



A Limited Liability Company

P. O. Box 789 • Lewisburg, WV 24901 • (304) 647-3439 • (800) 627-3439

December 9, 2000

Licensing Assistance Section
U.S. Nuclear Regulatory Commission
Atlanta Federal Center
81 Forsyth Street, SW, Suite 23T85
Atlanta, GA 30303

RE: CorScan Plus, LLC
Amendment Application
License Number: 47-25351-01

Dear License Reviewer:

Please amend the above referenced byproduct material license to reflect the following changes:

1. We request that a "second location of use" be approved for our byproduct material license. The address of the new facility is identified below:

CorScan Plus Imaging
587S Brano Road, Suite 601
Richmond, VA 23226

A diagram of the new nuclear medicine department has been enclosed in Attachment A. Please refer to this section for details.

2. We request that Massimo Giuatl, M.D. be named as an authorized user for all nuclear cardiology procedures listed on our byproduct material license. Dr. Giuati was an authorized user and radiation safety officer on the Tennessee Department of Environmental and Conservation Radioactive Material License Number: R-79253-C09. A copy of this document has been enclosed in Attachment B. Please refer to this section for details.
3. We request that Vipal K. Sabharwal, M.D. be added to our license as an authorized user for all cardiovascular procedures listed on our license. Dr. Sabharwal is currently listed

as an authorized user on Virginia Department of Health, Radioactive Material License Number: VA-502-01.

In addition, this physician has completed 200 hours of academic and 1,000 hours of clinical training. Documentation attesting to his training has been enclosed in Attachment B. Please refer to this section for details.

4. In regards to nuclear medicine equipment (intended for installation), the following list is provided for your review:
 1. SMV DSTi Imaging System or equivalent
 2. Capintec CRC-7 or equivalent
 3. Ludlum 14C Survey Meter and Pancake Probe Attachment
 4. Victoreen Wipe Test Deluxe Counter

All remaining items referenced on our byproduct material license are to remain unchanged. Any assistance you may provide in expediting this licensing request is greatly appreciated. We thank you in advance for your assistance with this pending licensing action.

If you have additional questions regarding this amendment request, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 447-3303.

Sincerely,



Steven Walter, M.D.
General Manager and CEO

enclosures

Attachment A



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION

3rd Floor, L & C Annex,
401 Church Street
Nashville, TN 37243-1532

March 22, 1999

Memphis Heart Clinic, PLLC
6025 Walnut Grove Rd., Suite 410
Memphis, TN 38120

Attention: Massimo Giusti, M.D., Radiation Safety Officer

Gentlemen:

Attached to this letter is your Tennessee Radioactive Material License numbered R-79263-C09 issued to expire on March 31, 2009.

A copy of 'State Regulations for Protection Against Radiation' referred to in Condition 12 of the license conditions and several copies of Form RIIS 8-3 for posting as noted on that form are being sent to you by a separate mailing. Your attention is directed to State Regulations and to specific license conditions 11 through 25 which are to be followed in the use this license.

If we can be further assistance to you, please contact us.

Sincerely,

A handwritten signature in cursive script, appearing to read "R. J. Parsons".

Ronald J. Parsons
Health Physicist
Division of Radiological Health

Attachments:

TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH



RADIOACTIVE MATERIAL LICENSE

Pursuant to Tennessee Department of Environment and Conservation Regulations, 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 and regulations of the Tennessee Department of Environment and Conservation and orders of the Division of Radiological Health, now or hereafter in effect and to any conditions specified below.

LICENSEE		3. License number
1. Name	Memphis Heart Clinic, PLLC	R-79263-C09
2. Address	6025 Walnut Grove Rd., Suite 410 Memphis, TN 38120	4. Expiration date March 31, 2009
		5. File no. R-79263
6. Radioactive Material (Element and Mass Number)	8. Chemical and/or physical form See Supplementary Sheets	9. Maximum Radioactivity and/or quantity of material which licensee may possess at any one time.

10. Authorized Use

See Supplementary Sheets

CONDITIONS
11. Unless otherwise specified, the authorized place of use is the licensee's address stated in item 2, above.

