St.Vincent's Medical Center

May 10, 2005

Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

03001245

RE: License #06-00843-03 Amendment

To Whom It May Concern:

Please amend our license as follows:

> Please add Adam Tazi, Ph.D. as an Authorized Medical Physicist for brachytherapy procedures on our license. A copy of Dr. Tazi's training and experience is attached.

Thank you for your prompt attention to this matter.

Sincerely,

Susan L. Davis, R.N., Ed.D.
President/CEO

SLD:dm

ATT: Training & Experience Documentation for Adam Tazi, Ph.D.

2800 Main Street • Bridgeport, Connecticut 06606 • (203) 576-6000 • www.stvincents.org

Affiliate: New York-Presbyterian Healthcare System
Columbia University College of Physicians & Surgeons

ASCENSION HEALTH

Adam Tazi, Ph.D.
Physicist at
Saint Vincent Medical Center
Radiation Therapy Department
2800 Main Street
Bridgeport, CT 06606

Medical Radioisotopes for Brachytherapy use
Education and Experience

1. **Education:**

- Ph.D in Solid State Physics from "Université de Rennes-I, Rennes, FRANCE, 06/1990)
- M.Sc in Radiological Physics, specialty: Therapy from "Wayne State University (WSU), School of Medicine, Detroit , MI. 12/2004)
  The medical physics program at WSU is accredited by CAMPEP
  The following courses in the above program related to radioactive isotopes include:
  - **Brachytherapy course**
    * Traditional Systems: Manchester, Quimby and Memorial
    * Source strength, specification and measurements
    * Dose Calculations (Using both the traditional formalism and TG-43)
    * Radiobiology of brachytherapy
    * Prescription, planning and evaluation
    * Quality management program
    * Chart documentation
    * Introduction to the operating room and aseptic techniques: various brachytherapy GYN techniques (clinician's perspective)
    * Permanent implants of the prostate (I-125, Pd-103)
    * Establishing an HDR program
    * Planning and practical aspects of "Mammosite, HDR for sarcoma"
    * Regulatory Affairs and Accreditation
    * Safety surveys
    * Source management: shipping, inventory, assay, periodic QA, and disposal.
    * Emerging modalities: Vascular brachytherapy and real time planning.
    * **Training sessions:**
  - PLATO Treatment planning (Vaginal cylinders)
  - HDR Unit (MicroSelectron) monthly QA
    * The following AAPM Task Group Reports were used as supporting documents (TG-43, TG-40, TG-56, and TG-59) as well as the Federal regulations: 10 CFR19, 10CFR21, AND 10CFR35.)

- **Radiation Safety course and projects on "shielding calculation for 18 MV linac" and "Evaluation of the Total Fetal Dose from Nuclear Medicine procedures and Pelvis CT"**

* Biological effects of radiation. Radiation protection quantities and units. Sources of radiation exposure
* Health physics instrumentation
* Personnel monitoring
* Protection and monitoring for internal exposures
* Control of radioactive substances
* Radiation incidents and accidents
* General principles of operational radiation protection.
* Time, distance and shielding
* Radiation protection in radiotherapy: external beam and brachytherapy
* Legislation and regulation of ionizing radiation:

- 10 CFR Part 19: Notices, instructions and reports to worker
- 10 CFR Part 20: Standards for protection against radiation
- 10 CFR Part 35: Medical use of biproduct material

* Principles of protection. ALARA
* Radiation safety in nuclear medicine

- **Nuclear Medicine course and laboratory sessions:**

* Production of radionuclides.
* Detection of radioactive decay
* Scintillation detectors and spectrometry
* Radiation safety and regulations
* Internal dosimetry
* Gamma camera:

- Basics
- Acceptance testing

* Digital Data Acquisition and Display
* PET Imaging

- Basics
- 3D Data Acquisition
- Kinitic Models

* Radiopharmacy

2. Continuing Education and experience with Isotopes

I have done the following procedures, under the direct supervision of Vas Krithivas, Ph.D and chief physicist at Saint Vincent Medical Center in Bridgeport, Connecticut since 01/03/2005:

- Ir-192 monthly QA of the microSelectron HDR unit:

  - The monthly QA on microSelectron HDR unit (Ir-192) includes:

