

August 17, 2011

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

Dear Sir or Madam:

Northwest Radiology Network would like to amend its NRC Byproduct Materials License, Number 13-32258-01 to add Vincent L. Flanders, M.D. and Marc P. Underhill as Authorized Users of materials licensed under 10 C.F.R. 35.100, 35.200, and 35.392. Enclosed are copies of Drs. Flanders and Underhill's American Board of Radiology certificate (AU Eligible) as well as USNRC forms 313A(aud) and 313A(aut).

If there are any questions concerning this license amendment, please contact our nuclear medicine physicist, Mr. Patrick J. Byrne, DABR, CHP, DABSNM at 877-317-5811.

Sincerely, Bricke

Lori Bricker

RECEIVED AUG 2 3 2011

The American H ~1 Organized through the cooperation of the . ເມ 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 RADIOLOGY University Radiologists, and the American Association of Physicists in Medicine . Hereby certifies that Marc Patrick Anderhill, MD Has pursued an accepted course of graduate study and clinical work, has met centuin 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, AH Fligible and is therefore awarded the Board's certification in the speciality of 7702985 Biagnostic Radiology RESIGNE BOT 10 Effective June 30, 2010 Certificate No. 58715 Balid through 2020 N

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

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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 CER 35 190 35 290 and 35 590]

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012

| [10 CFR 35.190, 3 | 5.290, and 35.590] | | |
|---|--|---|-------------------------|
| ame of Proposed Authorized User | State or Territory Where Lice | nsed | |
| farc Patrick Underhill, M.D. | Indiana | | |
| equested Authorization(s) (check all that a | pply) | nnann an ann an Anna Anna Anna Anna Ann | , |
| 35.100 Uptake, dilution, and excretion st | udies | | |
| 35.200 Imaging and localization studies | | | |
| 35.500 Sealed sources for diagnosis (sp | ecify device |) | |
| | RT I TRAINING AND EXPERIENCE ect one of the three methods below) | | |
| Training and Experience, including board the date of application or the individual me | certification, must have been obtained with ust have obtained related continuing educat completed. Provide dates, duration, and de | ion and experie | nce since |
| 1. Board Certification | | | |
| a. Provide a copy of the board certifica | tion. | | |
| b. If using only 35.500 materials, stop the Preceptor Attestation. | here. If using 35.100 and 35.200 materials, | skip to and con | nplete Part II |
| 2. Current 35.390 Authorized User Se | eking Additional 35.290 Authorization | | |
| a. Authorized user on Materials License State requirements seeking authoriz b. Supervised Work Experience. (If more than one supervising individ 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: | <u>I</u> | |
| Supervising Individual | License/Permit Number listi authorized user | ng supervising inc | lividual as an |
| | ow, or equivalent Agreement State requiren | nents <i>(check all</i> | that apply). |

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION (3-2009) AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) 3. Training and Experience for Proposed Authorized User a. Classroom and Laboratory Training. Dates of Clock Description of Training Location of Training Training* Hours Radiation physics and instrumentation Radiation protection Mathematics pertaining to the use and measurement of radioactivity Chemistry of byproduct material for medical use (not required for 35.590) Radiation biology **Total Hours of Training:** 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.) A & T PE LITER TRANSPORT Omentional Mark Experie

| Supervised Work Experience | | Total Hours of Experience: | | |
|--|--|-------------------------------|-------------------------|--|
| Description of Experience Must Include: | Location of Experience/Licens Permit Number of Facility | Lonurm | Dates of Experience* | |
| Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys | | Yes No | | |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | | Yes No | | |

| Training and Experience for Propo | sed Authorized User (continu | ed) | | | | |
|---|--|---|------------------------|--|--|--|
| b. Supervised Work Experience. (continued) | | | | | | |
| Description of Experience Must Include: | Location of Experience Permit Number of F | | Dates of Experience | | | |
| Calculating, measuring, and safely preparing patient or human research subject dosages | | Yes No | | | | |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | | Yes No | | | | |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | | Yes No | • • | | | |
| Administering dosages of radioactive drugs to patients or human research subjects | | Yes 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 | e | Yes | · · · · · · | | | |
| Supervising Individual | License/Pern authorized us | nit Number listing supervising ind ser | ividual as an | | | |
| Supervisor meets the requirements b 35.190 35.290 5. For 35.590 only, provide documen | 35.390 35.390 + ger | nerator experience in 35.290(c | • | | | |
| Device | Type of Training | Location and Da | ates | | | |
| | | | | | | |
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d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

