

HEART AND VASCULAR CENTER

January 12, 2005

United States Regulatory Commission, Region I
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415

05 JAN 14 P2:07

RECEIVED
REGION 1

Re: License # 45-25576-01

03035822

To Whom It May Concern:

Please note that effective December 31, 2004, the new corporate name to be listed on the above referenced license is "BT Heart and Vascular Center, PLLC". Attached please find a letter of "Guidance On Change Of Control Of Ownership" addressing questions 1, 2, 3, 5, and 6. A copy of our current surveillance program is also attached. Please note that this program will remain unchanged. Should you have questions, please do not hesitate to contact Chastity McGrady at (276) 238-3318 or myself at (336) 765-2500.

Sincerely,

B. Taghizadeh MD
Behzad Taghizadeh, MD, FACC

cc: Lesa Bowman, Operations Manager

136295
NMSS/RGNI MATERIALS-002

WINSTON-SALEM • MOUNT AIRY • GALAX • STUART

606 EAST STUART DRIVE GALAX, VA 24333 P:276.238.3318 F:276.236-4204 WWW.THEHVC.COM

ATTACHMENT TO GUIDANCE ON CHANGE OF CONTROL OF OWNERSHIP

The Heart and Vascular Center, PLLC, sole member, Joseph A. Puma, D.O., has transferred certain assets, including business equipment, property leases, and the name "The Heart and Vascular Center, PLLC" to The BT Heart and Vascular Center, PLLC, sole member, Behzad Taghizadeh, MD. The BT Heart and Vascular Center, PLLC, is duly organized under the laws of the State of North Carolina as shown in the attached Articles of Organization on file with the North Carolina Department of the Secretary of State. Dr. Taghizadeh is properly licensed in both North Carolina and Virginia. He was the radiation safety officer with the Transferor (The Heart and Vascular Center, PLLC) and will continue to be the radiation safety officer with the Transferee (The BT Heart and Vascular Center, PLLC).

There should be no changes with respect to Section 9B and C with the exception that Dr. Joseph A. Puma will no longer be associated with the medical practice operating the equipment. With respect to Section 9E, the facility is not being decommissioned. With respect to Section 9 F, the Transferee will abide by all constraints, conditions, requirements and commitments of the transferor.

**Heart and Vascular Center
Galax, VA
Quarterly Review
December 6, 2004**

This radiation safety review was performed by Frederic Fahey on November 5, 2004. Dr. Behzad Taghizadeh, MD is the radiation safety officer at this clinic. Dr. Taghizadeh and Dr. Yetunde Olowe are the authorized users for this clinic. This laboratory is working under Virginia Radioactive Materials License Number VA-505-07 which expires on September 1, 2005 and US NRC Radioactive Materials License 45-25576-01 which expires on September 30, 2011. ✓

1. Dose Calibrator Quality Control (Atomlab 100, SN# 1998008)

A. Accuracy

The dose calibrator was last tested for accuracy on 5/7/04. It was tested with ^{57}Co and ^{137}Cs . The dose calibrator passed this test easily. This needs to be tested again before 5/7/05.

B. Geometry

The dose calibrator was tested for geometry on 6/4/02 and passed. There is no need for geometric correction since no deviation was greater than 5%. Geometry need not be retested unless the dose calibrator undergoes a major repair.

C. Linearity

The dose calibrator was tested for linearity on 11/5/04. The shield method using the CaliCheck kit was used. The dose calibrator easily passed these tests. The linearity needs to be tested again prior to 2/5/05.

D. Constancy

The dose calibrator is tested daily for constancy on the days that patients are injected. The constancy records from 8/7/04-11/5/04 were reviewed. There were no deficiencies in the records.

2. Well Counter Calibration

The well counter (used for leak testing solid sources and received packages as well as weekly area wipe tests) was calibrated on 8/6/04. The chi square test was performed and this counter easily passed. It should be calibrated again by 2/6/05.

3. Detection Survey Instrument (Ludlum 14C, SN # 183136)

This meter was last calibrated on 6/22/04. It needs to be calibrated again by 6/22/05. The check source was calibrated to read 1.0 mR/h and read 1.0 mR/h on 11/5/04.

4. Sealed Source Leak Test

The laboratory currently has 4 sources as listed below under the inventory section. These sources were leak tested on 8/6/04. The maximum removable activity measured in these tests was 2.1×10^{-4} μ Ci which is far less than the required 5×10^{-3} μ Ci, so the sources easily passed these tests. The sources need to be tested again by 2/6/05.

