



MERCY

Hospitals & Health
Services of Detroit

P.O. Box 35-945, Detroit, MI 48235

A Division of the Sisters of Mercy Health Corporation

June 23, 1988

U.S. Nuclear Regulatory Commission
Region III
Material Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Subject: Renewal of NRC License #SNM-1374

Dear Sir:

I am writing this letter to request renewal of the NRC License #SNM-1374 currently held by Mount Carmel Mercy Hospital.

The hospital name and mailing address should be listed on the license as follows:

Mount Carmel Mercy Hospital
6071 West Outer Drive
Detroit, MI 48235

The reason for renewal of the license is to follow patients with implanted pacemakers and to return explanted pacemakers to the manufacturer for proper disposal. We will not be implanting any nuclear pacemakers in the future.

The physicians involved in the nuclear pacemaker program are:

Dr. Ronaldo N. San Juan
6001 West Outer Drive, Suite 330
Detroit, MI 48235
(313) 864-9200

Dr. San Juan is licenced in Michigan. He is an active member of our medical staff and has interpreted pacemaker follow-up tests in his office and here at Mount Carmel Mercy Hospital for more than 10 years.

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REG3 LIC70
SNM-1374

PDR

CONTROL NO. 85692

Mount Carmel Mercy Hospital
6071 West Outer Drive
Detroit, MI 48235
Phone: 313/927-7000

Mercy Family Care
10201 E. Jefferson Ave.
Detroit, MI 48214
Phone: 313/824-7866

Samaritan Health Center
5555 Conner Avenue
Detroit, MI 48213
Phone: 313/579-4000

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REGION III

July 3rd
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pacemaker
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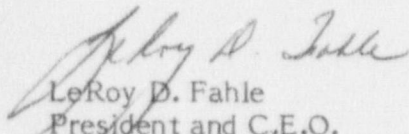
NRC License #SNM-1374
Page 2.

Dr. Ramegowda Rajagopal
22341 Eight Mile Rd.
Detroit, MI 48219
(313) 538-4700

Dr. Rajagopal is licenced in the state of Michigan. He is board certified in internal medicine and cardiology. Dr. Rajagopal is the President-Elect of the Medical Staff at Mount Carmel Mercy Hospital and has been interpreting pacemaker follow-up tests for more than 10 years in his office and here at the hospital.

If you require further information, please do not hesitate to contact me.

Sincerely,



LeRoy D. Fahle
President and C.E.O.
Mercy Hospitals and Health Services of Detroit

CONTROL NO. 85692



**MOUNT CARMEL
MERCY HOSPITAL**

6071 West Outer Drive, Detroit, MI 48235
Phone: 313 / 927-7000

Mercy Hospitals & Health Services of Detroit
A Division of The Sisters of Mercy Health Corporation

June 23, 1988

U. S. Nuclear Regulatory Commission
Region III
Material Licensing Section
799 Roosevelt Rd.
Glen Ellyn, Illinois 60137

Re: NRC License #SNM-1374

Dear Sir:

This is to state that I am familiar with the Medtronic Pacing Systems' NRC-approved protocol for follow-up of nuclear generators and agree to follow that protocol.

Sincerely,

Ronaldo N. San Juan, M.D.
Ronaldo N. San Juan, M.D.

RSJ:ala

**Mount
Carmel**

Celebrating
the Past
Creating
the Future

CONTROL NO. 85692

70-1388
renewal

Mount Carmel
MERCY HOSPITAL

June 9, 1983

'83 JUN 15 P3:07

Ms. Patricia C. Vacca
Material Licensing Branch
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: Renewal of NRC License #SNM-1374

Dear Ms. Vacca:

I am writing this letter to request renewal of the NRC License #SNM-1374 currently held by Mount Carmel Mercy Hospital.

The hospital name and mailing address should be listed on the license as follows:

Mount Carmel Mercy Hospital
6071 West Outer Drive
Detroit, MI 48235

The reason for renewal of the license is to follow patients with implanted pacemakers and to return explanted pacemakers to the manufacturer for proper disposal. We will not be implanting any plutonium pacemakers in the future.

The physicians involved in the plutonium pacemaker program are Drs. Seymour Wilhelm and Joseph Bassett as listed on the current license. We wish to involve no other physicians in the program at this time. Please note, however, that Dr. Wilhelm is no longer in private practice, but is a full-time member of the Mount Carmel Mercy Hospital staff. Correspondence for him should be sent to Mount Carmel Mercy Hospital. His office telephone number is (313) 927-7000, Ext. 7085.

If you require any further information, please do not hesitate to contact me.