| NRC FC (3-2009) | ORM 313A (AUD) | USER TRAININ | IG AND EXPERI | ENCE AND PRECEP | U.S. NUCLEAR REGULATORY COMMISSION TOR 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 s individual as long as the preceptor provides, directs, or verifies training and experience required. If one preceptor is necessary to document experience, obtain a separate preceptor statement from ex- required to meet training requirements in 35.590) | | | | | |
| | | | | esting that the individ s "general clinical cor | ual has knowledge to fulfill the duties of the npetency." |
| | ection one of the follow | ving for each u | se requested: | | |
| | 35.190 | | | | |
| | Board Certification | on | | | |
| | ✓ I attest that | Marc Underhill | | has satisfactorily c | ompleted the requirements in |
| | | | sed Authorized User | | |
| | | | | l of competency sufficed under 10 CFR 35.1 | cient to function independently as an 00. |
| | | | | OR | |
| | Training and Exp | perience | | | |
| | I attest that | | | has satisfactorily c | ompleted the 60 hours of training and |
| | | • | sed Authorized User | 99 Y | |
| | 35.190(c)(1), | and has achiev | ed a level of com | | atory training, required by 10 CFR unction independently as an 00. |
| For | 35.290 | | | | |
| | Board Certification | on | | | |
| | ✓ I attest that | Marc Underhill | | has satisfactorily c | ompleted the requirements in |
| | | | sed Authorized User | _ | |
| | | | | l of competency sufficed under 10 CFR 35.1 | ient to function independently as an 00 and 35.200. |
| | Training and Eve | orianaa | | OR | |
| | Training and Exp | <u>berience</u> | | has actisfactorily a | empleted the 700 hours of training |
| 1 | I attest that | Name of Propo | sed Authorized User | has satisfactorily c | ompleted the 700 hours of training |
| | CFR 35.290(| ce, including a r c)(1), and has a | minimum of 80 hc chieved a level o | | laboratory training, required by 10 nt to function independently as an 00 and 35.200. |
| Secon | d Section | ی وال کا بنا کا کا کا کا کا کا کا ا | | | |
| Compl | ete the following | for preceptor a | attestation and s | signature: | |
| | ✓ I meet the red | quirements belo | w, or equivalent <i>i</i> | Agreement State requ | irements, as an authorized user for: |
| | ✔ 35.190 | ✔ 35.290 | \$ 35.390 | 35.390 + gener | rator experience |
| Name o | f Preceptor | | Signature | | Telephone Number Date |
| Peter A | rfken, M.D. | | (SE() A | th NI | (317) 328-5050 8/5/11 |
| License | /Permit Number/Fac | cility Name | | | ······································ |
| 13-3225 | 8-01/Northwest Rad | iology Network | | | |

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| NR | C FO | RM 313A (AUT) U.S. NUC | LEAR REGULATORY COMMISSION | |
|-------|----------|--|---|--|
| (3-20 | U9) | AUTHORIZED USER TRAINING AND AND PRECEPTOR ATTEST (for uses defined under 35 [10 CFR 35.390, 35.392, 35.394, a | ATION .300) | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012 |
| Nai | ne c | of Proposed Authorized User | State or Territory Where License | ed |
| Ma | rc P | atrick Underhill, M.D. | Indiana | |
| Re | que | sted Authorization(s) (check all that apply): | | |
| | | 35.300 Use of unsealed byproduct material for wh | nich a written directive is require | ed |
| | OR | | | |
| | ✓ | 35.300 Oral administration of sodium iodide I-131 1.22 gigabecquerels (33 millicuries) | requiring a written directive in o | quantities less than or equal to |
| | | 35.300 Oral administration of sodium iodide I-131 gigabecquerels (33 millicuries) | requiring a written directive in o | quantities greater than 1.22 |
| | | 35.300 Parenteral administration of any beta-emit than 150 keV for which a written directive | | lide with a photon energy less |
| | | 35.300 Parenteral administration of any other radi | onuclide for which a written dire | ective is required |
| | | | NG AND EXPERIENCE three methods below) | |
| * | of ex | aining and Experience, including board certification, application or the individual must have related conti perience was completed. Provide dates, duration, a the uses checked above. | nuing education and experience | e since the required training and |
| | 1. | Board Certification | | |
| | a. | Provide a copy of the board certification. | | |
| | b. | For 35.390, provide documentation on supervised be used to document this experience. | clinical case experience. The t | able in section 3.c. may |
| | C. | For 35.396, provide documentation on classroom a and supervised clinical case experience. The table document this experience. | | |
| | d. | Skip to and complete Part II Preceptor Attestation. | | |
| | 2. | Current 35.300, 35.400, or 35.600 Authorized Us | er Seeking Additional Author | ization |
| | a. | Authorized User on Materials License | | er the requirements below or |
| | | equivalent Agreement State requirements (check a | all that apply): | |
| | | 35.390 35.392 35.394 | 35.490 35.69 | 0 |
| | b. | If currently authorized for a subset of clinical uses required supervised case experience. The table in experience. Also provide completed Part II Precep | section 3.c. may be used to do | |
| | C. | If currently authorized under 35.490 or 35.690 and documentation on classroom and laboratory trainin clinical case experience. The tables in sections 3. experience. Also provide completed Part II Preception of the tables of ta | ng, supervised work experience a., 3.b., and 3.c. may be used to | , and supervised |

