

# INGHAM

## REGIONAL MEDICAL CENTER

A McLAREN HEALTH SERVICE

June 6, 2011

United States Nuclear Regulatory Commission  
Region III, Materials Licensing  
2443 Warrendale Road Suite 210  
Lisle, IL 60532-4352

RE: Amendment to NRC License No. 21-04073-01  
Ingham Regional Medical Center

Dear Sir/Madam:

We would like to amend our current NRC license to reflect the following changes.

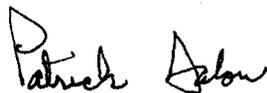
**Item #1** Please add the following authorized users to our NRC Materials License:

Amy Warpinski, D.O.	35.100 and 35.200
Amy Federico, D.O.	35.100 and 35.200

Preceptor forms and ABR Board certifications for both physicians are included for your review.

Thank you for your cooperation. If you have any questions or require additional information, please contact our medical physics consultant, Kevin B. Miller at 734-662-3197.

Sincerely,



Patrick Salow  
Chief Executive Officer  
Ingham Regional Medical Center

RECEIVED JUN 8 3 2011

**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.100, 35.200, and 35.500)  
[10 CFR 35.190, 35.290, and 35.590]

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

Name of Proposed Authorized User  
Amy Federico, DO

State or Territory Where Licensed  
Michigan

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 35.500 Sealed sources for diagnosis (specify device \_\_\_\_\_)

**PART I -- TRAINING AND EXPERIENCE**  
(Select one of the three 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. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

**2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

- a. Authorized user on Materials License \_\_\_\_\_ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work 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 Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

**Total Hours of Experience:**

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User**

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			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
<b>Total Hours of Training:</b>			

b. Supervised Work Experience (completion of this table is not required for 35.590).  
*(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)*

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Supervising Individual	License/Permit Number listing supervising individual as an authorized user		
Supervisor meets the requirements below, or equivalent Agreement State requirements ( <i>check one</i> ).			
<input type="checkbox"/> 35.190 <input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 <input type="checkbox"/> 35.390 + generator experience in 35.290(c)(1)(ii)(G)			

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

**AUTHORIZED USER 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. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

**First Section**

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that Amy Federico, DO has satisfactorily completed the requirements in  
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

**OR**

Training and Experience

I attest that \_\_\_\_\_ has satisfactorily completed the 60 hours of training and  
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that Amy Federico, DO has satisfactorily completed the requirements in  
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**OR**

Training and Experience

I attest that \_\_\_\_\_ has satisfactorily completed the 700 hours of training  
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**Second Section**

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

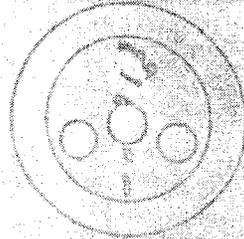
Name of Preceptor Thomas Archambeau, MD	Signature 	Telephone Number (517) 975-6382	Date 04/14/2011
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License/Permit Number/Facility Name  
21-04073-01 / Ingham Regional Medical Center

The American Osteopathic Association

upon recommendation  
of the

American Osteopathic Board of Radiology



certifies that

Amy Marie Federico, D.O.

having met the prescribed qualifications and standards and  
passed the required examinations at this Board,  
is qualified as a specialist in

Diagnostic Radiology

and is hereby awarded this certificate for the period from  
July 28, 2005 - December 31, 2015



American Osteopathic Association

*Jan B. Cury*  
Executive Director

Certificate No. 1065

American Osteopathic Board of Radiology

*Joseph J. ...*  
*[Signature]*

**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.100, 35.200, and 35.500)  
[10 CFR 35.190, 35.290, and 35.590]

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

Name of Proposed Authorized User Amy Warpinski, DO	State or Territory Where Licensed Michigan
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Requested Authorization(s) (check all that apply)

35.100 Uptake, dilution, and excretion studies

35.200 Imaging and localization studies

35.500 Sealed sources for diagnosis (specify device \_\_\_\_\_ )

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- a. Provide a copy of the board certification.
  - b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.
- 2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**
- a. Authorized user on Materials License \_\_\_\_\_ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
  - b. Supervised Work 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 Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

**Total Hours of Experience:**

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290       35.390 + generator experience in 32.290(c)(1)(ii)(G)