See Supplementary Sheets

For the Commissioner
Tennessee Department of Environment and Conservation

Date of Issuance March 22, 1999

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By: 
DIVISION OF RADIOLOGICAL HEALTH

Ronald J. Parsons
Health Physicist

TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

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License Number R-79263-C09

6. Radioactive
Material (Element
and Mass Number)

8. Chemical and/or
Physical Form

9. Maximum Radioactivity
and/or Quantity of
Material Which
Licensee May Possess
at Any One Time

A. Any radioactive material
authorized for diagnostic
nuclear cardiology in Group II
(Rule 1200-2-10-.14(6)(b) of
"State Regulations for
Protection Against Radiation").

A. Any radiopharmaceutical
authorized for diagnostic
nuclear cardiology in Group II
(Rule 1200-2-10-.14(6)(b) of
"State Regulations for
Protection Against Radiation").

A. As necessary for the
uses authorized in
Item 10A.

B. Cobalt 57

B. Sealed Source (Any sources
used for calibration or as a
reference standard which have
been evaluated and approved by
an Agreement State and/or
Licensing State agency, as
appropriate)

B. No single source to
exceed the maximum
activity authorized in
the Registry of Sealed
Sources and Devices
for that source.

C. Cesium 137

C. Sealed Source (Any sources
used for calibration or as a
reference standard which have
been evaluated and approved by
the NRC, and/or Agreement State)

C. No single source to
exceed the maximum
activity authorized in
the Registry of Sealed
Sources and Devices
for that source.

10 Authorized Use

A. Any diagnostic nuclear cardiology procedures specified in Group II (Rule 1200-2-10-.14(6)(b) of "State Regulations for Protection Against Radiation").

B. and C. Instrument calibration and reference standards.

TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

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License Number R-79263-C09

Conditions (continued)

12. The licensee shall comply with applicable provisions of 1200-2-4, 1200-2-5, and 1200-2-10 of "State Regulations for Protection Against Radiation".
13. A. Radioactive material authorized by this license shall be used by, or under the supervision of, Massimo Giusti, M.D., or Michael Kinnard, M.D.

B. The Radiation Safety Officer for this license is Massimo Giusti, M.D.
14. Radioactive material authorized by this license shall be used and stored at 6025 Walnut Grove Road, Suite 410, Memphis, Tennessee.
15. A. Sealed sources authorized by this license 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 transfer, the sealed source shall not be put into use until tested.

B. 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 surface of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.

C. 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 Department regulations. A report shall be filed within five (5) days of the test with the Division of Radiological Health, Tennessee Department of Environment and Conservation, 3rd Floor, I. & C Annex, 401 Church Street, Nashville, Tennessee, 37243-1532, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by persons authorized by this Department, the U. S. Nuclear Regulatory Commission, an Agreement State, or Licensing State to perform such services.

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License Number R-79263-C09

16. Notwithstanding the periodic leak test required by Condition 15, any licensed 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.
17. The licensee shall not open sealed sources containing radioactive material.
18. The licensee in making disposal of radioactive wastes to the sanitary sewer system shall do so in conformity with 1200-2-5-.122 of "State Regulations for Protection Against Radiation."
19. The licensee shall maintain complete and accurate records of the receipt and disposal of radioactive material. The licensee shall, for radioactive material no longer useful for any purpose and for any equipment or supplies contaminated with such material for which further use and decontamination is not planned, define those materials as radioactive waste and treat them as such in accordance with the following provisions:
 - A. Radioactive waste material shall not be stored with non-radioactive waste.
 - B. A written record of all radioactive waste material shall be maintained until it has been determined by a suitable survey or radioassay that it has decayed to background levels or until it has been shipped to an authorized recipient in accordance with all applicable regulations. Accountability of radioactive waste material prepared for shipment but not yet shipped from the licensee's premises shall be maintained by the licensee by an internal record system such that the licensee is constantly aware of the material's location and the proposed time of shipment. Individuals who are involved in the shipping of such material and/or the storage of such material prior to shipment, shall be trained in the precautions necessary for such handling and storage.
 - C. For material which has decayed to background levels as determined by radioassay or external level as measured with appropriately calibrated instruments, records shall indicate that the material was determined to be no longer radioactive and will indicate the methods and results of the survey or analysis.
 - D. Shipment records of radioactive waste material shall be maintained and the licensee shall require written confirmation from the authorized recipient of such material that this material has been received.
 - E. All records and written confirmations required by this condition shall be maintained for inspection by the Department.

