St.Vincent's Medical Center

ST. VINCENT'S HEALTH SERVICES

AM581

February 13, 2006

RECEIVED
REGION 1
2006 FEB 16 PM 1:39

Nuclear Regulatory Commission
Region 1
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

03001245

REFERENCE: License # 06-00843-03 Amendment

To Whom It May Concern:

Please amend our license as follows:

1. 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.

2. Add the use of Sirtex SIR-Spheres Y-90 microspheres for treatment of liver cancer. We will follow the attached procedures for its use.

Thank you for your prompt attention to this matter.

Sincerely,

Susan Davis

Susan Davis
President & CEO

Cc: Training & Experience documentation for Adam Tazi, Ph.D.
"Radiation Safety Procedures During Sirsphere Y-90 Microsphere Treatment"

138433

NMSS/RGN1 MATERIALS-002

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

ST. VINCENT'S MEDICAL CENTER – BRIDGEPORT, CT
LICENSE NO. 06-00843-03
RADIATION SAFETY PROCEDURES DURING SIRSPHERE Y-90 MICROSPHERE TREATMENT

Applicability:
This procedure describes the activities to be performed starting from patient admission until release to ensure that an appropriate level of radiation safety is followed during treatments involving Yttrium-90 (Y-90) microspheres and to comply with the NRC regulations. Also, that radioactive sources are handled in a safe manner in order to keep radiation doses received by radiation workers, visitors, and the public as low as reasonably achievable (ALARA).

Scope:
This procedure applies to all Y-90 microsphere treatments performed at the St. Vincent's Medical Center. This procedure is also supplemented by implementation of the Radiation Safety Manual Section 20 "General Radiation Safety Regulations For The Laboratory", and Section 5 "Quality Management Program".

Procedure:

1. **Training:**

a. Authorized users must meet the training and experience requirements of either 10 CFR 35.490 or, until October 25, 2005, 10 CFR 35.940 as well as the specific vendor training in the use of the microspheres and the microsphere delivery system before involved in this procedure.

b. The Nuclear Medicine Technologist must receive the Vendor's training for drawing the appropriate dose per the written directive without causing any contamination.

c. All personnel providing care for a patient receiving Y-90 microspheres implant therapy shall receive Radiation Safety Training, with refresher training provided at annual intervals.

d. The Radiation Safety Training provided shall include:
- The size and appearance of the Y-90 microspheres brachytherapy sources.
- Safe handling and shielding instructions, Labeling.
- Procedures for patient control.
- Procedures for visitor control.
- Patient Release Criteria (10 CFR 35.75).
- Written Directive and Quality Management program.
- Procedures for notification of the Radiation Safety Officer and Authorized User if the patient dies or encounters a medical emergency.
- The training and experience requirements for an Authorized User.

e. Radiation Oncology shall maintain a record of training of these individuals, a description of the training (an outline), the date of training, and the name of the individual providing the training for three years following the date of training.

f. Before releasing from inpatient care, the patient shall be provided with written radiation safety instructions that will help to maintain the radiation dose to other family members and the public ALARA per the requirements of 10 CFR Part 35.

2. Description of Duties:

a. **Interventional Radiologist:**
- Prepares patient for dose delivery.
- Contacts other team members when patient is ready.
- Assembles microsphere delivery system.
- Assists in microsphere delivery.
- Assists in disposal of delivery system.

b. **Radiation Oncologist:**
- Ensures that a written directive is completed and signed.
- Ensures delivery system is correctly assembled.
- Ensures that the dose to be delivered is in accordance with that prescribed in the written directive.
- Delivers dose.

c. **Medical Physicist (In consultation with the Radiation Safety Officer):**
- In conjunction with the Interventional Radiologists and Radiation Oncologist, the Medical Physicist calculates the required activity based on the intended dose for specific patient.
- Orders correct radioactive material dose from the manufacturer.
- The dose will be drawn up by a trained Nuclear Medicine Technologist in the Nuclear Medicine hot lab. Appropriate shielding and remote handling tools will be utilized. The prescribed dose will be dispensed into the "V" vial supplied, be in appropriate shielding and labeled with date, nuclide, patient name, and microspheres "Sirspheres". At the end of the administration, the Nuclear Medicine Technologist will perform a final assay of remaining dose to determine amount delivered to patient. The initial dose preparation for use in delivery system, and the final assay will be over sighted by the Medical Physicist to ensure the correctness of the dose.
- Before moving the brachytherapy sources from the source storage area, performs a survey to ensure that the sources are adequately shielded. Transports sources to/from the patient's room with appropriate shielding for beta emitters in place (the manufacturer's shipping container) to keep the exposure to personnel ALARA. The dose will be transported to the Interventional suite in a beta waste container on a cart. The "V" vial placed in the plexiglass delivery system setup will be located in an area convenient to the physician for dispensing the treatment on a small covered table. The sources must be under constant surveillance and control of either the NM Technologist or Radiation Safety staff all the time until delivered.
- The dose will be measured with a portable ion chamber ion chamber on four sides (360 degrees) of the beta waste container, prior to being delivered, to determine the exposure for dose calculations.

