David Schmitt, R.Ph., R.S.O., B.C.N.P. President

> Barbara Riedel Office Manager



December 27, 2010

Colleen Casey Nuclear Regulatory Commission Region III Materials Licensing Branch 2443 Warrenville Road, Ste 210 Lisle, IL 60532-4352

Re: Amendment to License #21-32444-01MD

Dear Ms. Casey:

This is an amendment to add an additional new authorized nuclear pharmacist to our current site in Port Huron, Michigan. Our current site license number is 21-32444-01MD. The new authorized nuclear pharmacist is Amanda M. Miller. All of Amanda's documentation is enclosed.

If you have any questions, then please call me at 810.987.3317.

Warm Regards,

David Schmitt, R.Ph. Radiation Safety Officer

ADD TO ADAMS THIS COPY FOR 575049

RECEIVED JAN 0 3 2011

2001 11th Avenue • Port Huron, MI 48060 (810) 987-3317

| NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012 | | | | |
|---|---|--|--|--|--|
| (3-2009) | Estimated burden per response to comply with this mandatory collection request: 4.3 | | | | |
| 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40 | hours. Submittal of the application is necessary to determine that the applicant qualified and that adequate procedures exist to protect the public health and safet Sand commants regarding hundra estimate to the Decords and EOIA/Drivery Sandar | | | | |
| APPLICATION FOR MATERIALS LICENSE | Send comments regarding builden estimate to the Records and FOUAPrivacy Service Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-001 or by internet e-mail to infocollects resource@mrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Managemer and Budget, Washington, DC 20503. If a means used to impose an informatio collection does not display a currently valid OMB control number, the NRC may no conduct or sponsor, and a person is not required to respond to, the informatio collection. | | | | |
| INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION G | UIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. | | | | |
| APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: | APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. | | | | |
| OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 | ILLINOIS, INDIANA, 10WA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEM APPLICATIONS TO: | | | | |
| ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: | MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352 | | | | |
| IF YOU ARE LOCATED IN: | | | | | |
| ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: | ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: | | | | |
| LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19408-1415 | NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 612 E. LAMAR BOULEVARD, SUITE 400 ARLINGTON, TX 76011-4125 | | | | |
| PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICT | R REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED TIONS, | | | | |
| 1. THIS IS AN APPLICATION FOR (Check appropriate item) | 2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) | | | | |
| A. NEW LICENSE | Lakeview Diagnostic LLC | | | | |
| B. AMENDMENT TO LICENSE NUMBER 21-32444-01MD | 2001 11th Avenue | | | | |
| C. RENEWAL OF LICENSE NUMBER | Port Huron, Michigan 48060 | | | | |
| 3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED | 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION | | | | |
| | David W. Schmitt, R.Ph. | | | | |
| | TELEPHONE NUMBER | | | | |
| | (810) 987-3317 | | | | |
| SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMAT | TION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE. | | | | |
| RADIOACTIVE MATERIAL Element and mass number; b. chemical and/or physical form; and c. maiximum amount which will be possessed at any one time. | 6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. | | | | |
| 7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE. | 8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. | | | | |
| 9. FACILITIES AND EQUIPMENT. | 10. RADIATION SAFETY PROGRAM. | | | | |
| 11. WASTE MANAGEMENT. | 12. LICENSE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY AMOUNT S ENCLOSED S | | | | |
| CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT JPON THE APPLICANT. | | | | | |
| THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF TI CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 3 CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. | 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND | | | | |
| WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRI ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN IT DETUCING OFFICE | S JURISDICTION. | | | | |
| CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE David W. Schmitt, R.Ph., Radiation Safety Officer | SIGNATURE DATE 12/27/2010 | | | | |
| | USE ONLY NUMBER COMMENTS | | | | |
| S DATE | | | | | |
| IRC FORM 313 (3-2009) | PRINTED ON RECYCLED PAPER | | | | |



