



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

**JUN 12 2011**

Randall J. Phillips, M.D.  
Radiation Safety Officer  
QHG of Indiana  
7950 W. Jefferson Boulevard  
Fort Wayne, IN 46804-1677

Dear Dr. Phillips:

This refers to your letter received March 14, 2011, concerning additional information to control number 573544 for your NRC byproduct materials license no. 13-01535-01. Your letter received March 14, 2011, was assigned **new control number 574713**. Please make a note of this new number as you will need it to respond to the information requested below.

**Please note that I was still unable to approve Ryan Buss, M.D. as an authorized user (AU) for materials in 10 CFR 35.100, 35.200 and 35.300, limited to iodine-131 only in quantities greater than and less than 33 millicuries at this time because the information in your letter dated May 13, 2010, and letter received March 14, 2011, was insufficient to complete my review.**

**If you wish to pursue this request, please submit the information requested below in accordance with the guidance given.**

**Dr. Buss was not approved as an AU because we were still unable to verify the qualifications of his preceptor, Dr. James Ball, because Dr. Ball references the license, under which training of Dr. Buss took place, as Wake Forest University Baptist Medical Center ("WFUBMC") in North Carolina.**

**This is an Agreement State license (that we do not have access to) that appears to be a broad scope license, i.e., it does not name AU's on its license document directly; rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.**

**Please submit a complete, signed and dated copy of the most recent Agreement State License for WFUBMC. The information attached to your letter received March 14, 2011, consisted of only the first four pages (of eight pages) of the WFUBMC license that was unsigned, undated and did not show who the RSO was, so his identity could be corroborated with the attached letter dated January 28, 2011, signed by David C. Howell.**

**Upon receipt of this information, we will continue our review. The following information is reiterated from my letter dated December 16, 2010, for completeness' sake.**

**Please do not submit copies of minutes from the licensee's RSC meetings or other documents from the Agreement State licensee, especially patient records, or extraneous documentation that we must protect, per 10 CFR 2.390.**

**Please note that the email submitted with your letter dated September 2, 2010, was insufficient to accept Dr. Ball as a preceptor for Dr. Buss. The email did not contain the information I requested in my letter dated August 1, 2010, and no copy of the WFUBMC**

R. Phillips

license was provided. I specifically requested the exact information needed to proceed with this review.

Also, please note that it is not necessary to resubmit information for Dr. Buss again that we have already reviewed. We now have two sets of his preceptor forms and neither is acceptable because of the preceptor issue that was inappropriately responded to.

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your response. Please note that consulting these references, understanding them and applying them to these requests should be very helpful in preparing an appropriate response.

If Forms 313a will be used in support of your response, please use the newly revised Forms found on our website at:

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

In addition, if, you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf>

Please do not submit emails, resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

Please provide this information in a written response that is currently dated and signed by a senior management official, addressed to my attention and reference it as "additional information to control number 574713," to facilitate proper handling.

Please also include your fax number, as a check of our records indicates that we do not have this information on file for you and your letter dated September 2, 2010, and your letter received March 14, 2011, did not include it either.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information," ..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

Please note that I was still unable to approve your request to add Andrew V. Barger, M.D. as an authorized user for the use of materials in 10 CFR 35.100, 35.200 and 35.300, limited to the oral administration of iodine-131 because the information in your letter dated September 2, 2010, and your letter received March 14, 2011, was insufficient to support this request.

Dr. Barger received his training at Mayo Clinic in Rochester, Minnesota. Again, this is a broad scope license in an Agreement State. We do not have access to the Mayo Clinic license and it does not list authorized users on the license document itself. So we cannot accept Dr. Barger's preceptor, Brian P. Mullan, M.D. because we cannot verify his acceptability as a preceptor.

R. Phillips

Please submit a complete, signed and dated copy of the most recent Agreement State License for Mayo Clinic. The information attached to your letter received March 14, 2011, consisted of an attached letter dated January 28, 2011, signed by Glenn M. Sturchio, Ph.D.

Since a copy of the Mayo Clinic license was not submitted, I cannot verify that Dr. Sturchio is the RSO, which would enable us to accept his letter of support for Dr. Mullan to serve as preceptor for Dr. Barger.

I also noted that you provided information about Dr. Barger's specialty board certification in an attachment to the letter received March 14, 2011. However, please note that Dr. Barger's certification is in Diagnostic Radiology, which does not qualify him for the use of any materials in 10 CFR 35.300.

Please submit the information required by 10 CFR 35.392 in order to enable us to continue our review.

Guidance concerning the specialty certification boards that we accept can be found on our website at:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

A portion of this guidance is copied below and a hard copy is attached to this letter:

**“§35.390 Training for use of unsealed byproduct material for which a written directive is required American Board of Nuclear Medicine certification process from October 20, 2005 to 2007 and from 2007 to present for all physicians before and after these dates issued an ABNM certification with the word “United States” appearing under the certification number. \***

**American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiation Oncology specialty with the words "AU eligible" appearing above the ABR seal. \***

**American Osteopathic Board of Radiology (AOBR) certification process from May 1, 2007 forward for the Radiation Oncology specialty. \***

**\*Diplomates of this specialty board also satisfy the training and experience requirements in 10 CFR 35.392 and 35.394. “**

As you can see, Dr. Barger's specialty board certification is not listed here.

In addition Part I, section 5, last column and section 6.A. of Dr. Barger's preceptor forms are incomplete. Dr. Barger's preceptor forms must be completely filled out in order to capture credit for all of his training and experience and fully support his application to become an authorized user.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is (630) 515-1078.

