

US Nuclear Regulatory Commission
Region III
Materials Licensing Branch
801 Warrenville Road
Lisle, Illinois 60532



A member of Henry Ford Trinity Health Network
15855 Nineteen Mile Road
Clinton Township, MI 48038
(810) 263-2300
www.stjoe-macomb.com

Re: Amendment to 21-11850-01

Dear Sir or Madam:

We wish to amend our Materials License 21-11850-01 as follows:

AUTHORIZED USER

ADD: John Kalabat, M.D. 10 CFR 35.100, CFR 35.200, CFR 35.300

Dr. Kalabat is board certified in Diagnostic Radiology (June 2003), and is pending his Nuclear Medicine board certification. Form 313A, Training and Experience and Preceptor Statement is attached.

Please note that our license renewal is currently in progress, and has been submitted in a timely manner.

Thank you for your attention to these matters.

Sincerely,

A handwritten signature in cursive script that reads "Michael Ward".

Michael Ward
Supervisor
Nuclear Medicine

OCT 6 2004

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|--|--|------------------------------------|------------------------------|---|--|
| NRC FORM 313A (10-2002) | | U.S. NUCLEAR REGULATORY COMMISSION | | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2006 | |
| TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT | | | | | |
| PART I - TRAINING AND EXPERIENCE | | | | | |
| Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations. | | | | | |
| 1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50) <u>John Kalas</u> <u>Authorized User</u> | | | | | |
| 2. For Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed <u>Michigan</u> | | | | | |
| 3. CERTIFICATION | | | | | |
| Specialty Board | | Category | | Month and Year Certified | |
| <u>Radiology</u> <u>Nuclear Medicine Boards</u> pending 2004 | | <u>Diagnostic</u> | | <u>6/2003</u> | |
| <i>Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.</i> | | | | | |
| 4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists) | | | | | |
| Description of Training | | Location | Clock Hours | Dates of Training | |
| Radiation Physics and Instrumentation | | Brigham Women's Hospital | 38 hrs. class 32 hrs. lab | 9/3/03 - 1/23/04 | |
| Radiation Protection | | ↓ | 28 hrs. | 4/2/04 - 6/4/04 | |
| Mathematics Pertaining to the Use and Measurement of Radioactivity | | | 5 hrs. | 11/04 | |
| Radiation Biology | | | 10 hrs | 2/3/04 - 3/31/04 | |
| Chemistry of Byproduct Material for Medical Use | | | 11 hrs. | Nov. 04 | |
| OTHER | | | | | |

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NRC FORM 313A (10-2002) TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued) U.S. NUCLEAR REGULATORY COMMISSION

5a. WORK EXPERIENCE WITH RADIATION

| Description of Experience | Name of Supervising Individual(s) | Location and Corresponding Materials License Number | Dates and Clock Hours of Experience |
|---|--|---|-------------------------------------|
| Nuclear Medicine Presidency Rotation | Alan J. Fishman MD, PhD mat Lic # 66-0055 | Massachusetts General Hosp. | Jul-Oct 2003 640 hrs |
| | Rachel A. Powsner, MD Mat Lic # 20-00671-02 | VA Boston Healthcare System | Nov-Dec 2003 |
| | S. Ted Treves, MD mat Lic # 60-0187 | Children's Hospital Boston | Jan-Feb 2004 |
| | Annick D. Van den Abbeele M.D. mat Lic # 60-0037 | Dana-Farber Cancer Institute | Mar-Jun 2004 |
| | | Please see attached sheet | |
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5b. SUPERVISED CLINICAL CASE EXPERIENCE

| Radionuclide | Type of Use | No. of Cases Involving Personal Participation | Name of Supervising Individual | Location and Corresponding Materials License Number | Dates and Clock Hours of Experience |
|--------------|-----------------------|---|---|---|-------------------------------------|
| I-131 | HYPERTHYROID | 7 | Eric K. Alexander M.D. | Brigham Women's Hospital mat Lic # 44-0004 | Jan-Feb- 2004 |
| I-131 | Thyroid CA | 7 | | | Jan-Feb 2004 |
| I-131 | THYROID CANCER | 1 | David Drum MD PhD | VA Boston West Roxbury | 4/21/03 |
| I-131 | Hypertthyroid | 1 | David Drum MD PhD | VA Boston Healthcare West Roxbury | 12/4/03 |
| I-131 | Autonomous No date | 1 | J. Anthony Parker MD PhD | Beth Israel Deaconess Medical | 9/3/03 |
| Samarium | Prostate CA | 3 | David Israel, MD, PhD Annick Vanden Abbeele MD | Dana-Farber Cancer Institute | May+June 2004 |
| | | | | | |
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MPC, Inc. No. 2467, Rev. 10-01-03

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NRC FORM 31JA
(10-2002)

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicists)

| Degree, Area of Study or Residency Program | Name of Program and Location with Corresponding Materials License Number | Dates | Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490) |
|--|--|-----------------|---|
| Joint Program in Nuclear medicine Residency Training Program | Joint Program in Nuclear medicine Brigham Women's Hospital 75 Francis St. Boston, MA 02115 | 7/1/0 - 6/30/04 | ACGME |

7. RADIATION SAFETY OFFICER - ONE-YEAR FULL-TIME WORK EXPERIENCE

YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision of _____ the RSO for License No. _____

N/A

8. MEDICAL PHYSICIST - ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of _____ who meets requirements for Authorized Medical Physicists; and

N/A

YES Completed 1-year of full-time work experience (for areas identified in item 5a) for _____ who meets requirements of Authorized Medical Physicists for _____ modality(ies).

