



ACMUI SUBCOMMITTEE MEETING

NUCLEAR REGULATORY COMMISSION  
11545 ROCKVILLE PIKE, ROCKVILLE, MD

JUNE 21, 2002

**ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**

**June 21, 2002  
8:00 am - 12:00 pm**

**U.S. Nuclear Regulatory Commission  
Two White Flint Building-T2B3  
Rockville, Maryland**

**AGENDA**

8:00 - 8:15 Opening Remarks - John Hickey, NRC and Dr. Richard Vetter, Chairman, ACMUI Subcommittee

8:15 - 8:30 ACMUI Subcommittee Charter - Dr. Richard Vetter, Chairman, ACMUI Subcommittee

8:30 - 9:45 Discussion of Subcommittee Recommendations - ACMUI Subcommittee

9:45 - 10:00 **BREAK**

10:00 - 11:45 Public Comments/Additional Discussion

11:45 - 12:00 Summary of Meeting - Dr. Richard Vetter, Chairman, ACMUI Subcommittee

12:00 **ADJOURN**

**ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**

**June 21, 2002  
8:00 am - 12:00 pm**

**U.S. Nuclear Regulatory Commission  
Two White Flint Building-T2B3  
Rockville, Maryland**

**ACMUI Subcommittee Members:**

Richard J. Vetter, PhD., Radiation Safety Officer, ACMUI Subcommittee Chairman  
Ruth McBurney, State Representative  
Jeffrey F. Williamson, PhD., Therapy Physicist  
David A. Diamond, M.D., Radiation Oncologist  
Jeffrey A. Brinker, M.D., Interventional Cardiologist (designee)

**Additional ACMUI Attendee:**

Manuel D. Cerqueira, M.D., Nuclear Cardiology, ACMUI Chairman

**ACMUI Subcommittee Charter:**

Develop the concept for a draft rule that restores board certifications as the primary pathway for becoming an AMP, RSO, and authorized medical user.

UNITED STATES NUCLEAR REGULATORY COMMISSION  
CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES  
(Pursuant to Section 9 of Public Law 92-463)

1. **Committee's Official Designation:**

Advisory Committee on the Medical Uses of Isotopes

2. **Committee's objectives, scope of activities and duties are as follows:**

The Committee provides advice, as requested by the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy.

3. **Time period (duration of this Committee):**

From March 20, 2002, to March 20, 2004

4. **Official to whom this Committee reports:**

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

5. **Agency responsible for providing necessary support to this Committee:**

U.S. Nuclear Regulatory Commission

6. **The duties of the Committee are set forth in Item 2 above.**

7. **Estimated annual direct cost of this Committee:**

- a. \$160,000.00 (includes travel, per diem, and compensation)
- b. Total staff-year of support: 1.5 FTE

8. **Estimated number of meetings per year:**

Three meetings per year except when active rulemaking is conducted, then five meetings per year.

9. **The Committee's termination date.**

March 20, 2004

10. **Filing date:**

March 20, 2002

Andrew L. Bates  
Andrew L. Bates  
Advisory Committee Management  
Officer  
Office of the Secretary of the  
Commission

## DRAFT

**Draft: June 14, 2002**

### NRC ACMUI SUBCOMMITTEE ON TRAINING AND EXPERIENCE REQUIREMENTS

#### INTRODUCTION

A revision of 10 CFR Part 35, Medical Use of Byproduct Material, was published on April 24, 2002 (Federal Register Vol. 67(79) 20371-20397). The revision contains new training and experience requirements for individuals to become authorized as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), and authorized user (AU). These new requirements provide several options for individuals to become authorized. One option is for individuals to be certified by a specialty board whose certification process includes all the requirements in an alternate pathway. The alternate pathway includes specified numbers of hours of training and written certification signed by a preceptor that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an RSO, AMP, ANP, or AU. Currently, most specialty boards do not require candidates to meet these specific requirements.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) appointed a subcommittee on training and experience requirements to develop recommendations that would restore board certification as the default pathway for individuals to become authorized as RSO, AMP, or AU. The ACMUI subcommittee has developed the following drafts of new training and experience requirements.

The draft rule language in these draft recommendations is based on the following assumptions:

- (1) Currently accepted boards should be listed explicitly in the regulations;
- (2) To facilitate addition of future certification mechanisms to the T&E qualification process without rulemaking initiatives, criteria should be included in the rule to provide a basis for recognizing such boards;
- (3) It is expected that the currently accepted boards will meet the criteria in (2);
- (4) The preceptor concept should be modified to become documentation of successful completion of a training program rather than a testament to clinical competence; and;
- (5) Specific training should be required for certain new devices or modalities. This training is considered to be a separate requirement that is decoupled from the core training and supervised experience.

These drafts and any public input will serve as a basis for discussion at a meeting of the subcommittee on June 21 in Rockville, Maryland. The subcommittee will develop recommendations from the June 21 meeting to the full ACMUI.

**§ 35.50 Training for Radiation Safety Officer**

Except as provided in § 35.57, the licensee shall require the an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who –

- (a) Is certified by:
  - (1) American Board of Health Physics in Comprehensive Health Physics;
  - (2) American Board of Medical Physics in Medical Health Physics;
  - (3) American Board of Radiology;
  - (4) American Board of Nuclear Medicine;
  - (5) American Board of Science in Nuclear Medicine;
  - (6) Board of Pharmaceutical Specialties in Nuclear Pharmacy;
  - (7) American Board of Medical Physics in Radiation Oncology Physics
  - (8) American Board of Medical Physics in Diagnostic Radiology Physics
  - (9) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine;
  - (10) American Osteopathic Board of Radiology;
  - (11) American Osteopathic Board of Nuclear Medicine; or

- (b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomates:
  - (1) To hold a bachelors or graduate degree from an accredited college or university in physical science or biological science with a minimum of 20 college credits in physical science;
  - (2) To have six or more years of responsible professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics;
  - (3) To provide a written certification from the supervising physicist or RSO that the individual has completed the training and experience described in paragraph (b)(2) of this section; and
  - (4) To pass an examination administered by diplomates of the specialty board, which evaluate knowledge and competence in radiation physics; and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology; or

- (c) (1) Has completed a structured educational program consisting of 200 hours of didactic training in the following areas--
  - (A) Radiation physics and instrumentation;
  - (B) Radiation protection;
  - (C) Mathematics pertaining to the use and measurement of radioactivity;
  - (D) Radiation biology; and
- (2) Has one year of full-time radiation safety experience under the supervision of an individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar types(s) of use(s) of byproduct material involving the following--
  - (A) Shipping, receiving, and performing related radiation surveys;

- (B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- (C) Securing and controlling byproduct material;
- (D) Using administrative controls to avoid mistakes in the administration of byproduct materials;
- (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- (F) Using emergency procedures to control byproduct material; and
- (G) Disposing of byproduct material; or

(d) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

(e) In addition to meeting the requirements of (a), (b), (c), or (d) of this section, the licensee shall require a Radiation Safety Officer to have training in the radiation safety, regulatory issues, emergency procedures, and proposed clinical procedures of any modality for which the licensee seeks authorization. This training requirement may be satisfied by satisfactorily completing training that is supervised by an Authorized Medical Physicist or Radiation Safety Officer authorized for the modality for which the licensee is seeking authorization.

**§ 35.51 Training for an authorized medical physicist.**

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who –

- (a) Is certified by the American Board of Radiology in--
  - (1) Therapeutic radiological physics;
  - (2) Roentgen ray and gamma ray physics;
  - (3) X-ray and radium physics; or
  - (5) Radiological physics; or
- (b) Is certified by the American Board of Medical Physics in radiation oncology physics; or
- (c) Is certified by a specialty board in radiation oncology physics (for clarity and simplification, these subfields (or relevant portion thereof) of the specialty boards in (a) and (b) of this section will henceforth be referred to as "radiation oncology physics") whose certification has been recognized by the Commission and requires all diplomates;
  - (1) To hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body
  - (2) To have two years of full-time supervised practical training and/or supervised radiation oncology physics experience that
    - (i) Is supervised by medical physicist who is certified in radiation oncology physics by the board in question.

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- (ii) Occurs in a clinical radiation oncology facility that provides megavoltage external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 35.400 or 35.600
- (3) To successfully passes an examination administered by diplomates of the certification board in question that assesses knowledge and competence in clinical radiation oncology, radiation safety, calibration, quality assurance, treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery.

Or

- (d)
  - (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body
  - (2) Has completed 1 year of full-time training in radiation oncology physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the modality in which the individual is seeking authorization in a clinical radiation oncology facility providing megavoltage external beam therapy and brachytherapy services that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable
  - (3) Has obtained written certification from the supervising medical physicist that the individual has satisfactorily completed the training and experience described in paragraph (b)(2) of this section and identifies the byproduct material modalities included.
- (e) In addition to meeting the requirements of (a), (b), (c), or (d) of this section, an authorized medical physicist must have training in the modality for which authorization is sought that includes device operation, safety procedures, clinical use, and operation of treatment planning system that is equivalent to instruction provided by the vendor to new customers. This training requirement may be satisfied by satisfactorily completing a training program provided by the vendor or by training supervised by an AMP authorized for the modality in which the individual is seeking authorization.

**Sec. 35.190 Training for uptake, dilution, and excretion studies.**

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.100 to be a physician who—

- (a) Is certified in--
  - (1) Nuclear medicine by the American Board of Nuclear Medicine;
  - (2) Diagnostic radiology by the American Board of Radiology;
  - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
  - (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

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(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(b) Is certified by a medical specialty board whose certification process:

(1) Includes all of the requirements in paragraph (d)(1) of this section;

(2) Requires successful completion with a passing grade of written and oral exams administered by diplomates of the certification board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; and

(3) Has been recognized by the Commission; or

(c) Is an authorized user under Secs. 35.290 or 35.390 or equivalent Agreement State requirements; or

(d)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.190, Sec. 35.290, or Sec. 35.390 or equivalent Agreement State requirements, involving--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in Secs. 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

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**Sec. 35.290 Training for imaging and localization studies.**

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.200 to be a physician who--

- (a) Is certified in--
  - (1) Nuclear medicine by the American Board of Nuclear Medicine;
  - (2) Diagnostic radiology by the American Board of Radiology;
  - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
  - (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;
  - (5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;
  - (6) Nuclear cardiology by the Certification Board of Nuclear Cardiology;or
- (b) Is certified by a medical specialty board whose certification process:
  - (1) Includes all of the requirements in paragraph (d)(1) of this section;
  - (2) Requires successful completion with a passing grade of written and oral exams administered by diplomates of the certification board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; and
  - (3) Has been recognized by the Commission; or
- (c) Is an authorized user under Sec. 35.390 or equivalent Agreement State requirements; or
- (d)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum--
  - (i) Classroom and laboratory training in the following areas--
    - (A) Radiation physics and instrumentation;
    - (B) Radiation protection;
    - (C) Mathematics pertaining to the use and measurement of radioactivity;
    - (D) Chemistry of byproduct material for medical use;
    - (E) Radiation biology; and
  - (ii) Work experience, under the supervision of an authorized user, who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, including--
    - (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    - (B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
    - (C) Calculating, measuring, and safely preparing patient or human research subject dosages;

- (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
  - (E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
  - (F) Administering dosages of radioactive drugs to patients or human research subjects; and
  - (G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
- (2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

**Sec. 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.**

Except as provided in Sec. 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under Sec. 35.600 to be a physician who—

- (a)(1) Is certified by a medical specialty board whose certification process requires successful completion of a three year residency program in radiation oncology approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education;
  - (2) Has passed an examination that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; and
  - (3) Whose certification has been recognized by the Commission; or
- (b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes--
- (i) 200 hours of classroom and laboratory training in the following areas--
    - (A) Radiation physics and instrumentation;
    - (B) Radiation protection;
    - (C) Mathematics pertaining to the use and measurement of radioactivity; and
    - (D) Radiation biology; and
  - (iii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements at a medical institution, involving—
    - (A) Reviewing full calibration measurements and periodic spot-checks;
    - (B) Preparing treatment plans and calculating treatment doses and times;

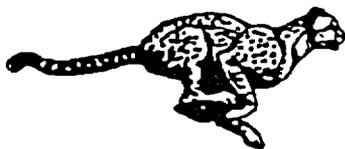
**DRAFT**

- (C) Using administrative controls to prevent a medical event involving the use of byproduct material;
  - (D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
  - (E) Checking and using survey meters; and
  - (F) Selecting the proper dose and how it is to be administered; and
- (2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and
- (3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section for each type of therapeutic medical unit for which authorized user status is requested. The written certification must be signed by a preceptor authorized user who meets the requirements in Sec. 35.690 (or equivalent Agreement State requirements for an authorized user) for each type of therapeutic medical unit for which authorized user status is requested.
- (c) Boards currently recognized by the Commission to meet all the requirements of paragraph (a) of this section include the American Board of Radiology, the American Osteopathic Board of Radiology, British Royal College of Radiology, and the Canadian Royal College.
- (d) In addition to meeting the requirements of paragraphs (a) or (b) of this section, an authorized user of a sealed source authorized under 35.600 must have training in the modality for which authorization is sought. This includes training in device operation, safety procedures, and clinical use that is equivalent to that instruction provided by the vendor to new customers. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the modality in which the individual is seeking authorization.

