

## MATERIALS LICENSE

Amendment No. 05

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. The Lutheran Hospital of  
Fort Wayne, Inc.
2. 3024 Fairfield Avenue  
Fort Wayne, IN 46807

In accordance with letter dated  
April 25, 1985

3. License number SNM-1551 is amended in its  
entirety to read as follows:

4. Expiration date June 30, 1990

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 source

A. One source not  
to exceed 250  
milligrams

B. Plutonium (Principal  
radionuclide Pu-238)

B. Sealed source

B. One source not  
to exceed 250  
milligrams

C. Plutonium (Principal  
radionuclide Pu-238)

C. Sealed source

C. Two sources not  
to exceed 150  
milligrams

9. Authorized Use

- A. As a component of Coratomic Model C-101 nuclear-powered cardiac pacemaker for clinical evaluation purposes. This license authorizes possession of the pacemaker for purposes of explantation, recovery and disposal, but not for implantation.
- B. As a component of Coratomic Model C-100 nuclear-powered cardiac pacemaker for clinical evaluation purposes. This license authorizes possession of the pacemaker for purposes of explantation, recovery and disposal, but not for implantation.
- C. As a component of Medtronic Model 9000 nuclear-powered cardiac pacemakers for clinical evaluation purposes. This license authorizes possession of the pacemakers for purposes of explantation, recovery and disposal, but not for implantation.

CONDITIONS

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

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**MATERIALS LICENSE**  
**SUPPLEMENTARY SHEET**

License number

SNM-1551

Docket or Reference number

070-01993

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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 report to the Material Licensing Branch, U. S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Washington, D.C. 20555, within twenty-four (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 thirty (30) days.
13. The licensee shall report to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555, within ten (10) days, loss of contact with a nuclear pacemaker patient.
14. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.
15. 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.; letter dated May 28, 1980 signed by Richard E. Gilliland, Senior Vice President; and letter dated April 25, 1985 signed by William W. Wissman, Interim 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.



For the U.S. Nuclear Regulatory Commission

Original Signed

By B.J. Holt

Materials Licensing Section, Region III

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Date May 31, 1985