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BT Heart and Vascular Center, pllc
847 Westlake Drive
Mount Airy, NC 27030
Phone: 336-719-7892
Fax: 336.719.6870

To: Tom Thompson From: Resa Bonuma

Fax: _____ Pages Plus Cover: _____

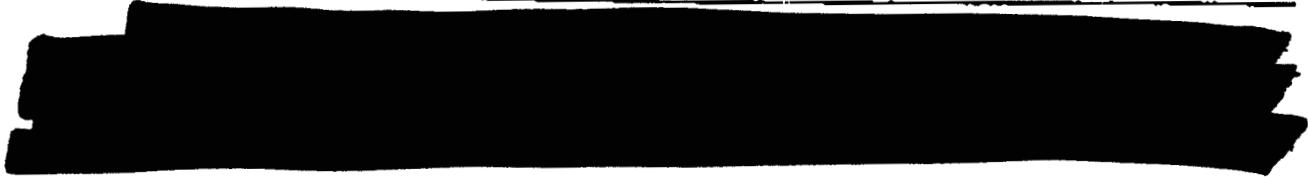
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Urgent For Review Please Comment Please Reply

Comments:

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**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

RADIOACTIVE MATERIALS LICENSE

Pursuant to North Carolina Regulations for Protection Against Radiation and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer, and import radioactive materials listed below; and use such radioactive material for the purpose(s) and at the place(s) designated below. This License is subject to all applicable rules and regulations of the North Carolina Department of Environment and Natural Resources now and hereafter in effect and to any conditions specified below.

1. Licensee Name: NovantHealth Triad Region D/B/A Forsyth Medical Center		3. License No: 034-0878-6		License Type 0210
2a. Mailing Address: 3333 Silas Creek Parkway Winston Salem, NC 27103		4. Expiration Date: May 31, 2008		
b. Physical Address: Cardiology Specialists of North Carolina 180 Kimel Park Drive, Suite 110 Winston Salem, NC 27103		<input type="checkbox"/> New License	<input checked="" type="checkbox"/> Routine	<input type="checkbox"/> Corrected Copy
		<input type="checkbox"/> Renewal	<input type="checkbox"/> Administrative	<input type="checkbox"/> Termination
c. Radiation Safety Officer: Carmine M. Plott, PhD, CHP		5.a. Amendment No.: 05		
		b. Issuance Date: July 25, 2006		
6. Radioactive Material (element and mass no.)	7. Chemical and/or Physical Form	8. Maximum Amount of Radioactivity and/or Quantity of Radioactive Material which Licensee May Possess at Any One Time.		
A. Technetium 99m	A. Per technetate	A.-C. Any amount necessary for those uses described in a written directive from an authorized user authorized by this license.		
B. Technetium 99m	B. Any FDA approved form for cardiovascular imaging (Cardiolite or Myoview)	D. 50 millicuries		
C. Thallium 201	C. Thallous Chloride	E. 1 millicurie		
D. Technetium 99m	D. Any form	F. No single source to exceed 1 millicurie		
E. Thallium 201	E. Any form	G. No single source to exceed 300 microcuries		
F. Any radioactive material between atomic number 3 to 83	F. Sealed Sources	H. No single source to exceed 6 millicuries		
G. Cesium 137	G. Sealed Sources	I. No single source to exceed 10 millicuries		
H. Cobalt 57	H. Sealed Sources			
I. Cobalt 57	I. Sealed Sources			

- 9. Authorized Use (To be used for):**
- A. - C. To be used in accordance with a written directive from an authorized user authorized by this license.
 - D. - I. To be used for instrument quality assurance/quality control.

