



August 8, 2013

To: Frank Tran  
U.S. Nuclear Regulatory Commission, Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL. 60532-4352  
**Attention:** Nuclear materials/Licensing

From: The New Liberty Hospital  
Radiology Department  
2525 Glenn Hendren Drive  
Liberty, MO 64069-1002  
NRC Materials License # **24-16178-01**

Mr. Tran,

We wish to notify you that we have two physicians that we would like to add to our NRC Materials License. Liberty Hospital operates under License # **24-16178-01**.

Dr. Dwarakraj Soundarraj, M.D. was on License # **L04996** at Cardiovascular Associates of San Antonio PA, 1200 Brooklyn Ave, Suite 200. San Antonio, TX 78212. We are including a copy of the license he was on as well as his education record.

Dr. Arnold Pollak, M.D. was on License # **WN-M0264-1** at Heartbeat Medical Institute, PLLC, Suite 260, 16233 Sylvester Road SW, Burien, Washington, 98166. We are including a copy of the license he was on.

Sincerely,

Julie Osbahr, RT (R) (CT)  
Director, Diagnostic Imaging  
Liberty Hospital  
P: 816.792.7081  
[www.libertyhospital.org](http://www.libertyhospital.org)

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# Radioactive Materials License



As stated in the Nuclear Energy and Radiation Act, Revised Code of Washington 70.98, and the Radiation Protection Regulations, chapters 246-220 through 246-254 of the Washington Administrative Code, and in reliance on statements and commitments made by the licensee identified below, a license is issued authorizing the licensee to transfer, receive, possess and use the radioactive material authorized below; and to use such radioactive material for the purpose(s) and at the place(s) authorized below. This license is subject to all applicable rules and regulations issued by the State of Washington Department of Health.

<p>1. Licensee Name:</p> <p style="text-align: center;"><b>HEARTBEAT MEDICAL INSTITUTE, PLLC</b></p>	<p>3. License Number:</p> <p style="text-align: center;"><b>WN-M0264-1 Renewal Amendment No. 5</b></p> <p>Fee Code 15</p>
<p>2. Address:</p> <p style="text-align: center;">Suite 260 16233 Sylvester Road SW Burien, Washington 98166</p>	<p>4. Expiration Date:</p> <p style="text-align: center;">31 March 2015</p> <hr/> <p>5. Reference Number(s):</p> <p style="text-align: center;">10-02-55.</p>

6. Radioactive Material  
(element and mass number).

A. Any radioactive material authorized by WAC 246-240-157.

7. Chemical and/or Physical Form.

A. Any.

8. Maximum quantity licensee may possess at any one time.

A. As necessary for the uses authorized in Condition 9.A.

## CONDITIONS

In addition to the restrictions in Item 6 and the possession limits in Item 8, the licensee shall further restrict their possession of licensed material to quantities below the limits specified in WAC 246-235-150, Schedule C which require consideration of the need for an emergency plan for responding to release of licensed material and to quantities below the minimum limit specified in WAC 246-235-075 for establishing decommissioning financial assurance.

9. Authorized use.

A. Any nuclear cardiology imaging or localization study authorized by WAC 246-240-157 for which a written directive is not required.

10. Radioactive materials authorized in Subitem A of Items 6, 7, and 8 shall be stored and/or used *at the licensee's address in Item 2.*

State of Washington  
**Radioactive Materials License**



Page 2 of 6

License Number: WN-M0264-1  
Amendment No. 5

11. The licensee shall comply with the provisions of chapter 246-220 WAC, "Radiation Protection -- General Provisions"; chapter 246-221 WAC, "Radiation Protection Standards"; chapter 246-222 WAC, "Radiation Protection -- Worker Rights"; chapter 246-235 WAC, "Radioactive Materials -- Specific Licenses"; chapter 246-240 "Radiation Protection -- Medical Use of Radioactive Material"; chapter 246-247 WAC, "Radiation Protection -- Air Emissions"; chapter 246-231 WAC, "Packaging and Transportation of Radioactive Material"; and chapter 246-249 WAC, "Radioactive Waste -- Use of the Commercial Disposal Site".

