

MATERIALS LICENSE

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. Ponce District Hospital	3. License number	SNM-1951
2. Machuelo Road 14 Ponce, Puerto Rico 00731	4. Expiration date	May 31, 1990
	5. Docket or Reference No.	SNM-1363 070-01336/070-03019
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 in cardiac pacemaker	A. One source not to exceed 150 milligrams (2.5 curies in 1972)
9. Authorized use		
A. Implantation in humans as a component of Medtronic Model 9000 nuclear-powered cardiac pacemaker for clinical evaluation. (Note: The device is already implanted in a patient. This license is for patient follow-up.)		

CONDITIONS

10. Licensed material shall be used only at Ponce District Hospital, Machuelo Road 14, Ponce, Puerto Rico.
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. 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.
13. The licensee shall not receive or transfer in any single transaction one (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 70.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

SNM-1363

Docket or Reference number

070-01336

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CONDITIONS

14. 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.
15. 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.
16. 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.
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 listed below. 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.
- A. Application(s) dated:
- (1) April 25, 1985 signed Evelyn Cintron Ruiz, M.D.
 - (2) Application enclosed with letter dated October 6, 1972.
- B. Letter(s) and attachments thereto dated:
- (1) May 29, 1973 signed Mr. Angel Franceschi
 - May 29, 1973 signed Dr. Rodriguez
 - October 6, 1972 signed Dr. Hector F. Rodriguez

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

EARL G. WRIGHT

Date MAY 30 1985

By

Earl G. Wright
Region II, Nuclear Materials
Safety Section
101 Marietta Street, Suite 2900
Atlanta, GA 30323