Form NRC-374

cy Charles Norrenberg

U. S. NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSE

Amendment No. 04

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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 1, Parts 30, 31, 32, 33, 34, 35, 36, 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); and to import such byproduct and source material. 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. The Lutheran Hospital of Fort Wayne, Inc. 2. 3024 Fairfield Avenue Fort Wayne, Indiana 46807	In accordance with letter dated May 28, 1980 3. License number SNM-1551 is amended in its entirety to read as follows:
	4. Expiration date June 30, 1985
	5. Docket or Reference No. 070-01993

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. Plutonium (Principal radionuclide Pu-238)	A. Sealed sources	A. 15 grams (60 individual sources not to exceed 250 milligrams each)
B. Plutonium (Principal radionuclide Pu-238)	B. Sealed sources	B. 2.25 grams (10 individuals sources not to exceed 225 milligrams each)
C. Plutonium (Principal radionuclide Pu-238)	C. Sealed sources	C. 1.5 grams (10 individual sources not to exceed 150 milligrams each

9. Authorized use

A. Implantation in humans as a component of Coratomic Model C-101 nuclear-powered cardiac pacemakers for clinical evaluation purposes. This license also authorizes possession of Coratomic Model C-100 pacemakers for explantation, recovery and disposal but not for reimplanation.

B. Implantation in humans as a component of Cordis Nuclear Omni-Stanicor Model 184A nuclear-powered cardiac pacemakers for clinical evaluation purposes.

C. Implantation in humans as a component of Medtronic Model 9000 nuclear-powered cardiac pacemakers for clinical evaluation purposes.

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Supplementary Sheet

License Number SNM-1551

CONDITIONS

Docket or Reference No. 070-01993

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10. Licensed material shall be used only at The Lutheran Hospital of Fort Wayne, Inc., 3024 Fairfield Avenue, Fort Wayne, Indiana.

11. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients or otherwise in use.

12. The licensee shall not receive or transfer in any single transaction, 1 gram or more of plutonium 238 contained in nuclear-powered pacemakers without notifying the Division of Safeguards, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, and, in addition, completing and distributing Form NRC-741 as required by Section 70.54 of 10 CFR Part 70.

13. The licensee shall report to the Material Licensing Branch, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, within 24 hours of occurrence, the death of any nuclear pacemaker patient, and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. A written report giving details of the adverse reaction and/or malfunction shall be submitted within 30 days.

14. The licensee shall report to the Material Licensing Branch, U.S. Nuclear Regulatory Commission, Washington, D. C. 20555, within 10 days, loss of contact with a nuclear pacemaker patient.

15. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient; and procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.

16. 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 letter dated April 21, 1975 signed by E. Dan Butz, Assistant Vice President and August N. Tomusk, M.D.; letter dated June 24, 1975 signed by E. Dan Butz, Assistant Vice President; letter dated August 19, 1976 signed by R. E. Gilliland; letter dated March 1, 1977 signed by August N. Tomusk, M.D.; and letter dated May 28, 1980 signed by Richard E. Gilliland, Senior Vice President. 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.

JUN 18 1980

Date

For the U. S. Nuclear Regulatory Commission

Patricia Vasca

by Material Licensing Branch

Division of Fuel Cycle and Material Safety
Washington, D.C. 20555