

Copley Hospital

528 Washington Highway
Morrisville, VT 05661
(802) 888-4231
www.copleyvt.org

RECEIVED
REGION 1

2007 JUL 16 PM 12: 59

NMSBL

July 12, 2007

FROM: Melvyn Patashnick, CEO
TO: US Nuclear Regulatory Commission
Region 1, 475 Allendale Road
King of Prussia, PA 19406-1415
REF: License No. 44-19196-01
SUBJ: Addition of New Authorized User

03017125

Please find enclosed material documenting appropriate training and experience for our new Radiologist, Dr. Daniel Fodor. Please permit him to have 35.100, 35.200, and Oral Administration of Sodium Iodide Iodine-131 in quantities less than or equal to 33 millicuries.

Should you have further questions regarding this matter, please don't hesitate to contact Bradley Collette, RSO at (802)888-8387. Thank you, in advance, for your consideration of this matter.

Melvyn Patashnick, CEO
Copley Hospital
528 Washington Highway
Morrisville, VT 05661

14086

NMSS/RGN1 MATERIALS-002

Copley, Keeping You Healthy - For Life!

Section A: I am board certified as listed below.

SECTION A

CERTIFICATION SPECIFICATION

Name of Governing Board: _____
 Certification Specification: _____
 Date of Certification: _____

Section B: I am not board certified. Information regarding applicable training and experience, and appropriate preceptor statements are provided.

TRAINING AND EXPERIENCE

| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING | |
|---|---|---|--|
| | | CLOCK HOURS IN LECTURE OR LABORATORY | CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE |
| a. RADIATION PHYSICS AND INSTRUMENTATION | University Hospital E. L. Saenger Radioisotope Laboratory Stephen R. Thomas, Ph.D. Ranasing Samaratinga, Ph.D. | 60 hours | 20 hours |
| b. RADIATION PROTECTION | University Hospital E. L. Saenger Radioisotope Laboratory Michael Burba, Deputy RSO | 9 hours | 2 hours |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | University Hospital E.L. Saenger Radioisotope Laboratory Ranasing Samaratinga, Ph.D. | 2 hours | 1 hour |
| d. RADIOPHARMACEUTICAL CHEMISTRY OF BY-PRODUCT MATERIAL FOR MEDICAL USE | University Hospital E.L. Saenger Radioisotope Laboratory Lee Washburn, Ph.D. Chemistry | 2 hours | 2 hours |
| e. RADIATION BIOLOGY | University Hospital E.L. Saenger Radioisotope Laboratory Stephen R. Thomas, Ph.D | 10 hours | ----- |

5. EXPERIENCE WITH RADIATION (Actual use of Radioisotopes or Equivalent Experience)

| ISOTOPE | mCi USED AT ONE TIME (Maximum Activity) | LOCATION | CLOCK HOURS | TYPE OF USE |
|---|--|---|-------------|--|
| Tc-99m Tl-201 111-In Ga-67 I-123 I-131, etc. | ~1.5 Curie per elution 5 mCi 500 uCi 10 mCi 200 uCi 250 mCi | Nuclear Medicine Laboratories at University, Veterans and Children's Hospitals | 700 hours | Imaging studies, generator elution; kit preparations including Tc-MAA, Tc-MDP |
| Additional: | clinical lectures - 83 hours Radiology T-meeting - 20 hours Board review - 25 hours PET conference - 12 hours | University Hospital | 140 hours | Case review |

PRECEPTOR STATEMENT

PRECEPTOR STATEMENT Page 2 of 3

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement for each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME **Daniel Fodor, M.D.**

STREET ADDRESS **5027 Village Drive**

CITY **Cincinnati** STATE **OH** ZIP CODE **45244**

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | AVERAGE NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION | COMMENTS <i>(Additional information or comments may be submitted in duplicate on separate sheets.)</i> |
|--------------|---|---|---|
| | Thyroid uptake and scan | 81 | |
| | Lung perfusion scan | 253 | |
| | Xenon ventilation study | 251 | |
| | Aerosol ventilation scan | 7 | |
| | Renal flow and scan | 58 | |
| | Brain scan | 20 | |
| | Liver/spleen scan | 5 | |
| | Bone scan | 449 | |
| | Gastric emptying study | 34 | |
| | Blood volumes | 16 | |
| | G-I bleeding study | 10 | |
| | Cardiac perfusion imaging | 245 | |
| | Cardiac stress ventriculogram | 1 | |
| | Cardiac rest ventriculogram | 122 | |
| | Gallium scan | 1 | |
| | Hepatobiliary scan | 48 | |
| | White cell scan | 12 | |
| | Lymph node scans | 32 | |
| | Other | 594 | Other includes tumor imaging, lacrimal imaging, PET scans, DEXAs, CSF shunt, GFR, C-14 breath test, parathyroid, adrenal scan, cisternogram, thyroid cancer workups |

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE A | PROCEDURES PERFORMED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION | COMMENTS <i>(Additional information or comments may be submitted in duplicate on separate sheets.)</i> |
|-----------------------|--|---|---|
| P-32 | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | 26 | |
| | TREATMENT OF HYPERTHYROIDISM | 31 | |
| Au-198 | INTRACAVITY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITY TREATMENT | | |
| | TELE THERAPY TREATMENT | | |
| Sr-90 | TREATMENT FOR EYE DISEASE | | |
| Mo-99 | GENERATOR ELUTION | 5 | |
| Tc-99m | REAGENT KIT PREPARATION | 5 | |
| In-111 | WHITE BLOOD CELLS PREPARATION | | |
| Other | Sm-89 THERAPY | 1 | |

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

| | | |
|--|-----------------------|----------------------------------|
| LOCATION | DATES | CLOCK HOURS OF EXPERIENCE |
| Nuclear Medicine Departments at University, Children's and Veterans Hospitals | July 2002 - June 2006 | 1048 hours |

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:


Mariano Fernandez-Ulloa, M.D.
Edward B. Silberstein, M.D.
Jonathan Rubin, MD.
 Names of supervising physicians

The University Hospital
 Name of Institution

234 Goodman Street, Nuclear Medicine, ML 0577
 Mailing Address

| | | |
|-------------------|-----------|-------------------|
| Cincinnati | OH | 45219-2316 |
| City | State | Zip Code |

5. MATERIALS LICENSE NUMBER (S)
 University of Cincinnati 34-06903-05


 PRECEPTOR'S SIGNATURE

7. **Mariano Fernandez-Ulloa, M.D.**
Medical Director, Nuclear Medicine

PRECEPTOR'S PRINTED/TYPE

8. **June 8, 2006**

DATE

This is to acknowledge the receipt of your letter/application dated 7/12/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 44-19196-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 140816.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

Sincerely,
Licensing Assistance Team Leader