



16001 West Nine Mile Road  
Southfield, MI 48075

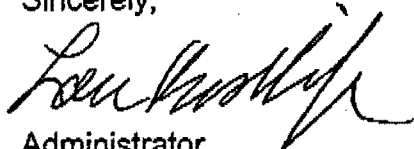
UNITES STATES NUCLEAR REGULATORY COMMISSION  
Region III, Materials Licensing Section  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

Re: Amendment to License No. 21-02802-03

1. Please add Ali N. Harb, MD as an authorized user for 35.100, 35.200 and 35.300 (oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels and in quantities greater than 1.22 gigabecquerels). Please find the enclosed NRC forms 313A(AUD) and 313A(AUT) for your review.

Thank you for your cooperation with this matter. If you have any question please contact our physicist, Michelle Kritzman, at (734) 662-3197 or by email at [mkritzman@mpcphysics.com](mailto:mkritzman@mpcphysics.com)

Sincerely,



Administrator  
Providence Hospital  
Southfield, Michigan

NRC FORM 313A (AUD)  
(3-2009)

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: 3/31/2012

Name of Proposed Authorized User <b>All N. Harb, MLD</b>	State or Territory Where Licensed <b>Michigan</b>
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Requested Authorization(s) (check all that apply)

35.100 Uptake, dilution, and excretion studies

35.200 Imaging and localization studies

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

**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)

NRC FORM 313A (AUD)  
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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

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

**a. Classroom and Laboratory Training.**

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
<b>Total Hours of Training:</b>			

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

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

NRC FORM 313A (AUD)  
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

**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.**

NRC FORM 313A (AUD)  
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

**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 Ali N. Harb, 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 Ali N. Harb, 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 <u>Allan Fraiberg RSO</u>	Signature 	Telephone Number <u>248-849-2644</u>	Date <u>8-14-12</u>
License/Permit Number/Facility Name <u>St. John Providence Hospital NRC # 21-02802-03</u>			

# 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 Radiation Oncology, the Association of  
University Radiologists, and the American Association of Physicists in Medicine*

*Hereby certifies that*

**Ali N. Harb, MD**

*Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications, including  
passing the examinations conducted under the authority of*

*The American Board of Radiology,*

*demonstrating to the satisfaction of the Board that he is qualified to practice,*

*and is therefore awarded the Board's certification in the specialty of*

**Diagnostic Radiology**

*Effective November 8, 2010*

*Sam J. Harney*  
President

*Richard L. Morin*  
Secretary-Treasurer

*Hayden S. ...*  
Executive Director



**AB Eligible**



**Certificate No. 58369**

**Valid through 2020**

NRC FORM 313A (AUT)  
(3-2009)

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: 3/31/2012

Name of Proposed Authorized User

State or Territory Where Licensed

Ali N. Harb, M.D.

Michigan

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.

NRC FORM 313A (AUT)  
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

**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			
<b>Total Hours of Training:</b>			

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	



NRC FORM 313A (AUT)  
(2-2008)

U.S. NUCLEAR REGULATORY COMMISSION

**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)	3	St John Providence Hospital Diagnostic Radiology NRC # 21-02802-03	12/11/09 12/2/09 11/20/09
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3	St. John Providence Hosp't = Diagnostic Radiology NRC # 21-02802-03	3/5/12 8/14/12 8/14/12
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	N/A	N/A	N/A
Parenteral administration of any other radionuclide for which a written directive is required	N/A	N/A	N/A
_____ (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
------------------------	--

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

- |  |  |
|--|--|
| <input type="checkbox"/> 35.390<br><input type="checkbox"/> 35.392<br><input type="checkbox"/> 35.394<br><input type="checkbox"/> 35.396 | With experience administering dosages of:<br><input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)<br><input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)<br><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<br><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.

**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 Ali N. Harb, M.D. 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 \_\_\_\_\_ 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 Ali N. Harb, 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 Ali N. Harb, 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)  
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

**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>Allan Fraiberg, RSO</i>	Signature <i>[Signature]</i>	Telephone Number <i>248-849-2699</i>	Date <i>8-14-12</i>
License/Permit Number/Facility Name <i>St. John Providence Hospital NRC # 21-02802-03</i>			

# 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 Radiation Oncology, the Association of  
University Radiologists, and the American Association of Physicists in Medicine

Hereby certifies that

**Ali N. Harb, MD**

Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications, including  
passing the examinations conducted under the authority of  
The American Board of Radiology,  
demonstrating to the satisfaction of the Board that he is qualified to practice,  
and is therefore awarded the Board's certification in the specialty of

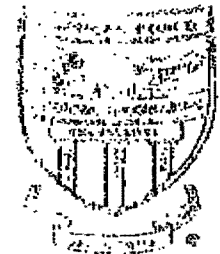
**Diagnostic Radiology**

Effective November 8, 2010

*Paul J. Harter*  
President

*Richard L. Moran*  
Secretary-Treasurer

*Harold S. ...*  
Executive Director



Certificate No. 58869

Valid through 2020



# PROVIDENCE

## FACSIMILE TRANSMITTAL SHEET

To: Material Licensing	From: Nuclear Medicine Dept. Providence Hospital
Fax Number: (630) 515-1078	Date: Southfield, MI 48075
Company: NRC	Number of pages including cover: 14
Phone Number:	Phone Number: 248-849-3262
RE:	
Notes or comments:	
<p>Attn: Material Licensing</p>	

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