CONDITIONS



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CONDITIONS (continued):

11. The licensee shall comply with the provisions of 15A NCAC 11 .1600 "Standards for Protection Against Radiation," and 15A NCAC 11 .1000 "Notices, Instructions, Reports and Inspections." (The North Carolina Regulations for Protection Against Radiation are contained in 15A NCAC 11.)
12. A. Radioactive material listed above shall be used by physicians who: (1) either have a certification as outlined in Condition B below, or have been previously named as an authorized user on a North Carolina Radioactive Materials License; (2) have been approved, in writing, by both the Radiation Safety Committee and the Radiation Safety Officer; (3) are licensed to practice medicine in the State of North Carolina; and (4) perform only those procedures for which the certification applies or the procedures the prospective user was approved to perform under the previous license. Users who do not meet the requirements of this paragraph must be approved by the Radiation Protection Section and named on the license prior to their first use of radioactive material under this license.
 - B. To be named by the licensee as a user for uptake, dilution, excretion, imaging, or localization studies, a prospective user must be certified as described in either 5a, c, e, or h below;
 5. Certifying agencies and certifications:
 - a. American Board of Nuclear Medicine (in nuclear medicine);
 - b. American Board of Nuclear Medicine;
 - c. American Board of Radiology (in diagnostic radiology);
 - d. American Board of Radiology (in radiology, therapeutic radiology, or radiation oncology);
 - e. American Osteopathic Board of Radiology (in diagnostic radiology or radiology);
 - f. American Osteopathic Board of Radiology (after 1984);
 - g. American Osteopathic Board of Radiology (in radiation oncology);
 - h. American Osteopathic Board of Nuclear Medicine (in nuclear medicine).
 - C. The licensee shall maintain a record of the certificate from the certifying organization or a copy of the previous license, the written approvals of the Radiation Safety Committee and the Radiation Safety Officer, records indicating date(s) each physician first assumes the duties of an authorized user at the licensee's facility, and other supporting documentation as required by the agency.
 - D. The licensee shall maintain records specified by Condition C. above for a minimum of two (2) years after the physician leaves the employment of the licensee.
 - E. Radioactive material for cardiac studies only may be used by Usman A. Khawaja, MD, Blane W. Yelton, Jr. MD, Theodore A. Keith, M.D., and Ernest Paul Phillips, M.D.
 - F. The Radiation Safety Officer for the activities authorized by this license shall be Carmine M. Plott, PhD, CHP.
13. Radiopharmaceuticals and reagent kits or generators used in their preparation shall be procured from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and pyrogenicity.
14. A. Provided that the licensee is authorized for possession of Molybdenum-99 / Technetium-99m generators in Items 6., 7., 8., & 9. of this license, those generators shall be used in accordance with 15A NCAC 11 .0361 (a) - (d).
 - B. Radioactive materials shall not be used on humans until its pharmaceutical quality and assay have been established.
15. A. The licensee shall establish written procedures for performing the following tests on dose calibrator(s) used to determine the quantity and quality of radiopharmaceuticals:
 1. Geometric variation to be performed upon installation and following repair.
 2. Accuracy to be performed upon installation and at intervals not to exceed one (1) year and following repair.



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CONDITIONS (continued):

15. A. 3. a. The dose calibrator shall be tested for linearity from the highest dosage administered to a patient down to 30 microcurie.
- b. The licensee may use a commercially available attenuator set for performing linearity tests of his dose calibrator provided that the current manufacturer instructions are followed.
4. Constancy to be performed daily and following repair.
- B. Records of the results of the tests outlined in Condition A above shall be maintained for a minimum of three (3) years following the completion of the test for inspection by the agency.
- C. The licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (0.37 MBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
16. A. Each sealed source containing radioactive material, other than Hydrogen 3, with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested.
- B. Notwithstanding the periodic leak test required by this condition, any licensee sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma-emitting material or 10 microcuries or less of alpha-emitting material.
- C. The test shall be capable of detecting the presence of 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 microcuries and maintained for inspection by the Agency.
- D. If the test reveals the presence of 0.005 microcurie 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 of in accordance with Agency regulations. A report shall be filed within five (5) days of the test with the Radioactive Materials Branch, Radiation Protection Section, Department of Environment and Natural Resources, 1645 Mail Service Center, Raleigh, N.C. 27699-1645 describing the equipment involved, the test results, and the corrective action taken.
- E. Tests for leakage and/or contamination shall be performed by persons specifically authorized by the Agency to perform such services.
17. The licensee shall conduct a physical inventory every three (3) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.
18. The licensee may transport licensed material or deliver licensed material to a carrier for transport, in accordance with the provisions of Section 71.5, Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material For Transport."
19. In addition to the possession limits in Item 8 above, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 15A NCAC 11 .0353 for establishing decommissioning financial assurance.
20. The licensee is authorized to conduct a decay-in-storage program in accordance with 15A NCAC 11 .0362.
21. Provided that the licensee has been authorized in Items 6., 7., 8., & 9. of this license for the use of agency approved radioactive gases, gases-in-solution, or aerosols, the licensee shall:



