MATERIALS LICENSE

Amendment No. 23

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 CO

Licensee	
1. Mercy Hospital	In accordance with application dated March 15, 1985 3. License number 37-00897-01 is amended in its entirety to read as follows:
2. 25 Church Street Wilkes-Barre, Pennsylvania 18765	4. Expiration date June 30, 1990
	5. Docket or Reference No. 030-02971

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. 2 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 Section 31.11(a) of 10 CFR 31	D. Prepackaged kits	D. 3 millicuries of each byproduct material authorized in Subitem 6.D.
E. Xenon 133	E. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed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	E. 200 millicuries

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(continued)

F. Americium 241	F. Sealed Source (Amersham Model No. AMC.24)	F. 14 millicuries
G. Iodine 131	G. Iodomethylnorcholesterol	G. As necessary for use authorized in item 9.G.

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, 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. In vitro studies.
E. Blood flow and pulmonary function studies.
F. For use in Searle Analytic Model SS-10244 Anatomical Marker.
G. Adrenal imaging in accordance with IND 21,805.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities, Mercy Hospital, 25 Church Street, Wilkes-Barre, Pennsylvania.

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:

Salvator Imperiale, M.D.	Groups I, II, III and IV In vitro studies Xenon 133 Iodine 131 as Iodomethylnorcholesterol Americium 241 as an anatomical marker
Juan Gaia, M. D.	Groups I, II, III and IV In vitro studies Xenon 133 Iodine 131 as Iodomethylnorcholesterol Americium 241 as an anatomical marker
Champak M. Dedhia, M.D.	Groups I, II and III In vitro studies Xenon 133 Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction Americium 241 as an anatomical marker

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(12. continued) CONDITIONS

Ron Konecke, M.D.

Groups I, II and III
In vitro studies
Xenon 133
Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction
Americium 241 as an anatomical marker

13. 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.

14. 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 the 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.

15. 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.

16. 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. 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.

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(16. continued) CONDITIONS

(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.

(3) 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 prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

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.

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 5 days of the test with the U. S. Nuclear Regulatory Commission, Region I, 631 Park Avenue, King of Prussia, Pennsylvania 19406, 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.

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

18. Notwithstanding the requirements of Section 35.14(b) of Title 10, Code of Federal Regulations, the licensee may receive Iodine 131 as iodomethylnorcholesterol from the University of Michigan, Ann Arbor, Michigan.

19. The licensee shall notify the U.S. Nuclear Regulatory Commission within thirty days of the termination of IND 21,805.

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(continued) CONDITIONS

20. 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 15, 1985 and letters dated August 10, 1981, October 15, 1981 and May 17, 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 17 1985

By Original Signed By:
John D. Kinneman
Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406