  * The length of 5 source guides using appropriate jig,
  * the dwell times at several source positions
  * the total radiation time
  * the source tip for the last position
  * the functioning of the emergency stop button
  * Calibration of the source (Ir-192) with a well chamber in a current mode (Comparison of the manufacturer stated activity to the measured activity: % difference should not exceed 2%)
  * the accuracy of the source stepping: On film, comparing the position of the source center relative to the dummy markers and the center-to-center distance between source dwell positions. The tolerance is +/- 1.0 mm)

- I-125, Pd-103:
  - unpacking these radioisotopes,
  - prostate implants physics checks: Computing and checking prostate volume based seed activity using nanogram
- Cs-137 (Inventory check, and hot lab dose rate survey)

- Treatment planning relating to vaginal cylinders, bronchus and mammosite using PLATO treatment Planning system. (See attached document)

3. Radiation Safety specific to Nucletron HDR (MicroSelectron Unit)

Attended an In-Service mHDR V-1 on MicroSelectron Classic HDR Unit Radiation Safety on 02-22-2005. Instructor: Jeffrey Clay from Nucletron. (See Attached doc)

4. ABR Board Exam Registration:

I have already registered to take Part-I of the ABR Board Exam on August 22, 2005.

Nucletron®

Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133

Telephone: 410-312-4100
Toll Free: 800-336-2249
Canada Toll Free: 800-445-2249
FAX: 410-312-4196

Nucletron Training Seminar
Attendance Registration

Hospital: St Vincents Med Ctr Date: Tuesday, February 22, 2005

Course: In Service mHDR V-1

Instructor: Jeffrey Clay

	Name	Department	Title	Signature
1	Adam Tazi Ph.D	Rad Onc	Physicist	Tue Feb 2005 02/22/05 11:16:43
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

I certify that the above individuals have been instructed in Equipment Operation, Safety Precautions and Emergency Procedures in accordance with Nucletron Corporation Training Standards.

Instructor Signature: Tue Feb 2005 02/22/05 11:16:58

Instructor Title: Service Rep

Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133

Telephone: 410-312-4100
Toll Free: 800-336-2249
Canada Toll Free: 800-445-2249
FAX: 410-312-4196

Nucletron Training Seminar

Institution: ST Vincents Med Ctr

City, State/Province, Zip: Bridgeport CT 06606

1 Teaching Aids Used

- [x] User's Manual
- [ ] Applicators and Accessories
- [x] Source Container and Dummy Sources
- [x] Other

2 Topics Covered

- [x] Explanation of Remote Afterloading
- [x] Explanation of Radiation Protection

3 Applications

- [ ] Bronchus
- [ ] Interstitial
- [ ] Intracavitary
- [ ] Intraoperative

4 Applicators/Accessories

- [ ] Bronchus
- [ ] GYN
- [ ] Esophagus
- [ ] Interstitial
- [ ] Other

5 Equipment Operation

- [x] Treatment Unit
- [x] Handling
- [x] Power Requirements
- [x] Console
- [x] Treatment
- [x] Start
- [x] Interrupt
- [x] Emergency Stop
- [x] Alarm and Error Codes

Radioactive Source: _____

6 Receiving

- [ ] Unpacking
- [ ] Acceptance
- [ ] Calibration
- [ ] Installation

7 Shipping

- [ ] Release
- [ ] Packing
- [ ] Documents
- [ ] Measurements

- [x] Emergency Procedures

All areas marked were covered during training

Tue Feb 2005 02/22/05 11:14:52
Instructor

Tue Feb 2005 02/22/05 12:56:04
Department Head

Sevice Rep
Title

Physicist Adam Tazi
Title

* List of all attendees accompanies this form

Nucletron

Field Training Report

Nucletron Corporation, Service Department, 8671 Robert Fulton Drive, Columbia, MD 21045 PH: 410-872-4400 Fax: 410-312-4196

St Vincents Med. CTR

dress 2800 Main St
Bridgeport, CT

one No. 203-576-5056

No.

