

Medtronic, Inc.  
3055 Old Highway Eight  
P.O. Box 1453  
Minneapolis, MN 55440 USA  
Telephone: (612) 574-4000  
Cable: Medtronic Telex: 29-0598

June 26, 1985

Dr. Bruce Mallett  
Materials Licensing Section  
U.S. Nuclear Regulatory Commission  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

Gentlemen:

The purpose of this letter is to apply for renewal of License SNM-1156 initially granted September 30, 1969. This license expires June 30, 1985. Information for license renewal as specified in Title 10 CFR §70.21, §70.22 and §70.33 is provided below or incorporated by references to the license and amendments. Seven copies of this license renewal application are enclosed.

1) Applicant

Medtronic, Inc.  
3055 Old Highway Eight  
P. O. Box 1453  
Minneapolis, Minnesota 55440

Applicant	July 9th
Check No.	570529
Amount/Fee	\$350
Type of Fee	Ren
Date Check Recd.	7/18/85
Received By	CP

Medtronic, Inc. is incorporated in the State of Minnesota with Corporate Headquarters at the address listed above. Principal Officers of the Corporation and their residential addresses are as follows:

Earl Bakken  
5424 West Bavarian Pass  
Fridley, MN 55432

Richard Sauter  
205 Kentucky Avenue North  
Golden Valley, MN 55427

Raymond Dittrich  
685 Old Long Lake Road  
Wayzata, MN 55391

Donald Stone  
1721 Canyon Lane  
New Brighton, MN 55112

Richard Fast  
5656 Woodcrest Drive  
Edina, MN 55424

Michael Boris  
18205 Third Avenue North  
Plymouth, MN 55447

Lowell Jacobsen  
6750 Olde Sturbridge  
Hamel, MN 55340

Franklin Rick  
15879 Tonkawood Drive  
Minnetonka, MN 55343

Dale Olseth  
132 Homedale Road  
Hopkins, MN 55343

John Pfouts  
5912 Schaefer Road  
Edina, MN 55436

Gerard Planchon  
4701 Golf Terrace  
Edina, MN 55424

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PDR

REGION III CONTROL NO. 7 927 7

With the exception of Mr. Gerard Planchon who is a citizen of France, all principal officers are U.S. citizens.

No control or controlling stock ownership is exercised over Medtronic, Inc. by any alien, foreign corporation or foreign government.

2) Activity for Which the Special Nuclear Material is Requested

Sealed plutonium sources are used as a power source for a cardiac pacemaker, specifically the Medtronic® Model 9000. Medtronic, Inc. no longer manufactures or sells nuclear powered cardiac pacemakers. License renewal is requested for the possession of sealed plutonium sources where the primary activity is associated with the receiving, analyzing and storing of explanted pacemakers. No tests or other activities will be performed that will in any way compromise the containment of the encapsulated plutonium source.

As described in our license (SNM-1156) and amendments, analysis and storage of sealed nuclear sources and nuclear powered cardiac pacemakers will occur at the following locations:

Rice Creek Facility  
7000 Central Avenue  
Minneapolis, MN 55432

Research Facility  
1500 Northdale Blvd.  
Minneapolis, MN 55433

The following facility is no longer being used for analysis and storage of sealed nuclear sources and nuclear powered pacemakers:

St. Anthony Facility  
3055 Old Highway Eight  
Minneapolis, MN 55418

Also, as described in our license and amendments, we are allowed to store one Medtronic Model 9000 pacemaker at each of seven of our District Offices. This was done to minimize delays and uncertainties in shipping these pacemakers to physicians and their patients. Medtronic wishes to retain storage capability at the District Offices listed below to provide a way-station, if necessary, in the return of explanted nuclear pacemakers to Medtronic's facilities in Minneapolis. The District Offices are:

Medtronic, Inc.  
Executive Place V, Suite 204  
60 Mall Road  
Burlington, MA 01803

Medtronic, Inc.  
1 Summit Square, Suite 102  
Langhorn, PA 19047

Medtronic, Inc.  
1901 North Moore Street, Suite 802  
Arlington, VA 22209

Medtronic, Inc.  
29100 Northwestern Highway, Suite 265  
Southfield, MI 48034

Medtronic, Inc.  
23811 Chagrin Blvd., Suite 335  
Beachwood, OH 44122

Medtronic, Inc.  
205 West Grand Avenue, Suite 103  
Bensonville, IL 60106

Medtronic, Inc.  
111 Westport Plaza, Suite 1015  
St. Louis, MO 63146

3) Time Period of License

License renewal is requested for a period of five (5) years through June 30, 1990.

4) Name, Amount and Specifications of Nuclear Material

The plutonium sources (Alcatel-GIPSIE) contain Pu<sup>238</sup> as the principle isotope. Possession limit under license SNM-1156 is 125 grams total with no more than 1 gram Pu<sup>238</sup> per source. It is requested that this limit be continued.

