

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Fairbanks Memorial Hospital **License No.:** 50-13648-01
Docket No.: 030-03509 **Mail Control No.:** 471203
Type of Action: Notify **Date of Requested Action:** 11-27-06
Reviewer Assigned: **ARM reviewer(s):** Torres

| Response | Deficiencies Noted During Acceptance Review |
|----------|---|
| | <input type="checkbox"/> Open ended possession limits. Limit possession. Submit inventory. <input type="checkbox"/> Submit copies of most recent leak test results. <input type="checkbox"/> Add - delete IC license condition. Add IC paragraph in cover letter. <input type="checkbox"/> Split license from cover letter. Add SUNSI marking to license. <input type="checkbox"/> Ask the licensee if they have any type-amount of EPAct Material. |
| | |

RTZ

Reviewer's Initials: _____ **Date:** _____

Yes No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
 Yes No Decommissioning notification should be completed within 30 days.
 Yes No Termination request < 90 days from date of expiration
 Yes No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
 Yes No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: _____ **Date:** _____

SUNSI Screening according to RIS 2005-31

Yes No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

- _____ RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- _____ Exact location of RAM (whether = or > than Category 3 or not)
- _____ Design of structure and/or equipment (site specific)
- _____ Information on nearby facilities
- _____ Detailed design drawings and/or performance information
- _____ Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- _____ RAM quantities and inventory
- _____ Manufacturer's name and model number of sealed sources & devices
- _____ Site drawings with exact location of RAM, description of facility
- _____ RAM security program information (locks, alarms, etc.)
- _____ Emergency Plan specifics (routes to/from RAM, response to security events)
- _____ Vulnerability/security assessment/accident-safety analysis/risk assess
- _____ Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: *RTZ* **Date:** *12/14/06*

Pre-Licensing Screening

Applicant Information:

Control No. 471203

| | | |
|-----------------------------------|--|-----------------------|
| Name: Fairbanks Memorial Hospital | Type of Request: Amend Program Code(s): | |
| Location: AK | License No.: 50-13648-01 | Docket No.: 030-03509 |

STEP 1—Radioactive Materials and Quantities Requested:

| | |
|---|-----------|
| Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay. | Yes or No |
| A. The request is from a new applicant. | No |
| B. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit. | No |
| C. The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer | No |

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

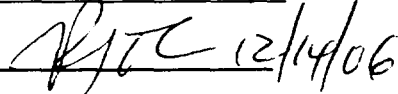
| Radionuclide | Risk Significant Quantity (TBq ¹) | Risk Significant Quantity (Ci ¹) | Radionuclide | Risk Significant Quantity (TBq ¹) | Risk Significant Quantity (Ci ¹) |
|--------------|---|--|---------------------|---|--|
| Am-241 | 0.6 | 16 | Pm-147 | 400 | 11,000 |
| Am-241/Be | 0.6 | 16 | Pu-238 | 0.6 | 16 |
| Cf-252 | 0.2 | 5.4 | Pu-239/Be | 0.6 | 16 |
| Cm-244 | 0.5 | 14 | Ra-226 ² | 0.4 | 11 |
| Co-60 | 0.3 | 8.1 | Se-75 | 2 | 54 |
| Cs-137 | 1 | 27 | Sr-90 (Y-90) | 10 | 270 |
| Gd-153 | 10 | 270 | Tm-170 | 200 | 5,400 |
| Ir-192 | 0.8 | 22 | Yb-169 | 3 | 81 |

¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.

² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

| | |
|--|---------------------------------|
| Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s). | Yes, No, or Not Applicable (NA) |
| Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide | / |
| Unity Rule—multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g., [(total activity for radionuclide A) + (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) + (risk significant quantity for radionuclide B)] ≥ 1.0. | / |

Signature and Date for Step 1:

 12/14/06



Denali Center
Fairbanks Memorial Hospital
Banner Health System

RECEIVED

DEC 11 2006

DNMS

November 27, 2006

ATC
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
Region IV
Nuclear Materials Safety Branch
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-4005

Re: Amendment for License 50-13648-01

Dear Sir or Madam:

In accordance with 10 CFR 35.14: We are requesting Claire M. Waite, M.D. to work at this facility as an authorized user for uses 10 CFR 35.100 and 10 CFR 35.200 and 10 CFR 35.300. Attached is a copy of Dr. Waite's preceptor statement that documents the required training.

If you require additional information, please call (907)-458-5660.

