



RECEIVED
REGION 1

'05 MAY 12 10:16

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.

137036

NMSS/RONI MATERIALS-CJ2

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 byproduct 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
 - Kinetic 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	 <small>Tue Feb 2005 02/22/05 11:16:43</small>
2				
3				
4				
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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



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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

User's Manual ☒
Applicators and Accessories ☐
Source Container and Dummy Sources ☒
Other ☒

2 Topics Covered

Explanation of Remote Afterloading ☒
Explanation of Radiation Protection ☒

3 Applications

Bronchus ☐
Interstitial ☐
Intracavitary ☐
Intraoperative ☐

4 Applicators/Accessories

Bronchus ☐
GYN ☐
Esophagus ☐
Interstitial ☐
Other ☐

5 Equipment Operation

Treatment Unit ☒
Handling ☒
Power Requirements ☒
Console ☒
Treatment ☒
Start ☒
Interrupt ☒
Emergency Stop ☒
Alarm and Error Codes ☒

Radioactive Source: _____

6 Receiving

Unpacking ☐
Acceptance ☐
Calibration ☐
Installation ☐

7 Shipping


Release ☐
Packing ☐
Documents ☐
Measurements ☐

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

Service 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 21046 PH: 410-872-4400 Fax: 410-312-4196

ST Vincents Med. CTR

2800 Main St
Bridgeport CT

Phone No. 203-576-5086

No.

Course Instructor

Margaret Peterson

Training Given

BPS 14.2.6 Training

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 9 AM Out 6 PM

Attendance Registration

Name

Title

Department

Signature

Adam Tazi

Ph.D
Physicist

Radiation Therapy

[Signature]

KRITHIVAS

Physicist

Radiation Therapy

[Signature]

Remarks

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

For Office Use Only - This Is Not An Invoice

Travel Charged	Hrs	Airline	Travel Expenses (Meals, Tolls, etc)
Vehicle Charged	Hrs	Rental Car	
Room Charged	Hrs	Hotel	
(Sundays & Holidays)	Hrs	No of Miles	\$0.00

We certify 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:

Course Instructor

Margaret Peterson

Customer

[Signature]



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

Amended

Reviewer Code: _____

MILESTONE FORM

Docket No.

License No.

Mail Control No.

137036

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

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.

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      :          (FOR LFMS USE)
      :          INFORMATION FROM LTS
      :          -----
      :
      : Program Code: 02230
      : Status Code: 0
      : Fee Category: 7C 2B
      : Exp. Date: 20131031
      : Fee Comments: CODE 21
      : Decom Fin Assur Reqd: N
      :
      : ::::::::::::::::::::::::::::::::::::

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A. REGION

2. FEE ATTACHED

Amount: _____
Check No.: _____

Signed W. A. Perkins
Date 5/14/2005

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____