

THE HEART GROUP

LANCASTER MEDICAL CENTER, SUITE 200
217 HARRISBURG AVENUE
LANCASTER, PA 17603-2962
(717) 481-7391
FAX (717) 481-7397
www.theheartgroup.com

ROLF L. ANDERSEN, M.D., F.A.C.C.
PAUL N. CASALE, M.D., F.A.C.C., F.S.C.A.I.
NEIL R. CLARK, M.D., F.A.C.C.
SCOTT J. DERON, D.O., F.A.C.C., F.S.C.A.I.
RUPAL P. DUMASIA, M.D., F.S.C.A.I.
MARK D. ETTER, M.D., F.A.C.C.
DOUGLAS C. GOHN, M.D., F.A.C.C.
JOSELUIS IBARRA, M.D., F.A.C.C.

TINA DAVIS, C.R.N.P.
SHERRI DELGADO, C.R.N.P.
DEANNA DUKES, C.R.N.P.
JON ECHTERLING, C.R.N.P.
TRICIA ECKMAN, C.R.N.P.
ANITA HOLZ, C.R.N.P.
CONNIE KISER, C.R.N.P.

DAVID M. LOSS, D.O., F.A.C.C.
R. WARD PULLIAM, M.D.
MELISSA L. McKERNAN, M.D.
JOHN P. SLOVAK, M.D., F.A.C.C.
ROY S. SMALL, M.D., F.A.C.C., F.S.C.A.I.
EDWARD W. SUPPLE, M.D., F.A.C.C., F.S.C.A.I.
SETH J. WORLEY, M.D., F.H.R.S., F.A.C.C.

LISA RATHMAN, C.R.N.P.
JILL REPOLEY, C.R.N.P.
KIMBERLY SHEA, C.R.N.P.
KELLY TRYNNOSKY, C.R.N.P.
JENNIFER WARDLE, C.R.N.P.
ALEXANDRA WYANT, C.R.N.P.
BRENDA YOUNG, C.R.N.P.

July 11, 2007

NH562

Ms. Michelle Beardsley
United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

Dear Ms. Beardsley:

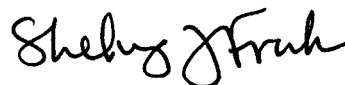
RE: Material License No. 37-30426-01

030 34622

The Heart Group is requesting to add Jeffrey M. Hardin, M.D. to the group's Materials License. Enclosed please find a copy of a Materials License from Moses Cone Health System d/b/a LeBauer Health Care listing Dr. Hardin as an authorized user and a copy of Dr. Hardin's Pennsylvania medical license. Dr. Hardin is relocating to Pennsylvania and will be employed by The Heart Group effective September 1, 2007.

Should you have any questions, please call me directly at 717-481-7391. Thank you for your time and consideration of this request.

Sincerely,



Shelvy J. Frank
VP & Chief Operating Officer

Enclosures

Cc: Department of Environmental Protection

140795

NMSS/RGN1 MATERIALS-002

RECEIVED
REGION 1
2007 JUL 12 AM 10:24

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs
Medical Physician and Surgeon

License Number
MD431809

Expiration Date
12/31/2008

Registration Code
21819118
JEFFREY M HARDIN

License Status
Active

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE:

1. SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED.
2. DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION.

JEFFREY M HARDIN

Registration Code

Your registration code is found on the attached wallet card.

Use this registration code online to: renew your license, change your personal or license address, or order duplicate licenses.

Visit our website at: www.mylicense.state.pa.us

First time users will be required to use this registration code to create a user ID and password.

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

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO Box 2649 Harrisburg PA 17105-2649

