



PARKVIEW

COMPREHENSIVE CANCER CENTER

March 3, 2009

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

RE: Control Number 317595 Additional Information

Ms. Casey:

Please allow this letter to address your request for additional information, made in the cover letter to amendment number 97 of Byproduct Materials License Number 13-01284-02 (Parkview Health).

We wish to have the authorization for 10 C.F.R. 35.500 removed from the license. We confirm that we are no longer in possession of any sources licensed under 10 C.F.R. 35.500. All sources that we had in possession were disposed of on 6/9/05 and are listed on the Uniform Low-Level Radioactive Waste Manifest as Gd-153 (Gadolinium-153). Attached are the Sealed Source Leak Tests for the sources marked with asterisks(*)

Please add Brad M. Johnston, M.D. as an Authorized User of materials licensed under 10 C.F.R. 35.100, 35.200, and 35.300. Enclosed are revised NRC Form 313As, showing his supervisor during his residency training.

Finally, we confirm that the address of use referred to as "Parkview Whitley Hospital" in the letter dated November 4, 2008 is listed in 10.d. as 353 North Oak Street, Columbia City, Indiana.

If there are any questions concerning this license amendment, please feel free to contact me directly at 260-266-9147.

Sincerely,

Subhash C. Sharma, Ph.D., F.A.C.R.
Radiation Safety Officer

Enclosures

RECEIVED MAR 10 2009

Medical Physics Consultants, Inc.

Sealed Source Leak Test

Licensee: Parkview Hospital

Date: 04/13/05

Calibration Calibration

| Nuclide | Type | Activity | Date | Location | M/N | S/N |
|----------|-------|-----------|---------|------------|----------|------------|
| Cs-137 | Vial | 105 uCi | 6/12/77 | Hot Lab | Capintec | 294-280-04 |
| Co-57 | Vial | 10.91mCi | 4/1/02 | Hot Lab | MED3550 | 17821 |
| Co-57 | Flood | 15 mCi | 5/03/04 | Hot Lab | BM01-15 | BM01150222 |
| Cs-137 | Vial | 253.1 | 8/1/04 | Hot Lab | Syncor | 1032-25-8 |
| * Cs-137 | Vial | 1 mCi | 4/1/71 | Hot Lab | 1DA | 045 |
| Cs-137 | Vial | 253.8 mCi | 3/1/05 | Cardiology | IPL | 1093-82-1 |

Comment: The sources listed above were leak tested using a dry wipe technique and were found to have less than 0.005 uCi removable activity. The following Minimum Detectable Activities are based upon a background at the indicated value. Background was at or below these levels when the above tests were completed.

Well Counter: Ludlum 2200 Scaler

| Nuclide | MDA | Background |
|---------|--------------------------|------------|
| Cs-137 | 1.9×10^{-4} uCi | 37 cpm |
| Ba-133 | 7.0×10^{-5} uCi | 285 cpm |
| Co-57 | 4.0×10^{-5} uCi | 285 cpm |

Tested by: *Robert R. [Signature]* Date: 4-13-05

RADIATION SAFETY OFFICER: *S. C. Shaheen*

Medical Physics Consultants, Inc.

Sealed Source Leak Test

Licensee: Parkview - Noble Hospital

Date: 04/01/05

| Nuclide | Type | Calibration | | Location | M/N | S/N |
|----------|-------|-------------|----------|----------|-----------|------------|
| | | Activity | Date | | | |
| Cs-137 | Vial | 197 uCi | 08/01/91 | Hot Lab | Nuc Assoc | 364-54-9 |
| * Ba-133 | Vial | 276.6 uCi | 08/01/83 | Hot Lab | BDC.VI | 2236MA |
| Co-57 | Flood | 10mCi | 11/02/04 | Hot Lab | BMO1-01 | BM01101465 |

Comment: The sources listed above were leak tested using a dry wipe technique and were found to have less than 0.005 uCi removable activity. The following Minimum Detectable Activities are based upon a background at the indicated value. Background was at or below these levels when the above tests were completed.

