

December 11, 2018

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

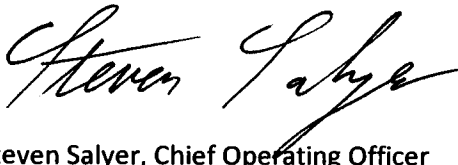
**Re: Materials License No. 21-05432-04**

This letter is to request authorization of Dr. John Cox for administration of oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) for the license listed above. Enclosed is the application form 313A (AUT).

Dr. Cox has education, familiarization, and training for 35.300. He has recently participated in three malignant therapies, which are documented on form 313A (AUT).

If you have further questions, please contact Jan Chudy, CNMT, at (906) 225-3545 or email at [janice.chudy@mghs.org](mailto:janice.chudy@mghs.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Salyer". The signature is fluid and cursive, with the first name "Steven" and last name "Salyer" clearly distinguishable.

Steven Salyer, Chief Operating Officer

RECEIVED DEC 18 2018

**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: 06/30/2019

Name of Proposed Authorized User

Dr. John Cox

State or Territory Where Licensed

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.

## 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: <input type="text"/>			

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

Dr. Michael Ouimette

License/Permit Number listing supervising individual as an authorized user

21-05432-04

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

- |  |   |
|--|---|
| <input type="checkbox"/> 35.390            | With experience administering dosages of: |
| <input type="checkbox"/> 35.392            |   |
| <input checked="" type="checkbox"/> 35.394 |   |
| <input type="checkbox"/> 35.396            |   |
|  |   |
- ☐ 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	UPHS Marquette	7-3-18 10-24-18 12-11-18
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 <div></div> <div>(List radionuclides)</div>			

**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

Dr. Michael Ouimette

License/Permit Number listing supervising individual as an authorized user

21-05432-04

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 Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☒ 35.394

☒ Oral Nal-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.

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 Dr. John Cox 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 Dr. John Cox 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 Dr. John Cox 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

Dr. Michael Quimette

Signature



Telephone Number

(906) 225-6970

Date

12/11/19

License/Permit Number/Facility Name

21-05432-04 UPHS Marquette

**UP HEALTH SYSTEM**  
MARQUETTE

A Duke LifePoint Hospital

Medical Staff Office  
420 West Magnetic Street, W-111, Marquette, MI 49855  
ADDRESS SERVICE REQUESTED



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