07 463564

License Type

Medical Physician and Surgeon

License Status

Active

Initial License Date

05/31/2007

JEFFREY M HARDIN

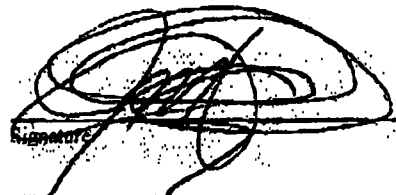
License Number

MD431809

Expiration Date

12/31/2008


Commissioner of Professional and Occupational Affairs


Signature



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

Page 1 of 4

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: Moses Cone Health System d/b/a LeBauer Health Care 2a. Mailing Address: 520 North Elam Avenue Greensboro NC 27403 b. Physical Address: 1126 North Church Street, Suite 300 Greensboro NC 27401 c. Radiation Safety Officer: Wanda H. Deal, RT-N	3. License No: 041-0925-1 4. Expiration Date: March 31, 2012 <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;"><input type="checkbox"/> New License</td> <td style="width: 25%;"><input type="checkbox"/> Routine</td> <td style="width: 25%;"><input type="checkbox"/> Corrected Copy</td> </tr> <tr> <td><input checked="" type="checkbox"/> Renewal</td> <td><input type="checkbox"/> Administrative</td> <td><input type="checkbox"/> Termination</td> </tr> </table> 5.a. Amendment No.: 28 b. Issuance Date: March 7, 2007	<input type="checkbox"/> New License	<input type="checkbox"/> Routine	<input type="checkbox"/> Corrected Copy	<input checked="" type="checkbox"/> Renewal	<input type="checkbox"/> Administrative	<input type="checkbox"/> Termination	License Type 0210
<input type="checkbox"/> New License	<input type="checkbox"/> Routine	<input type="checkbox"/> Corrected Copy						
<input checked="" type="checkbox"/> Renewal	<input type="checkbox"/> Administrative	<input type="checkbox"/> Termination						

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. Sodium Pertechnetate and other FDA approved forms	A. Any amount necessary for those uses described in a written directive from an authorized user authorized by this license.
B. Technetium 99m	B. Sodium Pertechnetate (Liquid)	B. 500 millicuries
C. Cesium 137	C. Sealed Source	C. No single source to exceed 1 millicurie; Total activity shall be less than 10 millicuries
D. Cobalt 57	D. Sealed Source	D. No single source to exceed 30 millicuries; Total activity shall be less than 20 millicuries

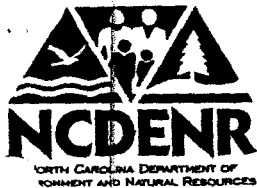
9. Authorized Use (To be used for):

A.-B. To be used in accordance with a written directive from an authorized user authorized by this license.

C.-D. To be used for instrument quality assurance/quality control.

CONDITIONS

10. A. The authorized place of use is the licensee's address stated in Item 2b. above.
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 shall be used by Peter Charles Nishan, MD, Brian Crenshaw, MD, Paula V. Ross, MD, Gregg Taylor, MD, Samuel McDowell, MD, Jeffrey D. Katz, MD, Robert Rothbart, MD, Guy E. DeGent, MD, Jeffery M. Hardin, MD, and Daniel Bensimhon, MD.
 - B. Radioactive materials shall not be used on humans without obtaining prior approval, in accordance with 15A NCAC 11 .0356, from an authorized user listed in Condition A above.
 - C. Radioactive material may be used by Guy E. DeGent, MD, Jeffrey M. Hardin, MD and Daniel Bensimhon, M.D. for cardiac studies only.



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

Page 2 of 4
License No.: 041-0925-1

CONDITIONS (continued):

12. D. The Radiation Safety Officer for the activities authorized by this license shall be Wanda H. Deal, RT-N, RSO.
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 NCA/C 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.
 3. Linearity to be performed upon installation and at intervals not to exceed three (3) months and following repair:
 - 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 licensed sealed source is exempt from such leak test 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 unit 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, 3825 Barrett Drive, Raleigh, N.C. 27609-7221 describing the equipment involved, the test results, and the corrective action taken.



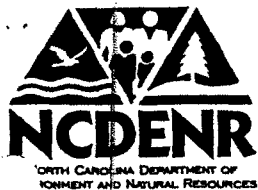
**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

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RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

16. 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:
 - 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.



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RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

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 and letter with attachments dated February 27, 2007, signed by Cameron M. Cox, Jr., COO.

For: Beverly O. Hall
Chief, Radiation Protection Section



North Carolina Department of Environment and Natural Resources
Radiation Protection Section

Michael F. Easley, Governor
William G. Ross, Jr., Secretary

Linda Sewall, Division Director
Beverly O. Hall, Section Chief

January 12, 2004

MARK A. BOLES MD RSO
ANNIE PENN HOSPITAL
618 SOUTH MAIN STREET
REIDSVILLE NC 27320-5020

SUBJECT: Amendment for Radioactive Materials License No. 079-0023-1

Dear Dr. Boles:

Enclosed is Amendment Number 42 to the Radioactive Materials License identified above. This amendment has been issued in accordance with the letter with attachments dated January 7, 2004.

Please review the license carefully to ensure that it includes the items and provisions you requested. If this agency can be of assistance to you at any time, please do not hesitate to contact me.

