

Winchester Cardiology and Internal Medicine
Cardiovascular Imaging Center
190 Campus Blvd., Suite 201
Winchester, VA
Phone Number: (540) 542-1844
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NH881

August 30, 2005

License Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety & Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

45-25541-01
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RECEIVED
REG-11

RE: Amendment Application
Winchester Cardiology & Internal Medicine
License Number: 45-~~2541~~-01

25541 mm

Dear License Reviewer:

Please amend our byproduct material license to add Jason T. Hall, M.D. for all materials and procedures approved on the above mentioned license. Confirmation of training and experience has been attached for review. Please refer to this documentation for details.

If you require additional information, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 693-2277.

137652

NUCLEAR MATERIALS-002

We thank you in advance for your assistance with this licensing action.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Dixon Brown M.D.", written in a cursive style.

James Dixon Brown, M.D.

Administrative Representative/Radiation Safety Officer

Attachment A

Re: certification of training for Jason T. Call, MD

4/1/04

Dear Colleague,

As the Director of Nuclear Medicine at Wake Forest University School of Medicine, I have clinical, academic and administrative oversight of Nuclear Medicine, which includes Nuclear Cardiology. I am also an Authorized user under the Nuclear License for Wake Forest University Health Sciences (#0340158-1, expires Dec 31, 2006). I am the authorized preceptor for Nuclear Cardiology training for the Cardiology fellows at this institution. Jason T. Call, MD, completed his General Cardiology fellowship at this institution on July 1, 2004. His training and experience provided Level 2 training in Nuclear Cardiology as outlined in the American College of Cardiology/American Society of Nuclear Cardiology COCATS Guidelines (revised 2000). Dr. Call also successfully completed all training requirements set forth by the Nuclear Regulatory Commission guidelines section §§35.290, paragraph c (1). This training, establishes that he has met the level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC guidelines §§35.100 and 35.200.

During his fellowship, Dr. Call received a minimum of 6 months of training in nuclear cardiology at Wake Forest University Health Sciences Center, Winston-Salem, NC. This training and experience included a minimum of the following:

A. Radionuclide handling techniques: Dr. Call 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, including:

- 1) 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
- 2) Work experience, under the supervision of authorized users (Kathryn A. Morton, MD, Paige B. Clark, MD and James D. Ball, MD) which meet the requirements in §§ 35.290 or 35.390, 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 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

B. Clinical Nuclear Cardiology: In addition, Dr. Call completed training in the clinical aspects of Nuclear Cardiology, which included the following:

- a) Interpretation of over 400 studies (gated SPECT myocardial perfusion scans, PET myocardial viability scans and radionuclide ventriculograms (MUGA's).
- b) Review of over 100 myocardial perfusion scans with clinical angiographic correlation.
- c) First-hand performance (with supervision) of all aspects of 25 nuclear cardiology exams, including:
 - i) preparation of nuclear radiopharmaceuticals
 - ii) camera quality control, set up and calibration
 - iii) patient preparation, dose administration
 - iv) scan acquisition and processing
 - v) interpretation and reporting results of exams

C. Patient care: In addition to the six months of Nuclear Cardiology training, Dr. Call also received extensive training during his General Cardiology fellowship, achieving competency in the following Nuclear Cardiology-related areas:

- a) Cardiac history and physical evaluation
- b) Risk factor assessment
- c) Diagnostic planning and assessment
- d) Stress testing (pharmacologic and exercise)
- e) Patient monitoring and management of symptoms and complications
- f) Post procedural assessment and therapeutic planning
- g) Correlative imaging (angiography, echocardiography, MRI)

Dr. Call has also supplemented his formal training with significant additional self study and attendance at lectures and meetings in nuclear cardiology provided both locally and nationally. I am pleased to confirm that he fully is competent in all aspects of Nuclear Cardiology, is eligible to take his certifying exam by the American Board of Nuclear Cardiology. He is qualified to serve as an authorized user.



Kathryn A. Morton, MD
Director of Nuclear Medicine and PET
Wake Forest University Health Sciences Center
Phone 336-716-3099, FAX 336-716-5639, Pager [REDACTED] Email kmorton@wfubmc.edu

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

This is to acknowledge the receipt of your letter/application dated

8/30/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 45-25541-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 137652.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.