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| AUTHORIZED USER TRAIN | IING AND EXPERIEN | CE AND PRECEF | TOR ATTESTAT | | TORY COMMIS ntinued) |
|---|-------------------------|--|---------------------------------------|---|-------------------------|
| 3. <u>Training and Experience for</u> | | | | | |
| a. Classroom and Laboratory Tra | | 35.392 | 35.394 | | 35.396 . |
| Description of Training | Locatio | on of Training | | lock ours | 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 | | | | The second | |
| | Total Hours of Train | ing: | | | |
| If more than one supervising in of this page. Supervised Work Experience | านิเขเนนส์ 18 กษณะจอล y | To document supe Total Ho Experier | ours of | | |
| Description of Experience Must Include: | | perience/License umber of Facility | or | onfirm | Dates of Experienc |
| Ordering, receiving, and unpacking radioactive | | | · · · · · · · · · · · · · · · · · · · | Yes | |
| materials safely and performing | | | | No | |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | | | • | No Yes No | |
| materials safely and performing the related radiation surveys Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of | | | | Yes | |
| materials safely and performing the related radiation surveys Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters Calculating, measuring, and safely preparing patient or human research subject | | | | Yes No Yes | |

| : FORM 313A (A ⁰⁹⁾ AUTHO | | U.S. NUCLEAR REGULATORY COMMISSION |
|---|--|--|
| | d Experience for Proposed Auti ed Work Experience (continued) | norized User (continued) |
| Supervising I | ndividual | License/Permit Number listing supervising individual as an authorized user |
| | individual meets the requirements | below, or equivalent Agreement State requirements (check all that |
| apply)**: | With experience administering | dosages of: |
| 35.390 35.392 | 1 1 2 | itten directive in quantities less than or equal to 1.22 |
| 35.390 35.392 35.394 | Oral Nal-131 requiring a wr gigabecquerels (33 millicuri | itten directive in quantities less than or equal to 1.22 |
| 35.390 35.392 | Oral Nal-131 requiring a wr gigabecquerels (33 millicuri Oral Nal-131 in quantities g Parenteral administration of | itten directive in quantities less than or equal to 1.22 es) |

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) | | | |
| 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) | | | |

| 3-200 | FORM 313A (AUT) 9) | U.S. NUCLEAR REGULATORY COMMISSIO | | |
|-------|---|---|--|--|
| | AUTHORIZED USER TRAINING AND | EXPERIENCE AND PRECEPTOR ATTESTATION (continued) | | |
| 3. | raining and Experience for Proposed Authorized User (continued) | | | |
| | c. Supervised Clinical Case Experience (c | ontinued) | | |
| | Supervising Individual | License/Permit Number listing supervising individual as an authorized user | | |
| | Supervising individual meets the requireme apply)**: | nts below, or equivalent Agreement State requirements (check all that | | |
| | 35.390 With experience administerir | ng dosages of: | | |
| | 35.392 Oral Nal-131 requiring a gigabecquerels (33 millic | written directive in quantities less than or equal to 1.22 uries) | | |
| | Oral Nal-131 in quantities | s greater than 1.22 gigabecquerels (33 millicuries) | | |
| | | of beta-emitter, or photon-emitting radionuclide with a photon / requiring a written directive is required | | |
| | Parenteral administration | of any other radionuclide requiring a written directive | | |
| | ** Supervising Authorized User must have experience requesting authorized user status. | e in administering dosages in the same dosage category or categories as the individual | | |
| ote | e: This part must be completed by the indiv | - PRECEPTOR ATTESTATION vidual's preceptor. The preceptor does not have to be the supervising | | |
| | | des, directs, or verifies training and experience required. If more than experience, obtain a separate preceptor statement from each. | | |
| | By checking the boxes below, the precept position sought and not attesting to the in | otor is attesting that the individual has knowledge to fulfill the duties of the ndividual's "general clinical competency." | | |
| | t Section ck one of the following for each requeste | d authorization: | | |
| | For 35.390: | | | |
| | Board Certification | | | |
| | I attest that | has satisfactorily completed the training and experience | | |
| | Name of Proposed Aut | norized User | | |
| | | | | |
| | requirements in 35.390(a)(1). | | | |
| | requirements in 35.390(a)(1). | OR | | |
| | requirements in 35.390(a)(1). <u>Training and Experience</u> | OR | | |
| | | OR has satisfactorily completed the 700 hours of training | | |
| | Training and Experience | has satisfactorily completed the 700 hours of training | | |

