MATERIALS LICENSE

Amendment No. 40

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. St. Joseph's Hospital	In accordance with letter received July 1, 1985 3. License number 13-00418-02 is amended in its entirety to read as follows:
2. 700 Broadway Ft. Wayne, IN 46802	4. Expiration date: October 31, 1990
	5. Docket or Reference No.: 030-01581

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 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. 1 curie total for all sources authorized in Subitem 6.E
F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	F. Prepackaged kits	F. 3 millicuries of each byproduct material authorized in Subitem 6.F

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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
G. Xenon-133	G. 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	G. 500 millicuries
H. Gadolinium-153	H. Sealed sources (Lunar Radiation Corp. Model GD Series)	H. 3 curies (2 sources not to exceed 1.5 curies each)
I. Iodine-125	I. Sealed sources (AECL Model Nos. C-235, C-324 in C-236 source holder)	I. 600 millicuries (2 sources not to exceed 300 millicuries each)

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.

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

F. In vitro studies.

9. Authorized Use (cont'd)

G. Blood flow studies. Pulmonary function studies.

H. One source to be used in a Lunar Radiation Corp. Model DP3 bone mineral analyzer for analysis of bone mineral content in humans. One source to be stored in its shipping container for source replacement purposes.

I. One source to be used in a Lunar Radiation Corp. Model SP2 bone mineral analyzer for analysis of bone mineral content in humans. One source to be stored in its shipping container for source replacement purposes.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 700 Broadway, Fort Wayne, Indiana.

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 listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Fouad Halaby, M.D.	Groups I, II, III, IV, V and VI Xenon-133 *In vitro* studies Gadolinium-153 and Iodine-125 in bone mineral analyzers
Richard Baumann, M.D.	Groups I, II and III Xenon-133 Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction
John Pasalich, M.D.	Groups I, II and III Xenon-133 Gadolinium-153 and Iodine-125 in bone mineral analyzers Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction
David Sorg, M.D.	Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction.

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Stephen R. Phillip, M.D.	Groups I, II and III Xenon-133 In vitro studies Gadolinium-153 and Iodine-125 in bone mineral analyzers Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction
Marc Thomas, M.D.	Groups I, II and III Xenon-133 In vitro studies Gadolinium-153 and Iodine-125 in bone mineral analyzers Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction

13. For a period not to exceed sixty (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 its Medical Isotopes Committee, and

    (b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

    (c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

    The licensee shall maintain for inspection by the Commission, copies of the written permission specified in Subitem (a) above and of the license(s) specified in Subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under Subitem (a) above.

14. 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.

15. 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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16. 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.

17. 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 January 29, 1980; letters dated March 28, 1980 and September 26, 1985; letter received May 28, 1985; and ALARA Program contained in letter dated September 26, 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 OCT 11 1985

Original Signed
By Cassandra McDonald
Materials Licensing Section, Region III

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