Hendricks
Regional Health

Corporate Offices
1000 East Main Street
Danville, IN 46122
317 745 4451
www.hendricksregional.org

April 23, 2009

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

Dear Sir or Madam:

Hendricks Regional Health would like to amend its NRC Byproduct Material License, Number 13-17082-01, to add Mark G. Ferrara, M.D. as an Authorized User of materials licensed under 10CFR 35.100, 35.200, and 35.392. Enclosed is documentation that Dr. Ferrara is certified by the American Board of Radiology in Diagnostic Radiology and has earned the "AU Eligible" designation, as well as completed Form 313A(AUD) and Form 313A(AUT).

In addition, we request that all Authorized Users listed on our license be granted authorization to utilize iodide-131 for diagnostic purposes.

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

Sincerely,

Joseph Hunt, M.D.
Radiation Safety Officer.

NRC FORM 313A (AUD) (10-2007) | U.S. NUCLEAR REGULATORY COMMISSION

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: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
Mark G. Ferrara, M.D.	Indiana

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

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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.

- [x] **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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	

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		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ 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		☐ Yes ☐ 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.

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
(10-2007)

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 Mark G. Ferrara, M.D. 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 Mark G. Ferrara, M.D 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	Signature	Telephone Number	Date
Joseph Hunt M.D.		317-745-3425	10-8-08

License/Permit Number/Facility Name
13-17082-01, Amendment No 17, Hendricks Regional Health.

NRC FORM 313A (AUT) (3-2007) | U.S. NUCLEAR REGULATORY COMMISSION

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: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
Mark G. Ferrara, M.D.	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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and **safely preparing patient or** human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ 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
See Attachment #1	13-02752-03, UHNM01, RINM01, WDNM01

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

With experience administering dosages of:

- ☐ 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

** 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)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3	Indiana University School of Medicine, NRC Lic. No. 13-02752-03, 13-02752-03, UHNM01, RINM01, WDNM01	1-30-2007
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 adminstration 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	License/Permit Number listing supervising individual as an authorized user
See Attachment #1	13-02752-03, UHNM01, RINM01, WDNM01

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

- ☑ 35.390
- ☐ 35.392
- ☐ 35.394
- ☐ 35.396

With experience administering dosages of:

- ☑ 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

** 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 Mark G. Ferrara, M.D. has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

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 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 Mark G. Ferrara, 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 Mark G. Ferrara, 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 Mark G. Ferrara, 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 Mark G. Ferrara, 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

NRC FORM 313A (AUT) (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USI (TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35 80 authorized user:

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

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

☐ Parenteral adn istration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV f which a written directive is required

☐ Parenteral adn stration 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 98(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CF 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and s achieved a level of competency sufficient to function independently as an authorized user fo

☐ Parenteral adn stration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV f which a written directive is required

☐ Parenteral adn stration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for eceptor attestation and signature:

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

☑ 35.390 ☐ 392 ☐ 35.394 ☐ 35.396

☑ I have experience adr istering dosages in the following categories for which the proposed Authorized User is requesting authorizati

☑ Oral NaI-131 requ g a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in qu ities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral adminis tion of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring written directive is required

☐ Parenteral adminis tion of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
Mark Tann, M.D.		317-274-1808	4/7/09

License/Permit Number/Facility me
License No. 13-02752-03, UHNI , RINM01, WDNM01 Indiana University School of Medicine

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The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Mark G. Ferrara, MD

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this third day of June, 2008
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

AM Eligible

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

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RADIATION
SAFETY OFFICE

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:

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*

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

Form B

I-131 Therapy Experience

MARK FERRARA
Resident Name

INDIANA UNIVERSITY
Program & Number

	Date	Dose Administered	Preceptor (AU) Print & Sign Name
1.	1/30/07	150 mCi	Print Name: M. Mark Tann Sign Name:
2.	1/30/07	150 mCi	Print Name: M. Mark Tann Sign Name:
3.	1/30/07	150 mCi	Print Name: Mark Tann Sign Name:
4.	1/30/07	100 mCi	Print Name: Mark Tann Sign Name:

	Date	Dose Administered	Preceptor (AU) Print & Sign Name
1.	2/1/08	100 mCi	Print Name: M. Mark Tann Sign Name:
2.			Print Name: Sign Name:

Hendricks
Regional Health

1000 East Main Street
Danville, IN 46122

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U.S. Nuclear Regulatory Commission

Materials Licensing Section

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Suite 210
Lisle, IL
60532-4352