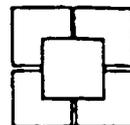
## **Public Comments on Training and Experience Requirements for Part 35**

### **Attached Handouts:**

1. Fax from Dr. Gopal Saha, American Board of Science in Nuclear Medicine, dated June 6, 2002.
2. Letter from Michael Herman, PhD., American College of Medical Physics, dated June 14, 2002.
3. E-mail from Andrew Taylor, M.D., American Board of Nuclear Medicine, dated June 14, 2002.
4. E-mail from William VanDecker, M.D., ACC/ASNC/SCAI, dated June 14, 2002.
5. E-mail from James Udelson, M.D., Certification Board of Nuclear Cardiology, dated June 14, 2002.
6. E-mail from Pamela Smith, American Osteopathic Board of Radiology, dated June 17, 2002.
7. E-mail from Richard Bertin, PhD., RPh., Board of Pharmaceutical Specialties, dated June 18, 2002.



THE  
CLEVELAND  
CLINIC FOUNDATION  
Cleveland, Ohio  
Dept. of Nuclear Medicine  
FAX: (216) 444-3943



When speed is of the essence . . . . .

TO: Linda Psyk FAX: (301) 415-5369

DATE: 6/6/02 NO. OF PAGES: 2 including this.

COMPANY: NRC

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Message From: Dr. Gopal Saha

Ms Psyk:

Enclosed are my comments for inclusion in the discussion at The ACMUI Subcommittee meeting on June 21, 2002. Since I am not the president of the ABSNM this yr, I have passed on your invitation to ABSNM office for further action. I would appreciate it if you include my comments at the Committee briefings.

Thanks.

Dr. Saha

If there is a problem with the transmission, call 216-444-2777

**Comments submitted by Gopal Saha, Ph.D. on Training and Experience requirement  
for Radiation Safety Officer**

In my opinion, the NRC has made a mistake in rule making for the training and experience requirement for the RSOs

The NRC allows three categories for RSO approval:

- (a) certification by an approved specialty board meeting the requirements in (b)
- (b) 200 hours of didactic lectures, one year of full-time radiation safety experience and written certification by a preceptor RSO attesting to the candidate's experience.
- (c) authorized users, authorized medical physicists, or authorized nuclear pharmacists with experience in radiation safety.

Now my question is the following.

Individuals in category (c) do not have an RSO preceptor's certification nor one year of radiation safety experience anywhere in their credentials or background, as required in category (b) and category (a). Let me elaborate

A physician can be an authorized user by being ABNM or other board certified without one year of full time radiation safety experience or RSO preceptor's certification.

A medical physicist can be an authorized physicist by having a board certification ( ABR, ABMP) that meets physics related experience and an authorized physicist preceptor's certification, again without one year of full-time radiation safety experience or RSO preceptor's certification

A nuclear pharmacist can be an authorized nuclear pharmacist by having a board certification specializing in nuclear pharmacy and meeting pharmacy related experience and an authorized nuclear pharmacist preceptor's certification, again without one year of full-time radiation safety experience or RSO's certification.

These three groups of individuals can be RSOs by their own board certification without one year of full-time radiation safety experience and RSO preceptor's certification. Why then can't the ABSNM diplomates specializing in nuclear physics and instrumentation, radiopharmaceutical science, and radiation protection be RSOs without one year of full-time radiation safety experience and RSO preceptor's certification?

Let me clarify that ABSNM candidates are required to have three years of professional experience for Ph D. degree holders and five years of professional experience for Masters degree holders and two letters of support from preceptors (one from basic scientist and another from clinical preceptor) to qualify for the examination. Also new regulations for low-level radioactivity are more lenient than the old ones, and radiation safety practice has become more practical and easier. I strongly believe that ABSNM diplomates are highly qualified to be Radiation Safety Officer at any institution, as much as ABNM diplomates, Medical Physicists and Nuclear Pharmacists are

Submitted by

Gopal B. Saha, Ph.D

Director of Nuclear Chemistry & Pharmacy

Cleveland Clinic Foundation

Cleveland, Ohio 44195

216-444-2777

Comment →



## American College of Medical Physics

11250 Roger Bacon Drive, #8 • Reston, Virginia 20190-5202

Phone (703) 481-5001 • Fax (703) 435-4390

[acmp@acmp.org](mailto:acmp@acmp.org)

ACMUI Subcommittee  
United States Nuclear Regulatory Commission  
Washington, DC 20555

June 14, 2002

Re: American College of Medical Physics comment on 10 CFR Part 35 and Training and Education of Authorized Medical Physicists for ACMUI subcommittee hearing June 21, 2002.

Dear ACMUI Committee:

I am writing to you to provide specific comments on behalf of the American College of Medical Physics (ACMP) regarding training and education requirements of the Authorized Medical Physicist (AMP) as published in 10 CFR 35.51, April 2002. The ACMP represents medical physicists who are primarily engaged in clinical practice. The ACMP is dedicated to the profession and the practice of clinical medical physics and our members are actively involved in implementing the technical aspects of radiation therapy treatment involving byproduct sources of ionizing radiation, including quality assurance, safety, delivery and verification of patient treatment.

The ACMP appreciates the action of NRC to delay fulfilling the new training and education requirements of 35.51 until 2 years from the implementation date of the final rule (October 24, 2002). We also appreciate the willingness to accept comment on this important matter.

The ACMP feels that the current wording of 35.51 puts restrictions on the certifying boards that would limit their ability to operate independently and effectively. In addition, requiring the board certification process to include all items in 35.51 paragraph (b) then minimizes the importance of board certification in the practice of medical physics. The ACMP believes that board certification in the appropriate subspecialty (currently ABR and ABMP) constitutes attainment of a demonstrated level of professional, clinical and intellectual competence to independently practice Radiation Oncology clinical physics. The ACMP feels that this should be a necessary condition for an AMP. Further, we would suggest that the specific criteria for recognizing a medical physics certification board be listed in the rule or in a companion guidance document. This should include that diplomates are required:

**Executive Committee:** Michael G Herman, Ph D, Chairman • Kenneth N Vanek, Ph.D, Immediate Past Chairman  
John L. Horton, Ph D., Vice-Chairman, Michael D. Mills, Ph.D., Secretary • James F. Astanta, M.S., Treasurer

**Board of Chancellors:** David S. Gooden, Ph.D., J.D. • Richard A. Keys, M A. • Richard G. Lane, Ph D  
Mary Ellen Masterson-McGary, M A, M S • Lawrence E. Reinstein, Ph.D  
Robert E Rice, M S. • Timothy D Solberg, Ph D. • Martin S Weinhaus, Ph D. • Andrew Wu, Ph.D

**Executive Director:** Lauren Rowland

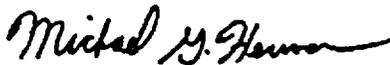
- (1) To hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body
- (2) To have two years of full-time practical training in therapeutic radiological physics or radiation oncology physics experience that
  - (i) is supervised by a medical physicist who is certified in therapeutic radiological physics or radiation oncology physics by an NRC recognized board.
  - (ii) occurs in a clinical radiation oncology facility that provides megavoltage external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 35.400 or 35.600
- (3) To successfully pass an examination administered by diplomates of the certification board in question that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery.

The ACMP believes that the statement *recognized by the Commission or an agreement state* is too broad, in that every agreement state could develop independent and potentially inconsistent criteria for recognizing certifying boards. The ACMP feels that recognition by an agreement state should be deleted.

The ACMP believes that 35.51 paragraph (b) would be appropriate for individuals who have not pursued and received certification by a recognized board.

Finally, to ensure that modality specific training and education occurs for any pathway to AMP, an additional requirement could include supplementary medical physicist training acquired through participation in vendor-supplied or AMP directed training for the modality in which AMP status is being requested.

Sincerely,



Michael G. Herman, Ph.D., FACMP  
Chairman, American College of Medical Physics

Comment # 3

6/14/02

June 14, 2002

ACMUI Subcommittee  
Nuclear Regulatory Commission

*Sent Via Email (2 pages)*

Dear Subcommittee:

Ms. Linda Psyk invited the American Board of Nuclear Medicine (ABNM) to comment on the proposed final rules under 10 CFR Part 35 - Medical Use of Byproduct Material. The NRC rules address the issue of public safety in regard to physician use of radioactive drugs and indirectly, the critical issue of public confidence that physicians using radioactive drugs are using them in a safe and competent manner. It is important both for patient care and NRC credibility that the final rules make a clear distinction between (1) the training required to handle radioactive material in a safe manner so that patients and members of the public are not exposed to unnecessary or dangerous levels of radiation and (2) the clinical competence and training required to perform a diagnostic procedure or treat a cancer patient using unsealed sources. A superficial reading of the rules might allow an observer to conclude, for example, that 700 hours of training and the supervised administration of > 33 mCi of I-131 to 3 patients certifies that the physician is competent to evaluate and treat a patient with thyroid cancer. In fact, this low level of training only ensures that the physician can administer radioiodine without exposing the public and medical staff to unnecessary radiation; it does not begin to be adequate to treat a patient with thyroid cancer. To avoid the potential confusion between clinical competency and competency in radiation safety, the final rules need a more forceful statement indicating that the NRC regulations are designed to ensure that physicians handling radioactive material will do so in a safe and responsible manner that will not endanger the public. The final rules need an equally clear and forceful statement that the NRC regulations are not designed to address the issue of which physicians are clinically competent to perform these procedures. The NRC is not equipped to determine clinical competence and the issue of clinical competence is beyond the NRC mandate.

The ABNM would like to reiterate its position stated in a previous letter to Mr. Cool of the NRC dated July 10, 2000 concerning the recognition of boards whose diplomates automatically fulfill the training and experience requirements for authorized use of byproduct materials. The American Board of Nuclear Medicine 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 67 nuclear medicine residency training programs. All nuclear medicine training programs are monitored and routinely audited by the Accreditation Council on Graduate Medical Education (ACGME).

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*. The two years of training are highly structured educational programs that encompass both basic science and clinical instruction. Basic science instruction substantially exceeds 200 hours of didactic instruction and includes the following areas: radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology and radiation dosimetry. In addition, during the two year training program, residents receive far more than 700 hours of training and supervised 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, the candidate must have a letter from the program director (preceptor) that the candidate has completed two years of training and satisfied all the requirements of the residency training program. Furthermore, the residency program is supervised and reviewed by the Residency Review Committee of the ACGME; consequently, both the NRC and the American public can be confident that a candidate who has completed a certified nuclear medicine residency program and passed a rigorous eight hour ABNM exam is well trained and competent to use radioactive materials in the clinical environment.

Accordingly, the ABNM requests that the NRC continue 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 continue 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,

Andrew T. Taylor, Jr., M.D.  
Chairman  
American Board of Nuclear Medicine

**Statement of William Van Decker, MD, Chairman of the ACC/ASNC/SCAI Joint Task Force on Nuclear Regulatory Commission (NRC) Regulations to the ACMUI Subcommittee on Training and Experience Requirements, June 21, 2002**

On very short notice, the ACC/ASNC/SCAI / Joint Task Force on NRC Regulations, would like to submit some preliminary comments on the charge and potential "options" to be discussed by the ACMUI subcommittee re: Training and Experience in Revised 10CRF35 (a final rule published in the Federal Register on April 24, 2002 with an effective date of October 24, 2002).

First, all three societies appreciate the opportunity to have participated in a variety of workshops, ACMUI presentations, and informal interactions with the NRC over the past approximately six years that this rule and its guidance/inspection have been open to public comment and the rule making process. We believe that a wide variety of viewpoints were expressed and the rule that was constructed represents the prevailing philosophy of those discussions. However, we also note that the prolonged process opens the opportunity for parties to disconnect from prior intense discussions or to seek last second modifications with less careful thought.

