NRC Form 374
(3-83)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 36

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93 - 438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, 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 byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Veterans Administration Medical Center	In accordance with application dated January 11, 1985,
2. 1310 - 24th Avenue, South Nashville, Tennessee 37203	3. License number 41-00104-04 is amended in entirety to read as follows:
	4. Expiration date July 31, 1990
	5. Docket or Reference No. 030-03250

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radio-pharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A.
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 5 curies of each byproduct material authorized in Subitem 6.B.
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radio-pharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C.
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radio-pharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D.

IN 20

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6. Byproduct, source and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 1 curie total for all sources authorized in Subitem 6.E.
F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	F. Any	F. 3 millicuries of each byproduct material authorized in Subitem 6.F.
G. Xenon 133	G. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA.	G. 3 curies
H. (1) Any byproduct material with atomic numbers 3-83 except as specified below	H. (1) Any	H. (1) 50 millicuries of each radionuclide with atomic numbers 3-83 with a total possession limit of 2 curies except as listed below

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6. Byproduct, source and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
H. (Cont'd)		
(2) Hydrogen 3	(2) Any	(2) 200 millicuries
(3) Iodine 125	(3) Any	(3) 150 millicuries

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

F. In-vitro studies.

G. Blood flow and pulmonary function studies.

H. Research and development as defined in Section 30.4(q), 10 CFR Part 30. Medical research. Tracer studies in humans as approved by a radioactive Drug Research Committee approved by the Food and Drug Administration (FDA).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities at 1310 24th Avenue, South, Nashville, Tennessee.

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(Cont'd) CONDITIONS

11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

12. A. Licensed material shall be used by, or under the supervision of, individuals designated by Medical Isotopes and Radiation Safety Committee, M. Reza Habibian, M.D., or Thomas Powers, M.D., Chairman.

B. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).

C. Phyicians designated to use licensed material in or on humans shall meet the training and experience criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980.

D. The Radiation Protection Officer for the activities authorized by this license is Jay Kumar, Ph.D.

13. Sealed sources containing licensed material shall not be opened.

14. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, 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.

(3) The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

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

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(Cont'd) CONDITIONS

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 Commission regulations. A report shall be filed within five (5) days of the test with the U.S. Nuclear Regulatory Commission, Region II, Division of Radiation Safety and Safeguards, Nuclear Materials Safety Section, 101 Marietta Street, Suite 2900, Atlanta, Georgia 30323, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

15. A. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

B. Notwithstanding the requirements of 10 CFR 35.14(b)(2), the licensee may receive Group III materials from Vanderbilt University provided the materials are distributed in accordance with an NRC or Agreement State License.

16. Experimental animals administered licensed materials or their products shall not be used for human consumption.

17. Licensed material shall not be used in products distributed to the public or in field applications where activity is released except as provided otherwise by specific condition of this license.

18. A. Individuals involved in operations which utilize, at any one time, more than 100 millicuries of Hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.

B. (1) Tritium shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 28 microcuries of tritium per liter when averaged over a calendar quarter.

(2) Urinalysis shall be performed at weekly intervals on all individuals who work in the restricted areas of facilities in which tritium is used. If the average concentration of tritium in urine for any single individual during a calendar quarter is less than 10 microcuries per liter, urinalysis may be performed on that individual at monthly intervals for the following calendar quarter and may continue at monthly intervals so long as the average concentration in the calendar quarter remains below 10 microcuries per liter. The urine specimen shall be collected on the same day of the week insofar as possible.

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(Cont'd) CONDITIONS

(3) A report of an average concentration in excess of the limit specified in B(1) above for any individual shall be filed, in writing, within thirty (30) days of the end of the calendar quarter with the Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the U. S. Regulatory Commission, Region II, Division of Radiation Safety and Safeguards, Nuclear Material Safety Section, 101 Marietta Street, Suite 2900, Atlanta, GA 30323. The report shall contain the results of all urinalyses for the individual during the calendar quarter, the cause of the excessive concentrations, and the corrective steps taken or planned to assure against a recurrence.

(4) Any single urinalysis which discloses a concentration of greater than 50 microcuries per liter shall be reported, in writing, within seven (7) days of the licensee's receipt of the results, to the Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the U. S. Regulatory Commission, Region II, Division of Radiation Safety and Safeguards, Nuclear Material Safety Section, 101 Marietta Street, Suite 2900, Atlanta, GA 30323.

19. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.

20. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

A. Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee, and

B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

C. Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

The licensee shall maintain for inspection by the Commission, copies of the written permission specified in subitem (a) above and of the license(s) specified in subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under subitem (a) above.

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(Cont'd) CONDITIONS

21. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days 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 ten (10) half-lives.

    B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

    C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

22. The licensee may use the Calicheck device for doing linearity tests of his dose calibrator provided he follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

23. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated January 11, 1985 and Model ALARA Program contained in Appendix O of Regulatory Guide 10.8 (Rev. 2) October 1980. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

EARL G. WRIGHT

Date JUL 22 1985 By Earl G Wright

Region II, Nuclear Materials
Safety Section
101 Marietta Street, Suite 2900
Atlanta, GA 30323

NRC Form 374A (8-82) U.S. NUCLEAR REGULATORY COMMISSION

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FOR THE U.S. NUCLEAR REGULATORY COMMISSION

EARL G. WRIGHT

Date JUL 22 1985

By Earl G Wright

Region II, Nuclear Materials
Safety Section
101 Marietta Street, Suite 2900
Atlanta, GA 30323

NRC FORM 218 (4 76) NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE: 7/15/85

TIME: ☐ A.M. ☐ P.M.

☐ INCOMING CALL ☒ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
E. Wright		

PERSON CALLED	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
Dr. Jay Kumar	VA Nashville	615-327-4751

CONVERSATION - X-5107

SUBJECT: General discussion about renewal application.

SUMMARY

1. Clasified that they will follow appendix O of Reg Guide 10.8 (Rev 1) October 1980.

2. Asked if RSO is a full time job at VA Nashville. Dr. Kumar works ½ days but is within Ten minutes and is on call for emergencies.

3. Ventillation system. Nuclear Medicine has hood for Xenon & for opening Therapeutic doses. Researchers each have hood facilites in their Lab. Only one experimenter is using amounts in the Millicurie range (I-125) VA Nash was inspected 2/25/85. No items of Non compliance. No program change.

REFERRED TO: License to be renewed as

ACTION REQUESTED: previously issued - WWD

☐ ADVISE ME OF ACTION TAKEN.

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE

NRC FORM 218 (4 76)