

April 26, 2006

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

NMSB2

03033157

2006 MAY -1 AM 10:19

RECEIVED
REGION I

RE: Material License #24-04206-17MD

Please Expedite Licensing Action

Dear License Reviewer:

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

1. Amend to name **Thu Dang, R.Ph.** as an Authorized Nuclear Pharmacist. Ms. Dang 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. Dang 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. Layne, Nuclear Pharmacy Manager (Bethlehem, PA)
K. Eberly, Radiation Safety Officer (Bethlehem, PA)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)

138773

NMCS/RCNI MATERIALS-002

ATTACHMENT
THU DANG DOCUMENTATION

tyco

Healthcare

Mallinckrodt

Mallinckrodt Inc.
2299 Broadhead Road
Suite 1
Bethlehem, PA 18020

Tele: 610 882-4367
Fax: 610 882-4374
Toll Free: 800 656-1000

April 27, 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

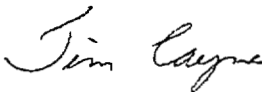
Re: Proposed Authorized Nuclear Pharmacist – Thu N. Dang, R.Ph.

Dear Kay:

Attached, please find documentation outlining the nuclear pharmacy training and experience received by Thu N. Dang, R.Ph. Ms. Dang received her "on the job" nuclear pharmacy training, practical experience and didactic hours under my supervision during the period of September 6, 2004 to October 9, 2004 and March 13, 2006 to April 26, 2006.

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

Sincerely,



Timothy D. Layne, R.Ph., BCNP
Nuclear Pharmacy Manager

Attachments

tyco

Healthcare

Mallinckrodt

Mallinckrodt Inc.
2299 Brodhead Road
Suite 1
Bethlehem, PA 18020

Tele: 610 882-4367
Fax: 610 882-4374
Toll Free: 800 656-1000

This letter is to document the experiential and didactic hours worked for Thu Dang while spending a 5 week intern rotation at Tyco Healthcare and to document her hours of additional training since she has become a full time employee on 3/13/06.

Date: September 6, 2004 – October 9, 2004

Time per Day: 8 Hours

Total experience hours: 120 hours

Didactic hours: 80 (see attached)

Experience:

1. Reviewed label requirements for radiopharmaceutical prescriptions.
2. Observed the preparation of radiopharmaceuticals.
3. Observed quality control tests performed for evaluation of radiopharmaceuticals.
4. Reviewed transportation rules and labeling for radiopharmaceutical shipments.
5. Practiced drawing up doses of methylene blue with syringe shields.
6. Visited Lehigh Valley Hospital's Nuclear Medicine Department to observe the use of radiopharmaceuticals for diagnostic imaging.

Date: March 13, 2006 – April 26, 2006

Time per Day: 8 Hours

Total experience hours: 264 hours

Experience:

1. Instructed on the use of internal order entry and inventory control.
2. Set up bio-hood and observed White Blood Cell Labeling.
3. Observed quality control. Practiced quality control procedures.
4. Performed pharmacy safety inspections and driver safety regulations while visiting a customer's site on a pharmaceutical delivery.
5. Under the supervision of a licensed pharmacist practiced drawing up doses.

Tim Layne

Tim Layne, B.C.N.P. RPh
Pharmacy Manager

Mallinckrodt Medical Inc.
2299 Brodhead Road
Suite I
Bethlehem, PA 18020

Hours of training received in Basic Radioisotope Techniques
Nuclear Pharmacy Internship Program
Pharmacy Manager: Timothy D. Layne, R.Ph. BCNP

Location of Training	Course Title	Total Clock Hours of Course	Radiation physics and instrumentation	Radiation protection	Math pertaining to radioactivity	Radiation biology	Radio pharmaceutical Chemistry
Mallinckrodt Med.	Clerkship Rotation	80	20	20	15	5	20

Authorized Mallinckrodt Pharmacy Manager

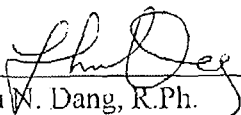
Tim Layne

Timothy D. Layne R.Ph. BCNP

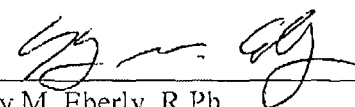
Hours of Radioactive Material Experience

Proposed Authorized Nuclear Pharmacist: Thu N. Dang, R.Ph.

