

June 2, 2009

U.S. Nuclear Regulatory Commission, Region III  
Nuclear Materials Safety Branch  
2443 Warrenville Road  
Suite 210  
Lisle, IL 60532-4352

**RE:** Material License #24-04206-10MD (Warren, MI Radiopharmacy)

*Please Expedite Review*

Dear License Reviewer:

Please amend the above referenced radioactive materials license to reflect the following modifications:

1. Amend to add **Gina Webb, R.Ph.** as an Authorized Nuclear Pharmacist. Ms. Webb has completed the necessary didactic and practical experience training in accordance with 10 CFR 35.55, provided as Attachment A. In addition, the Michigan Board of Pharmacy recognizes Ms. Webb as a Registered Pharmacist, provided as Attachment B.

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.

Attachments

cc: M. Klug, R.Ph., RSO (Detroit, MI)  
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)

**ATTACHMENT A**  
**NRC FORM 313a(ANP) DOCUMENTATION FOR**  
**GINA WEBB**

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND  
EXPERIENCE AND PRECEPTOR ATTESTATION**  
[10 CFR 35.55]

Name of Proposed Authorized Nuclear Pharmacist

GINA WEBB

State or Territory Where Licensed

MI

**PART I -- TRAINING AND EXPERIENCE**  
(Select one of the two methods below)

\* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

1. Board Certification

- a. Provide a copy of the board certification.
- b. Skip to and complete Part II Preceptor Attestation.

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist

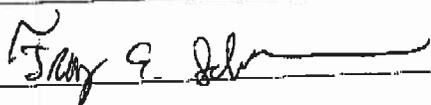
a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Purdue University	85	Oct 2008 to Dec 2008
Radiation protection	Purdue University	46	Oct 2008 to Dec 2008
Mathematics pertaining to the use and measurement of radioactivity	Purdue University	23	Oct 2008 to Dec 2008
Chemistry of byproduct material for medical use	Purdue University	40	Oct 2008 to Dec 2008
Radiation biology	Purdue University	21	Oct 2008 to Dec 2008
<b>Total Hours of Training:</b>		<b>215</b>	

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION (continued)**

**2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)**

**b. Supervised Practical Experience in a Nuclear Pharmacy.**

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys	Mallinckrodt, Inc. 2256 E. 14 mile Rd Warren, ME 48092 License # 24-04206-10MD	50	1/19/09 - 5/20/09
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides	Mallinckrodt, Inc. 2256 E. 14 mile Rd Warren, ME 48092 License # 24-04206-10MD	300	1/19/09 - 5/20/09
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Mallinckrodt, Inc. 2256 E. 14 mile Rd Warren, ME 48092 License # 24-04206-10MD	50	1/19-09 - 5/28/09
Using administrative controls to avoid medical events in administration of byproduct material	Mallinckrodt, Inc. 2256 E. 14 mile Rd Warren, ME 48092 License # 24-04206-10MD	50	1/19/09 - 5/28/09
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Mallinckrodt, Inc. 2256 E. 14 mile Rd. Warren, ME 48092 License # 24-04206-10MD	50	1/19/09 - 5/28/09
<b>Total Hours of Experience:</b>		<b>500</b>	
Supervising Individual 			

c. Go to and complete Part II Preceptor Attestation.

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION (continued)**

**PART II - PRECEPTOR ATTESTATION**

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

**First Section**

Check one of the following:

Board Certification

I attest that \_\_\_\_\_ has satisfactorily completed the requirements in  
Name of Proposed Authorized Nuclear Pharmacist  
10 CFR 35.55(a)(1), (a)(2), and (a)(3) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

OR

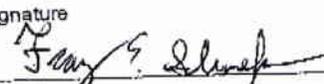
Structured Educational Program

I attest that Gina Webb has satisfactorily completed a 700-hour structured  
Name of Proposed Authorized Nuclear Pharmacist  
educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

**Second Section**

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for Mallinckrodt, Inc.  
Nuclear Pharmacy or Medical Facility  
24-04206-10MD  
License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
Franz E. Schmelzer		(586) 268-5300	5/29/09

Form Updated 08/07

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES\*

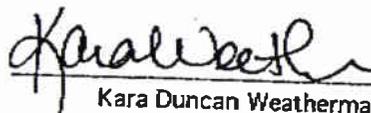
Trainee: GINA WEBB

Date issued: December 19, 2008

Location of Training	Date(s) of Attendance	Nuclear Pharmacy Certificate Program	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radio-pharmaceutical Chemistry
Purdue University	October 2008 to December, 08	DVD-Workbook	150	51	33	13	21	32
	December 2008	On-Site	65	34	13	10	0	8
Total Hours Received			<b>215</b>					
Hourly breakdown by topic				85	46	23	21	40

\* This form is representative of that which is used to apply for an NRC license amendment for an authorized user.

Director of Nuclear Pharmacy Training Programs:



Kara Duncan Weatherman, PharmD, BCNP, FAPhA  
 Assistant Professor of Nuclear Pharmacy  
 Purdue University  
 Division of Nuclear Pharmacy

**ATTACHMENT B**  
**GINA WEBB MICHIGAN BOARD OF PHARMACY LICENSE**


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## VERIFY A LICENSE/REGISTRATION

### Name and Address

**Name :** GINA RHENA WEBB  
**Address :** Troy, MI 48083

### Profession and License/Registration Information

<b>Profession :</b> Pharmacy		<b>Type :</b> Pharmacist	
<b>Permanent ID #</b>	<b>Status</b>	<b>Issue Date</b>	<b>Expiration Date</b>
5302026239	Active	08/20/1986	06/30/2011

### Complaint(s)

**Open Formal Complaints**  
None

### Disciplinary Action

Disciplinary Action	Date of Action	Date of Compliance
Probation	08/13/2008	

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### DISCLAIMER

The **Issue Date** is the date the license/registration was first issued. Please note this information is not always available in the data. **Expiration Date** given above is the date the license/registration expired or will expire. The license/registration may not have been the **Issue Date** to the **Expiration Date**. There may have been periods of non-licensure or registration.

For those licensees/registrants who have actions listed in the **Disciplinary Action** section above, the date the licensee/registrant c with their board order is listed for all disciplinary actions subsequent to January 1, 2005. The date of compliance is not listed for dis actions that began prior to that date. You should check with our office to confirm the status of the cases if the date of compliance is

You may fax a request for additional information under the Freedom of Information Act (FOIA) at 517-241-1212 or contact Mary E. FOIA Coordinator at [mehess@michigan.gov](mailto:mehess@michigan.gov) for directions on how to obtain more information regarding the license/registration hist disciplinary actions.

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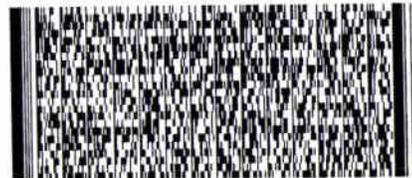
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Hazelwood, MO 63042



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U.S. NUCLEAR REGULATORY COMMISSION  
NUCLEAR MATERIALS LICENSING SECTION  
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LISLE, IL 60532



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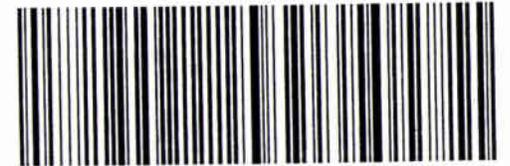
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