

August 1, 2006

NMSB2

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

03032971

RE: Material License #24-04206-16MD (Wilkes-Barre, PA)

Please Expedite Licensing Request

Dear License Reviewer:

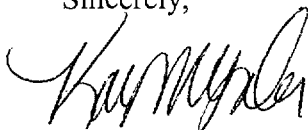
Please amend the above referenced material license to reflect the following modification:

1. Amend to name **Kerry Iannielli, R.Ph.** as an Authorized Nuclear Pharmacist. Ms. Iannielli 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 Ms. Iannielli 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, Radiation, Health and Safety, at (314) 654-7960 for additional information to support this request. Thank you for your prompt assistance regarding this matter.

Sincerely,



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

Attachment

cc: M. Loiseau, R.Ph., Radiation Safety Officer (Wilkes-Barre, PA)
A. Chance, Manager, Radiation, Health & Safety (Hazelwood, MO)

RECEIVED
REGION I
2006 AUG -3 AM 10:17

139215
NMSS/RONI MATERIALS-002

ATTACHMENT
DOCUMENTATION OF TRAINING AND EXPERIENCE
FOR KERRY IANNIELLI

tyco

Healthcare

Mallinckrodt

Mallinckrodt Inc.
300 Laird Street
Wilkes-Barre, PA 18702

Tele: 570 824-8980
Fax: 570 824-8987
Toll Free: 800 743-5054
www.mallinckrodt.com

July 28, 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 – Kerry M. Iannielli, R.Ph.

Dear Kay:

Attached, please find documentation outlining the nuclear pharmacy training and experience received by Kerry Iannielli, R.Ph. Ms. Iannielli received her “on the job” nuclear pharmacy training and practical experience under my supervision during the period of April 3, 2006 to July 28, 2006.

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

Sincerely,

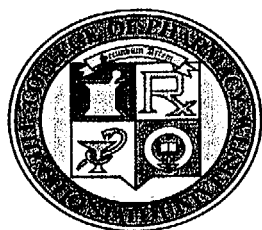


Christine A. Treolo, R.Ph.
Nuclear Pharmacy Manager

Attachments

ATTACHMENT I
DIDACTIC TRAINING DOCUMENTATION

Nuclear course documentation of hours
Course Certificate



THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

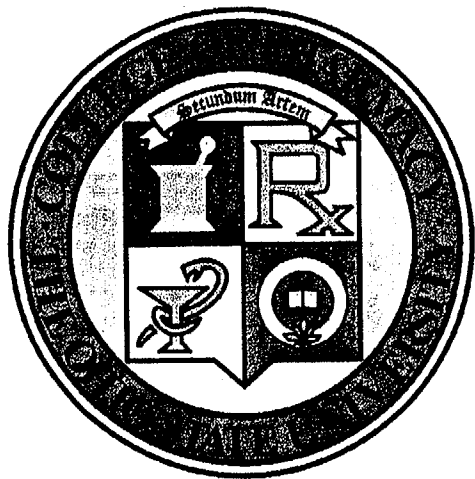
Name: Kerry M. Iannielli, R.Ph.

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	April 10, 2006 through May 5, 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. Winkle
George H. Winkle, RPh, MS, BCNP, FASHP, FAPhA

DATE: May 5, 2006



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



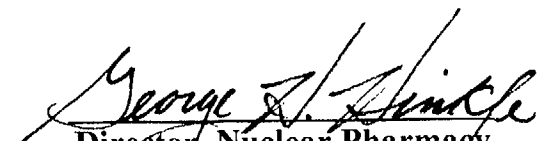
By this certificate warrants that

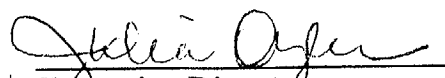
Kerry Iannielli, R.Ph.

has satisfactorily fulfilled all requirements
and completed the prescribed course


Nuclear Pharmacy Certificate Program

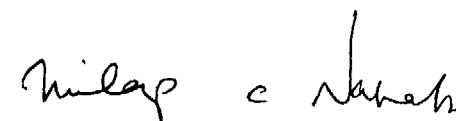
May 5, 2006


Director, Nuclear Pharmacy
Associate Professor of Pharmacy


Executive Director
Council of Ohio Colleges of Pharmacy




Dean, College of Pharmacy


Chair, Pharmacy Practice
and Administration


ATTACHMENT II
PRACTICAL TRAINING DOCUMENTATION

Hours of Radioactive Material Experience

Proposed Authorized Nuclear Pharmacist: Kerry M. Iannielli, R.Ph.

Dates of Use	Hours Worked Per Week	Location of Training	Isotope(s) Used	Max. activity used at any one time	Purpose(s) of Use ^a	Total Hours Worked Per Isotope
04/03/06 – 04/07/06	40	Mallinckrodt 300 Laird Street Wilkes-Barre, PA 18702	Mo-99	14 Ci	1,4,5,6	65
05/08/06 – 05/12/06	40		Tc-99m	11 Ci	1,2,3,4,5,6	325
05/15/06 – 05/19/06	40		In-111	10 mCi	1,2,3,4,5	50
05/22/06 – 05/26/06	40		Tl-201	60 mCi	1,2,3,4,5	24
05/30/06 – 06/02/06	32		Ga-67	15 mCi	1,2,3,4,5	6
06/05/06 – 06/11/06	46		Cs-131	200 uCi	2	12
06/12/06 – 06/16/06	40		I-131	20 uCi	1,2,3,4,5	24
06/19/06 – 06/25/06	46		I-123	5 mCi	1,3,4,5	6
06/26/06 – 06/30/06	40		Xe-133	100 mCi	1,3,4,5	3
07/03/06 – 07/07/06	32		Cr-51	50 uCi	1,3,4,5	1
07/10/06 – 07/14/06	40					
07/17/06 – 07/21/06	40					
07/24/06 – 07/28/06	40					
					Total Hours	516

Kerry M Iannielli
Kerry M. Iannielli, R.Ph.


Michael Loiseau, R.Ph.
Radiation Safety Officer

Christine A. Treolo, R.Ph.
Pharmacy Manager

- ^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: Kerry M. Iannielli, R.Ph.

Date: May 5, 2006

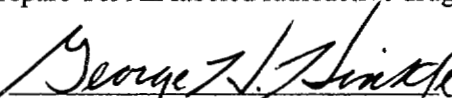
Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

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	4/10/06	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	5/5/06	
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: May 5, 2006

ATTACHMENT III
NUCLEAR PHARMACIST LICENSE

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

02 078802

License Type
Pharmacist

License Status
Active

Initial License Date
08/03/2000

Expiration Date
09/30/2006

KERRY MONAHAN IANNIELLI

License Number
RP045646L

Basil L. Monahan

Commissioner of Professional and Occupational Affairs

Kerry Monahan Iannelli
Signature

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

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



*Pennsylvania Department of State
Bureau of Professional and
Occupational Affairs*



License Verification

Person Information

Name: KERRY MONAHAN IANNIELLI

Address(city,state zipcode): Moscow PA 18444

Employer Information

No Information Found

License Information

Type: Pharmacist

Secondary Type: N/A

Number: RP045646L

Profession: Pharmacy

Status: Active

Obtained By: Application

Issue Date: 8/3/2000

Expires: 9/30/2006

Last Renewed: 8/12/2004

Standing: This license is in good standing.

Disciplinary action history: No disciplinary actions were found for this license.

[Return to Licensee Search](#) | [Back to Results](#)