Dates of Use	Location	Isotope(s) Used	Max activity used at any one time	Purpose(s) of Use ^a	Total Hours Worked
9/6/04 – 10/9/04	Mallinckrodt, Bethlehem PA	Mo-99	2 Ci	1,2,3,4,5,6	60
9/6/04 – 10/9/04	Mallinckrodt, Bethlehem PA	Tc-99m	1 Ci	1,2,3,4,5,6	60
1/10/05 – 2/11/05	PetNet, North Wales, PA see attached	FDG	3 Ci	1,2,3,4,5,6	200
3/13/06 – 4/26/06	Mallinckrodt, Bethlehem PA	Mo-99	10 Ci	1,2,3,4,5,6	90
3/13/06 – 4/26/06	Mallinckrodt Bethlehem PA	Tc-99m	8 Ci	1,2,3,4,5,6	90
3/13/06 – 4/26/06	Mallinckrodt Bethlehem PA	Tl-201	120 mCi	1,2,3,4,5,6	84
Total Hours					584



 Thu N. Dang, R.Ph.



 Kerry M. Eberly, R.Ph.
 Radiation Safety Officer

* "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



Barbara Missal BCNP RPh
Pharmacy Manager
398-402 Industrial Drive
North Wales, PA 19454
Phone 215-699-9042
barbara.missal@ctimi.com

This a letter to document the experience and hours for Thu Dang while spending a 6 week rotation at PETNET Pharmaceuticals in North Wales, PA.

Date: January 10, 2005 to February 11, 2005
Time per day: 8 hours
Total experience hours: 200 hours

Experience:

1. Assisted in the preparation and shipment of radioactive materials.
2. Assisted in daily constancy checks performed on the dose calibrator and single channel analyzer.
3. Assisted and performed daily surveys and wipes.
4. Assisted in Radiation Safety Officer functions:
 - A. Linearity
 - B. Efficiency on Single Channel Analyzer
 - C. Customer License review
 - D. Seal Source Inventory and Leak Test
5. Performed Quality control on FDG.
6. Observed the operation and functions of a cyclotron
7. Assisted with the preparation of FDG
8. Assisted in the dose drawing of FDG for human doses.

Thank you,

A handwritten signature in cursive script, reading "Barbara K. Missal".

Barbara K. Missal

Temple University School of Pharmacy Certificate of Completion

This certifies that

Thu Dang

Has satisfactorily fulfilled the experiential requirements
for **The Certificate in Nuclear Pharmacy**

Date of completion: May, 2005

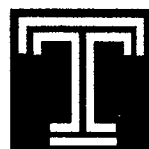


School of Pharmacy
TEMPLE UNIVERSITY®



Peter H. Doukas, Ph.D.
Dean

Certificate of Completion



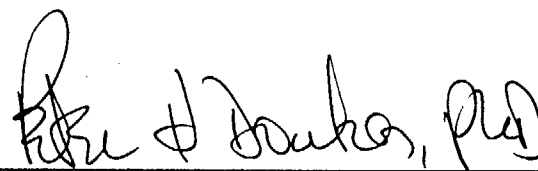
The School of Pharmacy
Temple University

This certifies that

Thu Dang

Has satisfactorily fulfilled the didactic requirements for
The Certificate in Nuclear Pharmacy

Date of completion: September, 2004



Peter H. Doukas, Ph.D.

Dean

Temple University, School of Pharmacy
3307 North Broad Street
Philadelphia, PA 19140

Hours of training received in Basic Radioisotope Techniques

Nuclear Pharmacy Elective Program

Director: Elaine D. Mackowiak, RPh, PhD

Professor Pharmacy Practice (School of Pharmacy)

Clinical Associate Professor Diagnostic Imaging (School of Medicine)

Location of training	Course title	Total clock hours of course	Radiation physics & instrumentation	Radiation protection	Math pertaining to radioactivity	Radiation biology	Radiopharmaceutical chemistry
School of Pharm.	Introduction to Nuclear Pharmacy	45	9	6	6	12	12
School of Pharm.	Advanced Radiopharmaceuticals	75	32	15	9	9	10
Centralized nuclear pharmacy	Clerkship rotation	200					

Authorized User Temple University


Elaine D. Mackowiak, RPh, PhD.

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

4/26/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ APPROD. 24-04206-17MD
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 138773.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.