We are thankful that the rule and the apparent recent discussions reaffirm the principle of equal access to medical isotope use by a variety of physicians/health professionals on a radiation safety basis. We are grateful that the recognized time of training for authorized usership is now more consistent with a risk informed/performance based philosophy. We are pleased that the NRC has recognized the Certification Board of Nuclear Cardiology (CBNC) as a board whose requirements for admission meet 10CFR Part 35 requirements to serve as an authorized user for diagnostic use of medical isotopes for imaging and localization. We are pleased the rule views intravascular brachytherapy as an "evolving medical treatment composed of diverse technologies" (Federal Register, April 24, 2002, page 20322) whose T&E will need to be evaluated as the field develops. It is only with open, flexible vision that we can create new medical paradigms to promote patient health care (the bottom line of performance based/outcome philosophy).

**We have serious reservations about proposals that have been submitted for the subcommittee's discussion on T&E criteria:**

1. T&E has already been discussed for many years and everyone has had a prior opportunity to express their viewpoint. Last minute changes to an already published rule are inappropriate unless there is widespread discussion and agreement. We do not understand the basis for reopening the discussion on training and experience for nuclear cardiology and adding a new section. What is the rationale for this addition? Nuclear cardiology is addressed in the April 24, 2002 rule in section 35.290. There is no need to have a new separate section.

2. Moving deemed board certification back into the rule is contrary to the NRCs reasoning in removing the boards in the first place. The NRC wants to avoid the situation in which a new rulemaking procedure would have to be undertaken whenever a new board is approved. If the rule changed every 30 years, it becomes very restrictive to new medical paradigms that may arise to promote patient care in the future. Is this change being proposed as an addition to the NRC's method of reviewing a board and adding it to the web site or is it a substitution for the policy that will take effect on October 24, 2002? Additionally, the NRC is not a regulator of the practice of medicine: other regulatory bodies do this. The stated goal of the NRC was to accept reasonable criteria for safe authorized usership that would allow equal access to a variety of physicians/patients. Physicians do not have the right to practice medicine on the basis of authorized usership. AU is only a vehicle for physicians to apply isotopes to patient care.
3. Examinations were discussed in great detail during the comment period. In the USA, there must always be an alternative pathway to qualifications to avoid anti-trust considerations. The NRC has not been willing due to manpower issues to be involved in either testing for all physicians or testing for the alternative pathway (which would have to be kept consistent). We understand the logistical problem of this issue and understand how preceptor papers come to play a role.
4. We note that preceptor papers have been used effectively in the past.

We thank you for your consideration of these very initial comments. We will take the opportunity to submit further comments as the discussion develops.

We appreciate the effort your agency has put into this process...

**Statement of James E. Udelson, MD, Vice President, Certification Board of Nuclear Cardiology, to the ACMUI Subcommittee on Training and Experience Requirements, June 21, 2002**

The Certification Board of Nuclear Cardiology (CBNC) was founded in 1996. CBNC is a not-for-profit corporation established to develop and administer practice-related examinations in the field of Nuclear Cardiology and to award certification to those physicians who successfully complete the CBNC examination process. CBNC is a fully autonomous entity, independent of any other association, society, or academy. This independence allows the CBNC to maintain integrity concerning policy matters related to certification. The CBNC will issue a certificate to successful candidates who then may present themselves to the public as specialists in the field of Nuclear Cardiology. To date there are 2,219 physicians certified by the CBNC.

Eligibility requirements to sit for the Certification Board of Nuclear Cardiology include: (1) a current unconditional, unrestricted license to practice medicine; (2) board certification by a board which holds membership in either the American Board of Medical Specialties, or the Bureau of Osteopathic Specialists of the American Osteopathic Association and (3) training and experience in the provision of nuclear cardiology services verified by a letter signed by a preceptor authorized user who meets the NRC requirements in Part 35.290 or equivalent Agreement State requirements. The letter must state: (A) that the candidate's training and experience in nuclear cardiology meets the requirements outlined in the ACC/ASNC/COCATS Guidelines and (B) that the candidate has "achieved a level of competence sufficient to function independently as an authorized user for medical uses authorized under NRC Subpart E-Imaging and localization."

On May 21, 2002 the Certification Board of Nuclear Cardiology was informed by John W.N. Hickey, Chief, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards that its certification process met the "new requirements in section 35.290" of the new 10 CFR Part 35. Accordingly, CBNC would be included on the web site list of boards which have been recognized by the NRC.

The CBNC was very careful to meet the NRC's new 10 CFR Part 35 requirements for certification which include all requirements in the alternate pathway including specified numbers of hours of training and written certification signed by a preceptor that the individual has satisfactorily completed the training requirement and has achieved a level of competency sufficient to function independently as an authorized user. Therefore the CBNC expresses its surprise that it has been included in proposals circulated for discussion at this subcommittee meeting. Because it has already met the requirements of 10 CFR Part 35 and has been recognized by the NRC there is no logical reason why the CBNC should be part of any of the discussions of this subcommittee. The CBNC

strongly opposes the draft proposal submitted for sections 35.190, 35.290, and 35.291. The board urges the subcommittee to drop all references to the CBNC in this proposal.

Furthermore the CBNC strongly opposes this draft proposal because it would place the boards in the text of the rule, a position that runs counter to the position of the NRC in the new 10 CFR Part 35 published in the Federal Register on April 24, 2002. This proposal is a step backward to the discredited past. The NRC struck the enumeration of specific boards from the rule for very good reasons. That part of the proposal clearly is unnecessary paperwork and creates the need for onerous rulemaking procedures whenever a new board is approved. The CBNC calls upon the subcommittee to strike all mention of any boards from any proposal submitted to the full ACMUI.

The CBNC also strongly opposes the new Section 35.291 which creates an entirely new section solely for nuclear cardiology. What is the purpose of this section? It is totally redundant. Nuclear cardiology is covered in 35.290 of the new rule and should remain there.

In conclusion, CBNC recommends that the subcommittee remove all consideration of its status as redundant, unnecessary, and duplicative. The CBNC also urges the subcommittee to strip all mention of specific boards from any proposal it submits to the full ACMUI. Finally, CBNC calls for removal of the proposed section 35.291 as completely unnecessary.

Comment #6

6/17/02

**From:** "Pamela Smith, American Osteopathic College of Radiology" <aocrps@nemr.net>  
**To:** <Imp1@nrc.gov>  
**Date:** 6/17/02 12:09PM  
**Subject:** NRC

June 14, 2002

Linda M Psyk

U.S. Nuclear Regulatory Commission

Two White Flint North, Mail Stop T8F5

11545 Rockville Pike

Rockville, MD 20852-2738

Dear Ms. Psyk

Thank you for notifying the American Osteopathic Board of Radiology (AOBR) that the Nuclear Regulatory Commission will be convening a meeting of the Subcommittee of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on June 21, 2002, to discuss its recommendations related to the training and experience of authorized users in the revised 10 CFR Part 35, Medical Use of Byproduct Material, published on April 24, 2002.

The AOBR will be represented at this meeting by Paul J. Chase, DO, Cherry Hill, New Jersey. He will participate in the discussion and answer any questions relating to training or experience of diplomates of the American Osteopathic Board of Radiology and the American Osteopathic Board of Nuclear Medicine

In reviewing the published regulations, we have noted a few areas in which we recommend revision. These revisions represent "housekeeping corrections" and I am not sure if the appropriate venue is the subcommittee or if they can be handled internally.

Specifically, the AOBOR has recommended revisions to:

- 1) Clarify the certificate(s) of certification that qualify under the specific regulations (35.930)
- 2) List radiation therapy as well as radiation oncology to recognize the diplomates receiving certificates prior to the certificate name change and list certification in radiology with the listings of radiation oncology and radiation therapy. Diplomates certified in radiology were trained and examined in radiation therapy. You will note that all listings for the American Board of Radiology also list these certifications (35.940, 35.950, and 35 960)
- 3) List the American Osteopathic Board of Nuclear Medicine in two sections where we believe it was inadvertently omitted (35 930 and 35.950)

These revisions were prepared to submit in 1998; however, our representatives at the NRC Medical Rulemaking Workshops in 1998 had the understanding that references to the Examination Boards were to be eliminated in the revision process. The new regulations include identification of qualifying certification boards and we would like to submit the revisions at this time

I have listed our recommendations for revisions on the attached sheet. We would appreciate your advice as to the appropriate manner in which to submit them for consideration

Sincerely

Pamela A Smith

Executive Director

AMERICAN OSTEOPATHIC BOARD OF RADIOLOGY

Recommended Revisions to 10 CFR Part 35, Medical Use of Byproduct

Material, published on April 24, 2002

Page 20390 - 35.930 Training for therapeutic use of unsealed byproduct material

(a)

(4) The American Osteopathic Board of Radiology in radiology, radiation therapy or radiation oncology,

(5) The American Osteopathic Board of Nuclear Medicine;

Page 20391 - 35.940 Training for use of brachytherapy sources

(a)

(2) Radiology, radiation therapy or radiation oncology by the American Osteopathic Board of Radiology

Page 20391 - 35 950 Training for use of sealed sources for diagnosis

(a)

(3) Diagnostic radiology, radiology, radiation therapy or radiation oncology

(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine

Page 20392 - 35 960 Training for use of therapeutic medical devices

(a)

(2) Radiology, radiation therapy or radiation oncology by the American

Osteopathic Board of Radiology

Comment # 7

**From:** "Bertin, Richard" <rbertin@aphanet.org>  
**To:** "Imp1@nrc.gov" <imp1@nrc.gov>  
**Date:** 6/18/02 11:31AM  
**Subject:** ACMUI Meeting

Ms. Psyk,

Below is a statement that BPS would like to have considered in the deliberations of the ACMUI this coming Friday. I have also received the draft recommendations you faxed to us, and sent copies to Richard Fejka (who will represent BPS at the meeting) and Stephen Dragotakes. Both are officers of the BPS Specialty Council on Nuclear Pharmacy.

I really appreciate the assistance you have provided to us in this process  
Dick Bertin

Richard J Bertin, PhD, RPh  
Executive Director, Board of Pharmaceutical Specialties  
2215 Constitution Avenue, NW  
Washington, DC 20037-2985  
202-223-7192, FAX 202-429-6304  
rbertin@aphanet.org (Please note new address)  
www.bpsweb.org

To ACMUI Subcommittee

The Board of Pharmaceutical Specialties (BPS) requests that its process culminating in certification as a Board Certified Nuclear Pharmacist be an acceptable alternative to submission of the preceptor statement as required in 35.55(b)(2). Eligibility to sit for the BPS examination includes the requirement for 4000 hours of training/experience in nuclear pharmacy practice in specified learning/work situations. The rigorous BPS written specialty examination in nuclear pharmacy, developed as a psychometrically sound, legally defensible certification tool, has the following content/examination specifications:

- Procurement (6% of the examination)
- Compounding (20%)
- Quality Assurance (15%)
- Dispensing (20%)
- Distribution (5%)
- Health and Safety (15%)
- Provision of Information & Consultation (15%)
- Monitoring Patient Outcomes (2%)
- Research & Development (2%)

BPS believes that achieving a passing score on this examination, in addition to completing the eligibility requirements, meets or exceeds the standards of competency to function independently as an authorized nuclear pharmacist that would be achieved by the proposed ANP preceptor statement. It is important to note that Health and Safety constitutes a significant portion of the BPS exam, and the majority of those questions, as well as some in other sections, relate directly to radiation safety

The quality of the standards and processes of the Board of Pharmaceutical Specialties in administering its five specialty certification programs have been recognized by several federal entities, including the Department of Defense (U.S. Army, U.S. Navy, U.S. Air Force), the U.S. Public Health Service, and the Department of Veterans Affairs in qualifying certified pharmacists for monetary benefits under their compensation systems

CC: "Stephen C. Dragotakes (dragotakes stephen@mgh.harvard.edu)" <dragotakes stephen@mgh.harvard.edu>, "Richard Fejka (rf67v@nih.gov)" <rf67v@nih.gov>

## Certification Board Correspondence

### Attached Handouts:

1. NRC letter to Board of Pharmaceutical Specialties, dated May 16, 2002.  
BNC letter to D. Cool, dated September 7, 2000.
2. NRC letter to Certification Board of Nuclear Cardiology, dated May 21, 2002.  
CBNC letter with attachment to D. Cool, dated November 9, 2000.
3. NRC letter to American Board of Science in Nuclear Medicine, dated May 21, 2002.  
ABSNM letter to D. Cool, dated December 6, 2000.
4. NRC letter to American Board of Health Physics, dated May 21, 2002.  
ABHP letter with attachments to D. Cool, dated July 20, 2001.
5. NRC letter to American Board of Nuclear Medicine, dated May 30, 2002.  
NRC letter to American Board of Nuclear Medicine, dated June 29, 2001.  
ABNM letter to D. Cool, dated November 29, 2000.  
ABNM letter to D. Cool, dated July 10, 2000.
6. NRC letter to American Board of Medical Physics, dated May 31, 2002.  
ABMP letter with attachment to D. Cool, dated September 28, 2001.  
ABMP e-mail to Sam Jones, dated October 25, 2000.  
ABMP letter to D. Cool, dated July 20, 2000.
7. Commissioner Meserve letter to W. Hendee, American Board Radiology, dated May 3, 2001.



