

  
**ST. JOHN DETROIT RIVERVIEW HOSPITAL**  
7733 E. Jefferson  
Detroit, MI 48214

**DATE: January 24, 2007**

United States Nuclear Regulatory Commission  
Region III, Materials Licensing  
2443 Warrenville Road Suite 210  
Lisle, IL 60532-4352

**RE: Additional information concerning license #21-32449-01  
Control Number 315868  
St John Detroit Riverview Hospital**

**Dear Sir/Madam:**

Per our phone conversation on January 16, 2007:

**Item #1. Please add the following physician to our current NRC license.**

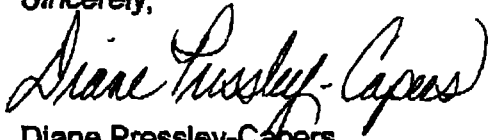
**Ted Harb, M.D.**

**Group 35.100 and 35.200**

We have enclosed a completed copy of his NRC form 313A (AUD).

Thank you for your cooperation. If you have any questions or require additional information, please contact our medical physics consultant, Kevin B. Miller at 734-662-3197.

Sincerely,



**Diane Pressley-Capers  
Vice President of Professional Services**

<b>NRC FORM 313A (AUD)</b> <small>(10-2006)</small>		<b>U.S. NUCLEAR REGULATORY COMMISSION</b>		<b>APPROVED BY OMB: NO. 3150-0120</b> <b>EXPIRES: 10/31/2008</b>	
<b>AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b> <b>(for uses defined under 35.100, 35.200, and 35.500)</b> <b>[10 CFR 35.190, 35.290, and 35.590]</b>					
Name of Proposed Authorized User <u>Ted Harb, MD</u>			State or Territory Where Licensed <u>Michigan</u>		
Requested Authorization(s) (check all that apply)					
<input checked="" type="checkbox"/> 35.100 Uptake, dilution, and excretion studies					
<input checked="" type="checkbox"/> 35.200 Imaging and localization studies					
<input type="checkbox"/> 35.500 Sealed sources for diagnosis (specify device _____)					
<b>PART I – TRAINING AND EXPERIENCE</b> <i>(Select one of the three methods below)</i>					
* 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.					
<input type="checkbox"/> <b>1. Board Certification</b>					
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.					
<input type="checkbox"/> <b>2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization</b>					
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. <i>(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)</i>					
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					
<b>Total Hours of Experience:</b>					
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).					
<input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 + generator experience in 32.290(c)(1)(ii)(G)					

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## 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	Harper University Hospital	60	2001-2002
Radiation protection	Harper University Hospital	5	2001-2002
Mathematics pertaining to the use and measurement of radioactivity	Harper University Hospital	5	2001-2002
Chemistry of byproduct material for medical use (not required for 35.590)	Harper University Hospital	5	2001-2002
Radiation biology	Harper University Hospital	5	2001-2002
Total Hours of Training:		80	

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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Harper University Hospital 21-04127-02	10	2001-2005
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Harper University Hospital 21-0412702	10	2001-2005
Calculating, measuring, and safely preparing patient or human research subject dosages	Same	10	2001-2005

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## 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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Hager University Hospital 21-04127-02	10	2001-2005
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Same	5	2001-2005
Administering dosages of radioactive drugs to patients or human research subjects	Same	675	2001-2005
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	Same	10	2001-2005

Total Hours of Experience: 730

Supervising Individual

Richard N. Soyritz, MD

License/Permit Number listing supervising individual as an authorized user

21-04127-02

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.

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## 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 \_\_\_\_\_ 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 Ted Harb, MD 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 Ted Harb, MD 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

Richard N Joyrich 190

Signature



Telephone Number

313 745 8585

Date

1/30/07

License/Permit Number/Facility Name