Well Counter: Ludlum 2200 Scaler

| Nuclide | MDA | Background |
|---------|--------------------------|------------|
| Cs-137 | 1.9×10^{-4} uCi | 37 cpm |
| Ba-133 | 7.0×10^{-5} uCi | 285 cpm |
| Co-57 | 4.0×10^{-5} uCi | 285 cpm |

Tested by: *[Signature]* Date: 4-1-05

RADIATION SAFETY OFFICER: *[Signature]*

Medical Physics Consultants, Inc.

Sealed Source Leak TestLicensee: Parkview Health-Whitley Memorial HospitalDate: 04/25/05

| | | | Calibration | Calibration | | |
|----------|-------|----------|-------------|-------------|---------|-------------|
| Nuclide | Type | Activity | Date | Location | M/N | S/N |
| Cs-137 | Vial | 205 uCi | 1/26/83 | Hot Lab | NES356 | 3560183A-19 |
| * Ba-133 | Vial | 289 uCi | 11/22/82 | Hot Lab | NES358 | 3581182A-39 |
| * Co-57 | Flood | 15 mCi | 1/21/98 | Hot Lab | MED3709 | A7809 |
| Co-57 | Flood | 15 mCi | 5/3/04 | Hot Lab | BM01-15 | BM01150220 |

Comment: The sources listed above were leak tested using a dry wipe technique and were found to have less than 0.005 uCi removable activity. The following Minimum Detectable Activities are based upon a background at the indicated value. Background was at or below these levels when the above tests were completed.

Well Counter: Ludlum 2200 Scaler

| Nuclide | MDA | Background |
|---------|--------------------------|------------|
| Cs-137 | 1.9×10^{-4} uCi | 37 cpm |
| Ba-133 | 7.0×10^{-5} uCi | 285 cpm |
| Co-57 | 4.0×10^{-5} uCi | 285 cpm |

Tested by: Rad & Mary, M.Eng. Date: 4-25-05RADIATION SAFETY OFFICER: S.C. Shamo



INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION

IUPUI Radiation Safety Office

August 13, 2008

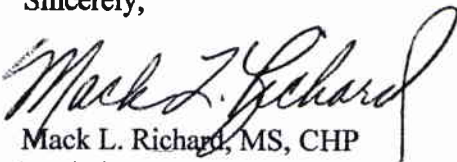
Ms. Mindy Gamble, MBA, CNMT
Parkview Hospital – Heart Institute
2200 Randallia Dr.
Fort Wayne, IN 46805

Dear Ms. Gamble:

This correspondence is to verify that James Fletcher, MD is currently an “Authorized User” as defined in the Nuclear Regulatory Commission (NRC) regulations for radiopharmaceuticals utilized under 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300. Dr. Fletcher was originally approved as an “authorized user” for the aforementioned radiopharmaceuticals by IU Medical Center’s Radionuclide Radiation Safety Committee on March 12, 2002 under the university’s broad medical NRC license number 13-02752-03.

Should you or others have specific questions regarding the aforementioned information, please do not hesitate to contact this office.

Sincerely,



Mack L. Richard, MS, CHP
Radiation Safety Officer

**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

Brad M. Johnston, M.D.

State or Territory Where Licensed

Indiana

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)

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 | Indiana University School of Medicine | 45 | 07/2000 to 03/2002 |
| Radiation protection | " | 10 | " |
| Mathematics pertaining to the use and measurement of radioactivity | " | 10 | " |
| Chemistry of byproduct material for medical use (not required for 35.590) | " | 10 | " |
| Radiation biology | " | 10 | " |
| Total Hours of Training: | | 85 | |

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: 200 | |
|--|--|--|--------------------------|
| 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 | Indiana University School of Medicine NRC License 13-02752-03 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 07/2000 to 03/2002 |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | " | <input checked="" 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)

| 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 | Indiana University School of Medicine NRC License 13-02752-03 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 07/2000 to 03/2002 |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | " | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | " | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |
| Administering dosages of radioactive drugs to patients or human research subjects | " | <input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |

Supervising Individual

Aslam Siddiqui, M.D.