N/A

9. 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. Name of Supervisor: S. Ted Treves, MD

B. Supervisor is:

Authorized User Authorized Medical Physicist

Radiation Safety Officer Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 105 CMR 120.502

for medical uses in Part 35, Section(s) 105 CMR 120.507-573

D. Address: Brigham - women's hospital
75 Francis Street
Boston, MA 02115

E. Materials License Number: see attached sheet

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No. 2467

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Sep. 15. 2004 10:20AM

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| NRC FORM 313A (10-2002) | U.S. NUCLEAR REGULATORY COMMISSION |
| TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued) | |

PART II -- PRECEPTOR STATEMENT

Note: 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. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

| | |
|---|--|
| <input type="checkbox"/> YES <input checked="" type="checkbox"/> N/A | 10. The individual named in item 1 has satisfactorily completed the training requirements in 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy. |
|---|--|

| | |
|---|---|
| <input type="checkbox"/> YES <input checked="" type="checkbox"/> N/A | 11a. The individual named in item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____ |
|---|---|

| | |
|---|---|
| <input checked="" type="checkbox"/> YES <input type="checkbox"/> N/A | 11b. The individual named in item 1 is competent to independently function as an authorized <u>USER</u> for <u>10 CFR 35.100</u> uses (or units). <u>35.200 and 35.300</u> |
|---|---|

12. PRECEPTOR APPROVAL AND CERTIFICATION

| | |
|-------------------------------------|--|
| <input type="checkbox"/> | I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist; |
| OR | |
| <input type="checkbox"/> | I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist; |
| OR | |
| <input checked="" type="checkbox"/> | I certify the approval of items 11a and 11b, and I certify that I meet the requirements of <u>105 CMR 120.502</u> or equivalent Agreement State requirements to be a preceptor authorized _____ for the following uses (or units) of byproduct material: <u>105 CMR 120.567-573</u> |

| | |
|--|---|
| A. Address Division of Nuclear Medicine Children's Hospital Boston 300 Longwood Avenue Boston, MA 02115 | B. Materials License Number <u>see attached sheet</u> |
|--|---|

| | | |
|--|-------------------------------------|----------------------------------|
| C. NAME OF PRECEPTOR (print clearly) <u>S. Ted Treves MD</u> | D. SIGNATURE - PRECEPTOR | E. DATE <u>9/22/04</u> |
|--|-------------------------------------|----------------------------------|

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JPNM Materials License Numbers

| <i>Supervisor & Location</i> | <i>Material License #</i> |
|--|---------------------------|
| Marcelo F. Di Carli, M.D. Chief, Division of Nuclear Medicine Brigham and Women's Hospital 75 Francis Street Boston, MA 02115 | 44-0004 |
| S. Ted Treves, M.D. Chief, Division of Nuclear Medicine Children's Hospital Boston 300 Longwood Avenue Boston, MA 02115 | 60-0137 |
| Rachel A. Powsner, M.D. Head, Division of Nuclear Medicine VA Boston Healthcare System 1400 VFW Parkway West Roxbury, MA 02132 | 20-00671-02 |
| Annick D. Van den Abbeele, M.D. Chief, Division of Nuclear Medicine Dana-Farber Cancer Institute 44 Binney Street Boston, MA 02115 | 60-0037 |
| Gerald M. Kolodny, M.D. Chief, Division of Nuclear Medicine Beth Israel Deaconess Medical Center 330 Brookline Avenue Boston, MA 02215 | 60-0011 |
| Alan J. Fischman, M.D., Ph.D. Chief, Division of Nuclear Medicine Massachusetts General Hospital 55 Fruit Street Boston, MA 02115 | 66-0055 |



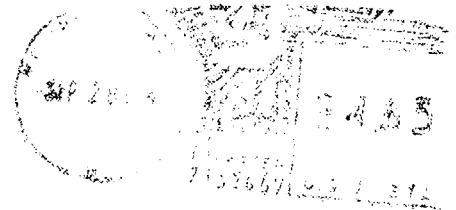
15855 Nineteen Mile Road
Clinton Township, MI 48038

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US NUCLEAR REGULATORY COMMISSION
REGION III
MATERIALS LICENSING BRANCH
801 WARRENVILLE RD
LISLE, ILLINOIS 60532

NUCL801 605323048 1404 30 09/30/04
NOTIFY SENDER OF NEW ADDRESS
:US NUCLEAR REGULATORY COMM
2443 WARRENVILLE RD STE 210
LISLE IL 60532-4352

809806

60532+1336 22