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| NRC FORM 313A (AUT) | | |
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| AUTHORIZE | D USER TRAINING AND I | EXPERIENCE AND PRECEPTOR ATTESTATION (continued) |
| Preceptor Attestation | (continued) | |
| First Section (con | tinued) | |
| For 35.392 (Identi | cal Attestation Statement | t Regardless of Training and Experience Pathway): |
| | | |
| ✓ I attest that | Marc Underhill Name of Proposed Authorit | has satisfactorily completed the 80 hours of classroom |
| | ry training, as required by [·] equired in 35.392(c)(2). | 10 CFR 35.392(c)(1), and the supervised work and clinical case |
| For 35.394 (Identi | cal Attestation Statement | t Regardless of Training and Experience Pathway): |
| I attest that | Name of Proposed Authoria | has satisfactorily completed the 80 hours of classroom |
| | ry training, as required by equired in 35.394(c)(2). | 10 CFR 35.394 (c)(1), and the supervised work and clinical case |
| Second Section | | |
| ✓ I attest that | Marc Underhill | has satisfactorily completed the required clinical case |
| | Name of Proposed Authoriz | zed User |
| experience re | equired in 35.390(b)(1)(ii)G | B listed below: |
| | 131 requiring a written dire uerels (33 millicuries) | ctive in quantities less than or equal to 1.22 |
| Oral Nal- | 131 in quantities greater th | an 1.22 gigabecquerels (33 millicuries) |
| | | nitter, or photon-emitting radionuclide with a photon a written directive is required |
| Parentera | al administration of any oth | er radionuclide requiring a written directive |
| | | |
| Third Section | | |
| ✓ I attest that | Marc Underhill | has satisfactorily achieved a level of competency to |
| V Factor that | Name of Proposed Authoriz | |
| function inde | pendently as an authorized | d user for: |
| | 131 requiring a written dire uerels (33 millicuries) | ctive in quantities less than or equal to 1.22 |
| Oral Nal- | 131 in quantities greater th | an 1.22 gigabecquerels (33 millicuries) |
| Parentera | al administration of beta-em | nitter, or photon-emitting radionuclide with a photon a written directive is required |
| Parentera | al administration of any oth | er radionuclide requiring a written directive |
| | | |

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| NRC FORM 313A (AUT) | |
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| (3-2009) | |
| | VING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) |
| Fourth Section | |
| For 35.396: | |
| <u>Current 35.490 or 35.690 auth</u> | iorized user: |
| I attest that | is an authorized user under 10 CFR 35.490 or 35.690 |
| | Proposed Authorized User |
| laboratory training, as requi | ate requirements, has satisfactorily completed the 80 hours of classroom and red by 10 CFR 35.396 (d)(1), and the supervised work and clinical case 396(d)(2), and has achieved a level of competency sufficient to function ized user for: |
| | n of any beta-emitter, or photon-emitting radionuclide with a photon energy less a written directive is required |
| Parenteral administration | n 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 P | Proposed Authorized User |
| required by 10 CFR 35.396 | has satisfactorily completed the 80 hours of classroom and laboratory training (d)(1) and the supervised work and clinical case experience required by eved a level of competency sufficient to function independently as an |
| | n of any beta-emitter, or photon-emitting radionuclide with a photon energy less a written directive is required |
| Parenteral adminstration | n of any other radionuclide for which a written directive is required |
| Fifth Section | |
| Complete the following for precepto | or attestation and signature: |
| I most the requirements below | or equivalent Assessment State requirements, on an authorized uppr for |
| ✓ 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 requesting authorization. | g dosages in the following categories for which the proposed Authorized User is |
| ✓ Oral Nal-131 requiring a wri millicuries) | itten directive in quantities less than or equal to 1.22 gigabecquerels (33 |
| ✓ Oral Nal-131 in quantities git | reater than 1.22 gigabecquerels (33 millicuries) |
| Parenteral administration of 150 keV requiring a written of | beta-emitter, or photon-emitting radionuclide with a photon energy less than directive is required |
| Parenteral administration of | any other radionuclide requiring a written directive |
| Name of Preceptor | Signature Telephone Number Date, |
| Peter Arfken, M.D. | (D) (1/ K) (317) 328-5050 8/5/1) |
| License/Permit Number/Facility Name 13-32258-01/Northwest Radiology Network | |
| 10-02200-01/1101 thinest Maulology Herwork | |

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Organized through the cooperation of the Organized through the cooperation of the American Cotlege 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