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The requirements for this condition are in addition to any other requirements for the handling and/or disposal of radioactive material contained in this license and "State Regulations for Protection Against Radiation".

20. In addition to the authorizations granted in 1200-2-10-14(6)(b).18 and 1200-2-10-14(6)(c).5 of "State Regulations for Protection Against Radiation", the licensee may possess and use prepared radiopharmaceuticals and reagent kits used to prepare radiopharmaceuticals for which a Product License Application (PLA) has been accepted by the U.S. Food and Drug Administration (FDA).
21. In addition to the possession limits in Item 9, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in "State Regulations for Protection Against Radiation" 1200-2- 10-.13(17)(a) which require consideration of the need for an emergency plan for responding to a release of licensed material.
22. 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 one (1) microcurie of molybdenum 99 per millicurie of technetium 99m or more than five (5) microcuries of molybdenum 99 per dose of technetium 99m at time of administration. The limits for molybdenum 99 contamination represent maximum values, and molybdenum 99 contamination should be kept as low as reasonably achievable below these limits.
C. 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 Item B of this Condition are detected.
D. Personnel performing tests to detect and quantify molybdenum 99 contamination shall be given specific training in performing these tests prior to conduction such tests.
E. The licensee shall maintain for inspection by the Department records of the results of each test performed to detect and quantify molybdenum 99 contamination and records of training given to personnel performing these tests.
23. Radioactive material to be administered to humans, including gases or gases in solution, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug, and Cosmetic Act.

TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

RADIOACTIVE MATERIAL LICENSE

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License Number R-79263-C09

24. No provision of this license relieves the licensee from compliance with other Federal, State, and local laws, ordinances, and regulations applicable to the licensee's activities.
25. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 8, and 9 of this license in accordance with statements, representations, and procedures contained in application dated March 1, 1999, with attachments, and letter dated February 17, 1999, with attachments.



July 12, 1999

Re: Vipal Sabharwal, MD

To Whom It May Concern:

As the Director of Nuclear Cardiology and the Chairman of Nuclear Medicine at the Medical College of Virginia Hospitals of Virginia Commonwealth University, I am writing to confirm that, during the course of his Cardiology Fellowship, Dr. Sabharwal spent over 500 hours performing stress tests in the Nuclear Medicine stress lab and performed at least 500 hours of nuclear cardiology film interpretation. In addition to the experience gained in two years of clinical fellowship, he spent his research year with the Acute Cardiac Team at MCVH and was involved with study interpretation on an almost daily basis.

If you have any questions, please do not hesitate to contact me or Ms. Kristin Schmidt.

Sincerely,

James L. Tatum, MD
Professor of Radiology and Medicine
Director, Nuclear Cardiology Section
Chairman, Department of Radiology

NUCLEAR CARDIOLOGY

P.O. Box 982001

Richmond, Virginia 23298-0001

804 828-5828

FAX: 804 828-4181

TDD: 1-800 828-1120

James L. Tatum, M.D.

DIRECTOR, NUCLEAR CARDIOLOGY

804 828-4177

EMAIL: JTATUM@MVC.VCU.EDU

Kristin L. Schmidt

Program Coordinator,

ACT/Nuclear Cardiology

804 828-4178

EMAIL: KCSCHM17@MVC.VCU.EDU

CERTIFICATION COUNCIL OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Vipal K. Sabharwal, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS COUNCIL
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,

IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

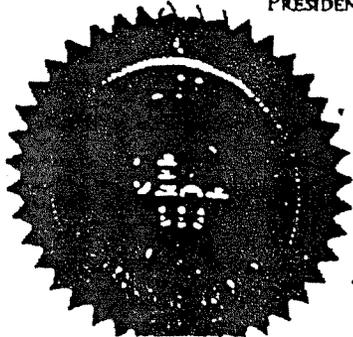
FOR THE PERIOD 1998 THROUGH 2008

A. S. Khandekar

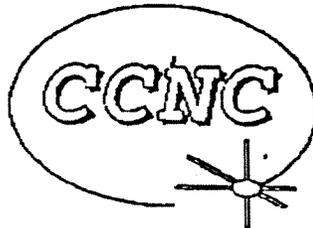
PRESIDENT

E. J. Sabharwal, MD

SECRETARY



CERTIFICATE # 1180



OCTOBER 25, 1998



Virginia Commonwealth University

August 12, 1998

Ms. Dyana M. Rothman
 CCNC Registration Coordinator
 Certification Council of Nuclear Cardiology
 712 Executive Drive
 Princeton, NJ 08540

