

REGION 1

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801 Ostrum Street Bethlehem, PA 18015 610-954-4000

NMSEL

September 6, 2007

Medical Licensing Branch U.S.N.R.C. Region I 475 Allendale Rd. King of Prussia, PA 19406-1415

To whom it may concern,

030 03 100

Please be advised of the following proposed addition to the list of authorized users on our N.R.C. license #37-07939-01 (St. Luke's Hospital).

We wish to add Courtney Lewis-Bui, M.D. to our list of authorized users for the following material and use:

 35.400; Iridium-192 in a High Dose Rate Remote Afterloader Unit; Iodine-125 for use in a seedSelectron 130.001 brachytherapy afterloader; Yttrium 90 Sirspheres.

Please find the attached copy of NRC Form 313A (AUS) detailing Dr. Lewis-Bui's training and experience.

If you have any questions, please contact our Radiation Safety Officer Mark Liddington at 1-800-446-7622 ext. 2.

Sincerely,

Lisa Dutterer

Associate Vice President, Administration St. Luke's Hospital and Health Network

141058



NRC FORM 313A (AUS) (3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120

| (for uses defined [10 CFR 35.49 | under 35.400 ar 90, 35.491, and 3 | | EXPIRES: 10/ | 31/2008 |
|---|--|--|-------------------|-----------------------|
| Name of Proposed Authorized User Courtney Lewis-Bui, MD | | State or Territory Where Licer Pennsylvania | sed | |
| Requested XXX 35.400 Ma | anual brachytherapy s | sources 35.600 Telethe | rapy unit(s) | |
| (check all that apply) | hthalmic use of stron mote afterloader unit | | a stereotactic ra | adiosurgery unit(s) |
| | PART I TRAINING | G AND EXPERIENCE three methods below) | | |
| * Training and Experience, including date of application or the individual required training and experience value and experience related to the use | al must have obtained was completed. Prov | I related continuing educatio | n and experien | ice since the |
| 1. <u>Board Certification</u> | | | | |
| a. Provide a copy of the board ce | ertification. | | | |
| For 35.600, go to the table in 3 which authorization is sought. | B.e. and describe trair | ning provider and dates of tra | aining for each | type of use for |
| c. Skip to and complete Part II Pi | eceptor Attestation. | | | |
| 2. Current 35.600 Authorized Use | er Requesting Addit | ional Authorization for 35. | 600 Use(s) Ch | ecked Above |
| a. Go to the table in section 3.e. | to document training | for new device. | | |
| b. Skip to and complete Part II Pr | eceptor Attestation. | | | |
| X 3. <u>Training and Experience for l</u> | Proposed Authorize | d User | | |
| a. Classroom and Laboratory Tra | ining XXX 35.490 | 35.491 XXXX 35 | 5.690 | |
| Description of Training | Locat | ion of Training | Clock Hours | Dates of Training* |
| Radiation physics and instrumentation | Hospital of | the Univ of Penna | 110 | 7/1/03- 6/30/07 |
| Radiation protection | Hospital of | the Univ of Penna | 11 | 7/1/03- 6/30/07 |
| Mathematics pertaining to the use and measurement of radioactivity | Hospital of | the Univ of Penna | 30 | 7/1/03- 6/30/07 |
| Radiation biology | Hospital fo | the Univ of Penna | 96 | 7/1/03- 6/30/07 |
| | Total Hours | of Training: | 247 | |

NRC FORM 313A (AUS) (3-2007)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