Vincent Corenzo Flanders, 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

AN Eligible



Diagnostic Radiology

Effective June 30, 2010

Richard 1 Monin

fame A Hupper



Dalid through 2020

Certificate No. 59583

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

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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

| [10 CFR 35.190, 3 | 5.290, and 35.590] | | |
|---|---|--------------------|-------------------------|
| Name of Proposed Authorized User | State or Territory Where Lice | nsed | |
| Vincent L. Flanders, M.D. | Indiana | | |
| Requested Authorization(s) (check all that ap | oply) | | |
| ✓ 35.100 Uptake, dilution, and excretion str | udies | | |
| ✓ 35.200 Imaging and localization studies | | | |
| 35.500 Sealed sources for diagnosis (spe | ecify device |) | |
| | RT I TRAINING AND EXPERIENCE act one of the three methods below) | | |
| the date of application or the individual mu | certification, must have been obtained with ust have obtained related continuing educa completed. Provide dates, duration, and do ses checked above. | tion and experie | nce since |
| ✓ 1. <u>Board Certification</u> | | | |
| a. Provide a copy of the board certificat | tion. | | |
| b. If using only 35.500 materials, stop h Preceptor Attestation. | nere. If using 35.100 and 35.200 materials, | , skip to and con | nplete Part II |
| 2. Current 35.390 Authorized User Se | eking Additional 35.290 Authorization | | |
| a. Authorized user on Materials License State requirements seeking authorize b. Supervised Work Experience. (If more than one supervising individ copies of this section.) | representation and a second | | - |
| 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: | | , als |
| Supervising Individual | License/Permit Number listi authorized user | ng supervising inc | lividual as an |
| Supervisor meets the requirements belo | ow, or equivalent Agreement State requiren | nents (check all | that apply). |
| 35.290 35.390 + gener | rator experience in 32.290(c)(1)(ii)(G) | | |

| FORM 313A (AUD) AUTHORIZED USER TRAINING A | ND EXPERIENCE AND PRECEPTOR ATT | NUCLEAR REGULA | |
|--|--|----------------|------------------------|
| . Training and Experience for Propos | sed 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</i> 35.590) | | | |
| Radiation biology | | | |
| | Total Hours of Training: | | |
| (If more than one supervising individu 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 | | Yes | |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | | Yes | |

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| Training and Experience for | Proposed | Authorized U | ser (continued) | | | |
|---|---------------------------------------|----------------|---|-----------------|----------------|------------------------|
| b. Supervised Work Experien | | | | | | |
| Description of Experience Must Include: | ce | | of Experience/Licer it Number of Facilit | | Confirm | Dates of Experience |
| Calculating, measuring, and sa preparing patient or human resoubject dosages | | | | | Yes | |
| Using administrative controls t prevent a medical event involv use of unsealed byproduct ma | ving the | | | | Yes | |
| Using procedures to contain s byproduct material safely and proper decontamination proce | using | | | | Yes | |
| Administering dosages of radio drugs to patients or human res subjects | | | | | Yes | |
| Eluting generator systems app for the preparation of radioacti drugs for imaging and localizar studies, measuring and testing eluate for radionuclidic purity, a processing the eluate with rea- kits to prepare labeled radioac drugs | ive ition g the and igent | | | | Yes | |
| Supervising Individual | <u></u> | | License/Permit Nur authorized user | mber listing su | pervising indi | vidual as an |
| Supervisor meets the requirem |) [] 35 | 5.390 | 35.390 + generato | or experience | | |
| Device | - | Type of Traini | ing | Loca | tion and Da | tes |
| | · · · · · · · · · · · · · · · · · · · | | | | | |
| | | | | | | |

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d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

| i | AUTHORIZED | USER TRAINING | G AND EXPERI | U.S. NUCLEAR REGULATORY COMMISSION ENCE AND PRECEPTOR ATTESTATION (continued) | | |
|------------------|-----------------------------|---|---------------------------------------|---|--|--|
| | - | | | | | |
| Note: | | | | | | |
| | | | | testing that the individual has knowledge to fulfill the duties of the I's "general clinical competency." | | |
| First S Check | ection one of the follow | ving for each us | se requested: | | | |
| For | <u>35.190</u> | | | | | |
| | Board Certification | on | | | | |
| | ✓ I attest that | Vincent Flanders | s ed Authorized User | has satisfactorily completed the requirements in | | |
| | | 90(a)(1) and has | achieved a leve | el of competency sufficient to function independently as an ed under 10 CFR 35.100. | | |
| | | | | OR | | |
| | Training and Exp | perience | | | | |
| | I attest that | Name of Propos | ed Authorized User | has satisfactorily completed the 60 hours of training and | | |
| | 35.190(c)(1), | ncluding a minim and has achieve | num of 8 hours c ed a level of con | f classroom and laboratory training, required by 10 CFR npetency sufficient to function independently as an ed under 10 CFR 35.100. | | |
| For | 35.290 | | | | | |
| | Board Certification | <u>on</u> | | | | |
| | ✓ I attest that | Vincent Flanders | | has satisfactorily completed the requirements in | | |
| | | Name of Propos | ed Authorized User | - | | |
| | | | | el of competency sufficient to function independently as an ed under 10 CFR 35.100 and 35.200. | | |
| | | | | OR | | |
| | Training and Exp | erience | | | | |
| | I attest that | | | has satisfactorily completed the 700 hours of training | | |
| | and evention | - | ed Authorized User | our of electrony and loberatory training, required by 10 | | |
| | CFR 35.290(| c)(1), and has ac | chieved a level o | ours of classroom and laboratory training, required by 10 of competency sufficient to function independently as an ed under 10 CFR 35.100 and 35.200. | | |
| | d Section | nga gan jum nga tan pak pak na gan ing nga na mak na ma | | | | |
| Compl | ete the following | • • | | • | | |
| | ✓ I meet the red | quirements below | w, or equivalent | Agreement State requirements, as an authorized user for: | | |
| | ✔ 35.190 | ✔ 35.290 | ✓ 35.390 | 35.390 + generator experience | | |
| Name o | f Preceptor | | Signature | Telephone Number Date | | |
| Peter A | rfken, M.D. | | | (317)328-5050 8/5/11 | | |
| License | /Permit Number/Fac | ility Name | V | | | |

