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August 7, 1969

Aedtronic Inc.

3055 OLD HIGHWAY EIGHT. MINNEAPOLIS. MINNESOTA 55418 AREA 612/781-6061

Director Division of Materials Licensing U.S. Atomic Energy Commission Washington, D. C. 20545

SUBJECT: SPECIAL NUCLEAR MATERIALS LICENSE FOR MEDTRONIC, INC.

BASIC SNM-1156 Drb. 9-30-69

Dear Sir:

Medtronic, Inc. submits this application for a license to handle encapsulated special nuclear material at our plant located at 3055 Old Highway Eight, Minneapolis, Minnesota 55418.

Communication concerning this application should be directed to Donald R. Stone, Patent Counsel for Medtronic, Inc. To expedite action on this license, it is requested that questions and need for any additional information be conveyed by telephone. Our number is (612) 781-6061. Mr. Stone's extension is 440.

This application requests licensing for five years to receive, possess, use and ship encapsulated Pu^{238} sources each containing a maximum of one gram of Pu^{238} with a possession limit of 20 grams of plutonium.

The attached supporting material is submitted for your consideration for this special nuclear materials license. Details concerning the encapsulated sources are being supplied, under separate cover, directly to the AEC by the Donald W. Douglas Laboratories, a Directorate of the McDonnell Douglas Astronautics Company, Richland, Washington 99352, the manufacturer of the source.

Sincerely,

MEDTRONIC, INC.

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Thomas E. Holloran Executive Vice-President & Secretary

TEH:DRS:mg

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APPLICATION FOR LICENSE BY AEC FOR SPECIAL NUCLEAR MATERIAL

BY

MEDTRONIC, INC., MINNEAPOLIS, MINNESOTA 55418

Medtronic, Inc. requests licensing for five years to receive, possess, use, and ship sealed plutonium sources each containing a maximum of one gram of plutonium-238, with a possession limit of 20 grams of plutonium having Pu²³⁸ as the principal isotope. Medtronic, Inc. is incorporated in the State of Minnesota with corporate headquarters at 3055 Old Highway Eight, Minneapolis, Minnesota 55418. This is the location at which the special nuclear material will be used.

The officers of the corporation and their residential addresses are as follows:

Earl E. Bakken, President 639 Driftwood Circle New Brighton, Minnesota 55112

Palmer J. Hermundslie, Vice-President 2816 Coolidge Street Northwest Minneapolis, Minnesota 55418

Thomas E. Holloran, Executive Vice-President & Secretary Route 4, Box 34 Excelsior, Minnesota 55331 Leslie F. Kotval, Vice President & Treasurer 4205 Stinson Boulevard Minneapolis, Minnesota 55421

Charles F. Cuddihy, Jr., Vice-President of Marketing 16993 Chiltern Hills Drive Minnetonka, Minnesota 55343

Lawrence Perlman, Assistant Secretary 1930 Girard Avenue South Minneapolis, Minnesota 55403

Statement of Citizenship of the Officers: Attachment 1 contains a proxy statement and other information establishing control and ownership of Medtronic, Inc. All of the officers of Medtronic, Inc. are U.S. citizens. No control or controlling stock ownership is exercised over Medtronic, Inc. by any alien, foreign corporation or foreign government.

Personnel

The Executive Engineering Director directs the research and development programs that will be utilizing the Pu²³⁸ heat sources. He will be chairman of a Radiation Safety Committee with four additional members (i.e., the Building Security Officer, Radiation Safety Officer, Director of Product Integrity, and Manager of Applied Research) who will review all use of the material and procedures governing this use, location, security, and radiological safety of the sources. They will meet as needed at a minimum of once a quarter.

Mr. Joel Dennis Hixson will be the Project Engineer and will serve as Radiation Safety Officer for Medtronic, Inc. His qualifications are listed in Attachment 2.

The following organization illustrates the management chain and responsibility for the safe use of the special nuclear material.