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

May 16, 2002

Board of Pharmaceutical Specialties  
ATTN: Richard J. Bertin, PhD, RPh, Executive Director  
2215 Constitution Avenue, NW  
Washington, DC 20037-2985

Dear Dr. Bertin:

I am responding to your letter of September 7, 2000, requesting Commission recognition of the Board of Pharmaceutical Specialties (BPS) certification process, under the new 10 CFR 35.55 "Training for an authorized nuclear pharmacist" (ANP), and under 10 CFR 35.50, "Training for Radiation Safety Officer".

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](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](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 BPS in 10 CFR 35.900 and 35.980 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.

Under 10 CFR 35.55(a), an individual may be designated as an authorized nuclear pharmacist if he or she is certified by a specialty board whose certification includes all of the training and experience (T&E) requirements contained in section 35.55(b), and whose certification has been recognized by the Commission or an Agreement State. These requirements include 700 hours of training in a structured educational program consisting of both didactic training and supervised practical experience in nuclear pharmacy. In addition, each board diplomate must have obtained written certification, signed by a preceptor authorized nuclear pharmacist, has satisfactorily completed the required 700 hours of training cited previously and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

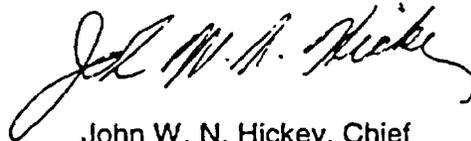
We have reviewed the information provided in your letter of September 7, 2000, requesting recognition of BPS's certification process, along with the information provided in your "BPS - Candidate's Guide" on your web site for compliance with our requirements for board recognition under §35.55(a). Based on our review, it appears that your board's certification requirements meet the requirements contained in §35.55(b)(1). However, there is no indication that the BPS requires the submission of the preceptor statement as required in §35.50(b)(2). Therefore, we request that you provide us with clarification as to whether the preceptor statement is required, and whether the preceptor must be an ANP under the definition of the Rule.

With respect to qualifications for RSOs, under the provisions of 10 CFR 35.50(a), the NRC staff cannot confirm whether the BPS certification process meets any of the requirements in 35.50(b). Therefore, you need to provide us with information which addresses whether the board certification process requires: (1) 200 hours of didactic training in the areas specified in 35.50(b), (2) one year of full-time radiation safety experience under the supervision of an individual identified as an RSO on a Commission or Agreement State license that authorizes similar types of medical uses, and (3) written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the 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. However, under the provisions of 10 CFR 35.50(c), persons named as ANPs on a NRC or Agreement State license can be named as RSOs for programs using similar types of byproduct materials for which they have radiation safety experience.

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.

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

# **bps** Board of Pharmaceutical Specialties

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September 7, 2000

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

Dear Mr. Cool:

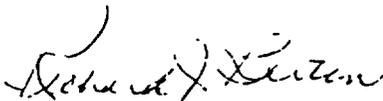
The Board of Pharmaceutical Specialties (BPS) thanks you for the opportunity to respond to the NRC for recognition of our organization in its process to recognize pharmacists as specialists in the practice of nuclear pharmacy.

Through requirements established by our Nuclear Pharmacy Specialty Council, including eligibility criteria and our written examination process, we grant the credential Board Certified Nuclear Pharmacist (BCNP) to qualified licensed pharmacists. Before receiving this recognition, each candidate must submit proof of being a licensed pharmacist, have completed a minimum of 4000 hours of training and experience in the field of nuclear pharmacy, and have passed the rigorous written BPS examination. In order to retain certification, a BCNP must also meet defined recertification requirements.

The Board of Pharmaceutical Specialties has reviewed 10 CFR 35.50 *Training for Radiation Safety Officer* and 10 CFR 35.55 *Training for an authorized nuclear pharmacist* and determined that our certification process requires an individual to meet all the requirements in paragraph (b) of these sections prior to being certified by our board.

If you have any further questions, please contact me at 202-223-7192 or [rjb@mail.aphanet.org](mailto:rjb@mail.aphanet.org).

Sincerely,



Richard J. Bertin, PhD, RPh  
Executive Director



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20655-0001

May 21, 2002

Certification Board of Nuclear Cardiology  
ATTN: Dr. Ami E. Iskandrian, M.D., President  
9111 Old Georgetown Road  
Bethesda, MD 20814

Dear Dr. Iskandrian:

I am replying to your letter dated November 9, 2000, to Donald Cool, requesting formal recognition, under the new 10 CFR Part 35, "Medical Use of Byproduct Material", for the Certification Board of Nuclear Cardiology (CBNC) diplomates.

In your letter of July 10, 2000, you stated that the CBNC certification process meets all of the requirements of subsection §35.290 "Training for imaging and localization studies" of the new 10 CFR Part 35.

We have reviewed your request, and concluded that the CBNC certification process, as described in your letter and your board's application requirements, does meet the new requirements in §35.290. We plan to list on our web site the boards which have been recognized. We will include CBNC on that list.

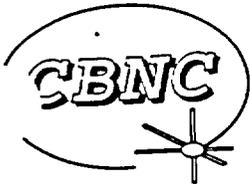
In a follow-up telephone query, your Executive Director asked whether the preceptors identified in 35.290 need to be authorized users for uses authorized under 35.100 and 35.190. The answer is no. The preceptors and preceptor statements do not need to cover 35.100, because the scope of the CBNC recognition request and certification process is limited to uses under 35.200.

If you have any questions, please contact Dr. Robert Ayres at 301-415-5746 or e-mail at [rx1@nrc.gov](mailto:rx1@nrc.gov).

Sincerely,

A handwritten signature in black ink that reads "John W. N. Hickey".

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



certification board  
Date: 11/9/2000  
11:51:3  
CT

# Certification Board of Nuclear Cardiology

9111 Old Georgetown Road Bethesda, MD 20814 Phone: (301) 493-2360 Fax (301) 493-2376

November 9, 2000

## BOARD OF DIRECTORS

Representing the American  
Society of Nuclear Cardiology

Jeffrey S Borer, MD

Manuel D Cerqueira, MD

E. Gordon DePuey, MD

Ami E. Iskandrian, MD

Steven C Port, MD

Frans J Th Wackers, MD, PhD

Barry L Zaret, MD

Jack A Ziffer, MD, PhD

Representing the American  
College of Cardiology

James E Udelson, MD

---

William D Nelligan, CAE  
Executive Director

Dr. Donald Cool, Director  
Office of Nuclear Material Safety & Safeguards  
Nuclear Regulatory Commission  
Washington, DC 20555-0001

Dear Dr. Cool:

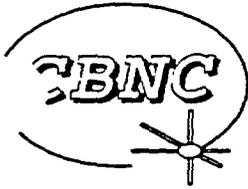
The Certification Board of Nuclear Cardiology is pleased to submit evidence that it meets the requirements for recognition by the NRC relative to "Training Requirements for Which NRC Plans to Recognize Board Certification" as announced in the Federal Register, November 2, 2000.

We have carefully reviewed the requirements for Training and Experience required in *Section 35.290, Training for imaging and localization studies* of NRC's medical use regulations in 10 CFR Part 35. To be eligible to sit for the exam given by our Board, all candidates must have completed the training and experience required in this section. We will be glad to supply NRC with a list of those physicians who successfully pass the exam. To date, there are 1,574 who have passed the exam. There will be an additional number by January 1, 2001 as our most recent exam was given on October 29, 2000.

Attached is a copy of Requirement 3 of the "Eligibility Requirements for US Candidates" who wish to sit for our certification examination. This pertains solely to Training/Experience. Also attached is a copy of the current American College of Cardiology/American Society of Nuclear Cardiology COCATS Guidelines which are referenced in Requirement 3.

By way of additional background relative to our exam, a national survey of experts in the field of nuclear cardiology periodically defines the knowledge areas appropriate for this exam. This forms the basis for the exam content area which we share with candidates in the Candidate Bulletin.

Formerly Certification Council of Nuclear Cardiology



## Certification Board of Nuclear Cardiology

9111 Old Georgetown Road Bethesda, MD 20814 Phone (301) 493-2360 Fax (301) 493-2376

PAGE TWO

### BOARD OF DIRECTORS

#### Representing the American Society of Nuclear Cardiology

Jeffrey S Borer, MD

Manuel D Cerqueira, MD

E. Gordon DePuey, MD

Ami E. Iskandran, MD

Steven C Port, MD

Frans J Th Wackers MD, PhD

Barry L Zaret, MD

Jack A. Ziffer, MD, PhD

#### Representing the American College of Cardiology

James E. Udelson, MD

---

William D Nelligan, CAE  
Executive Director

The examination is composed of 175-200 multiple-choice questions. Each question contains four options or choices, only one of which is the correct or best answer.

The examination questions are developed by the CBNC Examination Committee, an expert panel of the CBNC who work under the guidance of Knapp & Associates International, Princeton, NJ. The examination question pool is updated on a regular basis to reflect current knowledge. Individual questions are modified or deleted based on statistical analysis of the exam.

Knapp & Associates International is a research and development firm that serves certification bodies by planning, developing and administering assessment procedures and programs designed to measure professional competence.

We look forward to hearing from you relative to our request for recognition by the NRC. If we can supply your office with any additional details, please do not hesitate to let us know.

Sincerely,

Ami E. Iskandrian, M.D., President  
Certification Board of Nuclear Cardiology

# COCATS GUIDELINES

## AMERICAN COLLEGE OF CARDIOLOGY / AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY COCATS GUIDELINES FOR TRAINING IN NUCLEAR CARDIOLOGY

### Overview of Nuclear Cardiology Training

Training in nuclear cardiology at all levels should provide an understanding of the indications for specific nuclear cardiology tests, the safe use of radionuclides, basics of instrumentation and image processing, methods of quality control, image interpretation, integration of risk factors, clinical symptoms and stress testing and the appropriate application of the resultant diagnostic information for clinical management. Training in nuclear cardiology is best acquired in Accreditation Council for Graduate Medical Education (ACGME) approved training programs in cardiology, nuclear medicine or radiology. An exception to this ACGME requirement is the didactic and laboratory training in radiation safety and radioisotope handling that may be provided by qualified physicians/scientists in a non-ACGME program when such a program is not available as part of the clinical ACGME training program.

Didactic, clinical case experience and hands-on training hours require documentation in a logbook, having the trainee's name appear on the clinical report or other specific record. The hours need to be monitored and verified by the nuclear cardiology training preceptor.

### Specialized Training - Level 2 (Minimum of 4 Months)

Fellows who wish to clinically practice the specialty of nuclear cardiology are required to have at least 4 months of training. This includes a minimum of 700 hours of didactic, clinical study interpretation and hands-on clinical case and radiation safety training in nuclear cardiology. In training programs with a high volume of procedures, clinical experience may be achieved in as short a period as 4 months. In programs with a lower volume of procedures, a total of 6 months of clinical experience will be necessary to achieve Level 2 competency. The additional training required of Level 2 trainees is to enhance clinical skills and to qualify to become an authorized user of radioactive materials in accordance with the regulations of the Nuclear Regulatory Commission (NRC) and/or the Agreement States. Requirements do vary among the Agreement States; therefore those seeking licensure are advised to check the Agreement State/NRC internet web site at: <http://www.hsrsl.ornl.gov/nrc/home.html>.

### Didactic

**Lectures and self-study.** The didactic training should include in-depth details of all aspects of the procedures listed in Table 1 (see below). This program may be scheduled over a 12- to 24-month period concurrent and integrated with other fellowship assignments.

