| х | |
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| (02 2012) | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 05/31/2015 |
| 10 CFR 30, 32, 33, | Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to |
| 54, 55, 55, 55, 51, 45 | protect the public health and safety. Send comments regarding burden estimate to the Information Services |
| | Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, |
| | NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to |
| | impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection. |
| | |
| | GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. O THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS |
| THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NE | |
| APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: | IF YOU ARE LOCATED IN: |
| OFFICE OF FEDERAL & STATE MATERIALS AND | ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, |
| ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS | SEND APPLICATIONS TO: |
| U.S. NUCLEAR REGULATORY COMMISSION | MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III |
| WASHINGTON, DC 20555-0001 | 2443 WARRENVILLE ROAD, SUITE 210 |
| ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: | LISLE, IL 60532-4352 |
| ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, | ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, |
| KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOU | LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH TH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, |
| CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, | UTAH, WASHINGTON, OR WYOMING, |
| SEND APPLICATIONS TO: | SEND APPLICATIONS TO: |
| LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY | NUCLEAR MATERIALS LICENSING BRANCH |
| U.S. NUCLEAR REGULATORY COMMISSION, REGION I | U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD |
| 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713 | ARLINGTON, TX 76011-4511 |
| PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIO | NS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY |
| WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SI | JBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS. |
| 1. THIS IS AN APPLICATION FOR (Check appropriate item) | 2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) |
| A. NEW LICENSE | Vrinda Narayana, Ph.D. |
| 21-26632-01 | Providence Cancer Center, Providence Hospital |
| B. AMENDMENT TO LICENSE NUMBER | - 22301 Foster Winter Drive, I floor |
| C. RENEWAL OF LICENSE NUMBER | Southfield, MI 48075 |
| | |
| 3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED | 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION |
| | Vrinda Narayana, Ph.D. |
| Providence Cancer Center, Providence Hospital | BUSINESS TELEPHONE NUMBER BUSINESS CELLULAR TELEPHONE NUMBER |
| 22301 Foster Winter Drive, 1 floor | (248) 849-8622 (248) 867-8424 |
| Southfield, MI 48075 | BUSINESS EMAIL ADDRESS |
| | vrinda.narayana@stjohn.org |
| SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFOR | MATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE. |
| 5. RADIOACTIVE MATERIAL | 6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. |
| a. Element and mass number; b. chemical and/or physical form; and c. maiximum amount | 7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR |
| which will be possessed at any one time. | TRAINING EXPERIENCE. |
| 8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. | 9. FACILITIES AND EQUIPMENT. |
| 10. RADIATION SAFETY PROGRAM. | 11. WASTE MANAGEMENT. |
| LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31) | FEE CATEGORY AMOUNT ENCLOSED \$ |
| 13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS T UPON THE APPLICANT. | HAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING |
| THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF T | |
| CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, THE BEST OF THEIR KNOWLEDGE AND BELIEF. | 35 , 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO |
| | RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO |
| CERTIFYING OFFICER TYPED/PRINTED NAME AND TITLE | SIGNATURE |
| | |
| Vrinda Narayana/ Chief Physicist/RSO | Vund havy 21 Hey 213 |
| FOR | NRC USE ONLY |
| | ECK NUMBER COMMENTS |
| S S | |
| APPROVED BY | TELS IN CONTRACTOR AND A DESCRIPTION |
| | |
| NRC FORM 313 (03-2013) | RECEIVED MAY 2 3 2013 |
| | |



May 21, 2013

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

Ref: Material License # # 21-26632-01,

Subject: Request for license material amendment

To the person concerned,

Enclosed is our request to amend our material license **# 21-26632-01**, issued to Providence Hospital, Providence Cancer Center, 22301 Foster Winter Drive, Southfield, MI 48075.