- Monitors delivery system during dose delivery.
- Determines when maximum dose has been delivered.
- Keeps a log of the dose Received, Used, and Disposed.
- Prepares the patient room to control contamination. The IR suite will be draped with disposable coverings to aid in clean up of possible contamination.
- The patient shall be briefed on radiation safety procedures for confinement to bed, visitor control, and other items, as appropriate by the radiation safety personnel before treatment.
- Ensures all team members attending to brachytherapy implant patients wear whole body radiation dosimeters when in the patient's room. All personnel who handle the implant sources must wear a ring dosimeter in addition to a whole body dosimeter. Nursing personnel will be given pocket dosimeters to monitor their exposure.
- Visitors shall maintain a distance of at least one meter from the patient and not be issued a dosimeter.
- Ensures proper shielding and material handling practices are followed.
- Ensures proper radiation monitoring equipment is available.
- Ensures disposal container is available.
- Performs surveys of hands, feet, and clothing of all individuals leaving the room.
- Ensures that the "Caution Radioactive Material" form for Permanent Implant shall be completed and attached to the patient's chart. The door to the patient's room shall be posted with "Caution, Radioactive Material". Instructions for nurses shall be posted on the patient's door. Signs reminding housekeeping not to enter the room and not to remove trash or linen shall be posted.
- Ensures that pregnant nursing personnel shall not be responsible for the care of patients with appreciable external radiation exposure rates. A special duty nurse should not be assigned to care for a radioactive patient without the approval of the Radiation Safety Officer.
- Ensures that pregnant women and minors shall not be allowed to visit patients.
- Performs exposure rate (mrem/hr) measurement following the brachytherapy procedure at bedside, at one meter from bedside, in the visitors' safe area, at the doorway, and in the surrounding areas. The exposure rates in adjacent uncontrolled areas must conform to the federal regulations. Radiation safety staff shall keep a record of this and any other necessary information for at least three years.
- Assists in identification and collection of radioactive waste.
- Releases the patient
- Surveys room for contamination following patient release and completely decontaminate the contaminated areas room before releasing the room to be used by other non radiation patients.
- Collects and labels all radioactive waste and recovers packaging from source transport.
- Returns waste to designated waste disposal area or storage area for decay in storage.

d. **Nuclear Medicine Technologist:**

- Receives package from delivery service. Checks shipment for contamination and surveys the package within three hours after it is received to make sure that the package received is in accordance with the regulatory requirements, verify that the dose received matches with the dose ordered. Sources shall be stored in the manufacturer's shipping container in the hot lab.
- The dose will be drawn up by a trained Nuclear Medicine Technologist in the Nuclear Medicine hot lab. Appropriate shielding and remote handling tools will be utilized. The prescribed dose will be dispensed into the "V" vial supplied, be in appropriate shielding and labeled with date, nuclide, patient name, and microspheres "Sirspheres". At the end of the administration, the Nuclear Medicine Technologist will perform a final assay of remaining dose to determine amount delivered to patient. The initial dose preparation for use in delivery system, and the final assay will be over sighted by the Medical Physicist to ensure the correctness of the dose.

3. Radiation Safety During Dose Delivery:

All individuals entering the treatment room will be wearing protective equipment as needed, including scrubs, or disposable gown, hair net, face mask, gloves, double shoe covers, and lead aprons during fluoroscopy.

Al personnel participating in dose delivery shall wear personnel dosimeters.

No smoking, eating, or drinking shall be permitted in radioactive material handling areas.

4. Radiation Monitoring Instruments

(i) An ion chamber shall be used to perform monitoring during dose delivery and for patient release.

(ii) A GM detector shall be used for monitoring of contamination on equipment and personnel. Care must be taken to compensate for interference from background radiation near the patient following dose delivery.

5. Emergency Procedures

In case of a patient's death or medical emergency following the dose delivery, the Radiation Safety Officer (RSO), referring physician and the Authorized User shall be notified immediately.

