

April 28, 2009

Materials Licensing Branch Chief
U.S. Nuclear Regulatory Commission
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

To Whom It May Concern:

We wish to amend our license #24-18628-01 to add Dr. Patrick O'Keefe as an Authorized User for 35.394. Please find enclosed form NRC 313A (AUT) filled out and signed by Dr. Marci Brecheisen, his preceptor. Dr. O'Keefe is currently on our license for 35.392.

Please don't hesitate to call me at (816) 691-5204 if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Matt Foresman", written over a horizontal line.

Matt Foresman

Vice President of Professional Services

RECEIVED MAY 05 2009

**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

Patrick W. O'Keefe, M.D.

State or Territory Where Licensed

Missouri License Number 2007011172

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 24-18628-01 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 <input type="checkbox"/> 35.392 <input type="checkbox"/> 35.394 <input type="checkbox"/> 35.396 | With experience administering dosages of: <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"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <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) | | | |
| Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) | 3 | North Kansas City Hospital 24-18628-01 | 6/12/08 6/13/08 4/24/09 |
| 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) | | | |

3. Training and Experience for Proposed Authorized User (continued)

| | |
|--|--|
| Supervising Individual | License/Permit Number listing supervising individual as an authorized user |
| Carl VanTassell, M.D. | 24-18628-01 |
| Supervising individual meets the requirements below, or equivalent Agreement State requirements (<i>check all that apply</i>)**: | |

- ☐ 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

d. Provide completed 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 _____ 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
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 _____ 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 **Patrick W. O'Keefe, 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 **Patrick W. O'Keefe, 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 **Patrick W. O'Keefe, 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

North Kansas City Hospital
Dept of Nuclear Medicine
2500 Clay Edwards Drive
North Kansas City, Mo. 64116

AUTOPRESORTED FIRST-CLASS
604 605 60532 N2-66



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RETURN SERVICE REQUESTED

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LISLE IL 60532-4352

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