Sincerely,

Mark Burton, M.D.
Radiation Safety Officer

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Claire Margaret Waite, MD

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of

The American Board of Radiology

On this fourteenth day of June, 2006

Thereby demonstrating to the satisfaction of the Board
that she is qualified to practice the specialty of

Diagnostic Radiology

AM Eligible



Phy O Alderson, MD
President

Lith Eicken
Secretary-Treasurer

R.R. Hatten, MD
Executive Director



**MEDICAL USE TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**

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 regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

CLAIRE M. WAITE , MD

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

ALASKA

3. CERTIFICATION

- a. Provide a copy of the board certification. *(Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)*
 - b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
 - c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.
- Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

| Description of Training | Location | Clock Hours | Dates of Training |
|--|--|-------------|---------------------|
| Radiation Physics and Instrumentation | JACOBI MEDICAL CENTER BRONX, NEW YORK | > 20 Hours | 7/1/02 - 6/30/06 |
| Radiation Protection | JACOBI MEDICAL CENTER BRONX, NEW YORK | > 20 Hours | " |
| Mathematics Pertaining to the Use and Measurement of Radioactivity | JACOBI MEDICAL CENTER BRONX, NEW YORK | > 20 Hours | " |
| Radiation Biology | JACOBI MEDICAL CENTER BRONX, NEW YORK | > 10 Hours | " |
| Chemistry of Byproduct Material for Medical Use | JACOBI MEDICAL CENTER BRONX, NEW YORK | > 20 Hours | " |
| OTHER | | | |

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

| Description of Experience | Name of Supervising Individual(s) | Location and Corresponding Materials License Number | Dates and/or Clock Hours of Experience |
|--|-----------------------------------|---|--|
| Safe handling of radiopharmaceuticals - measurement and administration of doses, quality control of instruments, receipt and opening of packages, checking for contamination | Drs. Sarkar/Savitch/ Fine | JACOBI MEDICAL CENTER Lic# 91-3079-01 | 7/02-6/06 Approx. 50 Hours |
| Thyroid Therapy with I-131 | Drs. Sarkar/Savitch/ Fine | JACOBI MEDICAL CENTER Lic # 91-3079-01 | Approx. 5 Hours |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

| Radionuclide | Type of Use | No. of Cases Involving Personal Participation | Name of Supervising Individual | Location and Corresponding Materials License Number | Dates and/or Clock Hours of Experience |
|--------------|-----------------|---|--------------------------------|---|--|
| Tc-99m | General Imaging | 610 | Drs. Sarkar/ Savitch/Fine | Jacobi Med Ctr Lic# 91-3079-01 | 7/02-6/06 |
| Tc99m | Cardiac | 337 | " | " | " |
| I-123 | Thyroid | 56 | " | " | " |
| F-18 | Oncology | 38 | " | " | " |
| GA-67 | Infection/Other | 9 | " | " | " |
| In-111 | Infection/Other | 5 | " | " | " |
| I-131 | Therapy | 4 | " | " | " |
| | | | | | |

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

| Training Element | Type of Training * | Location and Dates |
|---|-------------------------|--------------------------------------|
| Selection, Performance and Interpretatin of Studies | Supervised and Didactic | Jacobi Medical Center 7/02 - 6/06 |
| Preparation and interview of patients | Supervised and Didactic | " |
| Dictation of Reports | Supervised | " |
| | | |

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical 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) |
|--|--|----------------|---|
| Certified by American Board of Radiology, 2006 | AECOM*-Jacobi Radiology Residency Program #4203521251 License # 91-3079-01 | 7/1/02-6/30/06 | Accreditation Council for Graduate Medical Education |

8. RADIATION SAFETY OFFICER (RSO) - ONE-YEAR FULL-TIME EXPERIENCE

YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
 N/A of _____ the RSO for License No. _____

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

YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____
 N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____
 N/A under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

*Albert Einstein College of Medicine

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. 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 Part 35, provide the following information for each) :

A. Name of Supervisor

Salil D. Sarkar, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 190, 290, 390

for medical uses in Part 35, Section(s) _____

D. Address Jacobi Medical Center

Nuclear Medicine Department - BN 13

1400 Pelham Parkway South

Bronx, New York 10461

E. Materials License Number

91-3079-01

PART II -- PRECEPTOR ATTESTATION

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 training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 190, 290, as documented in section(s) 5, 6 of this form.

11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for _____ types of use, as documented in section(s) _____ of this form.

