



GE Healthcare

Emile Poisson, CHMM
Pharmacy Regulatory Assurance Specialist

1623 Lotsie Boulevard
Overland, MO 63132
USA

T 314-733-0471
F 314-733-0479
E emile.poisson@ge.com

May 26, 2011

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

RE: NRC Material License No. 21-24828-01MD

To Whom It May Concern;

Please allow this letter to serve as notice that Medi-Physics, Inc., dba GE Healthcare wishes to amend the above referenced license as follows:

1. Change the Radiation Safety Officer (RSO) to **Bradley A. Ambs, R.Ph.** for the GE Healthcare Livonia, Michigan facility under license Condition 12. Mr. Ambs is a licensed Pharmacist in the State of Michigan, and an Authorized Nuclear Pharmacist (ANP) on the current Livonia, Michigan facility NRC Radioactive Materials License under license Condition 11B. Refer to *Attachment A* for proof Mr. Ambs has completed the training requirements for RSO described in 10 CFR 35.50(c)(2).
2. Remove **Kristin M. Anson** as the site Radiation Safety Officer (RSO) for the GE Healthcare Livonia, Michigan facility under license Condition 12. Ms. Anson will cease all duties as the site RSO on 6 June 2011 when she transitions to a new Quality Assurance role within GE Healthcare.

Should you have any additional questions or require further clarification, please contact me at (314) 733-0471.

Sincerely,

Emile J. Poisson, CHMM
Pharmacy Regulatory Assurance Specialist

enc. Attachment A

RECEIVED MAY 27 2011

Attachment A

1. State of Michigan Pharmacist License Verification
2. NRC Form 313A(RSO) – Preceptor Attestation



Department of Licensing and Regulatory Affairs



VERIFY A LICENSE/REGISTRATION

Name and Address

Name : BRADLEY ALLEN AMBS
Address : Newport, MI 48166

Profession and License/Registration Information

Profession : Pharmacy		Type : Pharmacist	
Permanent ID #	Status	Issue Date	Expiration Date
5302031035	Active	07/23/1997	06/30/2012

Complaint(s)

Open Formal Complaints
 None

Disciplinary Action

Disciplinary Action
 None

[New Search](#) [Return to Search](#)

The data on this web page is refreshed daily.

DISCLAIMER

The **Issue Date** is the date the license/registration was first issued. Please note this information is not always available in the database. The **Expiration Date** given above is the date the license/registration expired or will expire. The license/registration may not have been active from 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/registant complied with their board order is listed for all disciplinary actions subsequent to January 1, 2005. The date of compliance is not listed for disciplinary 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 not listed.

You may fax a request for additional information under the Freedom of Information Act (FOIA) at 517-241-1212 or contact Mary E. Hess, Asst. FOIA Coordinator at BHP-FOIAINFO@michigan.gov for directions on how to obtain more information regarding the license/registration history or disciplinary actions.

[Michigan.gov Home](#) | [LARA Home](#) | [LARA Contact](#) | [State Web Sites](#)
[Privacy Policy](#) | [Link Policy](#) | [Accessibility Policy](#) | [Security Policy](#)

Copyright © 2001- 2011 State of Michigan

**RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[10 CFR 35.50]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Radiation Safety Officer

Bradley A. Ambs, R.Ph.

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- 35.100
 35.200
 35.300
 35.400
 35.500
 35.600 (remote afterloader)
 35.600 (teletherapy)
 35.600 (gamma stereotactic radiosurgery)
 35.1000 (_____)

**PART I -- TRAINING AND EXPERIENCE
(Select one of the four 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 uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

OR

2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above

- a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.
- b. Skip to and complete Part II Preceptor Attestation.