Sincerely,

W. Lee Cox, III, Manager
Radioactive Materials Branch

smj

enclosures



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

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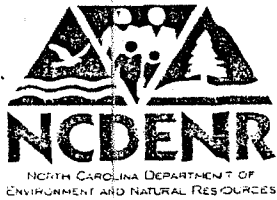
RADIOACTIVE MATERIALS LICENSE

Pursuant to North Carolina Regulations for Protection Against Radiation and in reliance on statements and representation 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: The Moses H. Cone Memorial Hospital Operating Corporation d b a Annie Penn Hospital 2a. Mailing Address: 618 South Main St. Reidsville, NC 27320-5020 b. Physical Address: 618 South Main St. Reidsville, NC 27320-5020 c. Radiation Safety Officer: Mark Alan Boles, MD	3. License No: 079-0023-1 4. Expiration Date: October 31, 2004 <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">New License</td> <td style="width: 33%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 33%;">Routine Administrative</td> <td style="width: 33%; text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Renewal</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Corrected Copy</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td></td> <td></td> <td>Termination</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table> 5.a. Amendment No.: 42 b. Issuance Date: January 12, 2004	New License	<input checked="" type="checkbox"/>	Routine Administrative	<input type="checkbox"/>	Renewal	<input type="checkbox"/>	Corrected Copy	<input type="checkbox"/>			Termination	<input type="checkbox"/>
New License	<input checked="" type="checkbox"/>	Routine Administrative	<input type="checkbox"/>										
Renewal	<input type="checkbox"/>	Corrected Copy	<input type="checkbox"/>										
		Termination	<input type="checkbox"/>										

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. Any radioactive material listed in Groups I – IV in DRP Publication 97-01	A. Any radiopharmaceutical listed in Groups I – IV in DRP Publication 97-01, except in the form of gases, gases in solution, and aerosols	A. As necessary for uses authorized in 9.A. Groups I – IV.
B. Any radioactive material authorized under 15A NCAC 11 .0321(c)(5).	B. Any form as specified in 15A NCAC 11 .0321(c)(5)(A) – (D).	B. No single source to exceed the limit specified in 15A NCAC 11 .0321(c)(5)(A) – (D).
C. Samarium 153	C. Samarium Chloride	C. 50 millicuries
D. Xenon 133	D. Gas or gas in solution	D. 100 millicuries
E. Iodine 131	E. Sodium Iodine	E. 200 millicuries
F. Iodine 131	F. Sulfate (MIBG)	F. 1.5 millicuries
G. Technetium 99m	G. DTPA Aerosol	G. 75 millicuries
H. Technetium 99m	H. Sulfur Colloid (filtered)	H. As needed

9. Authorized Use: A. See DRP Publication 97-01 "List of Radioactive Materials Approved for the Four 'Groups of Diagnostic Uses' as Defined in 15A NCAC 11.0321." DRP Publication 97-01 is available from the agency pursuant to 15A NCAC 11 .0321(d). B. To be used as calibration and reference standards. C. - E. To be used in accordance with a written directive from an authorized user. F. To be used in accordance with IND # 17,239 approved protocols and a written directive from an authorized user. G. To be used in accordance with a written directive from an authorized user under this license for lung imaging. H. To be used in accordance with a written directive from an authorized user under this license for Sentinel Node Tracking.	
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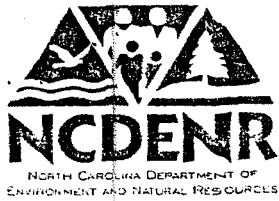


