NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 12

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. Marshfield Clinic	In accordance with application dated November 15, 1983 3. License number 48-10966-03 is amended in its entirety to read as follows:
2. 1000 North Oak Avenue Marshfiled, WI 54449	4. Expiration date: July 31, 1990
	5. Docket or Reference No.: 030-08688

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. 6.0 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 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. 4.0 curies total for all sources 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
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. 3.0 curies
G. Any byproduct material with Atomic Nos. between 3 and 83, inclusive	G. Any	G. 200 millicuries of each byproduct material with Atomic Nos. between 3 and 83 inclusive except as stated below
H. Gold-198	H. Any	H. 350 millicuries
I. Hydrogen-3	I. Any	I. 30 millicuries
J. Hydrogen-3	J. Foil	J. 150 millicuries
K. Uranium (Depleted in U-235)	K. Cadmium plated metal	K. 91 kilograms

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.

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9. Authorized Use (cont'd)

E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

F. Blood flow studies. Pulmonary function studies.

G. Through I. To be used for research and development as defined in 10 CFR, Section 30.4(q).

J. To be used in a gas chromatograph for sample analysis.

K. To be used as shielding in linear accelerator.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1000 N. Oak Avenue, Marshfield, Wisconsin; St. Joseph Hospital, 611 St. Joseph Avenue, Marshfield, Wisconsin; and Marshfiled Medical Foundation, 510 N. St. Joseph Avenue, Marshfield, Wisconsin.

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. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Robert Greenlaw, M.D., Chairman.

B. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).

C. 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.

D. The Radiation Protection Officer for the activities authorized by this license is Robert Peterson.

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 material or 10 microcuries or less of alpha emitting material.

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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.

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 III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, describing the equipment involved, the test results, and the corrective action taken.

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

15. Detector cells containing licensed material shall not be opened or the foil sources removed from the detector cell by the licensee.

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. 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.

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

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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.

20. 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.

21. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

22. Pursuant to Sections 20.106(b) and 20.302, 10 CFR 20, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR 20.

23. 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 November 15, 1983; letters dated July 7, 1982, April 12, 1985, May 16, 1985; and ALARA Program dated August 15, 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.

For the U.S. Nuclear Regulatory Commission

Original Signed
By William J. Adam, Ph.D.
Materials Licensing Section, Region III

Date June 28, 1985

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