

MATERIALS LICENSE

Amendment No. 25

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.

"OFFICIAL RECORD COPY"

Licensee

1. New England Deaconess Hospital Corporation
2. 185 Pilgrim Road
Boston, Massachusetts 02215

In accordance with letter dated November 25, 1985,
3. License number 20-00289-07 is amended in its entirety to read as follows:

4. Expiration date February 29, 1992

5. Docket or Reference No. 030-01808

6. Byproduct, source, and/or special nuclear material

- A. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35
- B. Uranium (depleted in Uranium 235)
- C. Any byproduct material with Atomic Nos. 3 through 83, inclusive
- D. Hydrogen 3
- E. Phosphorus 32
- F. Molybdenum 99
- G. Technetium 99m
- H. Iodine 131
- I. Iodine 125
- J. Dysprosium 165
- K. Xenon 133

7. Chemical and/or physical form

- A. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35
- B. Cadmium plated metal
- C. Any
- D. Any
- E. Any
- F. Any
- G. Any
- H. Any
- I. Any
- J. Any
- K. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA
- L. Sealed sources
- M. Seeds or wires
- N. Seeds
- O. Microspheres

8. Maximum amount that licensee may possess at any one time under this license

- A. 7 curies total for all sources authorized in Subitem 6.A.
- B. 204 kilograms
- C. 100 millicuries of each byproduct material with Atomic Nos. 3 through 83, inclusive
- D. 1000 millicuries
- E. 100 millicuries
- F. 2.5 curies
- G. 2.5 curies
- H. 500 millicuries
- I. 200 millicuries
- J. 300 millicuries
- K. 1 curie

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- L. Cesium 137
- M. Iridium 192
- N. Gold 198
- O. Yttrium 90

- L. 6.5 curies
- M. 3.5 curies
- N. 1 curie
- O. 1 curie

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9. Authorized use

- A. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- B. For use as shielding in a linear accelerator.
- C. through O. Medical research, diagnosis and therapy. Research and development as defined in Section 30.4(q), 10 CFR 30.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities, 185 Pilgrim Road, Deaconess, Farr, Baker, and Palmer Buildings; Cancer Research Institute, 195 Pilgrim Road; Meissner Building, 198 Pilgrim Road; Lowry Building, 110 Francis Street; rooms except as specified in letter dated December 8, 1986, located in the Shields Warren Radiation Laboratory, 50 Binney Street; 5th Floor of Building, 21-27 Burlington Avenue, Boston, Massachusetts; and Medical and Technical Research Associates, Inc., 408/410 South Huntington Avenue, Jamaica Plain, Massachusetts.
- 11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee.
- 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, 1985 (47 FR 54376).
- D. The Radiation Safety Officer for this license is Philip Cobb, M.P.H.
- 12. A(1) Each sealed source or detector cell 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 or detector cell 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 or detector cell is exempt from such leak tests when the source or detector cell 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.

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CONDITIONS

- B. Each sealed source or detector cell fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source or detector cell. 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 or detector cell 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 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. The test may be conducted at 3 year intervals provided the sources have been authorized by the Commission (or an Agreement State) for a three year leak test interval.
- 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 detector cell or from the surfaces of the device in which the sealed source or detector cell 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 or detector cell 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 I, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406, describing the equipment involved, the test results, and the corrective action taken.
13. 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.
- B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall 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.

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CONDITIONS

14. Experimental animals administered licensed materials or their products shall not be used for human consumption.
15. 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.
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.
17. The licensee may use the Calicheck device for ~~doing~~ linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.
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.
19. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices in Items 7.C. through 7.H. received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.
20. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".
21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

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CONDITIONS

- A. Application dated January 3, 1979
- B. Letter dated March 11, 1980
- C. Letter dated November 6, 1980
- D. Letter dated April 24, 1981
- E. Letter dated June 30, 1981
- F. Letter dated February 4, 1983
- G. Letter dated April 29, 1984
- H. Letter dated September 19, 1984
- I. Letter dated July 11, 1985
- J. Letter dated November 25, 1985, Items 2 through 11
- K. Letter dated August 11, 1986
- L. Letter dated September 4, 1986
- M. Letter dated September 15, 1986
- N. Two letters dated December 8, 1986

For the U.S. Nuclear Regulatory Commission

Original Signed By:

John E. Glenn

Date

FEB 17 1987

By

Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406