Course Instructor: Margaret Peterson

Charge Type
- [ ] Contract
- [ ] No Charge
- [ ] Bill
- [ ] Install
- [ ] Warranty
- [ ] Other

Call Number

[ ] Rtn. Visit Required

Date In 4-12-05 Out 4-14-05

Time In 9AM Out 6 PM

Training Given

BPS 14.2.6 Training

Attendance Registration

Name	Title	Department	Signature
Adam Tazi	Ph.D. Physicist	Radiation Therapy	
K Rithivas	Physicist	Radiation Therapy	

Remarks

FCO 629636 Installed Plato Sunrise Maintenance Release Software Ref # 235.941-02

For Office Use Only - This Is Not An Invoice

vel Charged	Hrs	Airline		Travel Expenses (Meals, Tolls, etc)
ular Charged	Hrs	Rental Car		
rtime Charged	Hrs	Hotel		
(Sundays & Holidays)	Hrs	No of Miles	$0.00	

We [illegible]fy that the training noted in this document has been carried out in accordance with the manufacturer's instructions by Nucletron's authorized representative and with proper supervision by:

e Instructor

Margaret Peterson

Customer

Nucletron

Nucletron Canada Inc.
411 Legget Drive, Suite 502
Kanata, ON K2K 3C9
Canada
Telephone: 800-826-2258
Fax: 613-592-6559

Plato BPS Planning

Day 1

Plato planning:Patient Selection System
- -Creating patients & Deleting patients

Customizing Files
- -Creating, loading and editing

Reconstruction Techniques
- -Reconstruction box
- -Film reconstruction

GYN
- -Cylinder by coordinates
- -Tandem/Ring

-Tracking/Catheter Describing
- -Source Position
- -Points (applicator, marker, patient)
- -Library Plans

Dose Distribution
- -3-D view and x, y, z planes
- -Optimization
- -Dose Points
- -Coordinate system
- -Applicator system

Plan Evaluation
- -Prescription
- -Dose to points
- -Normalization
- -Weighting/Optimization
- -Viewing options
- -Output options

Day 2

Edit Customization Files
Single/Double Catheter
- -Lung film

Plan Evaluation
- -Prescription
- -Dose to points
- -Normalization
- -Weighting/Optimization
  - -Viewing
- -Output/Print
- -Saving plan

Evaluation
- -DVH
- -Export
- -Dose to a point

CT Planning
- -IPS image transfer
- -Translating/loading
- -Patient information
- -Contouring

Day 3

CT Reconstruction/Planning
- -Mammosite
- -Offset
- -Indexer length
- -VOI editing
- -Insight-MPR

Mini Unix
CT image removal
Back Up/Restore
Review/Questions

Revised NRC Form 422

AMENDED

Reviewer Code: _____

MILESTONE FORM

Docket No.	License No.	Mail Control No.
		13703

Licensee:

	Milestone		Date
10	Received by Section/Region	(LAS WILL ENTER)	_____
12	Deemed Timely Letter Sent	(LAS WILL ENTER)	_____
13	Assigned to Reviewer		_____
14	Deficiency Letter Sent	(LAS WILL ENTER)	_____
15	Deficiency Telephone Call		_____
16	Deficiency Response Received	(LAS WILL ENTER)	_____
17	Threat to Abandon/Deny Letter Sent	(LAS)	_____
18	Response to Abandon/Deny Letter Received	(LAS)	_____
19	Regional Tech. Review/Outside Tech. Review	(TAR)	_____
20	Response to Technical Review		_____
21	Typing		_____
22	Licensing Action Completed	(LAS WILL ENTER)	_____
23	Void		_____
24	Denial		_____
25	Abandonment		_____

Reviewer Code: _____

This is to acknowledge the receipt of your letter/application dated

5/10/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 06-00843-03 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

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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** 137036.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

	:	(FOR LFMS USE)
	:	INFORMATION FROM LTS
BETWEEN:	:	----------
	:	
License Fee Management Branch, ARM	:	Program Code: 02230
and	:	Status Code: 0
Regional Licensing Sections	:	Fee Category: 7C 2B
	:	Exp. Date: 20131031
	:	Fee Comments: CODE 21
	:	Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: ST. VINCENT'S MEDICAL CENTER
   Received Date: 20050512
   Docket No: 3001245
   Control No.: 137036
   License No.: 06-00843-03
   Action Type: Amendment

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed M. A. Perkins
Date 5/16/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____