Dr. Brooke Trotter, MD will be joining our staff at Providence Hospital on July 22, 2013. I request that she be added as an Authorized User on our license for the use of Ir-192 in our HDR remote afterloading unit. I have attached the NRC Form 313 A(AUS) that documents her training and experience in anticipation of successfully completing her training at the Wayne State University and is signed by an Authorized User, Steven R. Miller on license number 21-04127-06.

Thank you,

Sincerely,

Vrinda Narayana, Ph.D RSO 22301 Foster Winter Drive, I Floor Southfield, MI 48075 248 849 8622

| NRC FORM 313A (AUS) | U.S. NUCL | EAR REGU | | | |
|---|---|---------------|-------------------------------|-------------------------------|-------------------------------|
| (05-2012) AUTHORIZED U AND PF (for uses de [10 CFR | ESTATIC 00 and 3 | 9N 85.600) | APPROVED BY EXPIRES: (05/3 | OMB: NO. 3150-0120 1/2015) | |
| Name of Proposed Authorized User | | State or T | erritory Where License | d | |
| Brooke Trotter | | | MI | | |
| Requested 35.400 M | lanual brachytherapy | sources | 35.600 Telethera | ipy unit(s) | |
| Authorization(s) 35.400 O (check all that apply) | phthalmic use of stro | ntium-90 | 35.600 Gamma s | stereotactic rac | liosurgery unit(s) |
| (check all that apply) 35.600 R | emote afterloader un | it(s) | | | |
| | PART I TRAINING (Select one of the th | | | | |
| * Training and Experience, includidate of application or the individuate of a specience and experience related to the use and experience re | ual must have obtained was completed. Pro | d related | continuing education | and experience | ce since the |
| 1. Board Certification | | | | | |
| a. Provide a copy of the board of | ertification. | | | | |
| b. For 35.600, go to the table in which authorization is sought | | ining prov | ider and dates of trai | ning for each t | ype of use for |
| c. Skip to and complete Part II P | receptor Attestation. | | | | |
| 2. Current 35.600 Authorized Us | ser Requesting Add | itional Au | thorization for 35.6 | 00 Use(s) Che | cked Above |
| a. Go to the table in section 3.e. | | | | | |
| b. Skip to and complete Part II P | Ŧ | | | | |
| 3. Training and Experience for | | ed User | | | |
| a. Classroom and Laboratory Tr | | | 35.491 35.4 | 690 | |
| Description of Training | Loca | ition of Tra | aining | Clock Hours | Dates of Training* |
| Dediction physics and | Wanyne St | ate U | niversity, | 10 | March 6,2009 |
| Radiation physics and instrumentation | Detroit | | t · | 50 | To |
| | | | | | April 30, 2013 |
| | Wayne St | ate V | niversity, | 50 | March b, 2007 |
| Radiation protection | Detroit | | - | 20 | 10 |
| | | - | | | April 30,2013 |
| Mathematics pertaining to the | Wayne St | ate 1 | Iniversity. | 50 | March 6,2009 |
| use and measurement of radioactivity | Detroit | | | 50 | |
| | Whyne Sta | | iversity | | April 30,2013 March 6,2009 |
| Radiation biology | Detroit | | p and a second p | 50 | April 30,2013 |
| L | | | ing: 200 | | |
| L | | | | | PAGE 1 |

