

# Lutheran Hospital

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

**5/13/2010**

**U.S Nuclear Regulatory Commission**

**Region III**

**Materials Licensing Branch**

**2443 Warrenville Road, Suite 210**

**Lisle, Illinois 60532**

**Re: Amendment to 13-01535-01**

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**Dear Madam or Sir:**

**We wish to amend our Materials License 13-01535-01 as follows:**

**ADD AUTHORIZED USER**

**Ryan Buss, M.D. for 10 CFR 35.100, 35.200 and 35.300, for I131 <33mCi and >33mCi.**

**In support of this request we have enclosed a copy of the NRC form 313A (AUT) and NRC form 313A (AUD).**

**If you have any questions this issue, please contact our Medical Nuclear Physicist Tom M. Kumpuris, M.S., DABR of Medical Physics Consultants, Inc. 800.321.2207.**

**Sincerely,**



**Karen Springer COO**

**Executive Management**

**Lutheran hospital**

**RECEIVED MAY 25 2010**

**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 Buss, 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	"

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

License/Permit Number listing supervising individual as an authorized user

JAMES D. BALL, M.D.

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	"

**Total Hours of Training:** 86 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>
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input checked="" type="checkbox"/> 35.390 <input checked="" type="checkbox"/> 35.392 <input checked="" type="checkbox"/> 35.394 <input type="checkbox"/> 35.396	With experience administering dosages of: <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"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <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 <b>JAMES D. BALL, M.D.</b>	License/Permit Number listing supervising individual as an authorized user <b>034-0158-1</b>
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 checked="" 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.	

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

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

