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STATE OF TENNESSEE

FAX TRANSMITTAL

TO: Tara Weidner	FROM: Jerry Bacon / Tenn. Rad. Health
AGENCY/COMPANY: NRC	DATE: 4-28-05
FAX NUMBER: 610-337-5393	TOTAL NUMBER OF PAGES INCLUDING COVER: 9
PHONE NUMBER:	SENDER'S PHONE NUMBER: 615-532-0364
SUBJECT: RAM License Authorized User	SENDER'S FAX NO.: 615-532-7938

☐ URGENT ☐ FOR REVIEW ☐ PLEASE REPLY

MESSAGE: Mail Control number 136500

[redacted]

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136500

NMSS/RGNI MATERIALS-002

TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

RADIOACTIVE MATERIAL LICENSE

Amendment 49

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: Wellmont Health System Holston Valley Medical center	R-82033-J14 AMENDED IN ITS ENTIRETY
2. Address: West Ravine Road P.O. Box 238 Kingsport, TN 37662	4. Expiration date October 31, 2014
	5. File no. R-82033

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.
See Supplementary Sheet		

10. Authorized Use: See Supplementary Sheet

CONDITIONS

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

See Supplementary Sheet

For the Commissioner
Tennessee Department of Environment and Conservation

Date of Issuance October 18, 2004

By: Sasi Krishnasarma
DIVISION OF RADIOLOGICAL HEALTH
Sasi Krishnasarma
Health Physicist

CN-0719 (Rev. 6-92)
Form RHS 8-7

Form RHS 8-7A
(9-92)

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License Number R-82033-J14

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 specified in Group I [Rule 1200-2-10.14(6)(a) of "State Regulations for Protection Against Radiation."]	A. Any radiopharmaceutical specified in Group I [Rule 1200-2-10.14(6)(a) of "State Regulations for Protection Against Radiation."]	A. As necessary for the uses authorized in Item 10.A.
B. Any radioactive material specified in Group II [Rule 1200-2-10.14(6)(b) of "State Regulations for Protection Against Radiation."]	B. Any radiopharmaceutical specified in Group II [Rule 1200-2-10.14(6)(b) of "State Regulations for Protection Against Radiation."]	B. As necessary for the uses authorized in Item 10.B.
C. Any radioactive material specified in Group III [Rule 1200-2-10.14(6)(c) of "State Regulations for Protection Against Radiation."]	C. Any radiopharmaceutical specified in Group III, except generators [Rule 1200-2-10-.14(6)(c) of "State Regulations for Protection Against Radiation."]	C. As necessary for the uses authorized in Item 10.C.
D. Any radioactive material specified in Group IV, except Iodine [Rule 1200-2-10.14(6)(d) of "State Regulations for Protection Against Radiation."]	D. Any radiopharmaceutical specified in Group IV, except Iodine [Rule 1200-2-10.14(6)(d) of "State Regulations for Protection Against Radiation."]	D. Total possession limit 200 millicuries.
E. Any radioactive material specified in Group V, except Iodine [Rule 1200-2-10.14(6)(e) of "State Regulations for Protection Against Radiation."]	E. Any radiopharmaceutical specified in Group V, except Iodine [Rule 1200-2-10.14(6)(e) of "State Regulations for Protection Against Radiation."]	E. Total possession limit 200 millicuries.

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F. Iodine 131	F. Sodium Iodide Capsules	F. 400 millicuries.
G. Iodine 131	G. Sodium Iodide capsules	G. 600 millicuries.
H. Barium 133	H. Sealed Source (Any sources used for calibration or as reference standards which have been evaluated and approved by either the U.S. NRC and/or an Agreement State).	H. No single source to exceed the maximum activity authorized in the Registry of Sealed Sources and Devices for that source. Total not to exceed two (2) sources.
I. Cesium 137	I. Sealed Source (Any sources used for calibration or as refer-ence standards which have been evaluated and approved by either the U.S. NRC and/or an Agreement State).	I. No single source to exceed the maximum activity authorized in the Registry of Sealed Sources and Devices for that source. Total not to exceed six (6) sources.
J. Cobalt 60	J. Sealed Source (Any sources used for calibration or as reference standards which have been evaluated and approved by either the U.S. NRC and/or an Agreement State).	J. No single source to exceed the maximum activity authorized in the Registry of Sealed Sources and Devices for that source. Total not to exceed two (2) sources.
K. Cobalt 57	K. Sealed Source (Any sources used for calibration or as reference standards which have been evaluated and approved by either an Agreement State and/or Licensing State).	K. No single source to exceed the maximum activity authorized in the Registry of Sealed Sources and Devices for that source, or for non-registered sources, not to exceed 100 microcuries each. Total not to exceed ten (10) sources.

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L. Gadolinium 153	L. Sealed source (Any source used for calibration or as a reference standard which has been evaluated and approved by the NRC and/or an Agreement State).	L. No single source to exceed the maximum activity authorized in the Registry of Sealed Source and Devices for that source. Total not to exceed six (6) sources.
M. Germanium 68	M. Sealed source (Any source which has been evaluated and approved for distribution by either an Agreement State and/or Licensing State)	M. No single source to exceed the maximum activity authorized in the Registry of Sealed Sources and Devices for that source. Total not to exceed twenty (20) sources.