| FORM 313A (AUS) | | | TORY COMMISSIO |
|--|--|----------------------------|--|
| | NG AND EXPERIENCE AND PRECEPTOR ATT | ESTATION (c | ontinued) |
| han ann an ann ann ann an tar an 11 - 2 a' an Ann, ann an tarairt ann ann ann ann ann ann ann ann ann an | posed Authorized User (continued) | | |
| | xperience for 10 CFR 35.490 (If more than one su sed work experience, provide multiple copies of th | | vidual is |
| Supervised Work Experience | Total Hours of Experience: | 500 | |
| 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 | Karmanos Cancer Center 21-04/27-06 | Ves | March 6, 200 Te April 30, 201 |
| Checking survey meters for proper operation | Karmanos Cancer Center 21-04127-06 | V Yes | March 6, 200 to April 30, 20 |
| Preparing, implanting, and safely removing brachytherapy sources | Karmanos Cancer Center 21-04127-06 | Yes | March 6, 200 to April 30, 201 |
| Maintaining running inventories of material on hand | Karmanos Cancer Center 21-04127-06 | Yes | March 6,30 50 50 50,20 |
| Using administrative controls to prevent a medical event involving the use of byproduct material | Karmonos Cancer Center 21-04127-06 | V Yes | March 6,200 to April 30,20 |
| Using emergency procedures to control byproduct material | Karmanos Cancer Center 21-04127-06 | V Yes | March 6,200 to April 30,30 |
| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience/License or Permit Number of Facility | r | Dates of Experience* |
| Approved by: Residency Review Committee for Radiation Oncology of the ACGME Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral Training of the American | Karmanos Cancer Center License # 21-04127-06 | | March6, 2009 to April 30, 2013 |
| Training of the American Osteopathic Association Supervising Individual Steven R. Miller, | MD License/Permit Number listin | g supervising in 1-0412 | dividual as an |

PAGE 2

| | | U.S. NUCLEAR REGULATORY COMMIS | | |
|--|--|------------------------------------|--|---|
| AUTHORIZED USER TRAIN | | | TESTATION (co | ontinuea) |
| c. Supervised Clinical Experience | | 4 | | |
| Description of Experience | Location of Experience Permit Number of | | 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 | | e/Permit Number listi ized User | ng supervising ind | ividual as an |
| d. Supervised Work and Clinical E | Experience for 10 CFR 35.690 |)) | vervædendet er er en statigten van van Statister og en Statister en under en statister en statister en statist | |
| Remote afterloader unit(s) | • | | na stereotactic ra | idiosurgery unit(|
| Supervised Work Experience | | Total Hours of E | xperience: 5 | 00 |
| Description of Experience Must Include: | Location of Experien Permit Number | | Confirm | Dates of Experience* |
| Reviewing full calibration measurements and periodic spot-checks | Karmanos Cancer License # 21-04 | | Ves | March 6,20 to April 30,20 |
| Preparing treatment plans and calculating treatment doses and times | Karmanos Cancer License # 21-04 | Center 27-06 | Ves | April 30, 20 March 6, 20 To April 30, 20 March 6, 2 |
| Using administrative controls to prevent a medical event involving the use of byproduct material | Karmanos Cancer License # 21-0 | - Center 1127-06 | V Yes | Jo April 30,7 |
| Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console | Karmanos Cancer License # 21-0 | Center 1127-06 | Yes | March 6, 20 to April 30, 20 |
| Checking and using survey meters | Karmanos Cancer License # 21-041 | | Yes | March 6,20 to April 30,20 March 6,20 to April 30,2 |
| Selecting the proper dose and how it is to be administered | Karmanos Cancer License # 21-041 | | V Yes | March 6,20 to April 30,2 |

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PAGE 3

| NRC FORM 313A (AUS) (05-2012) | | U.S. NUC | LEAR REGULATORY COMMISSION |
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| | INING AND EXPERIE | NCE AND PRECEPTOR ATTE | STATION (continued) |
| 3. Training and Experience for | Proposed Authorized | User (continued) | |
| d. Supervised Work and Clinic | al Experience for 10 CF | R 35.690 (continued) | |
| Clinical experience in radiation oncology as part of an approve formal training program | | ation of Experience/License or Permit Number of Facility | Dates of Experience* |
| Approved by: Residency Review Committee for Radiation Oncology of the ACGME Royal College of Physician and Surgeons of Canada Committee on Postdoctora Training of the American Osteopathic Association | s | Cancer Center # 21-04127-06 | March6, 2009 to April 30, 2013 |
| Supervising Individual Steven R. Miller e. For 35.600, describe training sought. | | License/Permit Number listing Authorized User 21-04127-0 f training for each type of use fo | 6 |
| Description of Training | | Training Provider and Dates | Commo Staroatantia |

