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WYTHEVILLE, VIRGINIA 24382
(276) 228-0200

NMSS1

July 3, 2007

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

To Whom It May Concern:

03011371

In regards to Nuclear Regulatory Materials License #45-16635-01, we would like to request the following amendments:

1. The addition of Dayne K. Roberts, MD as an authorized user.
2. The addition of Dayne K. Roberts, MD as an associate Radiation Safety Officer.

I am enclosing a copy of the North Carolina Radioactive Materials License that lists Dr. Roberts as an authorized user.

If you have any questions, please do not hesitate to contact me. Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Karl Ritch".

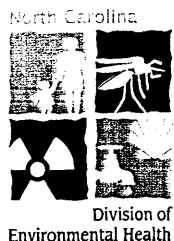
Karl A. Ritch, MD
Radiation Safety Officer

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REGION I

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NMSS/RGN1 MATERIALS-002



Division of Environmental Health

Terry L. Pierce, Director

Radiation Protection Section

Beverly O. Hall, Chief

State of North Carolina
Michael F. Easley, Governor

Department of Environment and
Natural Resources
William G. Ross, Secretary

June 12, 2007

Peter Gusmer, M.D., R.S.O.
Stanly Memorial Hospital
P.O. Box 1489
Albemarle, NC 28002-1489

SUBJECT: Amendment to Radioactive Materials License No. 084-0243-1

Dear Dr. Gusmer:

Enclosed is Amendment Number 41 to the North Carolina Radioactive Materials License identified above. This administrative amendment has been issued in order to update the authorized user listing on the license based on information previously submitted to the agency.

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,

A handwritten signature in black ink, appearing to read "W. Lee Cox, III".

W. Lee Cox, III, Manager
Radioactive Materials Branch

WLC/jme

Enclosure(s): as stated.



**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 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: Stanly Health Services d/b/a Stanly Memorial Hospital	3. License No: 084-0243-1	License Type 0110						
2a. Mailing Address: P.O. Box 1489 Albemarle, NC 28002-1489 b. Physical Address: 301 Yadkin Street Albemarle, NC 28002 c. Radiation Safety Officer: Peter Gusmer, MD	4. Expiration Date: July 31, 2009							
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">New License</td> <td style="width: 33%;">Routine</td> <td style="width: 33%;">Corrected Copy</td> </tr> <tr> <td style="text-align: center;">Renewal</td> <td style="text-align: center;">Administrative</td> <td style="text-align: center;">Termination</td> </tr> </table>	New License	Routine	Corrected Copy	Renewal	Administrative	Termination	
New License	Routine	Corrected Copy						
Renewal	Administrative	Termination						
	5.a. Amendment No.: 41 b. Issuance Date: June 12, 2007							

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 limits specified in 15A NCAC 11 .0321(c)(5)(A) – (D).
C. Technetium 99m	C. DTPA Aerosol	C. 100 millicuries
D. Technetium 99m	D. Filtered Sulfur Colloid	D. As necessary for uses described in a written directive from an authorized user.
E. Iodine 123	E. MIBG	E. As necessary for uses described in a written directive from an authorized user.

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. To be used for lung ventilation studies

D. To be used for Sentinel Node Biopsy.

E. To be used for diagnostic tumor imaging.

CONDITIONS

10. The authorized place of receipt and use of radioactive material is the licensee's address stated in item 2.b. above



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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," 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 manufacturers 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(c)(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.
15. Sealed sources containing radioactive material shall not be opened by the licensee.
16.
 - 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.
17.
 - A. Radioactive material listed above shall be used Peter Gusmer, MD, **Dayne K. Roberts, M.D., Robert B. Groves, M.D., John L. Green, M.D.**, 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.

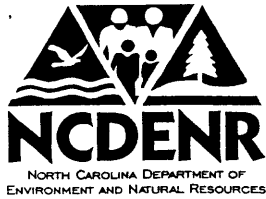


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CONDITIONS (continued):

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. The Radiation Safety Officer for the activities authorized by this license shall be Peter Gusmer, M.D.
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.
19. 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.
20. 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).
21. The licensee is authorized to conduct a decay-in-storage program in accordance with 15A NCAC 11 .0362.
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. 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):

23. A. 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].
26. 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.
27. 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.
28. 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.
29. This license may be subject to amendment, revision, modification, suspension, or revocation in accordance with the provisions of 15A NCAC 11 .0344.
30. 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 received August 2, 2004, signed by Debra D. Smith, Senior VP/COO, and Peter B. Gusmer, MD, RSO, and letter with attachments dated August 16, 2004, signed by Wendy Lee, Director of Imaging, and Peter Gusmer, MD, RSO.
 - B. Application for amendment dated April 5, 2005, signed by Peter B. Gusmer, RSO.



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CONDITIONS (continued):

30. C. Administrative amendment to complete authorized user listing based on application with attachments dated August 2, 2004.

For: Beverly O. Hall
Chief, Radiation Protection Section

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

7/3/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 45-16635-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 140731.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.