| Supervised Work Experience | | Total Hours of Experience: | | |
|---|--|--|----------------------|-------------------------|
| Description of Experience Must Include: | | perience/License or mber of Facility | Confirm | Dates of Experience* |
| Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys | Hospital of th 37-00118-07 | e Univ of Penna | Yes No | 7/1/03- 6/30/07 |
| Checking survey meters for proper operation | Hospital of th | e Univ of Penna | Yes No | 7/1/03- 6/30/07 |
| Preparing, implanting, and safely removing brachytherapy sources | Ho s pital of th | e Univ of Penna | X Yes | 7/1/03- 6/30/07 |
| Maintaining running inventories of material on hand | Hospital of th | e Univ of Penna | Yes No | 7/1/03- 6/30/07 |
| Using administrative controls to prevent a medical event involving the use of byproduct material | Hospital of th | e Univ of Penna | ▼ Yes | 7/1/03- 6/30/07 |
| Using emergency procedures to control byproduct material | Hospital of th | e Univ of Penna | Yes No | 7/1/03- 6/30/07 |
| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience/License or Permit Number of Facility | | Dates of Experience* | |
| Approved by: Residency Review Committee for Radiation Oncology of the ACGME | Hospital of the Univ of Penna | | 7/1/03- 6/30/07 | |
| Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral Training of the American Osteopathic Association | | | | |
| Supervising Individual Eleanor Harris, MD Robert Lustig, MD | | License/Permit Number listi Authorized User | ng supervising ind | ividual as an |

| Training and Experience for Prop | osed Authorized User (continued) | | |
|---|--|-------------------|------------------------|
| c. Supervised Clinical Experience fo | | | |
| Description of Experience | Location of Experience/License or Permit Number of Facility | Clock Hours | Dates of Experience |
| Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history | | | |
| Supervising Individual | License/Permit Number listing Authorized User | g supervising ind | ividual as an |
| d. Supervised Work and Clinical Exp | periance for 10 CEP 35 690 | | |
| Remote afterloader unit(s) | <u> </u> | stereotactic ra | diosurgery uni |
| 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 |
| Reviewing full calibration measurements and periodic spot-checks | Hospital of the Univ of Penna #37-00118-07 | X Yes | 7/1/03- 6/30/07 |
| Preparing treatment plans and calculating treatment doses and times | Hospital of the Univ of Penna | X Yes | 7/1/03- 6/30/07 |
| Using administrative controls to prevent a medical event involving the use of byproduct material | Hospital of the Univ of Penna | XX Yes | 7/1/03- 6/30/07 |
| Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console | Hospi ta l of the U m iv of Penna | X Yes | 7/1/03- 6/30/03 |
| Checking and using survey meters | Hospital of the Univ of Penna | X Yes | 7/1/03- 6/30/0 |
| Selecting the proper dose and how it is to be administered | Hospital of the Univ of Penna | XXXX Yes | 7/1/03- 6/30/07 |

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

| 3 | Training an | d Evnerience | for Proposed | Authorized User | (continued) |
|----|-------------|---------------|--------------|------------------------|-------------|
| J. | rranning ar | id Experience | tor Froposeu | Authorized Osei | (Continued) |

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience/License or Permit Number of Facility | Dates of Experience* | |
|--|--|----------------------|--|
| Approved by: | | | |
| Residency Review Committee for Radiation Oncology of the ACGME | Hospital of the Univ of Penna | 7/1/03- 6/30/07 | |
| Royal College of Physicians and Surgeons of Canada | | | |
| Committee on Postdoctoral Training of the American Osteopathic Association | | | |
| Supervising Individual Eleanor Harris, MD Robert Lustig, MD | License/Permit Number listing superv Authorized User 37-00118-07 | | |

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

| Description of Training | Training Provider and Dates | | | |
|---|---|--|------------------------------------|--|
| | Remote Afterloader | Teletherapy | Gamma Stereotactic Radiosurgery | |
| Device operation | Eleanor Harris, MD Robert Lustig, MD | | | |
| Safety procedures for the device use | Eleanor Harris, MD Robert Lustig, MD | | | |
| Clinical use of the device | Eleanor Harris, MD Robert Lustig, MD | | | |
| Supervising Individual. If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.) | | License/Permit Number listing su Authorized User 37-00118-07 | upervising individual as an | |
| Authorized for the | following types of use: | apy unit(s) | stereotactic radiosurgery unit(| |