The Ohio State University **College of Pharmacy** and **University Medical Center Department of Pharmacy**



Amanda M. Miller

has satisfactorily fulfilled all requirements and completed the prescribed course

Nuclear Pharmacy Certificate Program

December 23, 2009

Director, Nuclear Pharmacy **Associate Professor of Pharmacy**

Director. Outreach and Engagement **College of Pharmacy**



Kopht W. Brugg

Chair. Pharmacy Practice and Administration



THE OHIO STATE UNIVERSITY COLLEGE OF PHARMACY UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

RADIONUCLIDE HANDLING EXPERIENCE

Name: Amanda M. Miller

Date: December 23, 2009

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

| RADIONUCLIDE | RADIOACTIVITY | USE see below | EXPERIENCE Actual clock hours (Include date range of experience) | LOCATION |
|--------------|---------------|------------------|---|---------------------------|
| Mo-99 | 10 Curies | 1,2,3,4,5,6,7 | 11/30/09 | The Ohio State University |
| Tc-99m | 8 Curies | 1,2,3,4,5,6,7 | through | Medical Center |
| 1-131 | 200 mCi | 1,2,3,4,5,6 | 12/23/09 | Columbus, OH |
| I-123 | 1 mCi | 1.2,3,4,5,6 | | |
| Ga-67 | 25 mCi | 1,2,3,4,5 | | |
| TI-201 | 50 mCi | 1,2,3,4,5 | | |
| In-111 | 7.5 mCi | 1,2,3,4 | | |
| Sr-89 | 5 mCi | 1,2,3,4,5,6 | | |
| Sm-153 | 100 mCi | 1,2,3,4,5,6 | | |
| F-18 | 200 mCi | 1,2,3,4,5,6 | | |
| Cs-137 | 0.2 mCi | 1,2,5 | TOTAL HOURS: 40 hours | |

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each radionuclide.

- 1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.
- 2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if applicable, instruments used to measure alpha- or beta-emitting radionuclides.
- 3. Calculating, assaying and safely preparing dosages for patients or human research subjects.
- 4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material.
- 5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.
- 6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys and wipe tests.
- 7. Eluting Tc99m from generator systems, assaying the eluate for Tc99m and for Mo99 and processing the eluate with reagent kits to prepare Tc99m labeled radioactive drugs.

Authorized Nuclear Pharmacist:

George

Date: December 23, 2009



THE OHIO STATE UNIVERSITY

COLLEGE OF PHARMACY UNIVERSITY MEDICAL CENTER



NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Amanda M. Miller

| Location of | Dates of Attendance | Course | Total | BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS | | | | | |
|---|---|---|---|--|--|----------------------|----------------------------------|----------------------|--|
| Training | H | Clock Hours of Course | Radiation Physics & Instrumentation | Radiation Protection | Math Pertaining to Radioactivity | Radiation Biology | Radiopharmaceutical Chemistry | | |
| The Ohio State University, Columbus, OH | November 30, 2009 through December 23, 2009 | Nuclear Pharmacy Certificate Program | 214 | 88 | 45 | 20 | 22 | 39 | |
| *Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category) TOTAL HOURS 214 | | | 88 | 45 | 20 | 22 | 39 | | |
| Authorized Nu | clear Pharmacist/A | uthorized U | | rge H. Minkle, R | | Juilly NP,FASHP,F | | TE: December 23, 200 | |