For Contact:
Chris Iannuzzi, MD, Authorized User: Ph:203-576-5085 Pager: [redacted]
Gerald J. Randall, MS, RSO: Ph: 860-678-9082 Cell [redacted]

6. Spill Procedures

a. Minor Spills
- Notify all individuals in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with an absorbent material and controlling the movement of potentially contaminated individuals.
- Clean up the spill using protective clothing and absorbent material.
- Survey the area and affected individuals with an appropriate contamination monitoring instrument.
- Report the spill to the RSO immediately.

b. Major Spills
- Evacuate the area. Ensure all individuals leaving the area are monitored for contamination.
- Prevent the spread of contamination by covering the spill with an absorbent material and controlling the movement of potentially contaminated individuals.
- Shield the radiation source, if possible without significantly spreading the contamination of increasing individual doses.
- Secure the room to prevent entry.
- Perform personnel decontamination as necessary.
- All contaminated items will be bagged and stored for decay.
- Notify the RSO immediately.

7. Records and Reports

Records

Radiation safety records associated with delivery of Y-90 microsphere therapy may include:

- Records of material ordering and receiving, delivery and disposal
- Personnel training
- Dose assay and delivery
- Area [redacted]el surveys, and spill recovery.
- Patient Instructions [redacted]

Radiation safety survey records, Policies and procedures for Y-90 microsphere treatment shall be maintained in Radiation Safety office.

Reports

Certain reports may be required if a Y-90 microsphere delivery results in a spill, or medical event.
All required reports shall be prepared and submitted in accordance with the regulations.

References

Code of Federal Regulations 10: Part 35.
Radiation Safety Manual.
Regulatory Guide 8.39, "Release of Patients Administered with Radioactive Materials".

Miscellaneous:

Y-90 is a pure beta emitter with maximum beta energy of 2.3 mEv, and a physical half-life of 2.67 days. The range of the beta particle in soft tissue is 5 mm.

1/9/06

To:

Gerald Randall, M.S., DABR, RSO
Saint Vincent's Medical Center
Bridgeport, CT 06606

From:

Vas Krithivas, Ph.D., DABR
Physicist
Saint Vincent's Medical Center
Bridgeport, CT 06606

RE: Adam Tazi, Ph.D. –
Ir-192 High dose-rate (HDR) remote afterloader Nucletron Microselectron unit Training

This is to state that Adam Tazi, Ph.D., has been here with me working as a radiation therapy physicist since the beginning of January 2005. During this period he has received training and done procedures under my direct supervision, relating to HDR unit. The activities include the followings:

1. Source dwell position(s) verification using mechanical jig and auto-radiograph methods
2. Source dwell time and clock date & time accuracy verification
3. EMERGENCY STOP, RESET and START buttons operation
4. Emergency power failure procedures
5. Source activity entry and decayed activity verification
6. Safety – emergency response for the unit, door electrical interlock and minor trouble shoot
7. Radiation survey after source change
8. Full source calibration using a calibrated well ion chamber
9. Computerized patient dose calculations and transfer of treatment data to treatment console computer for vaginal cylinder, mammosite and bronchus cases.
10. Verification of dwell times/dose by an independent method

Dr. Adam Tazi has performed, between January and now, several clinical HDR brachytherapy cases, monthly quality assurance tests and tests following source change.

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 11:19:43
2				
3				
4				
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6				
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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 1:10:58

Instructor Title: Service Rep

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

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	☑

areas marked were covered during training

ue Feb 2005 02/22/05 11:14:52
tructor

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

/ice Rep
e

Physicist Adam Tazi
Title

st 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
No. 203-576-5056

Course Instructor: Margaret Peterson

Charge Type: Contract / Install / No Charge / Warranty / Bill / Other

Call Number:
Rtn. Visit Required

Date in: 4-12-05 Out: 4-14-05
Time in: 9 AM Out: 6 PM

Training Given

BPS 14.2.6 Training

Attendance Registration

Name	Title	Department	Signature
Adam Fazi	Ph.D Physicist	Radiation Therapy	[signature]
Krathras	Physicist	Radiation Therapy	[signature]

Remarks

...0 6296 36 Installed Plato Sunrise Maintenance Release Software Ref # 235.941-02

For Office Use Only - This Is Not An Invoice

...harged	Hrs	Airline		Travel Expenses (Meals, Tolls, etc)
...Charged	Hrs	Rental Car		
...Charged	Hrs	Hotel		
...days & Holidays)	Hrs	No of Miles	$0.00	

...that the training noted in this document has been carried out in accordance with the ... by Nucletron's authorized representative and with proper supervision by ...

...e Instructor: [signature: Margaret Peterson]

Customer:

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

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

2/03/2006, 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** 138433
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