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| NRC FORM 313, (3-2009) | A (AUT) U.S. N | UCLEAR REGULATORY COMMISSION | |
|---------------------------|---|--|--|
| , | UTHORIZED USER TRAINING AN AND PRECEPTOR ATTES (for uses defined under 3 [10 CFR 35.390, 35.392, 35.394] | TATION 35.300) | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012 |
| Name of Propo | sed Authorized User | State or Territory Where Licens | ed |
| Vincent L. Flar | iders, M.D. | Indiana | |
| Requested A | uthorization(s) (check all that apply): | | |
| 35.300 | Use of unsealed byproduct material for | which a written directive is require | ed |
| OR | | | |
| ✔ 35.300 | Oral administration of sodium iodide I-1 1.22 gigabecquerels (33 millicuries) | 31 requiring a written directive in | quantities less than or equal to |
| 35.300 | Oral administration of sodium iodide I-13 gigabecquerels (33 millicuries) | 31 requiring a written directive in | quantities greater than 1.22 |
| 35.300 | Parenteral administration of any beta-er than 150 keV for which a written directiv | | clide with a photon energy less |
| 35.300 | Parenteral administration of any other ra | adionuclide for which a written dir | ective is required |
| | | NING AND EXPERIENCE he three methods below) | |
| of applica experience | and Experience, including board certification ation or the individual must have related con- ce was completed. Provide dates, duration es checked above. | ntinuing education and experience | e since the required training and |
| ✓ 1. <u>Board</u> | Certification | | |
| a. Provi | de a copy of the board certification. | | |
| b. For 3 be us | 5.390, provide documentation on supervise ed to document this experience. | ed clinical case experience. The | table in section 3.c. may |
| and s | 5.396, provide documentation on classroor upervised clinical case experience. The ta nent this experience. | | |
| d. Skip t | o and complete Part II Preceptor Attestation | n. | |
| 2. <u>Curre</u> | <u>nt 35.300, 35.400, or 35.600 Authorized l</u> | Jser Seeking Additional Author | rization |
| a. Autho | rized User on Materials License | und | er the requirements below or |
| equiv | alent Agreement State requirements (chec | k all that apply): | |
| 3 | 5.390 35.392 35.394 | 35.490 35.69 | 0 |
| requir | ently authorized for a subset of clinical use ed supervised case experience. The table ience. Also provide completed Part II Prec | in section 3.c. may be used to de | |
| docur clinica | ently authorized under 35.490 or 35.690 an nentation on classroom and laboratory train al case experience. The tables in sections ience. Also provide completed Part II Prec | ning, supervised work experience 3.a., 3.b., and 3.c. may be used t | , and supervised |

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| FORM 313A (AUT) AUTHORIZED USER TRAININ | NG AND EXPERIENCE AND PRECE | | REGULATORY COMMIS |
|---|---|-------------|-------------------------|
| 3. <u>Training and Experience for Press</u> | roposed Authorized User | | |
| a. Classroom and Laboratory Train | ning 35.390 35.392 | 35.394 | 35.396 |
| Description of Training | Location of Training | Clos Hou | |
| Radiation physics and instrumentation | | | |
| Radiation protection | | | |
| Mathematics pertaining to the use and measurement of radioactivity | | | |
| Chemistry of byproduct material for medical use | | | |
| Radiation biology | | | |
| Τ | otal Hours of Training: | 1 | 1 |
| b. Supervised Work Experience | 35.390 35.392 | 35.394 | 35.396 |
| of this page. | lividual is necessary to document sup | | /ide multiple copies |
| Supervised Work Experience | Total H Experie | | |
| Description of Experience Must Include: | Location of Experience/License Permit Number of Facility | e or Confi | irm Dates of Experience |
| Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys | | Ye | |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of | | Ye | |
| survey meters | | Ye | |
| | | | כ |
| Calculating, measuring, and safely preparing patient or human research subject dosages Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | | No | 95 |