| of Training | Training Provider and Dates | | |
|---|--|--|------------------------------------|
| , and a second secon | Remote Afterloader | Teletherapy | Gamma Stereotactic Radiosurgery |
| Device operation | Steven R. Miller, mD Jan-Dec 2010 | | |
| Safety procedures for the device use | Steven R. Miller, MD Jan-Dez 2010 | | |
| Clinical use of the device | Steven R. Miller, MO Jan-Dez 2010 | | |
| Individual (If more than to document supervise copies of this page.) | | cense/Permit Number listing su uthorized User 21-04127-0 | |
| | following types of use: pader unit(s) | v unit/s) Gamma : | stereotactic radiosurgery unit(s |

| (05-2012) | AUTHORIZED LISER TRAINING AND EN | (PERIENCE AND PRECEPTOR ATTESTATION (continued) |
|-----------|---|--|
| | | |
| Note: | This part must be completed by the individuind individual as long as the preceptor provides | PRECEPTOR ATTESTATION ual's preceptor. The preceptor does not have to be the supervising s, directs, or verifies training and experience required. If more than xperience, obtain a separate preceptor statement from each. |
| | | or is attesting that the individual has knowledge to fulfill the duties of |
| | Section s one of the following for each requested a | authorization: |
| For 3 | <u>35.490:</u> | |
| E | Board Certification | |
| | I attest that | has satisfactorily completed the requirements in |
| | 35.490(a)(1) and has achieved a level | of competency sufficient to function independently as an py sources for the medical uses authorized under 10 CFR 35.400. |
| | | OR |
| T | raining and Experience | |
| | I attest that Brooke Trotter Name of Proposed Authorit | has satisfactorily completed the 200 hours of |
| | clinical experience in radiation oncology | hours of supervised work experience, and 3 years of supervised by, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved tion independently as an authorized user of manual brachytherapy of under 10 CFR 35.400. |
| For 3 | <u>35.491:</u> | |
| | I attest that | has satisfactorily completed the 24 hours of |
| | Name of Proposed Authorit | ized User |
| | has used strontium-90 for ophthalmic tr | icable to the medical use of strontium-90 for ophthalmic radiotherap reatment of 5 individuals, as required by 10 CFR 35.491(b), and ha ent to function independently as an authorized user of strontium-90 |
| Seco | ond Section | |
| | <u>35.690:</u> | |
| | Board Certification | |
| - | I attest that | has satisfactorily completed the requirements in |
| | 35.690(a)(1). Name of Proposed Authorit | |
| | Training and Experience | OR |
| | VI attest that Brooke Trotte | has satisfactorily completed 200 hours of classroom |
| | | supervised work experience, and 3 years of supervised clinical equired by 10 CFR 35.690(b)(1) and (b)(2). |
| | | AND |
| ~ | M 313A (AUS) (05-2012) | PA |

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| NRC FORM 313A (AUS) U.S. NUCLEAR REGULATORY COMMISSION |
|---|
| AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) |
| Preceptor Attestation (continued) |
| Third Section |
| For 35.690: (continued) |
| VI attest that Brocke Trotter has received training required in 35.690(c) for device |
| operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below. |
| Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s) |
| AND |
| Fourth Section |
| VI attest that Brooke Trotter has achieved a level of competency sufficient to |
| achieve a level of competency sufficient to function independently as an authorized user for: |
| Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s) |
| Fifth Section |
| Complete the following for preceptor attestation and signature: |
| |
| ✓ I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for: |
| ✓ 35.400 Manual brachytherapy sources ✓ 35.600 Teletherapy unit(s) |
| 35.400 Ophthalmic use of strontium-90 🗌 35.600 Gamma stereotactic radiosurgery unit(s) |
| St.600 Remote afterloader unit(s) |
| Name of Preceptor Signature // Telephone Number Date |
| Steven R. Miller, MD Stand 313-576-9545 521-13 License/Permit Number/Facility Name |
| Karmanes Cancer Center 21-04127-06 |
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