**Radiation Safety.** Classroom and laboratory training needs to include extensive review of radiation physics and instrumentation, radiation protection mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use and radiation biology. There should be a thorough review of regulations dealing with radiation safety for the use of radiopharmaceuticals.

### Interpretation of Clinical Cases

Fellows should participate in the interpretation of all nuclear cardiology imaging data for the 4-6 month training period. It is imperative that the fellows have experience in correlating catheterization/angiographic data with radionuclide-derived data in a minimum of 30 patients. A teaching conference in which the fellow presents the clinical material and nuclear cardiology results is an appropriate forum for such an experience. A total of 300 cases should be interpreted under preceptor supervision either direct patient studies or from a teaching file consisting of diverse set of procedures (see Table 1 below).

### Hands-on Experience

**Clinical Cases.** Fellows acquiring Level 2 training should have hands-on supervised experience in a minimum of 35 patients: 25 patients with myocardial perfusion imaging and 10 patients with radionuclide angiography. Such experience should include pretest patient evaluation, radiopharmaceutical preparation (including experience with relevant radionuclide generators), performance of the study, administration of the dosage, calibration and setup of the gamma camera, setup of the imaging computer, processing the data for display, interpretation of the studies and generating clinical reports.

**Work Experience.** This experience must be under the supervision of an authorized user who meets the NRC requirements of Part 35.290 or 35.390 or equivalent Agreement State requirements, and must include:

- a) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys,
- b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters,
- c) Calculating, measuring and safely preparing patient or human research subject dosages,
- d) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material,
- e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures,
- f) Administering dosages of radioactive drugs to patients or human research subjects; and
- g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity and processing the eluate with reagent kits to prepare labeled radioactive drugs.

### Additional experience

In addition, the training program for Level 2 training must provide experience in computer methods for analysis. This should include perfusion and functional data derived from thallium or technetium agents and ejection fraction and regional wall motion measurements from radionuclide angiographic studies.

Table 1.  
Classification of Nuclear Cardiology Procedures

- 1) Standard nuclear cardiology procedures
  - a) Myocardial perfusion imaging
    - i) Single photon emission computed tomography (SPECT) with technetium agents and thallium
    - ii) Planar with technetium agents and thallium
    - iii) ECG gating of perfusion images for assessment of global and regional ventricular function
    - iv) Imaging protocols
      - 1) Stress protocols
        - (1) Exercise stress
        - (2) Pharmacologic stress
      - vi) Viability assessment including reinjection and delayed imaging of thallium and metabolic imaging where available
    - b) Equilibrium gated blood pool or "first pass" radionuclide angiography at rest and during exercise or pharmacologic stress
    - c) Qualitative and quantitative methods of image display and analysis
  - 2) Less commonly used nuclear cardiology procedures
    - a) Metabolic imaging using single photon and/or positron emitting radionuclides
    - b) Myocardial infarct imaging
    - c) Cardiac shunt studies

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## **ELIGIBILITY REQUIREMENTS FOR UNITED STATES CANDIDATES**

### **Requirement 1: Licensure**

Applicants must hold a current, unconditional, unrestricted license to practice medicine at the time of application and must provide a copy of the current license. If the license is due to expire prior to the date of the exam and renewal is pending, the applicant must submit evidence that he/she holds a renewed license prior to sitting for the exam.

### **Requirement 2: Board Certification**

Applicants must be physicians who, at the time of application, are Board Certified by a board which holds membership in either the American Board of Medical Specialties, or the Advisory Board for Osteopathic Specialists of the American Osteopathic Association.

### **Requirement 3: Training/Experience in the provision of Nuclear Cardiology Services**

- **If you have completed formal training in nuclear cardiology in a cardiology fellowship, you must submit:**  
Written certification, signed by a preceptor authorized user who meets the NRC requirements in Part 35.290 or 35.390 or equivalent Agreement State requirements, that you have satisfactorily completed all requirements as outlined in the American College of Cardiology/American Society of Nuclear Cardiology COCATS Guidelines on page 13 of this Bulletin. The statement must also certify that you have achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under NRC Part 35.100 and 35.200.
- **If you have not completed formal training in nuclear cardiology in a cardiology fellowship, you must submit:**  
Written certification, signed by a preceptor authorized user who meets the NRC requirements in Part 35.290 or 35.390 or equivalent Agreement State requirements, that you have satisfactorily completed at least 700 hours of didactic training or work experience which includes radiation safety, interpretation of clinical cases and hands-on experience as outlined in the American College of Cardiology/American Society of Nuclear Cardiology COCATS Guidelines on page 13 of this Bulletin. The statement must also certify that you have achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under NRC Part 35.100 and 35.200.
- **If you have completed a residency in nuclear medicine or radiology, you must submit:**  
Written certification, signed by a preceptor authorized user who meets the NRC requirements in Part 35.290 or 35.390 or equivalent Agreement State requirements, that your training and experience is equivalent to Level 2 Training in Nuclear Cardiology as recommended in the American College of Cardiology/American Society of

Nuclear Cardiology COCATS Guidelines on page 13 of this Bulletin. The statement must also certify that you have achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under NRC Part 35.100 and 35.200

- **If you have completed a residency/fellowship in a specialty other than cardiology, nuclear medicine or radiology, you must submit the following:**  
Written certification, signed by a preceptor authorized user who meets the NRC requirements in Part 35.290 or 35.390 or equivalent Agreement State requirements, that you have satisfactorily completed at least 700 hours of didactic training or work experience which includes radiation safety, interpretation of clinical cases and hands-on experience as outlined in the American College of Cardiology/American Society of Nuclear Cardiology COCATS Guidelines on page 13 of this Bulletin. The statement must also certify that you have achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under NRC part 35.100 and 35.200.

## **ELIGIBILITY REQUIREMENTS FOR CANDIDATES RESIDING OUTSIDE THE UNITED STATES**

### **Requirement 1: Licensure**

Applicants must hold a current, unconditional, unrestricted license to practice medicine at the time of application and must provide a copy of the current license. If the license is due to expire prior to the date of the exam and renewal is pending, the applicant must submit evidence that he/she holds a renewed license prior to sitting for the exam

### **Requirement 2: Board Certification**

You must submit evidence that you are Board certified. If the country in which you practice does not certify your medical specialty, you must submit a letter stating this fact.

### **Requirement 3: Training/Experience in the provision of Nuclear Cardiology Services**

If you have had formal training in nuclear cardiology, nuclear medicine or radiology, you must submit a statement from your training director stating that this training was equivalent to Level 2 Training in Nuclear Cardiology as recommended in the American College of Cardiology/American Society of Nuclear Cardiology COCATS Training Guidelines [see page 13 of this Bulletin].

If you have not received formal training in nuclear cardiology, nuclear medicine or radiology and wish to qualify through your experience, you must submit a statement from your Division or Laboratory Head [for hospital/institution-based physicians OR a physician colleague [for non-hospital or non-institution-based physicians] - written on organizational letterhead - verifying that your experience was equivalent to Level 2 Training in Nuclear Cardiology as recommended in the American College of Cardiology/American Society of Nuclear Cardiology COCATS Training Guidelines [see page 13 of this Bulletin].



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

May 21, 2002

American Board of Science in Nuclear Medicine  
c/o Society of Nuclear Medicine  
ATTN: Gopal B. Saha, Ph.D.  
Chairperson  
1850 Samuel Morse Drive  
Reston, Virginia 22090-5316

Dear Dr. Saha:

I am replying to your letter, dated December 6, 2000, to Donald Cool, requesting NRC recognition of American Board of Science in Nuclear Medicine (ABSNM) certification under the new 10 CFR Part 35, "Medical Use of Byproduct Material".

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](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](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 ABSNM in 10 CFR 35.900 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.

You stated that the ABSNM certification process meets the certification requirements for NRC recognition of your Board's diplomates, as set forth in the new 10 CFR 35.50(a). In reviewing your Board's certification requirements, it is not clear that your certification process insures that all of the individual training and experience requirements for radiation safety officers (RSOs), as set forth in the new 10 CFR 35.50(b), are met. The two requirements of particular concern are: (1) one year of full-time radiation safety experience under the supervision of a radiation safety officer (RSO) identified on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct materials; and, (2) written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the 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.

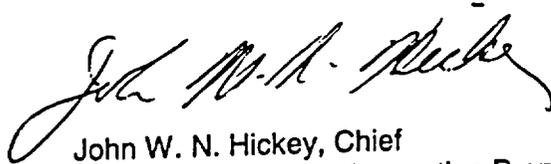
We request that you provide additional information which addresses whether these two criteria are met by the ABSNM certification process. Upon the receipt of this information, we will re-evaluate ABSNM's request for recognition based on the information provided by you.

In addition, the NRC Advisory Committee on Medical Uses 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 in the new Part 35. We would appreciate receiving any such comments by June 24, 2002.

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

Sincerely,

A handwritten signature in black ink, appearing to read "John W. N. Hickey". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

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



# American Board of Science in Nuclear Medicine

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December 6, 2000

Dr. Donald A. Cool  
Director  
Office of Nuclear Material Safety  
and Safeguards  
Nuclear Regulatory Commission  
Washington, DC 20555-0001

Dear Dr. Cool:

Pursuant to Federal Register Vol. 65, No. 213, dated November 2, 2000, pages 65,793-65,797, in 10 CFR part 35, entitled "Medical Use of Byproduct Material-Specialty Boards and Medical Specialty Boards: Solicitation", the American Board of Science in Nuclear Medicine (ABSNM) requests recognition by the NRC as a Specialty Board whose certification of the diplomates meets the training and experience requirements for a Radiation Safety Officer.

The ABSNM has reviewed 10 CFR 35.50 and has determined that its certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by the ABSNM. The ABSNM has been included in 10 CFR 35 as a Specialty Board whose diplomates are considered qualified to be Radiation Safety Officers under NRC regulations. Therefore, we request that under the new regulations, the ABSNM be included on the NRC web site as a Specialty Board whose diplomates would be eligible for certification as a Radiation Safety Officer by the NRC.

Thank you for your consideration.

Gopal B. Saha, Ph.D.  
President



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

May 21, 2002

American Board of Health Physics  
ATTN: Edward F. Maher, Sc.D., CHP  
Chairperson  
1313 Dolly Madison Boulevard, Suite 402  
McLean, Virginia 22101

Dear Dr. Maher:

I am replying to your letter dated July 20, 2001, to Donald A. Cool, requesting NRC recognition of the American Board of Health Physics (ABHP) certification under the new 10 CFR Part 35, "Medical Use of Byproduct Material".

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](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](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 ABHP in 10 CFR 35.900 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.

You requested recognition of the ABHP certification process, because you believe that the ABHP meets the intent of the new 10 CFR 35.50 (a) and (b). The two requirements of concern are: (1) one year of full-time radiation safety experience under the supervision of a radiation safety officer (RSO) identified on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct materials; and, (2) written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the 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.

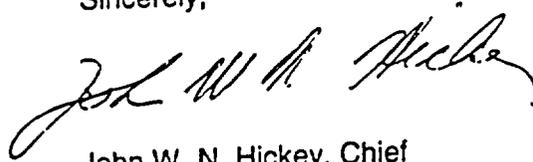
We have evaluated your request and have concluded that the ABHP certification process, does not meet either the intent or letter of these requirements. The intent of the new regulation is to ensure that the RSO has training and experience with the types of medical uses for which he or she has RSO responsibilities, and to require written certification by a preceptor RSO. Your certification process does not meet either of these requirements.

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.

Note that an individual, whether certified by ABHP or not, can still be authorized as an RSO, if the individual meets the criteria specified in the new §35.50(b) or (c).

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

Sincerely,

A handwritten signature in cursive script, appearing to read "John W. N. Hickey".

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

cc: Mr. Richard J. Burke, Jr.



# American Board of Health Physics

1313 Dolley Madison Boulevard • Suite 402 • McLean, Virginia 22101  
Telephone: (703) 790-1745 • FAX (703) 790-2672 • E-Mail. AAHP@BurkInc.com

July 20, 2001

Dr. Donald A. Cool  
Division of Industrial and Medical Nuclear Safety  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Subject: RECOGNITION OF BOARDS

Dear Dr. Cool

The American Board of Health Physics (ABHP) has reviewed the revised 10 CFR 35.50 (Training for Radiation Safety Officer) and has determined that our Board Certification process meets the intent of regulation. We believe that individuals who hold ABHP certification will have met equivalent requirements to those listed in paragraph (b) of the revised 10 CFR 35.50. The ABHP respectfully requests that the NRC make an exception to the literal interpretation of this section and recognize ABHP Certification as *prima facie* evidence that the revised preceptor and didactic requirements for Radiation Safety Officer have been satisfied.