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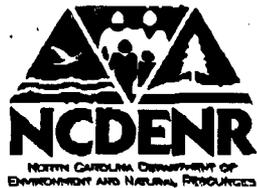
RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

- 21. A. Procure radioactive gases as free gas or gas-in-solution, to be administered to humans, from a supplier who distributes the product in accordance with the Federal Food, Drug, and Cosmetic Act.
- B. Comply with the applicable provisions of 15A NCAC 11 .0361(e)(1) – (5).
- 22. The licensee shall perform surveys of all areas where radioactive materials and/or radiopharmaceuticals are used, prepared, administered, and/or stored in accordance with 15A NCAC 11 .0360.
- 23. The licensee shall ensure that no individual "member of the public" [Reference: 15A NCAC 11 .0104(64)] receives a radiation dose in excess of the limits specified in 15A NCAC 11 .1611(a) while conducting licensed operations.
- 24. The licensee shall institute the provisions of 15A NCAC 11 .1610 when an occupationally exposed woman voluntarily informs her supervisor, in writing, of her pregnancy and the estimated date of conception.
- 25. The licensee shall annually review its Radiation Protection Program for content and implementation [Ref. 15A NCAC 11 .1603(c)]. Documentation of the Radiation Protection program reviews shall be retained for inspection by the agency [Ref. 15A NCAC 11 .1636].
- 26. Neither this license nor any subsequent amendments shall be deemed to constitute compliance with the requirements for health planning review contained in the Certificate of Need Statute, G.S. 131-175 *et seq.*, and regulations promulgated pursuant to that statute. Inquiries concerning the Certificate of Need Statute should be addressed to the Certificate of Need Section of the Division of Facility Services at (919)733-6360.
- 27. This license may be subject to amendment, revision, modification, suspension, or revocation in accordance with the provisions of 15A NCAC 11 .0344.
- 28. In addition to the possession limits referenced in Item 8. above, the licensee shall further restrict possession of radionuclides listed in the table below to the quantities noted within the table. Sum of fractions for the radionuclides listed below shall not exceed unity:

Radionuclide	Quantity (curies)	Radionuclide	Quantity (curies)
Am-241	16	Pm-147.....	11,000
Am-241:Be.....	16	Pu-238.....	16
Cf-252	5.4	Pu-239:Be.....	16
Cm-244	14	Se-75.....	54
Co-60.....	8.1	Sr-90 (Y-90).....	270
Cs-137.....	27	Tm-170.....	5,400
Gd-153	270	Yb-169	81
Ir-192.....	22		

- 29. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6., 7., and 8. of this license in accordance with statements, representations and procedures and attachments listed below. The North Carolina Regulations for Protection Against Radiation shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application with attachments dated May 5, 2003, signed by Jeff Teeter for Sallye Linc, EVP, COO of Forsyth Medical Center.
 - B. Corrected Copy.
 - C. Application for Amendment with attachments dated June 2, 2003, signed by Carmine M. Plott, Ph.D., RSO.
 - D. Application for Amendment with attachments dated August 20, 2003, signed by Carmine M. Plott, Ph.D., CHP, RSO.



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CONDITIONS (continued):

29. F. Application for Amcndment with attachments dated July 24, 2006, signed by Carmine M. Plott, Ph.D.,CHP, RSO.

For: Beverly O. Hall
Chief, Radiation Protection Section