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| J | RC FORM 313A | (AUT) | | L |
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| | -2009) | (| | |

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. <u>Training and Experience for Proposed Authorized User</u> (continued)

b. Supervised Work Experience (continued)

| Supervising I | | License/Permit Number listing supervising individual as an authorized user | | |
|--------------------------|--|---|--|--|
| Supervising apply)**: | individual meets the requirements below, or e | equivalent Agreement State requirements (check all that | | |
| 35.390 | With experience administering dosages of: | | | |
| 35.392 | gigabecquerels (33 millicuries) | e in quantities less than or equal to 1.22 | | |
| 35.396 | Oral Nal-131 in quantities greater than | Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) | | |
| 35.390 | Parenteral administration of beta-emitte energy less than 150 keV requiring a w | er, or photon-emitting radionuclide with a photon ritten directive is required | | |
| | Parenteral administration of any other r | adionuclide requiring a written directive | | |

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) | | | |
| 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) | | | |

| IRC FORM 313. 3-2009) | (AUT) U.S. NUCLEAR REGULATORY COMMISSIO |
|----------------------------|---|
| | HORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) |
| 3. Training | and Experience for Proposed Authorized User (continued) |
| c. Supe | vised Clinical Case Experience (continued) |
| Supervisi | ng Individual License/Permit Number listing supervising individual as an authorized user |
| | |
| Supervis apply)**: | ng individual meets the requirements below, or equivalent Agreement State requirements (check all that |
| 35.3 | 0 With experience administering dosages of: |
| 35.3 | diabecquerels (33 milliouries) |
| 35.3 | Oral Nal-131 in quantities greater than 1.22 globabecquerels (33 millicuries) |
| L., 00.0 | 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 |
| | sing Authorized User must have experience in administering dosages in the same dosage category or categories as the individual ing authorized user status. |
| d. Provi | e completed Part II Preceptor Attestation. |
| | |
| indivi | art must be completed by the individual's preceptor. The preceptor does not have to be the supervising lual as long as the preceptor provides, directs, or verifies training and experience required. If more than receptor is necessary to document experience, obtain a separate preceptor statement from each. |
| | ecking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of t n sought and not attesting to the individual's "general clinical competency." |
| irst Section heck one o | the following for each requested authorization: |
| For 35.3 | <u>10:</u> |
| Boar | Certification |
| | ttest that has satisfactorily completed the training and experience |
| re | quirements in 35.390(a)(1). |
| | OR |
| | |
| | ng and Experience |
| | ttest that has satisfactorily completed the 700 hours of training |
| | Name of Proposed Authorized User d experience, including a minimum of 200 hours of classroom and laboratory training, as required by CFR 35.390 (b)(1). |