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CONDITIONS

10. The authorized place of receipt and use of radioactive material is the licensee's address stated in item 2.b. above.
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," and 15A NCAC 11 .0700 "Use of Sealed Radioactive Sources in the Healing Arts" (when applicable). (The North Carolina Regulations for Protection Against Radiation are contained in 15A NCAC 11.)
12.
 - A. The licensee shall comply with the provision of 15A NCAC 11 .0321 in the procurement and use of radioactive materials authorized in this license.
 - B. Radiopharmaceuticals and 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.
13. The licensee is authorized to receive, acquire, possess, transfer, and use *in vitro* clinical or laboratory testing kits as authorized in 15A NCAC 11 .0314 without filing agency forms as required by 15A NCAC 11 .0314(b), provided that the licensee is subject to the other provisions of 15A NCAC 11 .0314.
14.
 - A. Sealed radioactive sources owned or possessed for calibration and reference standards shall be tested for leakage and/or contamination in accordance with 15A NCAC 11 .0321(e)(5).
 - B. The licensee shall conduct a quarterly physical inventory to account for all sealed sources received and possessed under this license which are used for the calibration/reference of the dose calibrator and patient imaging equipment. Records of the inventories shall be maintained for inspection by the agency and shall include the quantities and kinds of radioactive material, location of the sources, and the date of the inventory.
5. Sealed sources containing radioactive material shall not be opened by the licensee.
6.
 - A. The licensee is hereby authorized to use Molybdenum 99 / Technetium 99m generators for preparing Technetium 99m radiopharmaceuticals 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.
7.
 - A. Radioactive material listed above shall be used by Sam J. Morayati, MD, Fayegh Jadali, MD, Robert Reimen, MD, Mark Alan Boles, MD, Freman Randolph Jackson, MD and other 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.
 1. 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;
 2. To be named by the licensee as a user for therapeutic use of unsealed byproduct material, a prospective user must be certified as described in either 5a, b, d, or f below;
 3. To be named by the licensee as a user for brachytherapy sources or teletherapy, the prospective user must be certified as described in either 5d or g below;
 4. To be named by the licensee as a user for I-125, Am-241, or Gd-153 as a sealed source in a device for bone mineral analysis or I-125 as a sealed source in a portable imaging device for diagnosis, the prospective user must be certified as described in 5d, e, or h below.



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RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

17. B. 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 listed above shall be used by Robert M. Rothbart, MD, and Jeffrey M. Hardin, MD for nuclear cardiology studies only.
- F. The Radiation Safety Officer for the activities authorized by this license shall be Mark Alan Boles, MD.
18. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use the radioactive material under the terms of this license provided the physician:
- A. Has prior written permission of the hospital administrator and its Radiation Safety Committee; and
 - B. Is specifically named as a user on a N.C. Department of Environment and Natural Resources license authorizing use; and
 - C. Performs only those procedures for which specifically authorized by a N.C. Department of Environment and Natural Resources license.
9. Radioactive materials shall not be used on humans without the prior approval, in accordance with the provisions of 15A NCAC 11 .0356 from an authorized user who is either listed in or satisfies the requirements of Condition No. 17. above, or by a visiting physician who satisfies the requirements of Condition No. 18. above.
10. Provided that the licensee has been authorized in Items 6., 7., 8., & 9. of this license for the use of agency approved radioactive gases, gas-in-solution, or aerosols, the licensee shall:
- 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).
1. The licensee is authorized to conduct a decay-in-storage program in accordance with 15A NCAC 11 .0362.
2. 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.



RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION

N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES

RADIOACTIVE MATERIALS LICENSE

Page 4 of 5
License No.: 079-0023-1

CONDITIONS (continued):

23. 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.
 3. Linearity to be performed upon installation and at intervals not to exceed three (3) months and following repair:
 - 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.
24. 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.
25. The licensee shall annually review its Radiation Protection Program for content and implementation [Reference 15A NCAC 11 .1603(c)]. Documentation of the Radiation Protection Program reviews shall be retained for inspection by the agency [Reference: 15A NCAC 11 .1636].
6. The licensee shall institute the provisions of 15A NCAC 11 .1610 when an occupationally exposed woman voluntarily informs her supervisor, in writing, of the pregnancy and the estimated date of conception.
7. 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 activities.
8. For each patient administered radiopharmaceuticals, the licensee shall ensure compliance with Rule 15A NCAC 11 .0358.
9. For each patient receiving radiopharmaceutical therapy and hospitalized in compliance with Rule 15A NCAC 11 .0358, the licensee shall maintain documentation to demonstrate compliance with Rule 15A NCAC 11 .0318 (I).
0. Neither this license nor any subsequent amendments shall be deemed to constitute compliance with the requirements for health planning 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, Division of Facility Services at (919) 733-6360.
1. This license may be subject to amendment, revision, modification, suspension, or revocation in accordance with the provisions of 15A NCAC 11 .0344.
2. 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.



