

# Lutheran Hospital

7950 West Jefferson Boulevard Fort Wayne, IN 46804 (260) 435-7001

September 2, 2010

Colleen C. Casey  
Materials Licensing Branch  
U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville, Suite 210  
Lisle, Illinois 60532

Control # 319034 – Additional Information

Dear Ms. Casey:

The following is in response to your letter dated 08/01/2010 concerning Control Number 319034. Our responses are provided below.

1. With regards to the addition of SIRTex Model Sirspheres, we wish to request a possession limit of 2 Curies for this 35.1000 byproduct material. Additionally we propose Randall J. Phillips, M.D. as the authorized user for this material.
2. In support of adding Ryan Buss, M.D. as an authorized user, we have enclosed documentation from David C. Howell, Radiation Safety Officer of Wake Forest University Baptist Medical Center. Mr. Howell confirms that theirs is a broad scope license and that as a preceptor, James D. Ball, M.D. is and authorized user for 35.100, 35.200 and 35.300 byproduct material.
3. We wish to add Jeffery J. Freeman, M.D. as an authorized user for 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131). In support of the request we have enclosed a copy of Material's License 13-13028-02, which notes Dr. Freeman as an authorized user.
4. We wish to add Andrew V. Barger, M.D. as an authorized user for 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131). In support of this request we have enclosed a preceptor statement and attestation.

We look forward to our amendment. If you have any further questions, please contact our Medical Nuclear Physicist, Thomas M. Kumpuris, M.S., FACR of Medical Physics Consultants, Inc. 800.321.2207 and/or [tkumpuris@mpcphysics.com](mailto:tkumpuris@mpcphysics.com).

Sincerely,



Karen Springer, COO  
Executive Management

RECEIVED SEP 17 2010

Lutheran Health Network Members

Bluffton Regional Medical Center Community Memorial Hospital (an affiliate) Dukes Memorial Hospital Dupont Hospital  
Kosciusko Community Hospital Lutheran Children's Hospital Lutheran Hospital RediMed  
Rehabilitation Hospital of Fort Wayne St. Joseph Hospital

**RUSCHMEYER, JIM**

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From: David C. Howell [<mailto:dhowell@wfubmc.edu>]

Sent: Thursday, August 26, 2010 11:31 AM

To: Patrick Byrne

Subject: RE: Authorized User

Correct, 034-0158-1 is a broad scope medical license; Dr. Ball is approved, in writing by the Medical Radiation Safety Committee, as an

authorized user in Nuclear Medicine under 10 CFR 35.100 (Uptake, dilution, and excretion studies), 35.200 (Imaging and localization studies)

and 35.300 (Use of unsealed byproduct material for which a written directive is required and I-131 therapy.) I will scan and email Dr. Ball's approval in a few minutes.

David C Howell, Radiation Safety Officer

Wake Forest University

Baptist Medical Center

Phone (336)716-1202

Pager (336)806-3183

Fax (336)716-0588

Jim Ruschmeyer RT (R) (N) CNMT

Radiology Manager Lutheran Hospital of Indiana

Ph 260-435-7297 Fax 260-435-6961

e-mail [jruschmeyer@lutheran-hosp.com](mailto:jruschmeyer@lutheran-hosp.com)

**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  
*Ryan Bass, M.D.*

State or Territory Where Licensed  
*Indiana*

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	Wake Forest University Baptist Medical Center Medical Center Blvd Winston-Salem, NC 27157	60	7/1/2004- 6/30/2008
Radiation protection	"	14	"
Mathematics pertaining to the use and measurement of radioactivity	"	4	"
Chemistry of byproduct material for medical use (not required for 35.590)	"	2	"
Radiation biology	"	6	"

Total Hours of Training:

86 plus:

80 hr didactic clinical Nuclear Medicine Lectures + 104 hr Nuclear Med Conferences

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: 710	
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	Wake Forest University Baptist Medical Center Medical Center Blvd Winston-Salem, NC 27157	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2004- 6/30/2008
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	<input checked="" 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	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11
Administering dosages of radioactive drugs to patients or human research subjects	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11
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	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11

Supervising Individual

*JAMES D. BALL, M.D.*

License/Permit Number listing supervising individual as an authorized user

*034-0158-1*

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)**

**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 \_\_\_\_\_ 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 Ryan Buss, M.D. 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 \_\_\_\_\_ 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 Ryan Buss, M.D. 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	Signature	Telephone Number	Date
JAMES D. BALL, M.D.	James D. Ball, M.D.	336-716-3520	5/4/2010
License/Permit Number/Facility Name			

**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.300)  
[10 CFR 35.390, 35.392, 35.394, and 35.396]

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

Name of Proposed Authorized User

Ryan Buss, M.D.

