

## MATERIALS LICENSE

Amendment No. 18

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		In accordance with letter dated February 19, 1985	
1. Department of the Army Silas B. Hayes U. S. Army Hospital		3. License number	04-12727-02 is amended in its entirety to read as follows:
2. Fort Ord, California 93941		4. Expiration date	August 31, 1986
		5. Docket or Reference No.	030-08367
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. 3 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.	
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 Section 31.11(a) of 10 CFR 31	E. Any	E. 4 millicuries of each byproduct material authorized in Subitem 6.E.	

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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

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|------------------|---|---|
| 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. 100 millicuries  |
| G. Americium 241 | G. Sealed source (Amersham Corporation Model AMC.24)  | G. 30 millicuries (2 sources not to exceed 15 millicuries each) |

9. Authorized use

- A. An 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. In vitro studies, except iodination and tritium labeling procedures.
- F. Blood flow and pulmonary function studies.
- G. To be used in a Siemens Gammasonics, Inc. Dual Isotope Motion Correction Source Holder Model 035-42300C.

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10. Licensed material shall be used only at Silas B. Hayes Army Hospital; Fort Ord, 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. A. (1) Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Protection Committee.  
(2) The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).  
(3) Physicians 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 and as revised December 2, 1982 (47 FR 54376).  
B. The Radiation Protection Officer for the activities authorized by this license is Daniel Alan Boll, M.D.
13. The licensee shall include a cobalt 57 reference standard of one millicurie or more when performing dose calibrator accuracy and constancy tests.
14. The licensee shall open packages containing licensed material in accordance with the procedures set forth in Appendix F of Regulatory Guide 10.8: "Guide for the Preparation of Applications for Medical Programs", January, 1979.
15. Individuals who work in or frequent restricted areas shall be instructed in the items specified in 10 CFR 19.12 of the time of initial employment and at least annually thereafter.
16. Laboratory areas shall be surveyed for contamination in accordance with the frequency schedule set forth in Appendix I of Regulatory Guide 10.8: "Guide for the Preparation of Applications for Medical Programs", January, 1979.
17. Effluent from the xenon 133 charcoal trap shall be tested for the presence of xenon 133 at least monthly, in order to determine that the device is functioning properly and that filter saturation has not occurred.
18. 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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19. 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.
20. Sealed sources containing licensed material shall not be opened.
21. 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.
- 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 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.
- 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.
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 26, 1979; letters dated May 27, 1980, October 2, 1980 and March 23, 1981; Model ALARA Program contained in Appendix C of Regulatory Guide 10.8 (Rev.1), "Guide for the Preparation of Applications for Medical Programs", October 1980; and letters dated December 23, 1982, March 1, 1983, April 27, 1983, October 14, 1983, February 28, 1985, February 19, 1985, and May 10, 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.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 6 1985

By Beth A. Riedlinger  
Health Physicist (Licensing)  
Nuclear Materials Safety Section  
Region V