We support this request by comparing ABHP certification requirements with the training requirements for the Radiation Safety Officer under revised 10 CFR Part 35.50, paragraph (b). Attachment I contains excerpts from the ABHP Policy Manual and Prospectus that are provided to each applicant for Part I or II of the ABHP certification examination. These excerpts delineate all the mandatory requirements to be certified by the ABHP. These requirements include academics, work experience, demonstrated professional work, and examination testing. The latter requirement consists of two separate examinations, the first exam (150 question multiple choice) tests technical knowledge of health physics, whereas the second exam (essay format) tests practical, problem-solving application of health physics under "real world" scenarios.

In the mid-1980s, the ABHP performed an exhaustive role delineation study of what a typical health physicist does to perform his/her job under the direction of the Professional Examination Service. As a result of this study, five main categories (Domains of Practice) were selected based on subject matter. Since the goal of any job-related examination is to test the candidate on the information required to perform their job, the ABHP (in 1986) selected questions for their examinations that reasonably approximated the same breakdown as the percentages associated with each of the five Domains of Practice. Attachment II is a complete listing of these Domains of Practice, as well as the work activities described in the subcategories. In accordance with the ABHP Policy Manual, the Board is required to develop each examination using the Domains of Practice metrics.

Attachment III is a comparison of ABHP certification requirements with those contained in the revised 10 CFR Part 35.50. It is our intent and sincere hope that this comparison demonstrates to the NRC that ABHP Certification meets the full intent of the revised 10 CFR 35.50 and ensures the quality of Radiation Safety Officers with appropriate protection to patients, staff, and the general public.

We believe that ABHP certification in comprehensive practice prepares the individual to assume the duties and responsibilities of the Radiation Safety Officer, regardless of the occupational setting, and types, quantities and uses of byproduct materials. The ABHP's forty-one years of certification experience and our Code of Professional Responsibilities (Attachment IV) are further assurances that ABHP certification should be recognized as *prima facie* evidence of meeting the requirements of the revised 10 CFR 35.50.

Please contact me at (978) 568-2785 or at e-mail address: [efmaner@dukeengineering.com](mailto:efmaner@dukeengineering.com) if you require any clarifications regarding our response. Thank you for this consideration.

Respectfully Submitted,



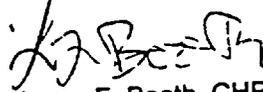
Edward F. Maher, Sc.D., CHP  
Past Chairman  
American Board of Health Physics

APPROVED BY:



Robert P. Miltenberger, CHP  
Chairman  
American Board of Health Physics

APPROVED BY:



Leroy F. Booth, CHP  
President  
American Academy of Health Physics

EFM/mrt

Encl: 4 Attachments

cc: ABHP (N. Johnson)  
HPS (R. Burke Jr.)  
AAHP (C. Rosseler)

## ATTACHMENT I ABHP POLICY MANUAL AND PROSPECTUS EXCERPTS

Candidates for certification must meet the following requirements:

1. **Academics.** An applicant must possess at least a bachelor's degree from an accredited college or university in physical science, engineering, or in a biological science with a minor in physical science or engineering. In lieu of a minor in a physical science or engineering, a candidate for certification may submit evidence of credit from an accredited college or university for course work in physical sciences, engineering, or mathematics equivalent to 20 semester hours.

Applicants shall have satisfied and documented all requirements for degrees claimed by the time application is made for either part of the written examination. Original transcripts must be submitted with the application.

1. **Experience.** An applicant must have at least six years of responsible professional experience in health physics as of July 1 of the year in which the examination is to be taken. At least three years of the experience must have been in applied health physics. The six years of professional experience, which must be documented by an applicant for Part II of the exam, must be experience that demonstrates that the candidate has been required to exercise judgment in one, or more, of the following:

- establishment and/or evaluation of a radiation protection program
- design and/or the evaluation of the design of the radiation protection aspects of a facility
- design and implementation of a radiation protection training course or program
- development of an experimental and/or measurement program designed to answer questions related to radiation protection
- evaluation of measurement data
- analysis and solution of radiation protection problems
- preparation, interpretation and implementation of recommendations and regulations.

At the discretion of the Board, advanced degrees in health physics or a closely related area of study may be substituted for a maximum of two years of the required experience. A master's degree may be substituted for one year, while a doctoral degree may be substituted for two years of the required experience. Technician-level experience will in no case be acceptable as meeting the experience requirements.

Only military service in the commissioned officer and warrant officer grades will be accepted towards professional health physics experience.

An applicant may claim professional experience for an advanced degree and work experience for the same period. A maximum of one year of experience can be claimed for each calendar year. This provision is effective with the 1993 exam.

1. **References.** Each applicant must be currently engaged in the professional practice of health physics a substantial portion of the time. Reference statements are required from the applicant's supervisor and, if applying for Part II, from at least two other individuals who are professionally qualified to evaluate the applicant's ability in health physics. It is required that at least one reference be from a health physicist already certified by the ABHP.
1. **Written Report.** Each applicant for Part II of the examination shall submit with the Application for Certification a document written by the applicant that reflects a professional health physics effort. This "effort" may be a substantive facility evaluation, a protection guidance document, a

major monitoring program, or some other complex or comprehensive effort. The criteria for ABHP acceptance of this report is that it (1) be on a topic for which the ABHP tests and certifies expertise, (2) contain elements of professional judgment or application of non-regulatory protection guidance, and (3) be written solely or principally by the candidate. The Board, after examination of the application materials, may request additional such reports. All reports will be treated as confidential material.

1. **Examination.** The written examination has two parts: Part I, which can be taken early in one's career, determines the competence of the applicant in fundamental aspects of health physics, and Part II determines his/her competence in applied health physics topics. Either part of the written examination must be taken within two years of notification of eligibility, or a new application must be submitted. After passing Part I, the applicant must pass Part II within a period of seven years, or retake both parts.

## **ATTACHMENT II ABHP DOMAINS OF PRACTICE**

Over a period of about three years in the mid-1980s, the ABHP performed an exhaustive role delineation study of what a typical health physicist does to perform his/her job. This role delineation and the detailed task analyses that followed involved approximately 100 Certified Health Physicists, and was done under the direction of the Professional Examination Service. The goal of this evaluation was to determine what subject areas, skills, and knowledge are required to perform the job of a Health Physicist, the relative importance of each subject area, and the relative seriousness involved with a lack of knowledge in each area. As a result of this study, five main categories (domains) were selected based on subject matter. Each of the five domains was further subdivided into sub-areas to account for the subjects covered in each domain. Based on the ratings done by the large group of Certified Health Physicists, the relative importance of each of the five domains was also determined and a percentage was assigned to each domain.

A survey of health physicists conducted by the ABHP in 1993, reaffirmed the results of the original role delineation study. Based on the results of this survey the relative importance of the domains remained unchanged.

Since the goal of any job-related examination is to test the candidate on the information required to perform their job, the ABHP started (in 1986) to select questions for the Part II examinations so that the subject matter covered by the test questions reasonably approximates the same breakdown as the percentages associated with each of the five domains from the role delineation. Beginning in 1987, questions for Part I were also selected by subject matter to closely represent the five-domain breakdown.

To assist you in understanding the subject matter included in each domain and in each sub-area, a listing of each domain and the sub-areas under each one, along with typical examples of the material covered in each sub-area, are provided. It must be recognized that a given question may be able to be placed into more than one domain and sub-area.

### **1. Measurements - 30% (45 questions on Part I)**

The Measurements domain covers the utilization of proper measuring instruments, and the interpretation of the values obtained from the instruments. It includes calibration of the instruments. Sample collection devices are included in this domain.

#### **1.1 Specification of Methods**

- Standards for calibration
- Effects of geometry, self absorption, energy and count rate
- Testing of exhaust hoods, air flow paths, and exhaust filters
- Proper use of instruments to evaluate hazards

#### **1.2 Assessment of Surface Contamination**

- Measuring removable and fixed contamination
- Analyzing swipe samples
- Resuspension and transfer of contamination
- Frisking and scanning techniques
- Application of counting statistics

#### **1.3 Presentation of Data and Reports**

- Application of statistical methods to data analysis
- Reporting and evaluation of measurement data

#### 1.4 Assessment of Internal Deposition and Calculations of Dose

- Uptake and internal dose measurements and calculations
- Use of ICRP and MIRD models
- Bioassay and Whole Body Counting
- DAC-hour calculations
- Application of statistics to internal dose calculations

#### 1.5 Measurement of Airborne Radioactivity Levels

- Use of various collection media
- Use of various air sampling devices
- Analysis of different types of air samples (particulates, radiohalogens, HTO, noble gases, etc.)
- Application of statistics to air sample results

#### 1.6 Collection and Analysis of Environmental Media

- Exposure Pathways
- Selection of proper media to be sampled, proper preparation of samples, and proper analytical methods
- Instrumentation used for analysis
- Quality Control associated with sampling and analysis
- Application of statistics to environmental monitoring measurements

#### 1.7 Quantitation of Radiation Fields in Workplaces

- Ionizing and nonionizing radiation
- Response and limitations of instruments
- Interpretation of instrument indications
- Calibration of instruments

#### 1.8 Measurement of External Radiation Dose

- Dosimeter response to different types and energies of radiation
- Proper location of dosimetry
- Dosimetry processing methods
- Application of ALARA to personnel exposures
- Evaluation of whole body and organ dose from dosimetry results
- Evaluation of dosimetry interferences

#### 1.9 Collection and Analysis of Process and Effluent Samples (Liquids, solids and gases)

- Collection equipment and sample media
- Sample handling and analysis
- Instrumentation (inline and laboratory)
- Evaluation of sample results
- Application of statistics to sample results

### 2. Regulations and Standards - 16% (24 questions on Part I)

The Regulations and Standards domain covers the regulations, standards, and guidelines of groups such as ICRP, NCRP, ANSI, ASTM, NRC, DOE, EPA, DOT, OSHA, FEMA, ANI, the Postal Service, State agencies, etc.

## 2.1 Assurance that Operations are ALARA. Regulations and guidelines on:

- Maintaining occupational and public exposures to radiation and radioactive materials ALARA
- Evaluation of new standards and regulations
- Knowledge of current regulations and standards
- Record keeping requirements
- Contamination
- Regulations on reporting methods
- Regulations and guidelines associated with uptakes and internal doses
- Regulations and guidelines associated with air sampling and evaluation of air sample results
- Regulations and guidelines associated with environmental monitoring and analysis of samples
- Regulations and guidelines pertaining to measuring external radiation
- Regulations and guidelines associated with personnel external exposure
- Regulations and guidelines related to process and effluent sampling
- Regulation and guidelines associated with the preparation and transportation of radioactive material

## 2.2 Maintenance of License

- Reporting requirements
- Maintaining radionuclide inventory requirements
- Maintain public image of facility
- Response to regulatory sanctions
- Testifying at hearings

## 2.3 Assure Proper Emergency Response

- Preparation of emergency plans (onsite and offsite)
- Preparation of emergency plan implementing procedures
- Training of emergency response personnel
- Preparations of drills and exercises
- Field monitoring methods
- Dispersion modeling and calculations
- Interpretation of effluent measurements and field monitoring data to determine doses and proposed protective actions
- Exposure pathways
- Handling contaminated injuries

## 3. Facilities and Equipment - 24% (36 questions on Part I)

The Facilities and Equipment domain covers primarily engineering and design efforts, and the technical aspects related to them.