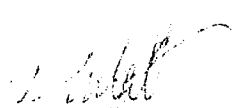
RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES

Page 5 of 5
License No.: 079-0023-1

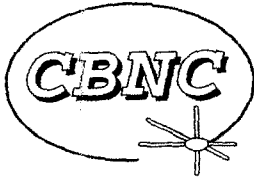
RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

32. A. Application with attachments received September 30, 1999, signed by Susan H. Fitzgibbon, President & CEO; letters with attachments dated October 13, 1999 and October 29, 1999 signed by Sam Morayati, MD; and letter with attachment dated November 22, 1999, signed by Jay Sprinkle.
- B. Letter with attachments May 10, 2001, signed by Gregory S. Beavers, RSO.
- C. Letter with attachments dated June 25, 2001 signed by Susan H. Fitzgibbon, President and facsimile dated July 13, 2001.
- D. Letter dated July 7, 2002 signed by Gregory S. Beavers, CNMT, RSO.
- E. Application for amendment with attachment dated August 26, 2002, signed by Gregory S. Beavers, RSO.
- F. Application for amendment with attachments dated May 5, 2003 signed by Susan H. Fitzgibbon, President, Annie Penn Hospital.
- G. Letter dated September 26, 2003 signed by Susan Fitzgibbon, President, and letter with attachments dated September 22, 2003, signed by Mark A. Boles, M.D.
- H. Letter with attachments dated January 7, 2004, signed by Susan Fitzgibbon, President.


For: Beverly O. Hall

Chief, Radiation Protection Section



Certification Board of Nuclear Cardiology

9929 Main Street Suite C Damascus, MD 20872 Phone: (301) 253-7122 Fax: (301) 253-7123

BOARD OF DIRECTORS

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Executive Director

November 28, 2001

Jeffrey M. Hardin, MD

ID #: 1001383

Dear Dr. Hardin:

We are pleased to inform you that the Board of Directors of the Certification Board of Nuclear Cardiology has determined that your score on the written examination of October 28, 2001 meets the standards it has established for certification in nuclear cardiology. Congratulations on your achievement!

A passing score of 72% correct was determined by an independent panel of peers, representing the disciplines involved in the practice of nuclear cardiology, drawn from both private practice and academia. This percentage is equivalent to a total of 126 correct questions on the 2001 examination.

The number of questions you answered correctly was 132 (75.4% correct). The attached chart shows the number of correct answers you had for each of the content areas.

As you may recall, the application form which you completed carried the wording "List name as you wish it to appear on certificate if you successfully pass the exam." Therefore, we will honor your request. You can expect receipt of the certificate in approximately six weeks.

It is important for future mailings and directories that you keep the CBNC headquarters office informed of any address changes.

On behalf of the Board of Directors, I wish to thank you for your participation in the CBNC examination and credentialing process.

Sincerely,

Manuel D. Cerqueira, M.D.
President

Enclosure

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Department of the Navy
Department of Nuclear Medicine
Naval Medical Center, San Diego
34800 Bob Wilson Drive
San Diego, California 92134

Phone: 619-532-8775

Board of Directors
The Certification Board in Nuclear Cardiology
9929 Main Street, Suite C
Damascus, Maryland 20872

17 May, 2001

Re: Eligibility for the 2001 Certification Examination in Nuclear cardiology for Jeffrey M.
Hardin, MD, FACP; [REDACTED]

Sirs;


I am pleased to write this letter in support of Dr. Hardin's application to take the certification examination in nuclear cardiology in October 2001. I was Chief of Radiology and the Head of Nuclear Medicine at the National Naval Medical Center in Bethesda, Maryland. Dr. Hardin was a fellow in Cardiology there from July 1997 to June 2000. We worked closely together over that time performing and interpreting myocardial perfusion imaging studies, radionuclide angiographic studies and single photon metabolic imaging studies.

Dr. Hardin spent a total of 6 months of his 36-month cardiology fellowship with us in Nuclear Medicine. He is well trained and clinically adept at the application and interpretation of nuclear cardiology procedures. Specifically he meets the COCATS Guidelines for Level 2 certification in Nuclear Cardiology as follows:

- 1) Successfully completed over 200 hours of didactic and laboratory training in nuclear medicine to include radiation physics, radioisotope handling and radiation safety.
- 2) Performed over 500 hours of technical work experience in nuclear cardiology under the supervision of an authorized user.
- 3) Performed over 500 hours of supervised clinical work experience in nuclear cardiology under the supervision of an authorized user.
- 4) Correlated over 100 catheterization/angiographic data sets on his patients and participated in the interpretation of over 400 total cases.
- 5) Participated in the computer processing and analysis of over 400 patient studies.