| NRC FORM 313A (10-2002) | TRAINING | | SNCE | | U.S. NUCLEAR REGULA | TORY COMMISSION | | |
|----------------------------|---|------------|------|---|--|--|--|--|
| <u> </u> | TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued) 5a. WORK EXPERIENCE WITH RADIATION | | | | | | | |
| 1 | Description of Experience | | | Name of Supervising Individual(e) | Location and Corresponding Materials License Number | Dates and Clock Hours of Experience | | |
| Studien | H Intern May | 07-pres | nt | BRICH.Schaaf | 1331 N. Colest Lima, 04 45801 | 1850 | | |
| Worker He pi | in all aspec | ts of | | | Hea. +Lizht Akram 0250002.0000 | (otto) | | |
| of the | 1so-topes. | | | | | | | |
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| | | | | | | | | |
| | · | 6b. SUPERV | ISED | CLINICAL CASE EXPERIEN | CE | | | |
| Radionuciide | Radionuclide Type of Use No. of Cas Involving Persona Participation | | | Name of Supervising Individual | Location and Corresponding Materials License Number | Dates and Clock Hours of Experience | | |
| | | ļ | | · · · · · · · · · · · · · · · · · · · | | | | |
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| | NRC FORM 313A U.S. NUCLEAR REGULATORY COMMISSION (10-2002) TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued) | | | | | | | |
|--|---|---|---|--|-------|--|--|--|
| 6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians) | | | | | | | | |
| | | e, Area of Study or dency Program | Name of Program and Location with Corresponding Materials License Numbers | Name of Program and Location with Corresponding Dates Materials | | Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Educatio and the Applicable Regulation (e.g., 10 CFR 35.490) | | |
| | | | | | | | | |
| | | 7. RADIA | TION SAFETY OFFICER - ONE | -YEAR FULL-TH | METR | AINING | | |
| | YES N/A | | ull-time radiation safety experien | | | | | |
| | ويعاين والمتحدث والمتحد | 8. MEDICAL PH | YSICIST - ONE YEAR FULL-TI | ME TRAINING/ | ORK | EXPERIENCE | | |
| | YES N/A | - | ull-time training in therapeutic rac who meets re | • • • | | | | |
| | YES | Completed 1-year of fi | ull-time work experience (for area | is identified in iter | m 5a) | for | | |
| | N/A | | e supervision of | | • | | | |
| | | | prized Medical Physicists for | | | | | |
| | | 9 SUDEDV | | | ALEN | CATIONS | | |
| SUPERVISING INDIVIDUAL IDENTIFICATION AND QUALIFICATIONS The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each): | | | | | | | | |
| | A. Nam | e of Supervisor | B. Supervisor is: | | | | | |
| | ELI | cH.Schoaf | Authorized U | ser | | Authorized Medical Physicists | | |
| | | | Radiation Sa | fety Officer | X | Authorized Nuclear Pharmacists | | |
| C. Supervisor meets requirements of Part 35, Section(s) | | | | | | | | |
| | for m | nedical uses in Part 35, | Section(s) | | | ······································ | | |
| | D. Addr | ess 1321N. | Cole St. | | | E. Materials License Number | | |
| | | |)H 4580] | | | 02500020000 | | |
| | | Unit, C | | | | (OH10) | | |

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| | | PAGE 4 | | | | | |
|---|---|--|--|--|--|--|--|
| NRC FORM 313A (10-2002) | · · · · · · · · · · · · · · · · · · · | U.S. NUCLEAR REGULATORY COMMISSION | | | | | |
| (10-2002) | TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued) | | | | | | |
| 1 | PART II PRECEPTOR STATEMENT | | | | | | |
| experier requiren Item 10 | ote: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590. Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. | | | | | | |
| | ors do not have to complete items 11a, 11b, or the certifying statements nents of 10 CFR Part 35, Subpart J. | s for other individuals meeting the | | | | | |
| YES 10. | The individual named in item 1has satisfactorily completed the traini | ing requirements in | | | | | |
| □ _{N/A} | 10 CFR 35.980 and is competent to independently operate a nuclea | r pharmacy. | | | | | |
| YES 11a | a. The individual named in Item 1 has satisfactorily completed the requand Paragraph(s) | uirements in Part 35, Section(s) | | | | | |
| YES 110 | D. The individual named in Item 1. is competent to independently funct NUCLAC PhasMacat for | | | | | | |
| | 12. PRECEPTOR APPROVAL AND CERTIFICATI | • | | | | | |
| A relative the t | approval of item 10 and certify I am an Authorized Nuclear Pharmacist; | | | | | | |
| I certify the | Or approval of items 11a and 11b and certify I am an Authorized Nuclear F | hamacist; | | | | | |
| I certify the | Or approval of Items 11a and 11b, and I certify that I meet the requirement | is of | | | | | |
| or equivalen | nt Agreement State requirements to be a preceptor authorized | ······································ | | | | | |
| for the following uses of byproduct material: | | | | | | | |
| | | B. Materials License Number | | | | | |
| | 1331 N. Cole St. 025000 20000 | | | | | | |
| | Umn,0H 4580] | | | | | | |
| C. NAME OF PREC ETEIC | CEPTOR (print clearly) D. SIGNATURE- PRECEPTOR | E. DATE 10/20/10 | | | | | |
| | 0 | PAGE 4 | | | | | |

