Form NRC-374

U. S. NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSE

Amendment No. 37

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 1, Parts 30, 31, 32, 33, 34, 35, 36, 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); and to import such byproduct and source material. 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. Department of the Army Fitzsimons Army Medical Center and U. S. Army Medical Research and 2. Nutrition Laboratory Denver, Colorado 80240	In accordance with application dated March 6, 1979 3. License number 05-00046-13 is amended in its entirety to read as follows:
	4. Expiration date July 31, 1985
	5. Docket or Reference No.

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 radiopharmaceutical 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 radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C.

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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
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D.
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. 2 curies total for all sources authorized in Subitem 6.E.
F. Xenon 133	F. 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	F. 2 curies
G. Any byproduct material with Atomic Nos. 3 through 83, inclusive	G. Any	G. 500 millicuries of each byproduct material with Atomic Nos. 3 through 83, inclusive
H. Hydrogen 3	H. Any	H. 5 curies
I. Cesium 137	I. Any	I. 1 millicurie
J. Iodine 131	J. Thyroxine	J. 2 millicuries
K. Iodine 125	K. Thyroxine	K. 1 millicurie
L. Hydrogen 3	L. Water	L. 25 millicuries
M. Sodium 24	M. Sodium chloride	M. 1 millicurie

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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. For blood flow and pulmonary function studies.
G. through I. Research and Development as defined in Section 30.4(q), 10 CFR 30.
J. and K. Determination of thyroxine turnover.
L. Determination of total body water.
M. Determination of total exchangeable sodium.

CONDITIONS

10. Licensed material shall be used only at Fitzsimons Army Medical Center, 12101 East Colfax Avenue, Aurora, Colorado.

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. Licensed material shall be used by, or under the supervision of, individuals designated by FAMC Radioisotope Committee.

13. The use of licensed material in or on humans shall be by a physician.

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

15. 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, except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three 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) Except for alpha sources, 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.

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 5 days of the test with the U. S. Nuclear Regulatory Commission, Region IV, Office of Inspection and Enforcement, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76012, 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.

16. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.

B. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.

CONDITIONS

17. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), Title 10, Code of Federal Regulations, Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

18. The licensee shall not use licensed material in field applications except as provided otherwise by specific conditions of this license.

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

20. Patients containing Iodine 131 for the treatment of thyroid carcinoma shall remain hospitalized until the residual activity is 30 millicuries or less.

21. A. Technetium-99m separated from molybdenum-99 either by elution of a molybdenum-99/technetium-99m generator or by an extraction process shall be tested to detect and quantify molybdenum-99 activity prior to administration to patients.

B. 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.

C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Subitem B. above are detected.

D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

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2. Records described in Subitem E.1. above shall be maintained for two (2) years following the performance of the tests and the training of personnel.

22. 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 March 6, 1979 and letter dated June 3, 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.

Date JUL 1 1980

7-11-80

For the U. S. Nuclear Regulatory Commission

by Original Signed by
Richard A. Conte
Material Licensing Branch

Division of Fuel Cycle and
Material Safety
Washington, D.C. 20555