Dr. Hardin is an excellent candidate for this examination. I am certain that he will do well and obtain certification in Nuclear Cardiology. I am currently stationed at the Naval Medical Center in San Diego in the Department of Nuclear Medicine. Please contact me if questions regarding Dr. Hardin's qualifications arise.

Sincerely,


Eugene D. Silverman, MD
CAPT, MC, USN

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Department of the Navy
Department of Nuclear Medicine
Naval Medical Center, San Diego
34800 Bob Wilson Drive
San Diego, California 92134

Phone: 619-532-8775

26 May, 2001

From: Head, Department of Nuclear Medicine, Naval Medical Center, San Diego, California
To: Chair, Radiation Safety Committee, Naval Hospital, Camp Lejeune, North Carolina
Re: Eligibility as an Authorized User for Imaging and Localization Studies for CDR Jeffrey M. Hardin, MC, USN; [REDACTED]

1. I am pleased to write this letter in support of Dr. Hardin's application to become an authorized user for imaging and localization at the Naval Hospital, Camp Lejeune. I was Chief of Radiology and the Head of Nuclear Medicine at the National Naval Medical Center in Bethesda, Maryland. CDR Hardin was a fellow in Cardiology there from July 1997 to June 2000. We worked closely together over that time performing and interpreting myocardial perfusion imaging studies and radionuclide angiographic studies.

2. CDR Hardin spent a total of 6 months of his 36-month cardiology fellowship with us in Nuclear Medicine. He is well trained and clinically adept at the application and interpretation of nuclear cardiology procedures. Specifically he meets the COCATS Guidelines for Level 2 certification in Nuclear Cardiology and qualifies under section 35.920 of the regulations of the Nuclear Regulatory Commission as follows:

- a) Successfully completed over 200 hours of didactic and laboratory training in nuclear medicine to include radiation physics, radioisotope handling and radiation safety.
- b) Performed over 500 hours of technical work experience in nuclear cardiology under the supervision of an authorized user.
- c) Performed over 500 hours of supervised clinical work experience in nuclear cardiology under the supervision of an authorized user.
- d) Correlated over 100 catheterization/angiographic data sets on his patients and participated in the interpretation of over 400 total cases.
- e) Participated in the computer processing and analysis of over 400 patient studies.

3. CDR Hardin is an excellent candidate for selection as an authorized user. I am certain that he will do well in the practice of nuclear cardiology at your hospital. I am currently stationed at the Naval Medical Center in San Diego in the Department of Nuclear Medicine. Please contact me if questions regarding Dr. Hardin's qualifications arise.

Sincerely,


Eugene D. Silverman, MD
CAPT, MC, USN

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DEPARTMENT OF THE NAVY

NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND 20889-5600

IN REPLY REFER TO

1520
0414/0002/100
29 March 2000

From: Director, Medical Officer's Course in Nuclear Medicine
and Radioisotope Techniques, National Naval Medical Center

To: Jeffrey M. Hardin, SSN: [REDACTED]

Subj: PRECEPTOR STATEMENT

Ref: (a) USNRC Regulatory Guide Title 10 of September 1995

1. Per reference (a), this preceptor statement is forwarded for your records. It documents the training you received after successfully completing the Medical Officer's Course in Nuclear Medicine and Radioisotope Techniques held at the National Naval Medical Center on 14 February to 17 March 2000.

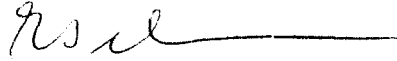
2. Training received in Basic Radioisotope Handling Techniques.

From Part 4 to NRC Form NRC-313M-Supplement A

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	Type & Length of Training	
		Lecture Laboratory Courses (hours) C	Supervised Experience (hours) D
a. RADIATION PHYSICS AND INSTURMENTATION	Medical Officers Course in Nuclear Medicine and Radioisotope Techniques. Class 9401. 13 September to 15 October 1993. Classes held at National Naval Medical Center, Bethesda, MD 20889-5000.	94	8
b. RADIATION PROTECTION		11	0
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		32	0
d. RADIATION BIOLOGY		18	0
e. RADIOPHARMACEUTICAL CHEMISTRY		33	4

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A total of 200 hours of training was received. The training and experience indicated above was obtained under the supervision of CAPT E.D. Silverman, MC, USN, Head, Nuclear Medicine Division, Radiology Department. Navy Radioactive Material Permit (NRMP) 19-00168-12NP applies.

A handwritten signature in dark ink, appearing to read 'E.D. Silverman', followed by a horizontal line.

E.D. SILVERMAN
CAPT, MC, USN