



November 13, 2007

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

Dear Sir or Madam:

This letter is a follow up for the request dated October 25, 2007. It contains the additional information requested by Mr. James Malow in a telephone conversation.

Bloomington Hospital would like to amend its Byproduct Materials License, Number 13-10408-02, to add Jonathan A. Staser, M.D. as an Authorized User for materials licensed under 10 C.F.R. 35.100, 35.200, and 35.392. Enclosed is a copy of Dr. Staser's American Board of Radiology certificate as well as a completed U.S.N.R.C. Forms 313A(AUD) and 313A(AUT).

Additionally, we request the addition to our license of John F. Alexander, M.D. as an Authorized User for materials licensed under 10 C.F.R. 35.100, 35.200, and 35.392. Dr. Alexander has previously been listed as an Authorized User for 35.100 and 35.200 materials on U.S.N.R.C. Byproduct Materials License Number 13-05605-01 (Jackson County Schneck Memorial Hospital). Enclosed is a copy of that license as well as N.R.C. Form 313A(AUT), documenting his 35.392 experience.

In addition, Appendix I contains a list of the Cs-137 brachytherapy tubes currently on site and the manufacturers that could potentially supply us with seeds for temporary and permanent implants.

If there are any questions concerning this license amendment, please contact our nuclear medicine consultant, Mr. Patrick J. Byrne, D.A.B.R., C.H.P., at 877-317-5811.

Sincerely,

William Van de Riet, Ph.D., D.A.B.R.
Radiation Safety Officer

RECEIVED DEC 13 2007



DIAGNOSTIC RADIOLOGY RADIATION ONCOLOGY RADIOLOGIC PHYSICS

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- Philip O. Alderson, M.D., President
L. Reed Dunnick, M.D., President-Elect
Beth A. Erickson, M.D., Secretary-Treasurer

June 5, 2007

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Thomas H. Berquist, M.D. Jacksonville, Florida
George S. Bisset, M.D. Durham, North Carolina
James P. Borgstede, M.D. Colorado Springs, Colorado
N. Reed Dunnick, M.D. Ann Arbor, Michigan
Glenn S. Forbes, M.D. Rochester, Minnesota
Valerie P. Jackson, M.D. Indianapolis, Indiana

54291 / DR / 14 / 22

Jonathan Andrew Staser, MD
520 E. 61st. St.
Indianapolis, IN 46220

Dear Dr. Staser:

I am pleased to inform you that you passed the oral examination held on June 3-6, 2007. The American Board of Radiology grants you its Certificate in Diagnostic Radiology. This is a ten-year time-limited certificate. In addition, because you received the appropriate training to make you AU-Eligible and passed the NRC-related portions of the nuclear medicine section, you will receive the AU-Eligible designation on your certificate.

Radiation Oncology

- Matthew A. Mauro, M.D. Chapel Hill, North Carolina
Christopher R. B. Merrill, M.D. Philadelphia, Pennsylvania
Anthony V. Proto, M.D. Richmond, Virginia
Anne C. Roberts, M.D. La Jolla, California
Janet L. Strle, M.D. Cincinnati, Ohio
Kay H. Vydarany, M.D. Atlanta, Georgia
Douglas H. Yock, Jr., M.D. Minneapolis, Minnesota

The certificate will be sent to the above address in approximately three months from our printer, Jim Henry, Inc. Your name will appear on the certificate as shown above. If you wish your name to appear differently or you have an address change, please notify the Board office in writing by July 05, 2007. Your name and demographic information will be included in a Directory published by the American Board of Medical Specialties. It is your responsibility to notify other local and state or national organizations of your certification.

Important information about your Maintenance of Certification process is enclosed. Please review it and respond as requested.

Personally and on behalf of the Board of Trustees of The American Board of Radiology, I wish to congratulate you for this distinguished achievement. You have accomplished one of the most significant milestones in your career.