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| NRC FORM 313A (10-2002) | APPROVED BY OMB: NO. 3150-0120 | | | | | | |
|---|---------------------------------------|--|---------------|-----------------------------|--|--|--|
| TRAINING AND EXPERIENC | E AND PRECEPTOR STA | TEMENT | EXPIRES: 10 | /31/2005 | | | |
| PART I TRAINING AND EXPERIENCE Note: Descriptions of training and experience must contain sufficient detail to match the training and experience citeria in | | | | | | | |
| the explored is required and expendence must contain something and expendence citeria in | | | | | | | |
| AMANDA M. Miller | - Pharm D. | | | | | | |
| Name of Individual, Proposed Authori | zation (e.g., Radiation Safety Office | cer), and Applicabl | e Training Re | equirements | | | |
| Avthoriz | cen Nuchen Murman | unt | | | | | |
| 2. For Physicians, Podiatrists, Dentists, | | | | | | | |
| | | | | | | | |
| | 3. CERTIFICATION | | | | | | |
| Specialty Board | | Category | | Month and Year Certified | | | |
| | | | | | | | |
| Stop hore when white Read Co | | | • | | | | |
| Stop here when using Board Ce 4. DIDACTIC OR CLASSRO | OM AND LABORATORY TRAINI | The second s | | | | | |
| Description of Training | Location | Clock Hours | | ates of Training | | | |
| | Location | CIOCK HOUR | | aurs of frammy | | | |
| Radiation Physics and Instrumentation | Through SU Prog | rom | | | | | |
| | 00000 | | | | | | |
| Radiation Protection | | | | | | | |
| | | | | | | | |
| Mathematics Pertaining to the Use and | | | | | | | |
| Measurement of Radioactivity | | | | | | | |
| | | | | | | | |
| Radiation Biology | | | | | | | |
| | | | | | | | |
| Chemistry of Byproduct Material for | | | | | | | |
| Medical Use | | | | | | | |
| | | | | | | | |
| OTHER | | | | | | | |
| | | | | | | | |
| IRC FORM 313A (10-2002) | PRINTED ON RECYCLED PAPER | | | PAGE 1 | | | |

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OHIO STATE BOARD OF PHARMACY Fax: 614/752-4836 021273 hennech Identification Number ĩ. Be it known that the individu in the State of Ohio until the 16. 9011. AMANDAMA RIB MIL 21387 RD 1 OAKWOÓD C PEIA-0402 (6/10) Completion of this form is required by OAC Rule 4729-5-02

The pharmacist or pharmacy intern signing below shall have this card on his/her person while engaged in the practice of pharmacy according to Section 4729.12, Ohio Revised Code.

In 1

Signature of Individual Named on Front Side

LAKEVIEW **DIAGNOSTIC, L.L.C.**

PRIORITY®

UNITED STATES POSTAL SERVICE

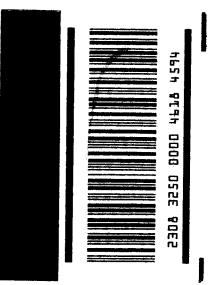
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2001 11th Avenue Port Huron, MI 48060







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



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