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User**

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Radiation protection			
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Radiation biology			
<b>Total Hours of Training:</b>			

b. Supervised Work Experience (completion of this table is not required for 35.590).  
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Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

**b. Supervised Work Experience. (continued)**

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual \_\_\_\_\_ License/Permit Number listing supervising individual as an authorized user \_\_\_\_\_

Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- 35.190     35.290     35.390     35.390 + generator experience in 35.290(c)(1)(ii)(G)

**c. For 35.590 only, provide documentation of training on use of the device.**

Device	Type of Training	Location and Dates

**d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.**

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

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By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

**First Section**

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For 35.190

Board Certification

I attest that Amy Warpinski, DO has satisfactorily completed the requirements in  
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that \_\_\_\_\_ has satisfactorily completed the 60 hours of training and  
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that Amy Warpinski, DO has satisfactorily completed the requirements in  
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that \_\_\_\_\_ has satisfactorily completed the 700 hours of training  
Name of Proposed Authorized User

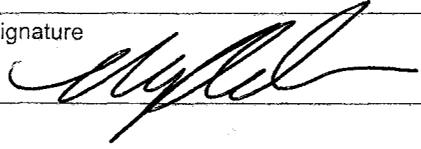
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**Second Section**

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

Name of Preceptor Thomas Archambeau, MD	Signature 	Telephone Number (517) 975-6382	Date 04/14/2011
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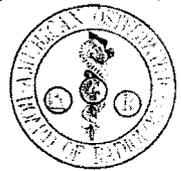
License/Permit Number/Facility Name  
21-04073-01 / Ingham Regional Medical Center

From:

06/10/2009 14:50 #631 P.008/008

The American Osteopathic Association  
upon recommendation  
of the

American Osteopathic Board of Radiology



certifies that

**Amy L. Warpinski, D.O.**

having met the prescribed qualifications and standards and  
passed the required examinations of this Board,  
is qualified as a specialist in

**Diagnostic Radiology**

and is hereby awarded this certificate for the period from  
July 30, 2007 - December 31, 2017



American Osteopathic Association

*John B. Coog*  
Executive Director

Certificate No. 1126

American Osteopathic Board of Radiology

*Mark A. Finkelshten DO, FAOCR*  
Chair

*Neely [Signature]*  
Secretary

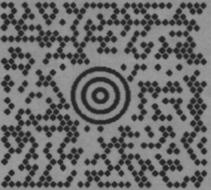
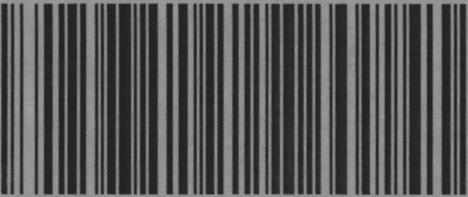
**UPS CampusShip: View/Print Label**

1. **Print the label(s):** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.
2. **Fold the printed label at the solid line below.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.
3. **GETTING YOUR SHIPMENT TO UPS**  
**Customers without a Daily Pickup**  
Schedule a same day or future day Pickup to have a UPS driver pickup all your CampusShip packages.  
Hand the package to any UPS driver in your area.  
Take your package to any location of The UPS Store®, UPS Drop Box, UPS Customer Center, UPS Alliances (Office Depot® or Staples®) or Authorized Shipping Outlet near you. Items sent via UPS Return Services<sup>SM</sup> (including via Ground) are also accepted at Drop Boxes.  
To find the location nearest you, please visit the Resources area of CampusShip and select UPS Locations.

**Customers with a Daily Pickup**

Your driver will pickup your shipment(s) as usual.

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GREENLAWN CAMPUS 5179757675 INGHAM REGIONAL MED CENTER GRN 401 W GREENLAWN AVE LANSING MI 48910	0.0 LBS LTR	1 OF 1
<b>SHIP TO:</b> REGION III, OFFICE OF MATERIALS LIC 6308299500 UNITED STATES NUCLEAR REG. COMM. SUITE 210 2443 WARRENVILLE RD. <b>LISLE IL 60532-4352</b>		<b>IL 603 9-03</b> 
<b>UPS NEXT DAY AIR</b>	<b>1</b>	
TRACKING #: 1Z 421 845 01 9930 9626		
BILLING: P/P		 ™
CS 13.1.13. WXP1E70 15.0A 04/2011		