

MATERIALS LICENSE

Amendment No. 51

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 July 19, 1985
1. V. A. Medical Center		3. License number 32-01134-01 is amended in its entirety to read as follows:
2. Fulton Street and Erwin Road Durham, North Carolina 27705		4. Expiration date February 28, 1991
		5. Docket or Reference No. 030-02630
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, atomic no. 3-83, incl.	A. Any	A. 30 mCi, each atomic no. 3-83 total 10 curies
B. Iodine 131	B. Any	B. 300 mCi
C. Gold 198	C. Any	C. 150 mCi
D. Hydrogen 3	D. Any	D. 300 mCi
E. Carbon 14	E. Any	E. 700 mCi
F. Phosphorus 32	F. Any	F. 150 mCi
G. Iodine 125	G. Any	G. 800 mCi
H. Molybdenum 99	H. Any	H. 3 Curies
I. Technetium 99m	I. Any	I. 5 Curies
J. Xenon 133	J. Any	J. 200 mCi
K. Iridium 192	K. Any	K. 100 mCi
L. Americium 241	L. Any	L. 50 mCi
M. Uranium 238 (depleted in U-235)	M. Cadmium-plated metal	M. 160 kg
9. Authorized use		
A. through M. Medical research, diagnosis and therapy. Research and development as defined in Section 30.4(q), 10 CFR Part 30.		

CONDITIONS

10. Licensed material shall be used only at Veterans Administration Medical Center, Fulton Street and Erwin Road, Durham, North Carolina.

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11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Medical Isotope Committee, C. Craig Harris, Chairman.
- B. The use of licensed material in or on humans shall be by a physician as defined in Section 35.3(b) of 10 CFR Part 35.
- C. Physicians designated to use licensed material in or on humans shall meet the training criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980, and as revised December 2, 1982 (47 FR 54376).
- D. The Radiation Protection Officer for the activities authorized by this license is Conrad M. Knight.
12. A. (1) Each sealed source acquired from another person and containing licensed material, other than Hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before 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 before any use or transfer to another person unless they have been leak tested within 6 months before 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.

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- C. Each sealed source containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.
- 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. Records may be disposed of following Commission inspection.
- 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 5 days of the date the leak test result is known with the U. S. Nuclear Regulatory Commission, Region II, Division of Radiation Safety and Safeguards, Nuclear Material Safety Section, 101 Marietta Street, Suite 1900, Atlanta, Georgia 30325, describing the equipment involved, the test results, and the corrective action taken.
13. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR 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.
14. Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.
15. 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.
16. 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.

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17. For a period not to exceed 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 Radiation Safety Committee, and
 - B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and
 - C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

The licensee shall maintain for inspection by the Commission copies of the written permission specified in A. above, and of the license(s) specified in B. and C. above for a period of 5 years from the date permission is granted under A. above.

18. Radioactive gases as free gas or in solution to be administered to humans shall be procured from a supplier which distributes the product indicated for human use in accordance with the Federal Food, Drug, and Cosmetic Act.
19. Needles or standard medical applicator cells containing cobalt-60 as wire shall not be opened by the licensee.
20. Patients containing cobalt-60, cesium-137 or iridium-192 implants shall remain hospitalized until a source count and surveys made with a 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 5 years from the time the implants are removed.
21. 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.
22. 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 10 half-lives.

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B. Letters dated:

- January 31, 1986
- July 19, 1985
- July 30, 1984
- October 29, 1984
- July 24, 1980

C. Radioisotope Safety Manual

- Revised January 1980



Date FEB 28 1986

By

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