

MATERIALS LICENSE

Amendment No. 21

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. V. A. Medical Center		In accordance with application dated August 30, 1984
2. 4150 Clement Street San Francisco, California 94121		3. License number 04-00421-05 is amended in its entirety to read as follows:
		4. Expiration date November 30, 1990
		5. Docket or Reference No. 030-01214
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. (1) Any byproduct material with atomic numbers 3 - 83 except as specified below	A. (1) Any	A. (1) 500 millicuries of each radionuclide with atomic numbers 3 to 83. Total possession limit for Subitem A(1) not to exceed 2 curies
(2) Phosphorus 32	(2) Any	(2) 600 millicuries
(3) Iodine 125	(3) Any	(3) 650 millicuries
(4) Carbon 14	(4) Any	(4) 1 curie
B. Hydrogen 3	B. Any	B. 12 curies
C. Technetium 99m	C. Any	C. 2.5 curies
D. Molybdenum 99	D. Any	D. 2.5 curies
E. Americium 241	E. Sealed Sources	E. 10 curies
F. Cesium 137	F. Sealed Sources	F. 218 millicuries
G. Cobalt 60	G. Sealed Sources	G. 1 millicurie
H. Barium 133	H. Sealed Sources	H. 1 millicurie
9. Authorized use		
A. through E. Medical research, diagnosis and therapy including research in laboratory animals.		
F. through H. Instrument calibration.		

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10. Licensed material shall be used only at the V. A. Medical Center 4150 Clement Street, San Francisco, California.
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 the Medical Isotope Committee, R. R. Cavalieri, M.D., Chairman.
13. A.
 - (1) Each sealed source acquired from another person and 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 contamination and/or leakage prior to use. 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 materials 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. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. 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.

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- D. 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 or semipermanently 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.
- E. If the test required by Subsection A. or C. of this condition 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 V, Office of the Regional Administrator, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596, describing the equipment involved, the test results, and the corrective action taken.
14. Sealed sources containing licensed material shall not be opened.
15. 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.
16. 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.
17. Experimental animals administered licensed materials or their products shall not be used for human consumption.
18. Patients containing cobalt 60, cesium 137 or iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.
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.

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20. Radioactive gases as free gas or in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug, and Cosmetic Act.
21. The Radiation Protection Officer for the activities authorized by this license is Aramaies Tahmassian, Ph.D.
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 August 30, 1984 and letters dated September 26, 1985 and November 7, 1985. 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.
23. 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 technetium-99m to patients if the technetium-99m contains more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or if it contains 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 reasonable 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.
- (2) Records described in Subitem E. (1) above shall be maintained for three (3) years following the performance of the tests and the training of personnel.

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24. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions".



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

NOV 21 1985

Date

By

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