Detailed information with respect to the chemical and physical form of plutonium sources has been supplied previously under license SNM-1156 (Docket No. 70-1209).

5) Qualification of Applicant

Medtronic has had over ten years of experience in the design, manufacture and testing of implantable nuclear powered cardiac pacemakers.



Mr. Thomas Hawkinson is the Radiation Safety Officer for Medtronic. His qualifications are provided in Attachment 1. Current members of the Radiation Safety Committee are as follows: Thomas Hawkinson, Chairman and Radiation Safety Officer; Charles Swanson, Ph.D., Director of Regulatory Affairs; Kenreth Kopesky, Manager of Product Analysis; Richard Holm, Manager of Configuration Assurance; and Rama Padmanabhan, Staff Scientist.

All Medtronic personnel responsible for the handling and testing of sealed nuclear sources and nuclear powered pace-makers have been instructed in proper handling and storage procedures as required by our License (SNM-1156).

6) Equipment and Facilities

Facilities in which sources are held and equipment used in monitoring and measuring are described in license SNM-1156 and amendments.

7) Procedures to Protect Health and Minimize Danger

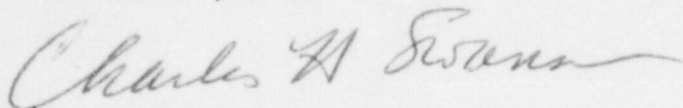
Security precautions and monitoring procedures to protect health and minimize danger to life or property are described in license SNM-1156 and amendments.

As required by 10 CFR 170, a check for \$350 is enclosed as the renewal fee for this license renewal application.

Communications with respect to this application for license renewal should be directed to Charles H. Swanson, Ph.D. at the telephone number listed below.

Sincerely,

MEDTRONIC, INC.



Charles H. Swanson, Ph.D.  
Director, Regulatory Affairs  
(612) 574-3409

cvs  
Att.

## CURRICULUM VITAE

Attachment 1

THOMAS E. HAWKINSON  
4349 McLeod Street N.E.  
Columbia Heights, MN 55421

Home Telephone: (612) 789-4832  
Office Telephone: (612) 574-3655

### PROFESSIONAL EXPERIENCE:

MEDTRONIC, INC., Minneapolis, Minnesota

January 1985 to Present

#### Health, Safety and Environmental Affairs Administrator

Duties include management of corporate health, safety and environmental strategy and program. Radiation Safety Officer for sealed and non-sealed isotopic sources and nonisotopic sources, including SNM Licenses 1156.

MEDTRONIC, INC., Minneapolis, Minnesota

July 1978 to December 1984

#### Industrial Hygienist

Duties include industrial hygiene assessments of workplace hazards, design of engineering controls, coordination with other corporate health services, radiation surveys for isotopic and nonisotopic sources of radiation in the plant, and advising line managers on proper disposition of nuclear materials. Radiation Safety Officer, NRC SNM 1156.

UNIVERSITY OF MINNESOTA

Department of Environmental Health

September 1977 to August 1978

#### Teaching Assistant

Duties included lecturing, supervising laboratories, preparing and correcting problem sets, labs, and examinations, and planning coursework for Environmental Health faculty.

### EDUCATION:

UNIVERSITY OF MINNESOTA, School of Public Health  
Minneapolis, Minnesota 55455

1978

Master of Science in Environmental Health

Coursework included concepts of health physics, radiation measurements and dosimetry, and environmental radioactivity.

ST. OLAF COLLEGE, Northfield, Minnesota 55057

1974

B.A., Chemistry

### PUBLICATIONS AND PRESENTATIONS:

Fruland, J.E., R.C. Patterson, T.E. Hawkinson, "Evaluation of Two Ethylene Oxide Monitors for Interference by Selected Organic Solvents," American Industrial Hygiene Conference, Las Vegas, Nevada, May, 1985.

Pollock, R.A., T.E. Hawkinson, "Implementing a Hazard Communication Program," American Industrial Hygiene Conference, Las Vegas, Nevada, May, 1985.

Korpela, D.B., T.E. Hawkinson, "Surface Contamination Effects on Organic Vapor Monitors," American Industrial Hygiene Conference, Las Vegas, Nevada, May, 1985.

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Korpela, D.B., C.E. McJilton, and T.E. Hawkinson, "Ethylene Oxide Dispersion from Gas Sterilizers," American Industrial Hygiene Association Journal, August 1983.

"Auxiliary Air Hood Field Evaluation," American Industrial Hygiene Conference, Philadelphia, Pennsylvania, May 1983.

"Radiation Aspects of Industrial Hygiene," University of Minnesota, Minneapolis, Minnesota, February 1983.

Hawkinson, T.E. and D.E. Barber, "The Industrial Hygiene Significance of Small Air Ions," American industrial Hygiene Association Journal, October 1981.

"The Industrial Hygiene Significance of Small Air Ions," American Industrial Hygiene Association Conference, Houston, Texas, May 1980.