### 3.1 Determination of Shielding Requirements

- Optimization of shielding for a given facility based upon the characteristics of the radiation associated with the facility. (x-ray, diagnostic, therapeutic, radiography, fission products, activation products, neutrons, accelerator produced radiation, etc.)
- Determining type, thickness, and placement of shielding
- Evaluation of doses resulting from different shielding options including consideration of occupancy factors, utilization factors, etc
- Interactions of different radiation with different types of shielding materials
- Methods to evaluate shielding integrity and effectiveness

### 3.2 Determination of Potential Environmental Impacts

- Preparation of environmental impacts related to radiation and radioactive material
- Modeling and calculating air dispersion
- Evaluating dispersion in rivers, lakes, and oceans
- Evaluating doses (both external and internal, and including proper environmental pathways) and comparing them to the biological effects expected

### 3.3 Determination of Containment and Ventilation Requirements

- Calculate effects on environment of releases from containment devices or structures
- Evaluate effectiveness of filters or treatment systems on the dose to personnel in the environment

### 3.4 Review of Current and Proposed Operations and Recommend Appropriate Engineering Controls

- Perform cost-benefit evaluations
- Recommend appropriate mechanical protective devices such as shielding, interlocks, ventilation controls, remotely operated equipment, and devices to minimize time of exposure

### 3.5 Performance of Hazards Analysis and Risk Assessment

- Evaluate proposed or actual facility or system operation with respect to potential hazards from radiation and radioactive material
- Analyze potential for failure of protective systems and radiological consequences of failure
- Estimate radiation dose (external and internal) to individuals and population groups
- Evaluate systems with potential for criticality and recommend methods for control

### 3.6 Specification of Warning and Access Control Systems

- Combine proper physical controls (interlocks, shielding, locked doors, labyrinths, alarms, etc.) with proper posting to achieve desired (or required) access control
- Evaluate different access control techniques as related to the specific radiological conditions of a given process or situation
- Use appropriate detectors and alarm systems to protect personnel from radiation, contamination, and airborne activity

### 3.7 Specification of Instrumentation for Measuring Radiation and Radioactivity

- Select proper instrumentation to monitor both the worker and the public for conditions of normal operation and emergencies
- Use effluent monitors to control the release of radioactivity, and to measure the amount released
- Design adequate sampling systems to assure that a representative sample reaches the monitor
- Use process monitors to warn facility operators of an off-normal situation and to protect facility personnel

### 3.8 Specification of Equipment for Remote Handling

- Recommend practical remote handling equipment by evaluating possible increased time that remote operation will require
- Evaluate decreased doses remote operation provides against increased maintenance doses because of repairs to complicated equipment
- Evaluate choice of remote handling device against characteristics of the radiation associated with the facility

### 3.9 Specification of Protective Equipment and Clothing

- Types, effectiveness, and selection of protective clothing
- Types, effectiveness, and selection of respiratory protection
- Design of respirator fit-test booth
- Use of eye protection to protect the eyes from radiation

#### **4. Operations and Procedures - 18% (27 questions on Part I)**

The Operations and Procedures domain covers those radiological aspects which are largely administrative in nature. It includes reviews and audits of proposed and actual operational and maintenance programs and their associated procedures. The application or incorporation of a health physics consideration into an operating program will fall in this domain.

##### **4.1 Review Current and Proposed Operations, Maintenance and Associated Procedures and Recommend Appropriate Health Physics Controls**

- Exposure control (ALARA) program and procedures
- Contamination control program and procedures
- Decontamination methods (facility, equipment, and people)
- Respiratory protection program and procedures
- Bioassay program and procedures
- Waste management program and procedures
- Environmental monitoring program and procedures
- Technical reviews of all or portions of the radiation protection program, with recommendations for improvements

#### **5. Education and Training - 12% (18 questions on Part I)**

The Education and Training domain includes questions associated with training the Health Physicist receives and with training the Health Physicist prepares, reviews, and/or presents.

##### **5.1 Training and Development of Personnel**

- Training of the Health Physicist. (Many fundamental questions which are part of the basic training of a Health Physicist are included in this sub-area. Where applicable, fundamental questions may also be included in other domains when the subject matter is closely related to that domain.)
- Preparation/review/presentation of General Employee type health physics training
- Preparation/review/presentation of health physics technician training
- Preparation/review/presentation of special health physics training such as operational ALARA, design ALARA, dose projection, use of a special instrument, etc.

##### **5.2 Education and Public Information**

- Preparation/review/presentation of technical seminars or technical papers to peer groups
- Preparation/review/presentation of informational sessions to the general public
- Communications with the press
- Communications with outside agencies and organizations

**ATTACHMENT III**  
**Comparison of ABHP Certification Examination Domains of Practice with the**  
**Radiation Safety Officer Training Requirements of 10 CFR 35.50**

10 CFR 35.50 Section	NRC Requirement	ABHP Equivalency
35.50(b)(1)(i)	200 hours of didactic training in the following areas:	<b>Academics:</b> "An applicant must possess at least a bachelor's degree from an accredited college or university in physical science, engineering, or in a biological science with a minor in physical science or engineering."
35.50(b)(1)(i)(A)	(A) Radiation physics and instrumentation;	<b>Exam Domains of Practice:</b> 1.5, 1.6, 1.7, 1.9, 3.6, 3.7, 3.8, and 5.1
35.50(b)(1)(i)(B)	(B) Radiation protection;	<b>Exam Domains of Practice:</b> 2.1, 2.2, 4.1, 5.1 and 5.2
35.50(b)(1)(i)(C)	(C) Mathematics pertaining to the use and measurement of radioactivity;	<b>Academics:</b> "a candidate for certification may submit evidence of credit from an accredited college or university for course work in physical sciences, engineering, or mathematics equivalent to 20 semester hours"
35.50(b)(1)(i)(D)	(D) Radiation biology; and	<b>Exam Domains of Practice:</b> 1.8, 2.1, 2.2, 3.2, 5.1 and 5.2
35.50(b)(1)(i)(E)	(E) Radiation dosimetry; and	<b>Exam Domains of Practice:</b> 1.4, 1.8, 2.1, 3.1, 3.5, and 5.1
35.50(b)(1)(ii)	One year of full-time radiation safety experience under the supervision of the individuals identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar type(s) of byproduct material involving the following--	<b>Experience:</b> "An applicant must have at least six years of responsible professional experience in health physics as of July 1 of the year in which the examination is to be taken. At least three years of the experience must have been in applied health physics"  <b>References:</b> "Reference statements are required from the applicant's supervisor and from at least two other individuals who are professionally qualified to evaluate the applicant's ability in health physics. It is required that at least one reference be from a health physicist already certified by the ABHP."

10 CFR 35.50 Section	NRC Requirement	ABHP Equivalency
35.50(b)(1)(ii) Continued		<b>Written Report:</b> <i>"Each applicant for Part II of the examination shall submit with the Application for Certification a document written by the applicant that reflects a professional health physics effort. This "effort" may be a substantive facility evaluation, a protection guidance document, a major monitoring program, or some other complex or comprehensive effort."</i>
35.50(b)(1)(ii)(A)	Shipping, receiving, and performing related radiation surveys;	<b>Exam Domains of Practice:</b> 1.2, 2.1, 2.2, and 4.1
35.50(b)(1)(ii)(B)	Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;	<b>Exam Domains of Practice:</b> 1.1, 1.3, 1.7, 2.1, 3.4, 3.6, 3.7, 3.8, and 4.1
35.50(b)(1)(ii)(C)	Securing and controlling byproduct material;	<b>Exam Domains of Practice:</b> 1.2, 2.1, 2.2, 2.3, 3.1, 3.3, 3.4, and 4.1
35.50(b)(1)(ii)(D)	Using administrative controls to avoid mistakes in the administration of byproduct material;	<b>Exam Domains of Practice:</b> 2.1, 3.4, 3.5, 3.6, 3.8, 4.1, and 5.1
35.50(b)(1)(ii)(E)	Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;	<b>Exam Domains of Practice:</b> 1.1, 1.2, 1.3, 3.9, 4.1, and 5.1
35.50(b)(1)(ii)(F)	Using emergency procedures to control byproduct material; and	<b>Exam Domains of Practice:</b> 2.3 and 3.9
35.50(b)(1)(ii)(G)	Disposing of byproduct material; and	<b>Exam Domains of Practice:</b> 2.1, 2.2, 3.2 and 4.1
35.50(b)(2)	Has obtained written certification, signed by a preceptor Radiation Safety Officer, 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 Radiation Safety Officer for a medical use licensee;	<b>Certification Award:</b> The ABHP Chairperson certifies that the individual <i>"has satisfactorily met the professional standards established by the American Board of Health Physics and is hereby certified in the comprehensive practice of health Physics and is entitled to be identified as a Diplomate of the American Board of Health Physics "</i>

## **ATTACHMENT IV**

### **Professional Responsibilities of Certified Health Physicists**

In achieving certification, the CHP recognizes and assumes the responsibilities due the profession of health physics. To uphold the professional integrity of health physics implied by certification, the relations of the CHP with other individuals and groups, including clients, colleagues, governmental agencies, and the general public, shall always be based upon and reflect the highest standards of professional ethics and integrity. Each CHP has a professional and ethical obligation to practice only in those areas in which he or she is competent. To maintain technical competence, the CHP has a commitment to remain professionally active in the field of health physics and knowledgeable of scientific, technical, and regulatory developments in the field.



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 is 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](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](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.

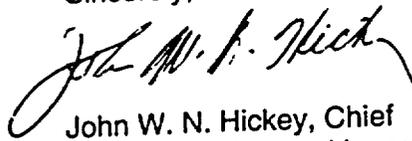
Dr. Ronald L. Van Heertum

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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 [rx1@nrc.gov](mailto:rx1@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 gigabecquerels (33 millicuries); and,
- §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).

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 [rx1@nrc.gov](mailto:rx1@nrc.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "John W. Hickey". The signature is fluid and cursive, with a large initial "J" and "H".

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



# The American Board of Nuclear Medicine

November 29, 2000

Chairman

Vice Chairman

Secretary/Treasurer

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

Executive Director

Associate Executive Director

Administrator



# The American Board of Nuclear Medicine

A Member Board of the American Board of Medical Specialties

**Chairman**  
WILLIAM H. HICKOM, M.D.  
COLUMBIA, MISSOURI

July 10, 2000

**Vice Chairman**  
GEOFFREY J. GIBBLE, M.D.  
COLUMBIA, MISSOURI

**Secretary-Treasurer**  
MELVIN J. NOSKOWITZ, M.D.  
HOUSTON, TEXAS

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

**Executive Director**  
WILLIAM H. HICKOM, M.D.  
COLUMBIA, MISSOURI

Dear Mr. Cool:

**Associate Executive Director**  
GEOFFREY J. GIBBLE, M.D.  
COLUMBIA, MISSOURI

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.

**Secretary**  
MELVIN J. NOSKOWITZ, M.D.  
HOUSTON, TEXAS

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.

**Assistant Secretary**  
GEOFFREY J. GIBBLE, M.D.  
COLUMBIA, MISSOURI

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

**Assistant Secretary**  
MELVIN J. NOSKOWITZ, M.D.  
HOUSTON, TEXAS

**Assistant Secretary**  
WILLIAM H. HICKOM, M.D.  
COLUMBIA, MISSOURI

**Assistant Secretary**  
GEOFFREY J. GIBBLE, M.D.  
COLUMBIA, MISSOURI

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MELVIN J. NOSKOWITZ, M.D.  
HOUSTON, TEXAS

**Executive Director**  
WILLIAM H. HICKOM, M.D.  
COLUMBIA, MISSOURI

**Associate Executive Director**  
GEOFFREY J. GIBBLE, M.D.  
COLUMBIA, MISSOURI

**Administrator**  
WILLIAM H. HICKOM, M.D.  
COLUMBIA, MISSOURI

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GEOFFREY J. GIBBLE, M.D.  
COLUMBIA, MISSOURI

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HOUSTON, TEXAS

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COLUMBIA, MISSOURI

**Administrator**  
MELVIN J. NOSKOWITZ, M.D.  
HOUSTON, TEXAS

Donald A. Cool  
July 10, 2000  
Page 2

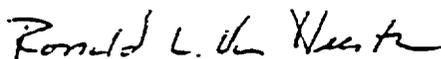
more than 700 hours of training and experience in basic radionuclide handling techniques that are applicable to the medical use of unsealed byproduct material for imaging and localization studies, and for radionuclide therapy that requires a written directive. The programs also provide training in radiation 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, M.D.  
Chairman  
American Board of Nuclear Medicine

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

May 31, 2002

The American Board of Medical Physics  
ATTN: Lawrence E. Reinstein, Ph.D, Chairman  
P.O. Box 1502  
Galesburg, Illinois 61402-1502

Dear Dr. Reinstein:

I am responding to your letter of July 10, 2000, Dr. Michael Gillin's e-mail to Sam Jones dated October 26, 2000, and Dr. Charles Coffey's letter of September 28, 2001. Dr. Gillin's e-mail asks questions related to Commission recognition of the American Board of Medical Physics (ABMP) certification process, and the new 10 CFR 35.51(a) and (b) "Training for an authorized medical physicist" (AMP). Dr. Coffey's letter provides a statement on behalf of the American Association of Physicists in Medicine (AAPM) regarding certification of medical physicists.

