NRC Form 374
(3-83)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 70

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 July 27, 1984 3. License number 09-00239-06 is amended in its entirety to read as follows:
2. 1201 N.W. 16th Street Miami, Florida 33125	4. Expiration date August 31, 1990
	5. Docket or Reference No. 030-01343

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. 2 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.

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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. 300 millicuries 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 withdnawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA.	G. 200 millicuries
H. Calcium 45	H. Any	H. 11 millicuries
I. Carbon 14	I. Any	I. 35 millicuries
J. Cesium 137	J. Any	J. 1 millicurie
K. Cesium 137	K. Sealed source	K. 1 millicurie
L. Chromium 51	L. Any	L. 35 millicuries
M. Cobalt 60	M. Any	M. 10 millicuries
N. Hydrogen 3	N. Any	N. 500 millicuries
O. Iodine 125 or 131	O. Prepackaged Kits	O. 50 millicuries

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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
P. Krypton 85	P. Any	P. 10 millicuries
Q. Phosphorus 32	Q. Any	Q. 25 millicuries
R. Potassium 42	R. Any	R. 25 millicuries
S. Rubidium 86	S. Any	S. 5 millicuries
T. Sulfur 35	T. Any	T. 10 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. - T. Laboratory research, in vitro studies or instrument calibration.

CONDITIONS

10. Licensed material shall be used only at Veterans Administration Medical Center, 1201 N.W. 16th Street, Miami, Florida.

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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 listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

S.K.C. Chandarlapaty, M.D.	Groups I, II, III, IV and V Xenon 133 In vitro studies Subitems 6.H through 6.T for laboratory research (nonhuman use)
Frank Gollan, M.D.	Groups I, II, III, IV and V Xenon 133 In vitro studies Subitems 6.H through 6.T for laboratory research (nonhuman use)
Stephen P. Rosenthal, M.D.	Groups I, II, III, IV and V Xenon 133 In vitro studies Submitem 6.H through 6.T laboratory research (nonhuman use)
Komanduri K.N. Charyulu, M.D.	Group VI

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

C. The Radiation Protection Officer for the activities authorized by this license is Robert M. Cobb.

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

14. 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.

15. 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.

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16. 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.

17. 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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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.

18. 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.

19. 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.

20. 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 July 27, 1984, letter dated July 17, 1985 and ALARA Program dated June 9, 1982. 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

Date AUG 05 1985

By EARL G. WRIGHT
Earl G Wright
Region II, Nuclear Materials
Safety Section
101 Marietta Street, Suite 2900
Atlanta, GA 30323

J POTTER RES 1

Medical Center

1201 Northwest 16th Street
Miami FL 33125

Veterans Administration

In Reply Refer To: (17941: 030-01343)

July 18, 1985

NRC

85 JUL 26 P10:15

James J. Smith, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D. C. 20420

Dear Dr. Smith:

Enclosed is the additional information requested by NRC for renewal of NRC license.

I request that the original be sent to the Regional Office in Atlanta for action.

Sincerely,

T. C. DOHERTY
DIRECTOR

Enc:

for JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

7/22/85

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