OR

3. Structured Educational Program for Proposed Radiation Safety Officer

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Radiation dosimetry			

Total Hours of Training:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ _____ _____ _____		

* Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual _____ License/Permit Number listing supervising individual as a Radiation Safety Officer _____

This license authorizes the following medical uses:

- 35.100 35.200 35.300 35.400
 35.500 35.600 (remote afterloader) 35.600 (teletherapy)
 35.600 (gamma stereotactic radiosurgery) 35.1000 (_____)

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Kristin M. Anson Radiation Safety Officer Medi-Physics, Inc. dba GE Healthcare 12300 Hubbard Street, Livonia, MI 48150	February 2005 to Present
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Kristin M. Anson Radiation Safety Officer Medi-Physics, Inc. dba GE Healthcare 12300 Hubbard Street, Livonia, MI 48150	February 2005 to Present
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Kristin M. Anson Radiation Safety Officer Medi-Physics, Inc. dba GE Healthcare 12300 Hubbard Street, Livonia, MI 48150	February 2005 to Present
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *If training was provided by supervising RSO, AU, AMP, or ANP (if more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)* License/Permit Number listing supervising individual

Kristin M. Anson - Radiation Safety Officer U.S. NRC Radioactive Materials License No. 21-24828-01MD

License/Permit lists supervising individual as:

- Radiation Safety Officer Authorized User Authorized Nuclear Pharmacist
- Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

- 35.100 35.200 35.300 35.400
- 35.500 35.600 (remote afterloader) 35.600 (teletherapy)
- 35.600 (gamma stereotactic radiosurgery) 35.1000 ()

d. Skip to and complete Part II Preceptor Attestation.

OR

4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license

- a. Provide license number.
- b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

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:

1. Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Radiation Safety Officer
10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

2. Structured Educational Program for Proposed Radiation Safety Officers

I attest that _____ has satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer
program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

Check one of the following:

3. Additional Authorization as Radiation Safety Officer

I attest that Bradley A. Ambs, R.Ph. is an
Name of Proposed Radiation Safety Officer

- Authorized User Authorized Nuclear Pharmacist
 Authorized Medical Physicist

identified on the Licensee's license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section

Complete for all (check all that apply):

I attest that Bradley A. Ambs, R.Ph. has training in the radiation safety, regulatory issues, and
Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

- 35.100
- 35.200
- 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required
- 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131
- 35.300 parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- 35.300 parenteral administration of any other radionuclide for which a written directive is required
- 35.400
- 35.500
- 35.600 remote afterloader units
- 35.600 teletherapy units
- 35.600 gamma stereotactic radiosurgery units
- 35.1000 emerging technologies, including:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)


AND

**Third Section
Complete for ALL**

I attest that Bradley A. Ambs, R.Ph. has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer
sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

**Fourth Section
Complete the following for Preceptor Attestation and signature**

I am the Radiation Safety Officer for Medi-Physics, Inc. dba GE Healthcare
Name of Facility
License/Permit Number: U.S. NRC Radioactive Materials License # 21-24828-01MD

Name of Preceptor	Signature	Telephone Number	Date
Kristin M. Anson		(734) 425-0425	05/26/2011

From: (314) 733-0471
Emile Poisson
GE Healthcare
1623 Lotsie Blvd

Origin ID: ZSVA



J11151102250225

Overland, MO 63132

SHIP TO: (630) 829-9841

BILL THIRD PARTY

U.S. Nuclear Regulatory Commission

2443 WARRENVILLE RD STE 210

LISLE, IL 60532

Ship Date: 26MAY11
ActWgt: 0.5 LB
CAD: 2602420/INET3130

Delivery Address Bar Code



Ref #
Invoice #
PO #
Dept #

**FRI - 27 MAY A1
STANDARD OVERNIGHT**

TRK# 7971 4042 4305

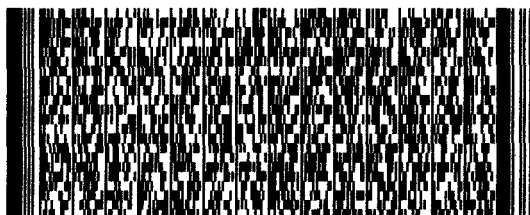
0201

**ASR
60532
IL-US
ORD**

NT BDFA



50DG1H5777EFB



After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.