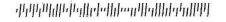
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| (3-2009) | | U.S. NUCLEAR REGULATORY COMM |
|---|---|---|
| AUTHORIZE | D USER TRAINING AND | EXPERIENCE AND PRECEPTOR ATTESTATION (continued) |
| Preceptor Attestation | n (continued) | |
| First Section (cor | ntinued) | |
| For 35.392 (Identi | ical Attestation Statemen | t Regardless of Training and Experience Pathway): |
| ✓ I attest that | Vincent Flanders Name of Proposed Author | has satisfactorily completed the 80 hours of classrool |
| | ory training, as required by required in 35.392(c)(2). | 10 CFR 35.392(c)(1), and the supervised work and clinical case |
| For 35.394 (Identi | ical Attestation Statemen | t Regardless of Training and Experience Pathway): |
| I attest that | Name of Proposed Authori | has satisfactorily completed the 80 hours of classroom |
| | ory training, as required by required in 35.394(c)(2). | 10 CFR 35.394 (c)(1), and the supervised work and clinical case |
| Second Section | | |
| ✓ I attest that | Marc Underhill | has satisfactorily completed the required clinical case |
| | Name of Proposed Authori | zed User |
| experience r | equired in 35.390(b)(1)(ii) | B listed below: |
| | -131 requiring a written dire querels (33 millicuries) | ective in quantities less than or equal to 1.22 |
| | 101 in availting constants | nan 1.22 gigabecquerels (33 millicuries) |
| Oral Nal- | - 13 Fin quantities greater tr | |
| Parenter | al administration of beta-en | nitter, or photon-emitting radionuclide with a photon a written directive is required |
| Parenter energy le | al administration of beta-er ess than 150 keV requiring | a written directive is required |
| Parenter energy le | al administration of beta-er ess than 150 keV requiring | |
| Parenter energy le Parenter | al administration of beta-er ess than 150 keV requiring | a written directive is required |
| Parenter energy le | al administration of beta-er ess than 150 keV requiring | a written directive is required |
| Parenter energy le Parenter | al administration of beta-en ess than 150 keV requiring al administration of any oth Vincent Flanders | a written directive is required er radionuclide requiring a written directive has satisfactorily achieved a level of competency to |
| Parenter energy le Parenter Third Section I attest that | al administration of beta-en ess than 150 keV requiring al administration of any oth Vincent Flanders Name of Proposed Author | a written directive is required her radionuclide requiring a written directive has satisfactorily achieved a level of competency to |
| Parenter energy le Parenter Third Section I attest that | al administration of beta-en ess than 150 keV requiring al administration of any oth Vincent Flanders | a written directive is required her radionuclide requiring a written directive has satisfactorily achieved a level of competency to |
| Parenter energy le Parenter Third Section I attest that function inde V Oral Nal- | al administration of beta-energy sthan 150 keV requiring al administration of any oth Vincent Flanders Name of Proposed Authorite pendently as an authorized | a written directive is required her radionuclide requiring a written directive has satisfactorily achieved a level of competency to |
| Parenter energy le Parenter Third Section I attest that function inde gigabecq | al administration of beta-energy sthan 150 keV requiring al administration of any other vincent Flanders Vincent Flanders Name of Proposed Authorities 131 requiring a written direct 131 requiring a written direct | a written directive is required ler radionuclide requiring a written directive has satisfactorily achieved a level of competency to zed User d user for: |
| Parenter energy le Parenter Third Section I attest that function inde gigabeco Oral Nal- gigabeco | al administration of beta-energies than 150 keV requiring al administration of any other Vincent Flanders Name of Proposed Authorit ependently as an authorized 131 requiring a written direct uerels (33 millicuries) 131 in quantities greater there al administration of beta-energies | a written directive is required ler radionuclide requiring a written directive has satisfactorily achieved a level of competency to zed User d user for: ective in quantities less than or equal to 1.22 |

| NRC FORM 313A (AUT) | | | | U.S. NUCLEAR REGULATORY COMMISSI |
|---------------------------------------|---|---|---------------------------|--|
| (3-2009) AUTHORIZ | ED USER TRAIN | ING AND EXPERIE | ENCE AND PR | RECEPTOR ATTESTATION (continued) |
| Fourth Section | | | | |
| For 35.396: | | | | |
| Current 35.49 | 0 or 35.690 autho | orized user: | | |
| I attest that | | oposed Authorized User | is an auth | orized user under 10 CFR 35.490 or 35.690 |
| laboratory t experience | nt Agreement Sta raining, as require | te requirements, ha ed by 10 CFR 35.3 96(d)(2), and has a | 96 (d)(1), and t | completed the 80 hours of classroom and the supervised work and clinical case I of competency sufficient to function |
| | | of any beta-emitte written directive is | | nitting radionuclide with a photon energy less |
| Parente | ral administration | of any other radior | nuclide for whic | ch a written directive is required |
| | | | OR | |
| Board Certific | ation: | | | |
| I attest that | | oposed Authorized User | has satisfa | actorily completed the board certification |
| required by | 10 CFR 35.396 (), and has achiev | d)(1) and the super | vised work and | hours of classroom and laboratory training d clinical case experience required by nt to function independently as an |
| | | of any beta-emitter written directive is | | nitting radionuclide with a photon energy less |
| Parente | ral adminstration | of any other radion | uclide for whicl | h a written directive is required |
| Fifth Section | | | | |
| Complete the follow | ing for precepto | r attestation and s | ignature: | |
| ✓ I meet the requ | uirements below, | or equivalent Agree | ement State rec | quirements, as an authorized user for: |
| ✔ 35.390 | 35.392 | 35.394 | 35.396 | |
| ✓ I have experience requesting aut | | dosages in the foll | owing categori | es for which the proposed Authorized User is |
| ✓ Oral Nal-13 millicuries) | 1 requiring a writ | ten directive in qua | ntities less thar | n or equal to 1.22 gigabecquerels (33 |
| 🖌 Oral Nal-13 | 1 in quantities gro | eater than 1.22 giga | abecquerels (3 | 3 millicuries) |
| | | beta-emitter, or pho irective is required | oton-emitting ra | adionuclide with a photon energy less than |
| Parenteral | administration of a | any other radionucl | ide requiring a | written directive |
| Name of Preceptor | | Signature A | $\langle \rangle \rangle$ | Telephone Number Date |
| Peter Arfken, M.D. | | 1000 | 'IN | (311)328-5050 8/5/1/ |
| icense/Permit Number | - | \smile | | , , , |
| 3-32258-01/Northwest F | adiology Network | | | |

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