5. Sealed Source Inventory

The 4 sealed sources currently onsite are

Co-57 reference source	5.414 mCi	SN:17751
Cs-137 reference source	192.8 μ Ci	SN:16681
Cs-137 standard source	0.0943 μ Ci	SN:16419
Co-57 sheet source	10 mCi	SN:BM01100438

All sources were inventoried on 11/5/04 and are located in the hot lab. These sources need to be re-inventoried before 2/5/04.

6. Patient Dose Log

Every patient injected with a radiopharmaceutical was logged with the patient's name, the assayed dose, the date and the time of injection. The records for 8/7/04-11/5/04 were reviewed and no deficiencies were found.

7. Radioactive Shipment Log

The radioactive shipment log was reviewed for accuracy for 8/7/04-11/5/04. All shipments during this period were appropriately logged and received.

8. Area Survey

Radioactive materials have been used in 3 rooms that are referred to as the hot lab, the imaging room and the treadmill room. These rooms were monitored with a survey meter at the end of each day that radioactivity was handled. They are not monitored on days when no patients are scanned and thereby no radioactivity is handled. The records were reviewed for 8/7/04-11/5/04. Surveys were performed and recorded on all days radioactive materials were handled, and there were no days where the survey found contamination.

9. Area Wipe Tests

The 3 rooms where radioactivity is used were wipe tested weekly. These records were reviewed for 8/7/04-11/5/04. There was no discrepancy in these records and no contamination during this period.

10. Radioactive Materials Disposal

No sources were disposed from 8/7/04-11/5/04. Sources that are disposed are held for 10 half-lives and not disposed until survey meter readings do not measure above background.

11. Hand and Clothing Contamination Log

All personnel who either handle unsealed sources of radioactivity or have direct contact with radioactive patients have surveyed their hands and clothing with a survey meter. These records were reviewed for 8/7/04-11/5/04. There have been no incidences of contamination.

12. Personnel Exposure

Film badge reports are received monthly for all badged personnel. These records were reviewed for the months for July, August and September 2004. The Heart and Vascular Center maintains 3 offices: one in Mount Airy, one in Winston-Salem, and one in Galax, VA. These readings are for exposures at all three offices.

Whole Body (Finger) Dose in mrem

<u>Employee</u>	<u>Apr. May. June 04</u>
[REDACTED]	218 (Finger 680)
[REDACTED]	233 (Finger 1010)
[REDACTED]	167 (Finger 230)
[REDACTED]	74
[REDACTED]	75
[REDACTED]	82
[REDACTED]	62

No other employees received more than 60 mrem in this period. [REDACTED] and [REDACTED] are above the ALARA I level for this clinic of 125 mrem whole body per quarter. They should both receive ALARA letters from the radiation safety officer reminding them to consider the three factors that reduce radiation dose: distance, time and shielding.

13. Floods and Bar Phantom Images

Flood images were acquired on each day that a patient is imaged, and the bar phantom (2, 2.5, 3, 3.5 mm bars) images were acquired weekly. These images were reviewed for 8/7/04-11/5/04. These images demonstrated excellent image quality with no evidence of nonuniformities

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

(integral uniformity 2-3.5% and 3 quadrants are seen on the bar phantom images).

14. Radioactive Materials Returns Log

This log of radioactive return shipments was reviewed for the dates between 8/7/04-11/5/04. It appropriately shows the pertinent data for all return shipments. All returned shipments have met DOT regulations.

15. Posting Requirements

The NRC required form is posted outside the scanning room and the treadmill room. The hot lab, the scanning room and the treadmill room are posted with, "No Eating..." sign and the emergency numbers. The hot lab, scanning room and the treadmill room are posted for Radiation Materials and the hot lab is posted as a Radiation Area.

16. ALARA Program

Syringe shields are available and regularly used. The hot lab door has a combination lock that is locked at all times. Only the technologist, the physics consultant and the radiopharmaceutical delivery person know the combination. The physics consultant reviewed the radiation safety program with nuclear medicine technologist on 2/13/04. This needs to be repeated by 2/13/05. Others working in the building underwent an in-service training with respect to radiation safety on 6/2/04. This training needs to be repeated by 6/2/05. The RSO performs an extensive review of the radiation safety program with the nuclear medicine technologist on a monthly basis.

The annual review was performed on 5/7/04. It is due to be repeated by 5/7/05. The quarterly review needs to be repeated by 2/5/05.