R. Phillips

Since I am unable to issue any part of your request at this time, I am voiding your request by taking it out of our active database. This affords you time to prepare a quality response without the burden of time constraints. This action is taken without prejudice to your later resubmission.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,



Colleen Carol Casey  
Materials Licensing Branch

License No. 13-01535-01  
Docket No. 030-01594

Enclosure:

Specialty Boards Acceptable  
To NRC, excerpted from webpage



Home > Nuclear Materials > Medical, Industrial, and Academic Uses of Nuclear Materials > Medical Uses > Licensee Toolkits > Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35

## Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35

*This page includes links to files in non-HTML format. See Plugins, Viewers, and Other Tools for more information.*

- §35.50 Training for Radiation Safety Officer  
**American Board of Health Physics from January 1, 2005 to present.**
- American Board of Science in Nuclear Medicine from June 2006 forward for the Nuclear Medicine Physics and Instrumentation Specialty and the Radiation Protection Specialty .**
- American Board of Radiology (ABR) certification process from June 2007 forward for the Radiologic Physics - Medical Nuclear Physics and the Radiologic Physics - Diagnostic Radiologic Physics specialties for diplomates who have been issued certificates before and after that date with the words "RSO Eligible" appearing above the ABR seal."**
- American Board of Medical Physics certification process for special competence in Medical Health Physics for diplomats that have been issued certificates with the words "RSO Eligible" on the certificate.**
- §35.51 Training for an authorized medical physicist  
**American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiologic Physics - Therapeutic Radiologic Physics specialty for diplomates who have been issued certificates before and after that date with the words "AMP Eligible" appearing above the ABR seal.\*\*"**
- Canadian College of Physicists in Medicine (CCPM) certification process from January 2009 forward for the Radiation Oncology Physics specialty\*\***
- \*\*Diplomates certified under 10 CFR 35.51 from June 2007 forward for the Therapeutic Radiologic Physics subspecialty of the ABR-Radiologic Physics specialty and from 2009 forward for the Radiation Oncology Physics specialty of the Canadian College of Physicists in Medicine also satisfy the certification portion of the regulatory requirements in 10 CFR 35.50(c)(1) for Radiation Safety Officer authorization.**
- §35.55 Training for an authorized nuclear pharmacist  
**Board of Pharmaceutical Specialties certification process for Board Certified Nuclear Pharmacist (BCNP) from March 6, 1996 to present.**
- §35.190 Training for uptake, dilution, and excretion studies  
**American Board of Nuclear Medicine certification process from October 20, 2005 to 2007 and from 2007 to present for all physicians before and after these dates issued an ABNM certification with the word "United States" appearing under the certification number.**
- §35.290 Training for imaging and localization studies
- Certification Board of Nuclear Cardiology certification process from October 29, 2000 to present physicians after this dates issued an CBNC certification before 2006 with the wording "for Physicians Residing in the United States" and on or after 2006 with the wording "for Physicians Trained in the United States" appearing in the certificate.**
- American Board of Nuclear Medicine certification process from October 20, 2005 to 2007 and from 2007 to present for all physicians issued an ABNM certification before and after these at dates with the word "United States" appearing under the certification number.**
- American Osteopathic Board of Radiology (AOBR) certification process from July 1, 2000 forward for the Diagnostic Radiology specialty.**
- American Osteopathic Board of Nuclear Medicine (AOBNM) certification process from May 18, 2006 forward for the Nuclear Medicine specialty.**
- American Board of Radiology (ABR) certification process from June 2006 forward for the Diagnostic Radiology certificates issued before and after that date with the words "AU eligible" appearing above the ABR seal.**
- §35.390 Training for use of unsealed byproduct material for which a written directive is required  
**American Board of Nuclear Medicine certification process from October 20, 2005 to 2007 and from 2007 to present for all physicians before and after these dates issued an ABNM certification with the word "United States" appearing under the certification number. \***
- American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiation Oncology specialty with the words "AU eligible" appearing above the ABR seal. \***
- American Osteopathic Board of Radiology (AOBR) certification process from May 1, 2007 forward for the Radiation Oncology specialty. \***
- \*Diplomates of this specialty board also satisfy the training and experience requirements in 10 CFR 35.392 and 35.394.**
- §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)
- American Osteopathic Board of Radiology (AOBR) certification process from July 1, 2000 forward for the Diagnostic Radiology specialty.**
- American Board of Radiology (ABR) certification process from June 2006 forward for the Diagnostic Radiology certificates issued before and after that date with the words "AU eligible" appearing above the ABR seal.**
- §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)
- American Board of Radiology (ABR) certification process from June 2011 forward for the Diagnostic Radiology certificates with the words "AU eligible" appearing above the ABR seal.**
- §35.490 Training for use of manual brachytherapy sources
- American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiation Oncology specialty with the words "AU eligible" appearing above the ABR seal.**
- American Osteopathic Board of Radiology (AOBR) certification process from May 1, 2007 forward for the Radiation Oncology specialty.**
- §35.590 Training for use of sealed sources for diagnosis  
 None
- §35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

**American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiation Oncology specialty with the words "AU eligible" appearing above the ABR seal.**

**American Osteopathic Board of Radiology (AOBR) certification process from May 1, 2007 forward for the Radiation Oncology specialty.**

*Page Last Reviewed/Updated Thursday, March 31, 2011*

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