10. Authorized use

A. Any diagnostic procedures specified in Group I [Rule 1200-2-10-.14(6)(a) of "State Regulations for Protection Against Radiation."]

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

C. Preparation and use of radiopharmaceuticals for any diagnostic procedures specified in Group III, except generators [Rule 1200-2-10-.14(6)(c) of "State Regulations for Protection Against Radiation."]

D. Any therapeutic procedures specified in Group IV, except Iodine [Rule 1200-2-10-.14(6)(d) of "State Regulations for Protection Against Radiation."]

E. Any therapeutic procedures specified in Group V, except Iodine [Rule 1200-2-10-.14(6)(e) of "State Regulations for Protection Against Radiation."]

F. For hypothyroidism and cardiac dysfunction.

G. For thyroid carcinoma.

H. through M. For use as calibration or reference sources.

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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, the following individuals as specified:

All radioactive material authorized by this license:

Preston Fox, M.D.
Thomas F. Pugh, M.D.
Larry H. Westerfield, M.D.
Gert van derWestthuizen, M.D.

All radioactive material authorized by this license except those listed in Items D and E:

Kelly J. Cassedy, M.D.
John Creasy, M.D.
Daniel Dsung Do-Dai, M.D.
Thomas C. Lepsch, M.D.
John M. McMurray M.D.
James C. Phillips, M.D.
Patrick M. Rao, M.D.
John R. Siner, M.D.
David A. Sparks, M.D.
Andrew P. Spillett, M.D.
David L. Wood, M.D.

All radioactive material authorized by this license for diagnostic nuclear cardiology:

Eduardo Balcells, M.D.
John Bertuso, M.D.
Gerald G. Blackwell, M.D.
Clair S. Hixson, M.D.
Gregory H. Miller, M.D.
Ann Jackson Smith, M.D.
Harrison D. Turner, M.D.

B. The Radiation Safety Officer for this license is Anthony Z. Cole, Ph.D., DABR.

C. The assistant Radiation Safety Officer for this license is Lisa M. Blankenship.

14. 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.

15. The survey meter shall be checked by a reference check source of long half-life, e.g. Cs-137. The reading shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

A. Before each use.
B. After each maintenance and/or battery change

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C. At least quarterly.

If any reading with the same geometry is not within ± 20% of the reading measured immediately after calibration, the instrument should be recalibrated.

16. In addition to the authorizations granted in 1200-2-10-.14(6)(b)(18), 1200-2-10-.14(6)(c)(5), 1200-2-10-.14(6)(d)(4), and 1200-2-10-.14(6)(e)(3), of "State Regulations for Protection Against Radiation," the licensee may possess and use prepared diagnostic and therapeutic 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).

17. 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.

18. 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.

19. 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 of 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 Tennessee Department of Environment and Conservation, Division of Radiological Health, L&C Annex – Third Floor, 401 Church Street, Nashville, Tennessee, 37243-1532, describing the equipment involved, the test results, and the corrective action taken.

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

19. Notwithstanding the periodic leak test required by Condition 19, 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.

20. The licensee shall not open sealed sources containing radioactive material.

21. 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."

22. The licensee is authorized to hold radioactive material with a physical half-life of 120 days or less for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as ordinary trash, radioactive waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. Records of each disposal made under this condition shall be retained for three years.

23. The licensee may use a shield device for performing linearity tests of his dose calibrator provided he or she follows the manufacturer's procedures for its use. These procedures shall be maintained for inspection by the Department.

24. The licensee is authorized to use Technetium 99m DTPA for lung aerosol studies. The licensee shall perform radiation surveys in conjunction with these studies and shall institute the use of any additional procedures or equipment to minimize exposure from radioactive material which may result from these studies. Records of these surveys shall be maintained for inspection by the Department.

25. The licensee may release patients who have been administered radiopharmaceuticals for therapy in accordance with the following requirements:

A. The licensee may authorize the release from its control any individual who has been administered radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem.[1]

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B. The licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem. If the total effective dose equivalent to a nursing infant or child could exceed 0.1 rem assuming there were no interruption of breast-feeding, the instructions must also include:

(1) Guidance on the interruption or discontinuance of breast-feeding; and
(2) Information on the potential consequences, if any, of failure to follow the guidance.

C. The licensee shall retain, for three (3) years after the date of release, a record that the instructions required by B were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 0.5 rem.

D. The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with C.

E. The authorized user shall sign, and the licensee shall retain, for three (3) years after the date of release, a record of the basis for authorizing the release of an individual, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;
(2) Using an occupancy factor less than 0.25 at 1 meter;
(3) Using the biological or effective half-life; or
(4) Considering the shielding by tissue.

F. The licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, for proper disposal of any resulting radioactive waste attributable to an individual's treatment performed by the licensee.

[1] Appendix O, "Release of Patients or Human Research Subjects Administered Radioactive Materials"

27. 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.

28. 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 the following:
- Application dated September 13, 2004, with attachments
- Letters dated July 12, 2004, with attachments, and September 21, 2004, with attachments.