Sincerely,

R.R. Hattery

Robert R. Hattery, MD

Radiation Oncology

- K. Kian Ang, M.D., Ph.D. Houston, Texas
Beth A. Erickson, M.D. Milwaukee, Wisconsin
Bruce G. Haffty, M.D. New Brunswick, New Jersey
Richard T. Hoppe, M.D. Stanford, California
Larry E. Kun, M.D. Memphis, Tennessee
Christopher G. Willett, M.D. Durham, North Carolina

Enclosures

Radiologic Physics

- G. Donald Frey, Ph.D. Charleston, South Carolina
Richard L. Morin, Ph.D. Jacksonville, Florida
Bhurdatt R. Paliwal, Ph.D. Madison, Wisconsin

Robert R. Hattery, M.D., Executive Director
Gary J. Becker, M.D., Associate Executive Director
Lawrence W. Davis, M.D., Associate Executive Director
Stephen R. Thomas, Ph.D., Associate Executive Director
Assistant Executive Directors: Primary Certification
Assistant Executive Directors: Maintenance of Certification

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 2 PAGES
Amendment No. 31

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>Licensee</p> <p>1. Jackson County Schneck Memorial Hospital</p> <p>2. 411 West Tipton P. O. Box 490 Seymour, IN 47274</p>	<p>In accordance with the letter dated November 23, 2004,</p> <p>3. License number 13-05605-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date September 30, 2014</p> <p>5. Pocket No. 030-01622 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 45.100</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>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 exceed 200 millicuries of iodine-131)</p>
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<p>9. Authorized Use:</p> <p>A. Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.</p> <p>B. Any imaging and localization study permitted by 10 CFR 35.200.</p> <p>C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma therapy).</p>

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at 411 West Tipton, Seymour, IN.
- 11. Radiation Safety Officer: Lisa Cosby, B.S., CNMT.



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-05605-01

Docket or Reference Number
030-01622

Amendment No. 31

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 the materials and uses indicated:

Authorized Users

Material and Use

Neil Edward Staib, M.D.

10 CFR 35.100, 35.200 and 35.300 (excluding iodine-131 for thyroid carcinoma therapy).

Gregory M. Sutliff, M.D.

10 CFR 35.100, 35.200 (limited to cardiovascular clinical procedures only).

John F. Alexander, M.D.

10 CFR 35.100 and 35.200

13. In addition to the possession limits in 10 CFR 35.26, 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.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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 March 11, 2004.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date FEB 02 2005

By William P. Reichhold
William P. Reichhold
Materials Licensing Branch
Region III

UNIVERSITY
UNIVERSITY
INDIANAPOLIS

NRC Form 313a (AUT)
Attachment #1



The individual applying for authorization on the attached NRC Form 313a (AUT) was trained in the Radiology Residency Program at the Indiana University School of Medicine which is fully accredited by the Accreditation Council for Graduate Medical Education (ACGME). The "Authorized Users" who supervised this training were approved by the Radionuclide Radiation Safety Committee under NRC License No. 13-02752-03. Those individuals whose names are listed below are fully authorized for all radionuclides and uses listed in 10 CFR 35.100 and 10 CFR 35.300:

RADIATION
SAFETY OFFICE

James W. Fletcher, M.D. – authorized March 12, 2002 to present*
Donald S. Schauwecker, M.D., Ph.D – authorized June 14, 1982 to present*
Aslam R. Siddiqui, M.D. – authorized July 1, 1976 to present*
Mark Tann, M.D. – authorized March 11, 2003 to present*
Steven M. Westphal, M.D. – authorized September 13, 2005 to present*

A handwritten signature in cursive script that reads "Mack L. Richard".

