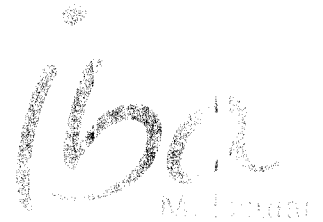


J-6



December 11, 2008

U.S. Nuclear Regulatory Commission, Region I
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License No. 45-25221-01MD – Item 11B

03032974

Amendment Request to Add Authorized Nuclear Pharmacists

Dear Sir:

IBA Molecular North America, Inc. would like to amend the aforementioned license.

Please add the following as *Authorized Nuclear Pharmacist* – Item #11B:

Kelli Rae Myers, PharmD

Ms. Kelli Rae Myer's qualifications as a nuclear pharmacists are enclosed.

All other RAM License conditions of the license remain in effect.

Thank you. If you have any questions about this amendment request, please contact me at the number on the stationary or on my cell phone. Or for quick questions and correspondence please contact my assistant Jim Kostka at his cell 202 207-5437.

Thank you.

Sincerely,

Duann Vanderslice

Duann Vanderslice, RPh, BCNP, FAPhA
Corporate RSO, IBA Molecular North America, Inc.
Cell (304) 215-3512

2008 DEC 12 AM 11:04

RECEIVED
REGION I

142856



Documentation of Authorized Nuclear Pharmacist Training

The training outline in the Authorized Nuclear Pharmacist Guidelines has been completed. The Pharmacist is qualified to assume the duties and responsibilities outlined in the guideline.

The training included:

Using administrative controls to avoid medical events in the administration of radioactive material

Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures

I Hereby certify that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Pharmacist Name (Print)

Kelli R Myers

Pharmacist Signature

Kelli R Myers

Date 12/9/08

Preceptor Name (Print)

Ronald K Lough

Preceptor Signature

Ronald K Lough

Date 12/9/08

Training record to support ANP on site in Sterling, Virginia
NRC RAM #45-25221-01MD

FIGURE G-4 - NUREG 1556, Vol. 13, Appendix G
AUTHORIZED NUCLEAR PHARMACIST
EXPERIENCE IN HANDLING RADIOISOTOPE

IBA Molecular North America
Corporate Headquarters
100 Executive Drive, Suite 100
Sterling, VA 20166
Phone (703) 787-7900
Fax (703) 787-4078

(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)

Name (Last, First, Initial) Myers, Kelli, R

Isotope(s) Used	Maximum amount used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience
Fluorine 18	4.5 Curies	[IBA Molecular] [Morgantown, WV]	1, 4, 5, 6, 7	280 hrs
Iodine 131	1 Curie		1, 4, 5, 6, 7	92 hrs
Iodine 125	8 mCi		1, 4, 5, 6, 7	24 hrs
Indium 111	16 mCi		1, 4, 5, 6, 7	24 hrs
Strontium 82	100 mCi		1, 6	5 hrs
Rubidium 82	10 mCi		1, 6	5 hrs
Cobalt 57	6 mCi		1, 2, 6	10 hrs
Cesium 137	215 µCi		1, 2, 6	10 hrs
Barium 133	270 µCi		1, 2, 6	10 hrs

Signature of Preceptor Authorized Nuclear Pharmacist:

"I certify that the above described training/experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy."

Signature:

Ronald Lough

Print:

Ronald Lough

Title:

Pharmacist in Charge

Date:

12/9/09

* Purpose of Use

- Shipping, receiving, and performing related radiation surveys.
- Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon-and high energy beta- emitting radionuclides.
- Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides.
- Calculating, assaying, and safely preparing dosages for patients or human research subjects.
- Use of administrative controls to avoid mistakes in the administration of byproduct material.
- Use of procedures to prevent or minimize contamination/or use of proper decontamination procedures.
- Compounding radiopharmaceuticals for distribution to authorized recipients.



THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

RADIONUCLIDE HANDLING EXPERIENCE

Name: Kelli Rae Myers

Date: September 5, 2008

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

RADIONUCLIDE	RADIOACTIVITY	USE see below	EXPERIENCE Actual clock hours (Include date range of experience)	LOCATION
Mo-99	10 Curies	1,2,3,4,5,6,7	8/11/08	The Ohio State University Medical Center Columbus, OH
Tc-99m	8 Curies	1,2,3,4,5,6,7	through	
I-131	200 mCi	1,2,3,4,5,6	9/5/08	
I-123	1 mCi	1,2,3,4,5,6		
Ga-67	25 mCi	1,2,3,4,5		
Tl-201	50 mCi	1,2,3,4,5		
In-111	7.5 mCi	1,2,3,4		
Sr-89	5 mCi	1,2,3,4,5,6		
Sm-153	100 mCi	1,2,3,4,5,6		
F-18	200 mCi	1,2,3,4,5,6		
Cs-137	0.2 mCi	1,2,5		
			TOTAL HOURS: 40 hours	

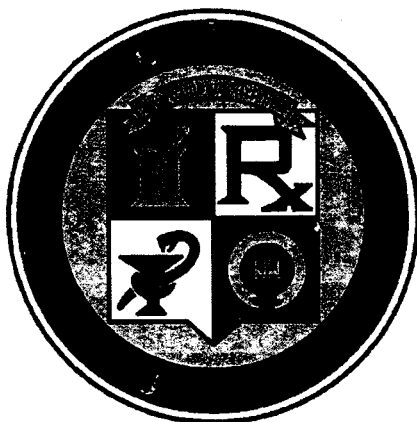
Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each radionuclide.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if applicable, instruments used to measure alpha- or beta-emitting radionuclides.
3. Calculating, assaying and safely preparing dosages for patients or human research subjects.
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material.
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys and wipe tests.
7. Eluting Tc99m from generator systems, assaying the eluate for Tc99m and for Mo99 and processing the eluate with reagent kits to prepare Tc99m labeled radioactive drugs.

Authorized Nuclear Pharmacist:


George H. Hinkle, RPh, MS, BCNP

Date: September 5, 2008



**The Ohio State University
College of Pharmacy
and
University Medical Center
Department of Pharmacy**



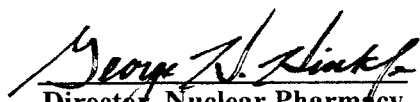
By this certificate warrants that

Kelli Rae Myers

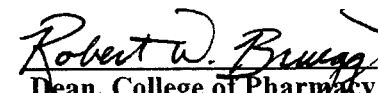
has satisfactorily fulfilled all requirements
and completed the prescribed course

Nuclear Pharmacy Certificate Program

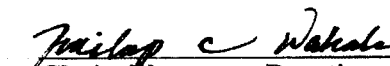
September 5, 2008


Director, Nuclear Pharmacy
Associate Professor of Pharmacy




Dean, College of Pharmacy


Executive Director
Council of Ohio Colleges of Pharmacy


Chair, Pharmacy Practice
and Administration



THE OHIO STATE UNIVERSITY
 COLLEGE OF PHARMACY
 UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Kelli Rae Myers

Location of Training	Dates of Attendance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
The Ohio State University, Columbus, OH	August 11, 2008 through September 5, 2008	Nuclear Pharmacy Certificate Program	214	88	45	20	22	39
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category) TOTAL HOURS			214	88	45	20	22	39

Authorized Nuclear Pharmacist/Authorized User:

George H. Hinkle
 George H. Hinkle, RPh, MS, BCNP, FASHP, FAPhA

DATE: September 5, 2008



Board of Pharmacy

REGISTERED PHARMACIST LICENSE
July 1, 2007 - June 30, 2009

Kelli R. Myers
Registered Pharmacist
License # RP0007081