State or Territory Where Licensed

Indiana

Requested Authorization(s) (check all that apply):

35.300 Use of unsealed byproduct material for which a written directive is required

OR

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

35.300 Parenteral administration of any beta-emitter, or 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

**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 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. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.
- c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.
- d. Skip to and complete Part II Preceptor Attestation.

**2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License \_\_\_\_\_ under the requirements below or equivalent Agreement State requirements (check all that apply):

35.390     35.392     35.394     35.490     35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

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

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

- a. Classroom and Laboratory Training  35.390  35.392  35.394  35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Wake Forest University Baptist Medical Center Medical Center Blvd Winston-Salem, NC 27157	60	7/1/2004- 6/30/2008
Radiation protection	"	14	"
Mathematics pertaining to the use and measurement of radioactivity	"	4	"
Chemistry of byproduct material for medical use	"	2	"
Radiation biology	"	6	"
<b>Total Hours of Training:</b>		<del>86</del> plus:	
80 hr didactic clinical Nuclear medicine lectures + 104 hr Nuclear Med Conferences			

- b. Supervised Work Experience  35.390  35.392  35.394  35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Supervised Work Experience		Total Hours of Experience:	
		710	
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	Wake Forest University Baptist Medical Center Medical Center Blvd Winston-Salem, NC 27157	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/1/2004- 6/30/2008
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	"
Calculating, measuring, and safely preparing patient or human research subject dosages	"	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	"
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	"
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	<input checked="" 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)**

Supervising Individual  <b>JAMES D. BALL, M.D.</b>	License/Permit Number listing supervising individual as an authorized user  <b>034-0158-1</b>
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Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)\*\*:

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 35.390 | With experience administering dosages of:   |
| <input checked="" type="checkbox"/> 35.392 | <input checked="" type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)   |
| <input checked="" type="checkbox"/> 35.394 | <input checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)  |
| <input type="checkbox"/> 35.396            | <input checked="" type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required |
|  | <input checked="" type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive   |

\*\* Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

**c. Supervised Clinical Case Experience**

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

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	11	WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER MEDICAL CENTER BLVD WINSTON-SALEM, NC 27157	3-16-06 → 4-21-08
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	16	11	12-15-05 → 4-9-08
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required			
_____ (List radionuclides)			

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

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

c. Supervised Clinical Case Experience (continued)

Supervising Individual  <i>JAMES D. BALL, M.D.</i>	License/Permit Number listing supervising individual as an authorized user  <i>034-0158-1</i>
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Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)\*\*:

- 35.390 With experience administering dosages of:
- 35.392  Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
  - 35.394  Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
  - 35.396  Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
  - Parenteral administration of any other radionuclide requiring a written directive

\*\* Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed 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.

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 requested authorization:

For 35.390:

Board Certification

I attest that \_\_\_\_\_ has satisfactorily completed the training and experience requirements in 35.390(a)(1).  
Name of Proposed Authorized User

**OR**

Training and Experience

I attest that *Ryan Buss, M.D.* has satisfactorily completed the 700 hours of training  
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that Ryan Buss, M.D. has satisfactorily completed the 80 hours of classroom  
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that Ryan Buss, M.D. has satisfactorily completed the 80 hours of classroom  
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

I attest that Ryan Buss, M.D. has satisfactorily completed the required clinical case  
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Third Section

I attest that Ryan Buss, M.D. has satisfactorily achieved a level of competency to  
Name of Proposed Authorized User

function independently as an authorized user for:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

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

**Fourth Section**

**For 35.396:**

**Current 35.490 or 35.690 authorized user:**

I attest that \_\_\_\_\_ is an authorized user under 10 CFR 35.490 or 35.690  
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

- Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- Parenteral administration of any other radionuclide for which a written directive is required

