

December 4, 2006

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

Br. 2

RECEIVED
REGION I
2006 DEC - 5 AM 10:46

RE: Material License #24-04206-22MD 03035461

Please Expedite Licensing Action

Dear License Reviewer:

Please amend the above reference material license to reflect the following modification:

1. Amend to name **Scott Delauter R.Ph.** as an Authorized Nuclear Pharmacist. Mr. Delauter has completed the necessary didactic and practical experience training in accordance with 10 CFR 35.980 (refer to attached documentation). In addition, the Pennsylvania Board of Pharmacy recognizes Mr. Delauter as a Registered Pharmacist.

An expedited review of this request would be appreciated due to extended staffing shortages in this pharmacy. All other items relating to our radioactive material license and established Radiation Safety Program remain unchanged at this time.

Please contact April Chance, Manager, Radiological Affairs at (314) 654-7960 for further information regarding this matter. Your prompt review and approval of this license modification is greatly appreciated.

Sincerely,



Kay M. Yoder
Director, Radiation, Environment, Safety & Health – Mallinckrodt Inc.

Attachment

cc: T. Hays, Radiation Safety Officer (Ebensburg, PA)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)

ATTACHMENT
SCOTT DELAUTER DOCUMENTATION

tyco

Healthcare

Mallinckrodt

656 Industrial Drive
Ebensburg, PA 15931

Tele: 814 471-2750
Fax: 814 471-2756
Toll Free: 877 781-2750
www.mallinckrodt.com

November 21, 2006

Kay M. Yoder, Director, Radiation, Environment, Safety & Health
Regulatory Compliance Department
Mallinckrodt Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

RE: Proposed Authorized Nuclear Pharmacist – Scott Delauter, R.Ph.

Dear Kay:

Attached, please find documentation outlining the nuclear pharmacy training and experience received by Scott Delauter, R.Ph.. Mr. Delauter received his “on the job” nuclear pharmacy training and practical experience under my supervision during the period of August 14, 2006 to December 4, 2006.

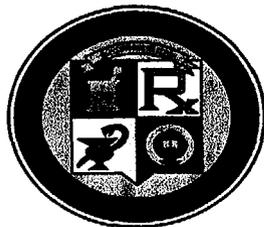
Based on Mr. Delauter’s training and experience, as outlined in the attached documents, I confirm that he has achieved a level of competency sufficient to independently operate a nuclear pharmacy. I recommend elevating Scott Delauter, R.Ph. to the status of Authorized Nuclear Pharmacist in accordance with 10 CFR 32.72.

Sincerely,



Mike Stipanovich, R.Ph.
Nuclear Pharmacy Manager

Attachments



THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Scott Delauter, R.Ph.

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	October 2, 2006 through October 27, 2006	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: October 27, 2006



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



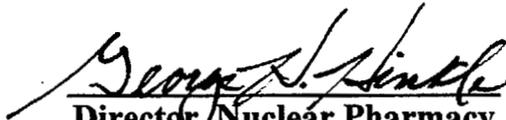
By this certificate warrants that

Scott R. Delauter, R.Ph.

has satisfactorily fulfilled all requirements
and completed the prescribed course

Nuclear Pharmacy Certificate Program

October 27, 2006



Director, Nuclear Pharmacy
Associate Professor of Pharmacy



Executive Director
Council of Ohio Colleges of Pharmacy




Dean, College of Pharmacy


Chair, Pharmacy Practice
and Administration

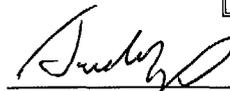
Hours of Radioactive Material Experience

Proposed Authorized Nuclear Pharmacist: Scott Delauter, R.Ph.

Dates of Use	Location	Isotope(s) Used	Max activity used at any one time	Purpose(s) of Use ^a	Total Hours Worked
8/14/06-10/1/06	Mallinckrodt Pharmacy Ebensburg, PA	Mo-99 Tc-99m I-131 I-123 Ga-67 Tl-201 In-111 Cs-137 Co-57 Eu-152	10 Ci 8 Ci 500 mCi 2 mCi 20 mCi 115 mCi 3 mCi 0.5 uCi 1 uCi 0.5 uCi	1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,5 1,2,5 1,2,5	272
10/2/06-10/27/06	Ohio State University	See attachment	See attachment	See attachment	40
10/28/06-12/4/06	Mallinckrodt Pharmacy Ebensburg, PA	Mo-99 Tc-99m I-131 I-123 Ga-67 Tl-201 In-111 Cs-137 Co-57 Eu-152	10 Ci 8 Ci 500 mCi 2 mCi 20 mCi 115 mCi 3 mCi 0.5 uCi 1 uCi 0.5 uCi	1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,3,4,5,6 1,2,5 1,2,5 1,2,5	192
				Total Hours	504



Scott Delauter, R.Ph.



Todd Hays, R.Ph.
Radiation Safety Officer

^a "Purpose of Use" should be designated as one or more of the following:

1. Ordering, shipping, and 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. Use of administrative controls to avoid mistakes in the administration of byproduct material
5. Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures.
6. Eluting Tc-99m from generator systems, assaying eluate for Tc-99m and Mo-99 and processing the eluate with reagent kits to prepare radioactive drugs

**THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER**

NUCLEAR PHARMACY CERTIFICATE PROGRAM

RADIONUCLIDE HANDLING EXPERIENCE

Name: Scott Delauter, R.Ph.

Date: October 27, 2006

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	10/2/06	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	10/27/06	
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: October 27, 2006

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

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO Box 2649 Harrisburg PA 17105-2649

06 305754

License Type
Pharmacist

License Status
Active

Initial License Date
08/05/1994

SCOTT R DELAUTER

License Number
RP040976L

Expiration Date
09/30/2008

Basil L. Wearda

Commissioner of Professional and Occupational Affairs

Scott R. DeLauter

Signature

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER 18 PA.C.S.S. 4911