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](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](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 ABMP in 10 CFR 35.961 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.

Under 10 CFR 35.51(a), an individual may be designated as an authorized medical physicist if he or she is certified by a specialty 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 include tasks involving sealed sources and brachytherapy sources, teletherapy units, remote afterloading units, and gamma stereotactic radiosurgery units (GSUs), as applicable. Dr. Gillin asks about the interpretation of the words "all of the training and experience requirements in §35.51(b)" and "as applicable" in §35.51(b)(1). In addition, he notes that there are limited opportunities for medical physicists to receive training on GSUs, and asks whether the regulations could be interpreted in any of the following ways: (1) certification candidates must spend at least one day at a medical institution with a GSU, or (2) candidates must read about tasks involving GSUs as part of their work experience, or (3) ABMP should inform NRC that ABMP certification covers all tasks except those involving GSUs.

The situations covered in the first two interpretations are still under review. The American Association of Physicists in Medicine (AAPM) has proposed training criteria for medical physicists to meet 35.51(b). We will work with our Advisory Committee on Medical Uses of Isotopes and other stakeholders to address this issue. The NRC Advisory Committee on Medical Use of Isotopes has established a subcommittee to develop recommendations on training and experience issues. Your letter and those from the other interested parties

(cited previously) will be provided to this subcommittee for their consideration. We would welcome any additional 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.

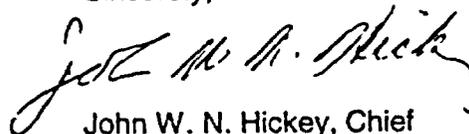
With respect to the third interpretation, if ABMP determines that its board certification process partially covers the requirements in §35.51(b), AMP may request recognition for the covered areas. For example, if the certification process covers 10 CFR 35.67, 35.633, 35.643, and 35.652, ABMP could request board recognition for medical physicist working with remote afterloaders. The scope of any NRC recognition of a board's certification process will be reflected in the list of recognized boards to be maintained on the NRC website. Note that even without NRC board recognition covering teletherapy or GSUs, the ABMP-certified individual could still be an authorized medical physicist, if the licensee submits an amendment request which demonstrates that the individual meets the requirements in §35.51(b) for one or more types of therapy units, as applicable.

Dr. Gillin also states that he believes that the current requirements of the ABMP meet the training and experience requirements for Radiation Safety Officers (RSOs). Accordingly, the ABMP could request recognition under section 35.50(a), if the board concludes that its certification process includes all of the requirements in section 35.50(b), including the requirements that: (1) candidates complete one year of full-time radiation safety experience under the supervision of an individual identified as an RSO on a Commission or Agreement State license that authorizes similar types of medical uses, and (2) candidates obtain written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the 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.

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

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: Michael Gillin, Ph.D  
Charles W. Coffey, II, Ph D

Enclosures:

1. Reinstein Ltr, dtd 7/20/2000
2. Gillin E-mail, dtd 10/26/2000
3. Coffey Ltr, dtd 9/28/2001



**American Association of Physicists in Medicine**

*Office of the President*  
Charles W. Coffey II Ph.D.  
Vanderbilt Medical Center  
Radiation Oncology Dept  
B902 Vanderbilt Clinic  
Nashville, TN 37232-5671  
Phone 615-322-2555 Fax 615-343-0161  
E-mail charles.coffey@mcm.vanderbilt.edu

September 28, 2001

Dr. Donald A. Cool  
Director,  
Division of Industrial and  
Medical Nuclear Safety  
U.S. NRC  
Two White Flint North  
11545 Rockville Pike,  
Mail Stop T8F5  
Rockville, MD 20852-2738

Dear Dr. Cool:

Please find enclosed a statement that addresses the American Association of Physicists in Medicine's (AAPM) concerns about the interpretation of the new Part 35, as it pertains to Authorized Medical Physicists. The AAPM strongly believes that board certification is essential to becoming a Qualified Medical Physicist and should not be diminished, as you implement new training and experience guidelines.

Sincerely,

Charles W. Coffey, II  
President

# Authorized Medical Physicists under the New Part 35 – Proposal from the American Association of Physicists in Medicine

## Introduction

A strict interpretation of the new Part 35 would diminish the importance of board certification for medical physicists, as board certification alone would not be a sufficient justification for the U.S. Nuclear Regulatory Commission (NRC) to certify an individual as an Authorized Medical Physicist (AMP). This is based upon the assumption that the American Board of Radiology (ABR), which will soon be the only board offering certification in radiation oncology physics, will not require candidates to have explicit experience with Co-60 units and high dose rate remote afterloading units and gamma stereotactic units. In recognizing Board certification as a pathway for certifying an individual as an AMP, the NRC expects that the ABR certification process include all of the training and experience requirements in paragraph (b) of 35.51. The training and experience requirements include a graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in:

- 35.67 Requirements for possession of sealed sources and brachytherapy sources
- 35.632 Full calibration measurements on teletherapy units
- 35.633 Full calibration measurements on remote afterloader units
- 36.635 Full calibration measurements on gamma stereotactic radiosurgery units
- 35.642 Periodic spot checks for teletherapy units
- 35.643 Periodic spot checks for remote afterloader units
- 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units
- 35.652 Radiation Surveys

It is expected that physicists, who are currently covered by NRC licenses, would be grandfathered to become AMP's. However, it is not clear how the NRC will handle the situation where a physicist is authorized for HDR, but whose name is not on a teletherapy license or a gamma stereotactic license. It is expected that new physicists would have to meet the above requirements. Under a strict interpretation, board certification would assume secondary importance, as medical physicists would focus on meeting these new regulatory training and experience requirements.

The NRC is focused on implementing this new rule and is not interested in considering changes to it. It is possible to petition for new rule making, but that would take 1.5 to 2 years to accomplish.

There is a consensus definition of a qualified medical physicist (QMP) ,namely a physicist who is board certified and who meets continuing education requirements. This certainly represents an industry standard for a QMP. The American Association of Physicists in Medicine, the American College of Medical Physics, and the American College of Radiology have adopted this concept. (There are minor differences in the exact statement of the various organizations.)

### Possible Solutions

The AAPM requests that the NRC define at least three sub-categories of AMP, namely, teletherapy AMP, remote afterloading AMP, and gamma stereotactic AMP.

The AAPM requests that the NRC clarify the situation with respect to physicists who are currently named on licenses for one or two of these categories, but not all three categories.

The AAPM proposes the following criteria for use by NRC staff to evaluate applications from medical physicists to be named Authorized Medical Physicists.

#### Teletherapy AMP

Board certified physicist

One independent calibration of a Co-60 teletherapy unit and one independent monthly spot check. Calibration and spot check to be signed off on by a teletherapy AMP  
OR

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a Co-60 teletherapy unit

Non-board certified physicist

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a Co-60 teletherapy unit

#### Remote Afterloading AMP

Board certified physicist

One independent calibration of a remote afterloading unit and one independent monthly spot check. Calibration and spot check to be signed off on by a remote afterloading AMP.  
OR

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a remote afterloading unit

**Non-board certified physicist**

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a remote afterloading unit

**Gamma stereotactic AMP**

**Board certified physicist**

One independent calibration of a gamma stereotactic unit and one independent monthly spot check. Calibration and spot check to be signed off on by a gamma stereotactic AMP.

OR

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a gamma stereotactic unit

**Non-board certified physicist**

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a gamma stereotactic unit

The justification for only one independent calibration and spot check for a board certified physicist is that board certification is a judgment by peers that a physicist has demonstrated minimum standards in his/her sub-specialty area and that a peer reviewed demonstration that the individual has understood the details associated with calibration or spot checks for that device. The board certified medical physicist could avoid the efforts of a peer reviewed calibration and spot check by meeting the same education and training requirements of the non-board certified physicist. The requirements for the non-board certified physicist are those found in Part 35.

**From:** Mike Gillin <mike\_gillin@radonc-qmail.fmlh.edu>  
**To:** Sam Jones <szj@nrc.gov>  
**Date:** Thu, Oct 26, 2000 12:49 PM  
**Subject:** Clarification Request

Sam Jones  
Mail Stop 9C24  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555  
(szj@nrc.gov)

Oct. 25, 2000

Dear Mr. Jones,

Thank you for following up with me via telephone the other day. As I discussed with you, the purpose of my inquiry, which was made on behalf of the American Board of Medical Physics (ABMP), was to seek additional information on the letter sent in June by Donald A. Cool, Ph.D., Director, Division of Industrial and Medical Nuclear Safety, to Larry Reinstein, Ph.D., Chairman, American Board of Medical Physics. At a recent meeting of the ABMP, Dr. Cool's letter was discussed and Dr. Reinstein requested that I seek additional information.

The second paragraph of the letter requesting that a letter be sent to Dr. Cool "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". The purview of the ABMP includes board certification in Medical Health Physics and Radiation Oncology Physics.

Upon reading 35.50, training for Radiation Safety Officer, it is my opinion that the current requirements of the ABMP meet the training and experience requirements. Thus, I do not believe that the ABMP has any questions pertaining to the training and experience of our candidates who take our Medical Health Physics examination.

Paragraph 35.51, training for an authorized medical physicist, lists the training and experience for an authorized medical physicist. Subparagraph (a) reads as follows "Is certified by a specialty board whose certification process includes all of the training and experience requirements in paragraph (b) of this section". Paragraph b contains educational requirements "and an additional year of full time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in paragraphs 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable".

Our question involves the use of the word "all" in paragraph (a) of 35.51, namely "all of the training and experience requirements". The phrase "as applicable" which appears in paragraph b may modify the all in paragraph a.

The tasks listed in paragraph b are as follows:

- 35.67 Requirements for possession of sealed sources and brachytherapy sources
- 35.433 Full calibration measurements on a teletherapy unit
- 35.632 Full calibration on remote afterloading units

35.635 Full calibration on gamma knives  
35.642 Periodic spot checks on teletherapy units  
35.643 Periodic spot checks on HDR  
35.645 Periodic spot checks for gamma knives  
35.652 Radiation surveys

As I mentioned in our phone conversation, there are only a limited number of gamma knives in the United States and thus only a limited opportunity for medical physicists to receive training on a gamma knife. It would be very helpful if you could clarify the goals of the NRC relative to this issue. (As a board certified physicist at an institution with a gamma knife, I received training on the gamma knife on site and again on site during installation.)

I can suggest several different interpretations of the above, namely:

Interpretation 1: Require all candidates to spend at least one day at a medical institution with a gamma knife as part of their additional year of work experience.  
Interpretation 2: Inform the NRC that ABMP candidates meet all of the tasks listed in paragraph b except those in 35.635 and 35.645.  
Interpretation 3: Require candidates to read about full calibration of gamma knives and periodic spot checks for gamma knives as part of their additional year of work experience.

Thank you for your help with this matter. It is my hope that the question is clear, although at times I am not sure that it is clear in my own mind

Best Wishes.

Michael Gillin, Ph.D.  
Professor, Radiation Oncology

# ABMP

## THE AMERICAN BOARD OF MEDICAL PHYSICS

C/o Credentialing Services, Inc  
P.O. Box 1502, Galesburg Illinois 61402-1502  
Telephone (309) 343-1202 Fax (309) 344-1715

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July 20, 2000

Donald A. Cool, Director  
Division of Industrial and Medical Nuclear Safety  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

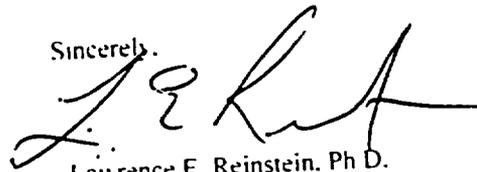
Dear Mr. Cool

I received your letter dated June 22, 2000 on the subject of "Recognition of Boards". As you probably know, certification by the ABMP is currently considered sole evidence for recognition as a "Qualified Medical Physicist" (QMP) by several state regulatory agencies as well as by the American Association of Physicists in Medicine (AAPM) and the American College of Medical Physics (ACMP). Thus I am writing to let you know that it is totally proper and appropriate for the American Board of Medical Physics to be fully recognized by the Nuclear Regulatory Commission.

I will respond to your request for information after I circulate the enclosures you sent to me amongst my board and the specialty panel chairmen and ask them to review and assist me with this.

Please let me know what your time frame is and I will try to meet any deadline imposed.

Sincerely,



Lawrence E. Reinstein, Ph D.  
Chairman



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

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,

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.