12. The Radiation Safety Officer for this program shall be Arnold J. Pollak, M.D.

**AUTHORIZED USERS**

13. Radioactive material as described in Subitems below shall be used by, or under the supervision of:

A. **Arnold J. Pollak, M.D.;** Subitem A of Items 6, 7, and 8.

14. A. For a period not to exceed sixty (60) days in any one calendar year, a visiting physician is authorized to use licensed material under the terms and conditions of this license, provided the visiting physician:

1. Has the prior written permission of the licensee's Administrator; and
2. Is specifically named as an authorized user on an Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license which authorizes human use; and
3. Performs only those procedures, which the physician is specifically authorized to perform pursuant to the license issued by an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

B. The licensee shall maintain for inspection by the Department copies of the written permission specified in License Condition 14.A.1, and any of the licenses specified in License Condition 14.A.2 and 14.A.3 for a period of at least five (5) years from the date permission is granted under License Condition 14.A.1.

State of Washington  
**Radioactive Materials License**



Page 3 of 6

License Number: WN-M0264-1  
Amendment No. 5

15. Radioactive material to be administered to humans shall be the subject of an FDA-approved "New Drug Application" (NDA) or an FDA-accepted "Notice of Claimed Investigational Exemption for a New Drug" (IND).
  
16.
  - A. Technetium 99m separated from Molybdenum 99 either by elution of a Molybdenum 99/Technetium 99m generator or by an extraction process shall be tested to detect and quantify Molybdenum 99 activity prior to administration to patients.
  
  - B. The licensee shall not administer to patients Technetium 99m containing more than 5550 becquerels (0.15 microcurie) of Molybdenum 99 per 37 megabecquerels (1.0 millicurie) of Technetium 99m. The limit for Molybdenum 99 contamination represents maximum values and Molybdenum 99 contamination should be kept as low as reasonably achievable (ALARA) below these limits.
  
  - C. In the absence of a certificate from a supplier for Technetium 99m which specifies the quantity of Molybdenum 99, the licensee shall establish written procedures for personnel performing tests to detect and quantify Molybdenum 99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of Molybdenum 99 in excess of the limits specified in Condition 16.B are detected.
  
  - D. Personnel performing tests to detect and quantify Molybdenum 99 contamination shall be given specific training in performing these tests prior to conducting such tests.
  
  - E. The licensee shall maintain records of the results of each test performed to detect and quantify Molybdenum 99 contamination and records of training given to personnel for performing these tests. These records shall be maintained for inspection by the Department for three (3) years following the performance of the tests and the training of personnel.
  
17.
  - A. Radioactive material to be administered to humans shall be assayed for activity to determine the dose within 20% accuracy prior to administration to patients. Doses which vary by more than  $\pm 20\%$  of the prescribed dose shall not be administered.

State of Washington  
**Radioactive Materials License**



Page 4 of 6

License Number: WN-M0264-1  
Amendment No. 5

17. B. The licensee shall establish written procedures for personnel to perform assays to an accuracy of 20% prior to being administered to patients.
- C. The licensee shall record the results of each assay performed to determine the activity of each dose administered to a patient. Records shall be maintained for inspection by the Department for three (3) years following the performance of the assay.
18. A. 1. Each sealed source containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a valid leak test certificate (or copy) from a transferor documenting that such a test has been made within six (6) months prior to the transfer, a sealed source received from another person shall not be put into use until tested and acceptable results received.
2. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries (3.7 megabecquerels) or less of beta and/or gamma emitting material or 10 microcuries (370 kilobecquerels) or less of alpha emitting material.
- B. The test shall be capable of detecting the presence of 185 becquerels (0.005 microcurie) of radioactive material on the test sample. The test sample shall be taken from the sealed source, or from the surfaces of the device in which the sealed source is permanently mounted or stored, on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of becquerels (or microcuries) and maintained for inspection by the Department.
- C. If the test reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Department describing the equipment involved, the test results, and the corrective action taken.



Department of State Health Services

**RADIOACTIVE MATERIAL LICENSE**

Pursuant to the Texas Radiation Control Act and Texas Department of State Health Services (Agency) regulations on radiation, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Agency now or hereafter in effect and to any conditions specified below.