**OR**

**Board Certification:**

I attest that \_\_\_\_\_ has satisfactorily completed the board certification  
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

- Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- Parenteral administration of any other radionuclide for which a written directive is required

**Fifth Section**

**Complete the following for preceptor attestation and signature:**

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

- 35.390       35.392       35.394       35.396

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor <i>JAMES D. BALL, M.D.</i>	Signature <i>James D. Ball, M.D.</i>	Telephone Number <i>336-716-3520</i>	Date <i>5/4/2010</i>
License/Permit Number/Facility Name <i>034-0158-1</i>			

NRC FORM 374

PAGE 1 OF 4 PAGES  
Amendment No. 36

U.S. NUCLEAR REGULATORY COMMISSION

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Howard Regional Health System</p> <p>2. 3500 S. La Fountain Street Kokomo, IN 46902</p>	<p>In accordance with the letter dated <b>June 22, 2010,</b></p> <p>3. License number 13-13028-02 is amended in its entirety to read as follows:</p> <p>4. Expiration date May 31, 2014</p> <p>5. Docket No. 030-13342 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed (not to exceed two curies of iodine-131)</p>
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9. Authorized Use:
- A. Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
  - B. Any imaging and localization study permitted by 10 CFR 35.200.
  - C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at 3500 South La Fountain Street, Kokomo, Indiana.
- 11. Radiation Safety Officer for this license is Rik Stephens, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
  - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
  - B. The following individuals are authorized users for medical uses:

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 2 of 4 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
13-13028-02Docket or Reference Number  
030-13342

Amendment No. 36

Authorized UserMaterial and Use

James M. Scheffler, M.D.	10 CFR 35.200.
Peter Nechay, M.D.	10 CFR 35.200.
Brett A. Hagedorn, M.D.	10 CFR 35.100, 35.200 and 35.300.
John Rock, M.D.	10 CFR 35.100 and 35.200.
Rik Stephens, M.D.	10 CFR 35.100, 35.200 and 35.300.
James C. Wehrenberg, M.D.	10 CFR 35.100 and 35.200.
James A. Arata, M.D.	10 CFR 35.100, 35.200 and 35.300.
David B. Janizek, M.D.	10 CFR 35.100, 35.200 and 35.300.
Christine Anne Tremper, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).
Randall J. Phillips, M.D.	10 CFR 35.100, 35.200 and 35.300.
John Pasalich, M.D.	10 CFR 35.100, 35.200 and 35.300.
Stephen R. Phillip, M.D.	10 CFR 35.100, 35.200 and 35.300.
Marc Thomas, M.D.	10 CFR 35.100, 35.200 and 35.300.
Diane D. Daly, M.D.	10 CFR 35.100, 35.200 and 35.300.
John L. Bormann, M.D.	10 CFR 35.100, 35.200 and 35.300.
Michael E. Parker, M.D.	10 CFR 35.100, 35.200 and 35.300.
Pamela Lee Strange, M.D.	10 CFR 35.100, 35.200 and 35.300.
Joseph R. Decamp, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).
John R. Kim, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 3 of 4 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-13028-02

Docket or Reference Number  
030-13342

Amendment No. 36

Authorized User

Material and Use

Frederick N. Vandeman, M.D.

10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).

Andre Byard Stovall, M.D.

10 CFR 35.100, 35.200 and 35.300.

Christopher Michael Kowalski, M.D.

10 CFR 35.100 and 35.200.

Richard W. Sibley, M.D.

10 CFR 35.100, 35.200 and 35.300.

Dakshesh S. Patel, M.D.

10 CFR 35.100 and 35.200.

Eric V. Heatwole, M.D.

10 CFR 35.100 and 35.200.

Shilpa Kashyap, M.D.

10 CFR 35.100 and 35.200.

Shawn Johnson, M.D.

10 CFR 35.100, 35.200 and 35.300.

Linda G. Hippenhammer, M.D.

10 CFR 35.100, 35.200 and 35.300.

Steven Hossler, M.D.

10 CFR 35.100 and 35.200.

Lawrence Gering, M.D.

10 CFR 35.100 and 35.200.

Jeffrey J. Freeman, M.D.

10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131).

Daniel Branam, M.D.

10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).

13. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Materials."
14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 4 of 4 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

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Amendment No. 36

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated April 20, 2004;
- B. Letter dated March 5, 2006, July 27, 2006, and November 30, 2006; and
- C. Facsimiles dated February 20, 2007, and February 21, 2007.

U.S. NUCLEAR REGULATORY COMMISSION



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 10 2010

By

*William P. Reichhold*

William P. Reichhold  
Materials Licensing Branch  
Region III

**MEDICAL USE TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 10/31/2008

**PART I -- TRAINING AND EXPERIENCE**

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Andrew Vernon Barger, M.D.

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

Minnesota and California

**3. CERTIFICATION**

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.  
Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

**4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS**

- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

**5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)**

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Radiation physics class, Radiation Safety Class & Radiopharmacy rotation; Mayo Clinic/Mayo Medical School, Rochester, MN	110	June 2003 - June 2007
Radiation Protection	"	30	
Mathematics Pertaining to the Use and Measurement of Radioactivity	"	35	
Radiation Biology	"	20	
Chemistry of Byproduct Material for Medical Use	"	40	
OTHER			

**MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION**

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Ordering, receiving, and unpacking material safely and performing related radiation surveys; performing quality control procedures on	Brian P. Mullan, M.D.	Mayo Clinic Rochester, MN #22-00519-03	June 2003 - June 2007
instruments used to determine dosages and performing checks for proper operation of survey meters; calculating, measuring and safely			
preparing patient dosages; using administrative controls to prevent a medical event involving unsealed byproduct material; using procedures			
to safely contain spilled radioactive material and using proper decontamination procedures; administering dosages of radioactive drugs to			
patients; and eluting generator systems appropriate for preparation of radioactive drugs, measuring and testing the eluate for purity, and processing			
the eluate with reagent kits to prepare labeled radioactive drugs.			

**6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)**

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
I-131	Nal Therapy < 33 mCi	4	Brian P. Mullan,	Mayo Clinic	June 2003 -
I-131	Nal Therapy > 33 mCi	3	M.D.	Rochester, MN #22-00519-03	June 2007

**MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)**

Training Element	Type of Training •	Location and Dates
N/A		

\* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

**7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists**

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
N/A			

**8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE**

- YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
- N/A of \_\_\_\_\_ the RSO for License No. \_\_\_\_\_

**9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE**

- YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of \_\_\_\_\_
- N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

**and**

- YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) \_\_\_\_\_
- N/A under the supervision of \_\_\_\_\_ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) \_\_\_\_\_

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each):

A. Name of Supervisor

Brian P Mullan, M.D.

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.57, 35.290, and 35.390

for medical uses in Part 35, Section(s) 35.100, 35.200, and 35.300

D. Address

Mayo Clinic  
200 First Street SW  
Rochester, MN 55905

E. Materials License Number

NRC - 22-00519-03

PART II -- PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.290, 35.392, 35.394, as documented in section(s) 5, 6a and 6b of this form.

11b. Select one

meets the requirements in  35.50(e)  35.51(c)  35.390(b)(1)(ii)(G)  35.690(c) for

N/A

types of use, as documented in section(s) of this form.

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized User for 35.100, 35.200 and uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR**  I am a Radiation Safety Officer; **OR**

I meet the requirements of 35.57, 35.290, 35.390 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor  AU or  AMP

for the following byproduct material uses (or units): 35.100, 35.200, 35.300

A. Address

Mayo Clinic  
200 First Street SW  
Rochester, MN 55905

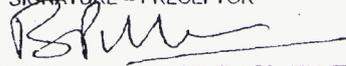
B. Materials License Number

NRC - 22-00519-03

C. NAME OF PRECEPTOR (print clearly)

Brian P. Mullan, M.D.

D. SIGNATURE -- PRECEPTOR



E. DATE

04/19/07

LUTHERAN HOSPITAL  
7950 W. JEFFERSON BLVD.  
FORT WAYNE, IN 46804

OCR Reject

N3-120

FIRST-CLASS MAIL  
US POSTAGE PAID  
Fort Wayne, IN  
PERMIT# 760



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4



US Nuclear Regulatory Commission  
Materials Licensing Branch  
Region III

ATTN: Colleen C. Casey

2443 Warrenville, Suite 210

Lisle, Illinois

60532