N/A

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized user for 190, 290 uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of 190, 290, 390 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units): _____

A. Address JACOBI MEDICAL CENTER
NUCLEAR MEDICINE, BN-13
1400 PELHAM PARKWAY SOUTH
BRONX, NEW YORK 10461

B. Materials License Number

91-3079-01

C. NAME OF PRECEPTOR (print clearly)

SALIL D. SARKAR, MD

D. SIGNATURE -- PRECEPTOR

Salil D. Sarkar

E. DATE

8/31/06

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. 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 Part 35, provide the following information for each) :

A. Name of Supervisor

Ina Savitch, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 190, 290, 390

for medical uses in Part 35, Section(s)

D. Address Jacobi Medical Center

Nuclear Medicine Department - BN 13

1400 Pelham Parkway South

Bronx, New York 10461

E. Materials License Number

91-3079-01

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11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for

N/A

types of use, as documented in section(s) of this form.

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized user for 190, 290 uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

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or equivalent Agreement State requirements to be a preceptor AU or AMP

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NUCLEAR MEDICINE, BN-13

1400 PELHAM PARKWAY SOUTH

BRONX, NEW YORK 10461

B. Materials License Number

91-3079-01

C. NAME OF PRECEPTOR (print clearly)

INA SAVITCH, MD

D. SIGNATURE -- PRECEPTOR

Ina Savitch

E. DATE

8/31/06

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. 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 Part 35, provide the following information for each):

A. Name of Supervisor

Eugene J. Fine, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 190, 290, 390

for medical uses in Part 35, Section(s) _____

D. Address Jacobi Medical Center
Nuclear Medicine Department - BN 13
1400 Pelham Parkway South
Bronx, New York 10461

E. Materials License Number

91-3079-01

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11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for _____ types of use, as documented in section(s) _____ of this form.

N/A

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized user for 190, 290 uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of 190, 290, 390 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units): _____

A. Address JACOBI MEDICAL CENTER
NUCLEAR MEDICINE, BN-13
1400 PELHAM PARKWAY SOUTH
BRONX, NEW YORK 10461

B. Materials License Number

91-3079-01

C. NAME OF PRECEPTOR (print clearly)

EUGENE J. FINE, MD

D. SIGNATURE -- PRECEPTOR

Eugene J. Fine, MD

E. DATE

5/31/06

01-04-07

DATE

This is to acknowledge the receipt of your letter/application dated 11-27-06, and to inform you that the initial processing, which includes an administrative review, has been performed.

- There were no administrative omissions. Your application will be 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:

The action you requested is normally processed within — days.

- 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** 471203.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Munnahan

Licensing Assistant

Align top of FedEx Express Shipping Label here.

9090 IIT 53*-762951 # JTB

FedEx PRIORITY OVERNIGHT MON

emp# 633351 08DEC06

TRK# 8585 3228 7265

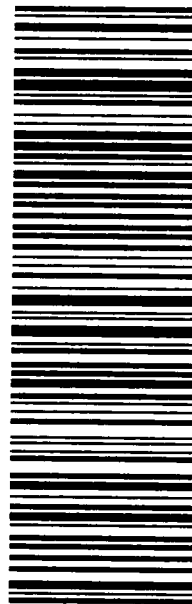
FORM 0215

DFM A1

Delivery By: 11DEC06

76011 -TX-US

XH FWA



FedEx US Airbill

Express

FedEx Tracking Number 8585 3228 7265

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.

Date 12/18/06 FedEx Tracking Number 858532287265

Sender's Name Sam Patterson Phone 907 458-6101

Company Address 50-13648-01 030-03509

City State ZIP

2 Your Internal Billing Reference

3 To Recipient's Name National Medicine Licensng Brnck

Company Address United States Warehouse Vegetables

Address 611 E. Main Plaza Blvd, STE 400

City State ZIP 76011 0806

4a Express Package Service

FedEx Priority Overnight

FedEx 2Day

FedEx 1Day Freight*

FedEx Standard Overnight

FedEx Express Saver

FedEx 2Day Freight

FedEx 3Day Freight

5 Packaging

FedEx Pak*

Envelope*

6 Special Handling

SATURDAY Delivery

HOLD Weekday at FedEx Location

HOLD Saturday at FedEx Location

Packages up to 150 lbs

Packages over 150 lbs

*Declared value limit \$500

7 Payment Bill to: Sender Recipient Third Party Credit Card Cash/Check

Total Packages Total Weight Total Charges