| NRC FORM 313A (AUS) | | U.S. NUCLEAR REGULATORY COMMISSION |
|------------------------------------|---|---|
| AUTHORIZED U | SER TRAINING AND EXPERIENC | E AND PRECEPTOR ATTESTATION (continued) |
| | PART II – PRECEPT | OR ATTESTATION |
| individual as long | as the preceptor provides, directs, c | ptor. The preceptor does not have to be the supervising or verifies training and experience required. If more than obtain a separate preceptor statement from each. |
| First Section | | |
| | ng for each requested authorizati | on: |
| <u>For 35.490:</u> | | |
| <u>Board Certification</u> | | |
| I attest that | | has satisfactorily completed the requirements in |
| | | ncy sufficient to function independently as an for the medical uses authorized under 10 CFR 35.400. |
| | OF | र |
| Training and Experi | ence | |
| X I attest that | Courtney Lewis-Bui, MD | has satisfactorily completed the 200 hours of |
| T allest that | Name of Proposed Authorized User | — The satisfactority completed the 200 floats of |
| clinical experie level of compe | ence in radiation oncology, as requir | pervised work experience, and 3 years of supervised ed by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a dently as an authorized user of manual brachytherapy CFR 35.400. |
| For 35.491: | | |
| I attest that | | has satisfactorily completed the 24 hours of |
| has used stror | itium-90 for ophthalmic treatment of el of competency sufficient to function | e medical use of strontium-90 for ophthalmic radiotherapy, 5 individuals, as required by 10 CFR 35.491(b), and has on independently as an authorized user of strontium-90 for |
| Second Section | | • |
| For 35.690: | | |
| Board Certification | | |
| I attest that | | has satisfactorily completed the requirements in |
| 35.690(a)(1). | Name of Proposed Authorized User | |
| | OF | र |
| Training and Expe | <u>rience</u> | |
| I attest that | Courtney Lwis-Bui, MD | has satisfactorily completed 200 hours of classroom |
| and laborate | Name of Proposed Authorized User | work experience, and 2 years of supervised clinical |
| | ry training, 500 nours of supervised I radiation therapy, as required by 1 | work experience, and 3 years of supervised clinical 0 CFR 35.690(b)(1) and (b)(2). |

| (3-2007) AUTHORIZED USER TRAIN | ING AND EXPERIENCE AN | U.S. NUCLEAR REGUL D PRECEPTOR ATTESTATION (c | |
|--|---|--|--|
| Preceptor Attestation (continued) | NO AND EXITERIOR AN | DI NEGEL TON ATTECTATION (C | ontinueuj |
| Third Section | | | |
| For 35.690: (continued) | | | |
| | | received training required in 35.69 | 0(c) for device |
| | Proposed Authorized User es, and clinical use for the ty | pe(s) of use for which authorization | is sought, as |
| ^X Remote afterloader unit | t(s) Teletherapy unit(s) | Gamma stereotactic radiosu | rgery unit(s) |
| | AND | | |
| Fourth Section | | | |
| rattest triat | | s achieved a level of competency su | ufficient to |
| | Proposed Authorized User ncy sufficient to function inde | ependently as an authorized user fo | r: |
| Remote afterloader unit | t(s) Teletherapy unit(s) | Gamma stereotactic radiosu | rgery unit(s) |
| Fifth Section | | | |
| Complete the following for precept | tor attestation and signatu | re: | |
| I meet the requirements in an authorized user for: | 10 CFR 35.490, 35.491, 35. | 690, or equivalent Agreement State | requirements, as |
| XXX 35.400 Manual brachytl | nerapy sources 35.600 | Teletherapy unit(s) | |
| 35.400 Ophthalmic use | of strontium-90 🔲 35.600 | Gamma stereotactic radiosurgery u | nit(s) |
| XX 35.600 Remote afterloa | der unit(s) | | |
| Name of Preceptor Robert Lustig, MD | Signature | Telephone Number 215/349-8429 | Date / 8 8 8 8 8 8 8 8 8 8 |
| License/Permit Number/Facility Name Univers | ityof Pennsylvania | #37-00118-07 | |
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| This is to acknowledge the receipt of the fraction of the following that the following that the following the following that the following the | nd to inform you that the initial processing which |
|---|--|
| | #39-5/ nissions. Your application was assigned to a that the technical review may identify additional nformation. |
| Please provide to this office with | in 30 days of your receipt of this card |
| Branch, who will contact you separately Your action has been assigned Ma | il Control Number ction, please refer to this control number. |
| NRC FORM 532 (RI) (6-96) | Sincerely, Licensing Assistance Team Leader |

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