Development Program and Technical Data

The sealed plutonium sources will be used in a research and development program to utilize Pu²³⁸ to reliably supply energy to power cardiac pacemakers. The initial program involves life tests of cardiac pacemakers powered by these sources. These devices will be submerged in a saline tank and their output monitored. Additional devices will be subject to tests with prototype power converters and pacemaker units. No test will be performed that will in any way compromise the containment provided by the encapsulation. The encapsulated plutonium source as supplied by the manufacturer is illustrated in Figure 1.

According to the manufacturer, the plutonium sources meet the following specifications:

The primary encapsulation is a 30-mil tantalum-10% tungsten wall with 40-mil end caps that is electron beam welded (100% penetration). The welded capsule is pressurized with helium, then tested with a helium leak detector at a sensitivity - 3 -

of 10⁻¹⁰ cc/sec STP. In addition, the primary encapsulation is checked by ultrasonic techniques to ensure maximum weld penetration and freedom from flaws in the encapsulation material. The primary containment is designed and tested to ensure that it will not rupture under any conditions likely to be met in use and testing.

The primary capsule is then inserted into a second containment vessel which, in turn, is welded shut, insulated, and welded into a stainless steel jacket which serves as the final containment.

The chemical form of plutonium will be PuO_2 which has a melting point of 22300 \pm 80°C. The PuO_2 is in the physical form of a pressed pellet.

Radiation Control Program

The contact dose rate from the device is less than 100 mRem/hr. The accumulated whole body dose to any individual required to accomplish the testing will be less than the 500 mRem/year permitted by part 20.105 of the Code of Federal Regulations without dosimetry. Dosimeters will be located in the room with the devices to establish the maximum dose that could be received by a person occupying the location 100% of the time.

The sources will be smear checked at least once every three months using a calibrated alpha detection instrument. If radiation is detected, the source will be placed in the shipping container and sealed. Radiological assistance can be obtained locally from the 3M Company in St. Paul and the Donald W. Douglas Laboratories, Richland, Washington, manufacturer of the sources.

The Radiation Safety Officer will be responsible for the following:

- 1. Establishing procedure to ensure that the radiation dose to personnel does not exceed 500 mRem/year.
- Establishing emergency procedures to be followed in case of an encapsulation failure or fire involving a plutonium source.
- 3. Providing training of personnel to ensure safe handling and storage of the source and on the action required if a source encapsulation failure occurs.
- 4. Establishing accountability for the sources to prevent naive or unauthorized handling.
- 5. Establishing a routine radiation control program with a minimum of quarterly inspection and smear test of each source.

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The sources will be tested and stored in the location shown in Attachment 3 (a floor plan of the facilities in which the sources are to be used). This location can be isolated from unauthorized personnel and the storage room locked when unattended. The walls, ceiling and floor of the location are concrete or cement block, and it contains automatic fire detection equipment. Off-shift, the location is checked by Plant Security, and access to the area marked on Attachment 3 is under control of Plant Security. The entrances to the room or rooms having a radioactive source shall be identified with a Caution - Radioactive Material sign as required by regulations. Each device containing a source will be identified as radioactive in such a manner as to be visible on the exterior surface of the device.

QUALIFICATIONS OF RADIATION SAFETY OFFICER

Joel Dennis Hixson

BS ME University of North Dakota -- 1968 MS ME University of North Dakota -- 1969

Major in Mechanical Engineering Minors in Nuclear Engineering & Physics

Experience Summary

Graduate Teaching Assistant -- 1966-1969 Summer Employment:

1967 & 1968 - Nuclear Power Div., Bremerton Shipyard 1966 - Webster Foster & Weston Engineer

Master Degree Thesis:

"Effects of Calcining Time and Temperature on Radioactive Waste Material"

Object: Optimize properties of radioactive wastes for use in Isotopic power sources

Member: American Nuclear Society (since 1966)



Figure 1. Isomite $_{TM}$ C Series Power Section