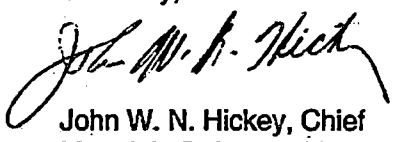
Please note that the revised Part 35 was issued on April 24, 2002, and the full text of the rulemaking (in PDF format) may be viewed on our web site at http://ruleforum.llnl.gov/cgi-bin/downloader/final_lib/280-0156.pdf, or just the rule itself may be viewed at http://ruleforum.llnl.gov/cgi-bin/downloader/final_lib/280-0161.pdf. The effective date of the new rule is October 24, 2002, but there is a 2-year transition period for the new training and experience requirements, so the previous recognition of the ABNM in 10 CFR 35.900, 35.910, 35.920, 35,930, and 35.950 will remain in effect for 2 years from the effective date of the new rule. During this transition period, the NRC staff will continue working with the medical community to resolve any concerns with implementing the training and experience requirements.

Note to Requester: A publicly available version of this letter is available in ADAMS at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML021500449

In addition, the NRC Advisory Committee on Medical Use of Isotopes has established a subcommittee to develop recommendations on training and experience issues. We would welcome any comments from your Board on concerns related to implementing the training and experience requirements in the new Part 35. We would appreciate receiving any such comments by June 24, 2002.

Please respond to our questions regarding the ABNM certification process within 30 days. If you have any questions, please contact Dr. Robert Ayres at 301-415-5746 or e-mail at rxa1@nrc.gov .

Sincerely,



John W. N. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

From: Thomas Essig
To: amaurer@temple.edu
Date: 6/18/03 12:58PM
Subject: Re: Board Certification

Dr. Mauer,

My apologies for taking so long to reply to your e-mail. Our response is attached. As noted in the attached, we have determined that the ABNM does not meet the criteria currently stated in 10 CFR 35.190, 35.290, or 35.390 for Boards seeking to be recognized by NRC. Our basis for this conclusion is also contained in the attached file.

This review was performed by Dr. Donna-Beth Howe of my staff and reviewed by Dr. Ronald Zelac, also of my staff. Should you have any questions regarding our response, please contact Dr. Howe. We believe all of the information regarding the content of the ABNM program cited in the attached note to be factual; however, if such is not the case, please advise us.

Thomas Essig, CHP
Chief, Materials Safety and Inspection Branch
Division of Medical and Industrial Nuclear Safety
Office of Nuclear Materials Safety and Safeguards

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>>> <amaurer@temple.edu> 06/02/03 09:10AM >>>
Thank you for your prompt attention to this. I wanted to add that the ABNM is having a board meeting begining this week on Thur. 6/6/03. I am sure there will be many questions raised at the meeting concerning the ABNM status with NRC. I know this is short notice but I will be leaving Thur. to attend the meeting and would like to be able to bring some news concerning our correspondence. Could you please get me some indication of ABNM status by Wed.? If not, the meeting will be at the Chatham Wayside Inn on Cape Cod MA. The telephone number there is 508-945-5550. Please contact me there if you get any news later in the week.

---- Original message ----
>Date: Mon, 02 Jun 2003 06:25:59 -0400
>From: "Sandra Wastler" <SLW1@nrc.gov>
>Subject: Re: Board Certification
>To: <amaurer@temple.edu>
(b)(6) >Cc: [redacted], <abnm@mednet.ucla.edu>, "Thomas Essig" <THE@nrc.gov>
>
>** High Priority **
>
>Dr. Mauer
>
>I have forwared the information and your request to Tom Essig, Branch Chief of the Material Safety and Inspection Branch. The responsibility for for reviewing and approving applications for Board certification lies in his Branch. He will be getting back to you shortly regarding your request.
>
>If you have any questions, please feel free to call or e-mail me or Mr Essig.
>
>Sandra Wastler
~~~~~~

>>>> <amaurer@temple.edu> 05/30/03 04:23PM >>>
>Dear Ms. Wastler,
>
>I forwarded the information you last sent me regarding the
>American Board of Nuclear Medicine's request for "deemed"
>status as a recognized board to the ABNM office for further
>clarification. Attached you will find a copy of a reply
>letter sent June 6, 2002 by Dr. Andrew Taylor who was then
>Chairman of the ABNM.
>
>In that letter he provided further details on the
>written preceptor certification process required by the ABNM
>for all diplomats requesting certification. This letter
>would appear to have satified the NRC's request for further
>information.
>
>I spoke today with Dr. Larry Holder who is current Chairman
>of the ABNM and told him I would send this letter to you. At
>this point it would seem that the ABNM did provide the
>information requested and demonstrated that it does require
>a written certification by the authorized-user program
>director which documents that ABNM diplomats are qualified
>to function independently.
>
>Can you clarify for us now what action was taken after
>receipt of the June 6, 2002 letter?
>
>
>
>----- Original message ----
>>Date: Tue, 27 May 2003 12:29:06 -0400
>>From: "Sandra Wastler" <SLW1@nrc.gov>
>>Subject: Board Certification
>>To: <Amaurer@temple.edu>
>>Cc: "Gary Janosko" <GSJ@nrc.gov>, "Patricia Holahan" <
>PKH@nrc.gov>, "Roger Broseus" <RWB@nrc.gov>
>>
>>** High Priority **
>>
>>Dr. Mauer
>>
>>During the public meeting on May 20, 2003, you indicated
>that the ABNM had received an letter dated June 29, 2001 in
>which the NRC concluded that the ABNM certification process
>met the requirements for recognition under the new 10 CFR
>Part 35. Given the issuance of the new Part 35 on April 24.
>2002 and the public meeting regarding the on-going
>development of a proposed revisions to Part 35 Training and
>Experience, in particular Board certification, you
>questioned whether ABNM's was still a recognised Board.
>>
>>We have investigated this situation and have found that the
>ABNM was sent another letter on May 30, 2002 in this regard.
>Specifically, the letter indicated that, as a result of
>inquiries from other parties regarding the requirement for
>preceptor statements, NRC had determined that it needed

>additional information regarding the ABNM's certification
>process.
>>
>>I have attached a copy of the letter and it also can be
>found in ADAMS (ML021500449). I hope this answers your
>question. Should you need anything further, please let me or
>my staff know.
>>
>>Thanks
>>
>>Sandra Wastler
>>
>>_____
>>ML021500449.pdf (11k bytes)
>

CC: American Board of Nuclear Medicine; Charles Miller; Donna-Beth Howe;
(b)(6) [redacted] Patricia Holahan; Ronald Zelac; Sandra Wastler

Note to Requester: The document referenced as ML021500449 is publicly available at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML021500449