License/Permit Number listing supervising individual as an
authorized userIndiana University School of
Medicine NRC License 13-02752-03

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.

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 | Indiana University School of Medicine NRC License 13-02752-03 | 55 | 03/2002 to 06/2004 |
| Radiation protection | " | 15 | " |
| Mathematics pertaining to the use and measurement of radioactivity | " | 15 | " |
| Chemistry of byproduct material for medical use (not required for 35.590) | " | 15 | " |
| Radiation biology | " | 15 | " |
| Total Hours of Training: | | 115 | |

- 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: 300 | |
|--|---|--|--------------------------|
| 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 | Indiana University School of Medicine NRC License 13-02752-03 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 03/2002 to 06/2004 |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | " | <input checked="" 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)

| 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 | Indiana University School of Medicine NRC License 13-02752-03 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 03/2002 to 06/2004 |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | " | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | " | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |
| Administering dosages of radioactive drugs to patients or human research subjects | " | <input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |

Supervising Individual

James W. Fletcher, M.D.

License/Permit Number listing supervising individual as an
authorized userIndiana University School of
Medicine NRC License 13-02752-03

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.

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 Brad Johnston, M.D. 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 Brad Johnston, M.D. 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

Michael Kinzer, M.D.

Signature

Michael Kinzer

Telephone Number

260-469-0551

Date

3-02-09

License/Permit Number/Facility Name

Parkview Health

13-01254-02

**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

Brad M. Johnston, M.D.

State or Territory Where Licensed

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 | Indiana University School of Medicine NRC License 13-02752-03 | 55 | 03/2002 to 06/2004 |
| Radiation protection | " | 15 | " |
| Mathematics pertaining to the use and measurement of radioactivity | " | 15 | " |
| Chemistry of byproduct material for medical use | " | 15 | " |
| Radiation biology | " | 15 | " |
| Total Hours of Training: | | 115 | |

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: 300 | |
|--|--|--|--------------------------|
| 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 | Indiana University School of Medicine NRC License 13-02752-03 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 03/2002 to 06/2004 |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | " | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |
| Calculating, measuring, and safely preparing patient or human research subject dosages | " | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | " | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | " |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | " | <input checked="" 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 James W. Fletcher | License/Permit Number listing supervising individual as an authorized user IU / NRC License 13-02752-03 |
| Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**: | |
| <input checked="" type="checkbox"/> 35.390 | With experience administering dosages of: |
| <input type="checkbox"/> 35.392 | <input checked="" 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 checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) |
| <input type="checkbox"/> 35.396 | <input checked="" 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) | 15 | Indiana University School of Medicine NRC License 13-02752-03 | 03/2002 to 06/2004 |
| Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) | | | |
| 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) | | | |

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 James W. Fletcher, M.D. | License/Permit Number listing supervising individual as an authorized user Indiana University NRC License School of Medicine 13-02752-03 |
|---|--|

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

| | |
|--|---|
| <input checked="" type="checkbox"/> 35.390 | With experience administering dosages of: |
| <input type="checkbox"/> 35.392 | <input checked="" 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 checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) |
| <input type="checkbox"/> 35.396 | <input checked="" 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.

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 _____ 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 Brad M. Johnston, 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 _____ 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 Brad M. Johnston, 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 Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ Oral Nal-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 Brad M. Johnston, M.D. has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

- ☒ Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ Oral Nal-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 Michael Kinzer, M.D. | Signature <i>Michael Kinzer MD</i> | Telephone Number 260-469-0551 | Date 3-02-09 |
| License/Permit Number/Facility Name Parkview Health / 13-01284-02 | | | |



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U.S. Nuclear Regulatory Commission, Region III

Materials Licensing Section

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