<b>LICENSEE</b>			This license is issued in response to a letter	
1. Name	CARDIOVASCULAR ASSOCIATES OF SAN ANTONIO PA ATTN L PRASAD VEMULAPALLI MD		Dated: October 17, 2011	
2. Address	1200 BROOKLYN AVE SUITE 200 SAN ANTONIO TX 78212		Signed by: L. Prasad Vemulapalli, M.D.	
			3. License Number	Amendment Number
			L04996	18
<b>PREVIOUS AMENDMENTS ARE VOID</b>				
			4. Expiration Date	
			July 31, 2015	
<b>RADIOACTIVE MATERIAL AUTHORIZED</b>				
5. Radioisotope	6. Form of Material	7. Maximum Activity	8. Authorized Use	
A. Any radioactive material with a half-life < 120 days, except positron emitters	A. Any radiopharmaceutical except gas and aerosol	A. As needed for diagnostic purposes	A. Any diagnostic cardiology use indicated in Title 25 TAC <sup>o</sup> §289.256(hh), in unit dosage only.	

<sup>o</sup> Texas Administrative Code (TAC)

9. Radioactive material shall only be stored and used at:

<u>Site Number</u>	<u>Location</u>
001	San Antonio - 1200 Brooklyn, Suite #200

10. Each site shall maintain documents and records pertinent to the operations at that site. Copies of all documents and records required by this license shall be maintained for Agency review at Site 001.

11. The licensee shall comply with the provisions (as amended) of Title 25 Texas Administrative Code (TAC) §289.201, §289.202, §289.203, §289.204, §289.205, §289.251, §289.252, §289.256 and §289.257.

12. Radioactive material may be used only by the individuals listed below for the uses specified:

Diagnostic nuclear cardiology.

Devraj Nayak, M.D.	Subrata K. Talukdar, M.D.	L. Prasad Vemulapalli, M.D.
Dwarakraj Soundarraaj, M.D.		

13. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is L. Prasad Vemulapalli, M.D.

14. The licensee shall not open sealed sources containing radioactive materials.



Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
L04996	18

15. All radiopharmaceuticals to be used in humans must be from suppliers approved for distribution by the United States Food and Drug Administration (FDA) or obtained from a licensed nuclear pharmacy.
16. The licensee shall maintain a current copy of the safety evaluation from "The Registry of Radioactive Sealed Sources and Devices" for each sealed source received under authority of this license, in excess of 100 microcuries of beta/gamma-emitting material or 10 microcuries of alpha-emitting material.
17. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the following:


application dated April 4, 2003,  
letters dated May 4, 2005 (X2), July 25, 2007 and July 17, 2009.

Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

JSK:sk

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

Date November 9, 2011

  
 J. Scott Kee, Program Coordinator  
 Medical and Academic Licensing Program

*Consultants in Nuclear Medicine*

*2910 W. Estes Avenue*

*Chicago, IL 60645*

*This certificate verifies that on May 20, 2007*

***Dr. Dwarakraj Soundarraaj***

*Completed Part 2 (100 hours) of the  
Basic Radioisotope Handling Course  
Covering the Topics of*

***Radiopharmacy, Radiation Biology,  
Radiation Protection, and the  
Mathematics Associated with Radioactivity***

*And received a passing grade for Part 2. This course is designed to  
qualify a physician as an authorized user of radiopharmaceuticals,  
generators, and reagent kits and meets all requirements set forth by  
the US Nuclear Regulatory Commission and all agreement states as  
outlined in the Code of Federal Regulations.*



*Stephen M. Karesh, PhD, Course Director*



*Consultants in Nuclear Medicine*

*2910 W. Estes Avenue*

*Chicago, IL 60645*

*This certificate verifies that on August 13, 2006*

*Dr. Dwarakraj Soundarraaj*

*SS # 367-27-2617*

*Completed Part 1 (100 hours) of the  
Basic Radioisotope Handling Course  
Covering the Topics of*

*Physics and Instrumentation*

*And received a passing grade for part 1. This course is designed to  
qualify a physician as an authorized user of radiopharmaceuticals,  
generators, and reagent kits and meets all requirements set forth by  
the US Nuclear Regulatory Commission and all agreement states as  
outlined in the Code of Federal Regulations.*

*Stephen M. Kareski, PhD.*

*Stephen M. Kareski, PhD, Course Director*

Liberty Hospital  
Radiology Dept.  
2525 Glenn Hendren Dr.  
Liberty, Mo. 64068

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U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Rd. Suite 210  
Lisle, IL. 60532-4352  
Attention: Nuclear materials/Licensing