RE: Dr. Vipal K. Sabharwal
 2314 Crickhollow Court
 Richmond, Virginia 23233

NUCLEAR CARDIOLOGY

P.O. Box 900001

RICHMOND, VIRGINIA 23298-0001

804 828-8228

FAX 804 828-4121

TDD 1-800-828-1120

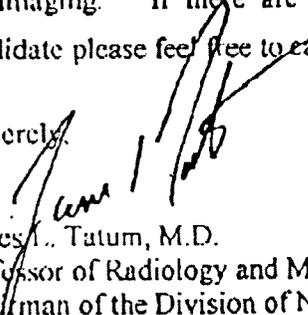
JAMES L. TATUM, M.D.
 Director, Nuclear Cardiology
 804 828-4177
 Email: tatum@vcu.edu

KRISTIE L. SCHMIDT
 Program Coordinator
 CCN Nuclear Cardiology
 804 828-4178
 Email: lschmidt@vcu.edu

Dear Ms. Rothman:

This is in response to your letter to Dr. Sabharwal of July 30, 1998, requesting verification of 200 hours of radiation safety training. As I stated in the original letter accompanying his application to the CCNC, Dr. Sabharwal performed as a full time Nuclear Cardiology fellow from June 1997 to July 1998. This complies with the highest level of training in accordance with the nuclear cardiology training guidelines. During this one year rotation in Nuclear Cardiology, Dr. Sabharwal completed in excess of 200 hours of class room training including radiopharmacy, instrumentation, radiation biology, and radiation safety. This in conjunction with his laboratory and clinical experience is in excess of the necessary training requirements for licensure by the NRC as a qualified user of radioactive materials for imaging. If there are any further questions regarding the qualifications of this candidate please feel free to call me.

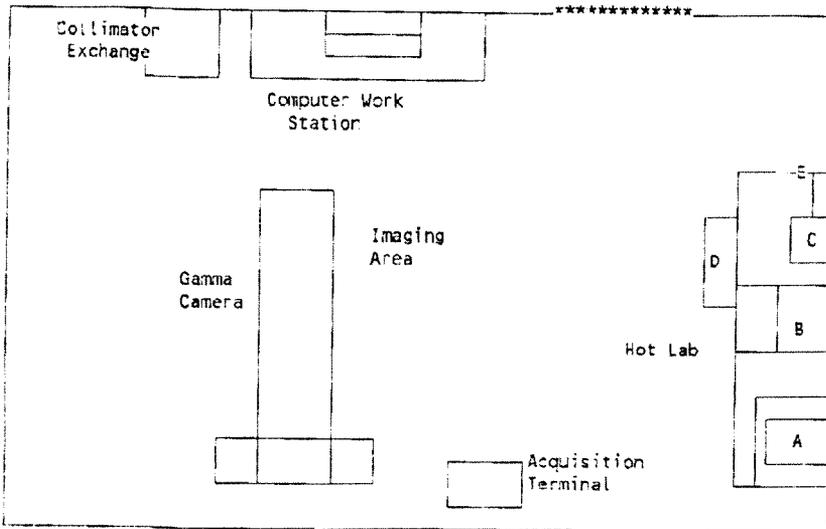
Sincerely,


 James L. Tatum, M.D.
 Professor of Radiology and Medicine
 Chairman of the Division of Nuclear Medicine
 Director of Nuclear Cardiology
 Medical College of Virginia Hospital
 Virginia Commonwealth University
 P. O. Box 900001
 Richmond, Virginia 23298-0001

Attachment B

CorScan Plus
587S Brano Road, Suite 601
Richmond, VA 23226

Nuclear Medicine Diagram



Legend:

- A. Lead Castle (Approximately 10 leaded bricks) - (2 x 4 x 8)
 - B. L-Shield & Preparation Area (1/4" leaded glass)
 - C. dose Calibrator
 - D. Lead-Lined Waste Container (1/8" lead-liner)
 - E. Lead-Lined Sharps Container (1/4" lead-lined)
- *** Locked Door