17. Quality Management Program

A written directive signed by the authorized user has been obtained on every patient who has been scanned. A copy of the directive is located in each patient's file. A random sample of 10 charts was reviewed for the dates between 8/7/04-11/5/04 to evaluate compliance. All patient's folders were located and contained a copy of the written directive.

18. Clinical Protocol Manual

The protocols in our protocol manual were all reviewed, modified and approved in 6/04. These protocols need to be reviewed again by 6/05.

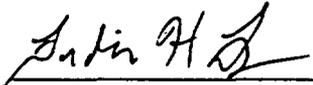
19. Policies and Procedures

A copy of the following policies and procedures or other radiation safety material resides on site: current radioactive materials license, license amendment correspondence, current list of authorized users, in service training records, operating and emergency procedures, pregnant

worker policy, misadministration policy and quality management procedures. The copy of the VA state and NRC regulations are kept onsite.

20. Inspection

The clinic was inspected by the NRC on 7/25/02. No violations were noted during either inspection.



Frederic H. Fahey, D.Sc.
Medical Physics Consultant

12/5/04
Date

I have read and approve this report.

Dr. Behzad Taghizadeh
Radiation Safety Officer

Date



NORTH CAROLINA

Department of The Secretary of State

To all whom these presents shall come, Greetings:

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify the following and hereto attached to be a true copy of

ARTICLES OF ORGANIZATION

OF

THE BT HEART AND VASCULAR CENTER, PLLC

the original of which was filed in this office on the 30th day of September, 2004.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 7th day of December, 2004

Elaine F. Marshall

Secretary of State

SOSID: 746007
 Date Filed: 9/30/2004 4:14:00 PM
 Elaine F. Marshall
 North Carolina Secretary of State
 C200427100077

State of North Carolina
 Department of the Secretary of State
ARTICLES OF ORGANIZATION
(PROFESSIONAL LIMITED LIABILITY COMPANY)

Pursuant to §§ 57C-2-01(c), 57C-2-20 and Chapter 55B of the General Statutes of North Carolina, the undersigned does hereby submit these Articles of Organization for the purpose of forming a professional limited liability company.

1. The name of the limited liability company is: The BT Heart and Vascular Center, PLLC
2. If the limited liability company is to dissolve by a specific date, the latest date on which the limited liability company is to dissolve: *(If no date for dissolution is specified, there shall be no limit on the duration of the limited liability company)* _____
3. The name and address of each person executing these articles of organization is as follows: *(State whether each person is executing these articles of organization in the capacity of a member or an organizer or both). Attach additional sheets as needed.)*
Behzad Taghizadeh, MD, Organizer and member
160 Kimel Forest Drive, Suite 250
Winston-Salem, NC 27103
4. The street address and county of the initial registered office of the limited liability company is:
 Number and Street 160 Kimel Forest Drive, Suite 250
 City, State, Zip Code Winston-Salem, NC 27103 County Forsyth
5. The mailing address of the initial registered office, *if different from the street address in item 4 above*, is:
 Number and Street _____
 City, State, Zip Code _____ County _____
6. The name of the initial registered agent is: Behzad Taghizadeh
7. The specific purpose for which the limited liability company is being formed: Medical Practice
8. Check one of the following:
 - (i) **Member-managed LLC:** all members by virtue of their status as members shall be managers of this limited liability company.
 - (ii) **Manager-managed LLC:** except as provided by N.C.G.S. Section 57C-3-20(a), the members of this limited liability company shall not be managers by virtue of their status as members.

P.L.L.C. Form 2

CERTIFICATION BY THE NORTH CAROLINA MEDICAL BOARD

The organizers of The BT Heart and Vascular Center, PLLC have certified to the North Carolina Medical Board the names and addresses of all persons who will be original members.

Based upon that certificate and my examination of the records of this office, I hereby certify that each person who will be an original member of said professional limited liability company is duly licensed to practice medicine in North Carolina.

This certificate is executed under the authority of the North Carolina Medical Board on 09/08/2004.

R. David Henderson

R. David Henderson
Executive Director
NORTH CAROLINA MEDICAL BOARD

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

1/12/2005, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 45-25596-C1 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 136295.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 02201
: Status Code: 0
: Fee Category: 7C
: Exp. Date: 20110930
: Fee Comments: _____
: Decom Fin Assur Reqd: N
: ::

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: HEART & VASCULAR CENTER, PLLC (THE)
Received Date: 20050114
Docket No: 3035822
Control No.: 136295
License No.: 45-25576-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed M. A. Perkins
Date 1/16/05

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 _____