Mack L. Richard, M.S., C.H.P.
Radiation Safety Officer
Indiana University School of Medicine
Indiana University Medical Center
IUPUI

*Last Update: May 1, 2007

Clinical Building 159
541 Clinical Drive
Indianapolis, Indiana
46202-5111

317-274-4797
Fax: 317-274-2332

IU School of Medicine
IU Medical Center &
Associated Facilities

Appendix 1
Bloomington Hospital License No. 13-10408-02
Bloomington, IN
Department of Radiation Oncology 35.400 Sealed Source Inventory
November, 2007

SEALED SOURCE

Element	Mass #	Maximum Activity	Mfg. Name	Model #	Storage Container	Type of Device	Number of These Devices
Cs	137	41.6 mCi each	Nuclear Assoc.	67-803	Lead Safe	sealed tube	3
Cs	137	58.3 mCi each	Nuclear Assoc.	67-804	Lead Safe	sealed tube	3
Cs	137	103 mCi each	Amersham	CDCCY102	Lead Safe	sealed tube	1

These sources are for temporary implants and are stored in a locked room on the first floor of the hospital

I	125	as needed	Amersham	6711	Shipping	sealed tube	as needed
I	125	as needed	Amersham	6733	Shipping	sealed tube	as needed
Pd	103	as needed	Best	2335	Shipping	sealed tube	as needed
I	125	as needed	North Am. Scientific	Prospera	Shipping	sealed tube	as needed
Pd	103	as needed	Theragenics	TheraSeed	Shipping	sealed tube	as needed
Pd	103	as needed	North Am. Scientific	Prospera	Shipping	sealed tube	as needed
I	125	as needed	Best	2301	Shipping	sealed tube	as needed
I	125	as needed	Imagyn (Bard)	STM-125	Shipping	sealed tube	as needed
I	125	as needed	Syncor	Pharmaseed	Shipping	sealed tube	as needed
Cs	131	as needed	IsoRay	Proxcelan	Shipping	sealed tube	as needed

Quantity on hand of I-125 at any time not to exceed 500 mCi; quantity on hand of Pd-103 at any time not to exceed 1600 mCi; quantity on hand of Cs-131 at any time not to exceed 2000 mCi.

These sources are used for permanent implants. Prior to use, they are stored in the Nuclear Medicine hot lab or in the Cs-137 storage room on the first floor of the hospital. Any left over seeds, are stored in lead shipping containers in the Cs-137 storage room for decay. An inventory of stored seeds is kept in the Cs-137 storage room.

**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. 3160-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User
John Alexander, 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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			

Total Hours of Training:

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:	
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	
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	

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	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements (<i>check all that apply</i>)**:	
<input type="checkbox"/> 35.390	With experience administering dosages of:
<input type="checkbox"/> 35.392	<input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.394	<input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.396	<input 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 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)	10	Indiana University School of Medicine/ 13-02752-03	07/1/00-06/30/04
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
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 James W. Fletcher, M.D.	License/Permit Number listing supervising individual as an authorized user 13-02752-03
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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.

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 _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).
Name of Proposed Authorized User

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 John Alexander, 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 _____ 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 John Alexander, 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 John Alexander, 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

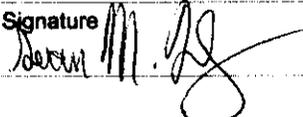
Complete the following for preceptor attestation and signature:

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 Sean Flynn, M.D.	Signature 	Telephone Number 812-833-7675	Date 12/6/7
License/Permit Number/Facility Name 13-10408-02/Bloomington Hospital			

**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. 3180-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User
Jonathan Andrew Staser, 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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			
Total Hours of Training:			

**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 (*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)

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that Jonathan A. Staser, MD 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 Jonathan A. Staser, MD 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.

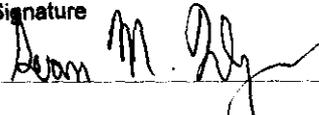
Second Section

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
Sean Flynn, M.D.

Signature


Telephone Number
812-333-7576

Date
12/6/7

License/Permit Number/Facility Name
13-10408-02/Bloomington Hospital



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Materials Licensing Section
2443 Warrenville Road, Suite 210
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