Sincerely,

LeRoy D. Fahle
LeRoy D. Fahle
Senior Vice-President
Operations

LDF/ala

June 11, 1983
FEE EXEMPT

Regulatory

70-1388

File Cy.

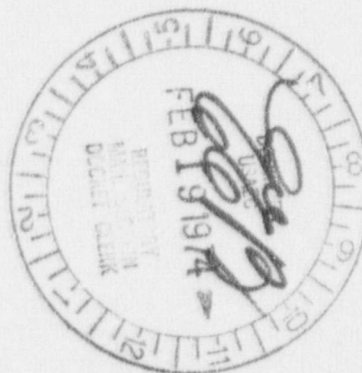
Over 20 Years of Community Service



MOUNT CARMEL MERCY HOSPITAL AND MEDICAL CENTER - 6071 West Outer Drive, Detroit, Michigan 48236 - (313) 864-6400

February 8, 1974

Mr. Cecil R. Buchanan, Asst. Chief
Materials Branch
Directorate of Licensing
U. S. Atomic Energy Commission
Washington, D.C. 20545



Dear Mr. Buchanan:

In reply to your letter of February 1, 1974 regarding the modification of license #SNM-1374--we have reviewed the modifications and do consent to these.

Sincerely,

Thomas R. O'Donovan

Thomas R. O'Donovan
Administrator

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Regulatory

File Cy.

DOCKET NO.

70-1388

Over 30 Years of Community Service

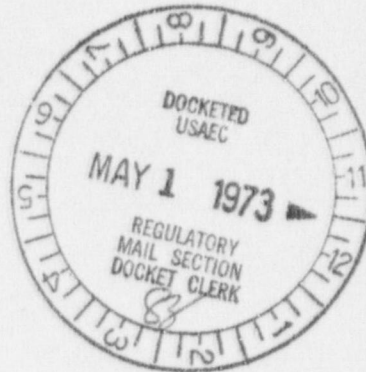


MOUNT CARMEL MERCY HOSPITAL AND MEDICAL CENTER - 6071 West Outer Drive, Detroit, Michigan 48235 - (313)864-5400

April 23, 1973

Chief of Materials Branch
Division of Materials Licensing
Atomic Energy Commission
Washington, D.C. 20545

Attention: James C. Malaro



Re: Application for License to Implant MedtronicTM Laurens-Alcatel Model 9000 Isotopic Pulse Generator

Gentlemen:

The following information is submitted in application for a license to implant the MedtronicTM Laurens-Alcatel Model 9000:

1. Applicant:

Mount Carmel Mercy Hospital and Medical Center

2. Physician Responsible for Study:

Name: Joseph S. Bassett, M.D.

Office Address: Suite 205 Northland Medical Building
20905 Greenfield Road, Southfield, Michigan 48075

Telephone Number: 313-353-8031

State Licensed to Practice In: Michigan

Medical School Affiliation: Wayne State University, School of Medicine, Detroit, Michigan

Specialty Board Certification: Thoracic Surgery

✓ Position with Applicant: Chief, Section of Thoracic and Cardiovascular Surgery

Fee. EX

Holder of 21-998-01 (78)

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4/6/76

2778

Previous experience in the clinical use of implantable pace-
makers by physician: 200 pacemaker implantations since
1969 with 150 of these done at Mount Carmel Mercy Hos-
pital and Medical Center and 1/3 of these having myocardial
leads. ✓ 1597

3. Other physicians and surgeons participating in study:

Name: Thomas B. Stock, M.D.

Office Address: 17000 West Eight Mile Road, Southfield,
Michigan 48075

Telephone Number: 313-357-0030

State Licensed to Practice In: Michigan

Medical School Affiliation: Wayne State University, School
of Medicine, Detroit, Michigan

Specialty Board Certification: Internal Medicine

✓ Position with Applicant: Chief, Section of Cardiac Phy-
siology and Cardiovascular Laboratories

Previous experience in the clinical use of implantable pace-
makers by physician: Engages in clinical follow up of patients
with implanted pacemaker at Mount Carmel Mercy Hospital
and Medical Center since 1964.

Name: S.K. Wilhelm, M.D.

Office Address: 13011 West McNichols Road, Detroit, Mich-
igan 48235

Telephone Number: 313-861-7920

State Licensed to Practice In: Michigan

Specialty Board Certification: Medicine

✓ Position with Applicant: Chief, Section of Electrocardio-
graphy

Previous experience in the clinical use of implantable pace-
makers by physician: Has been active in pacemaker implan-
tations and follow up at Mount Carmel Mercy Hospital and
Medical Center since 1960.

4. Protocol to be followed: MedtronicTM Laurens-Alcatel
Model 9000 Isotopic Pulse Generator Protocol dated March
21, 1973.

Modifications to Protocol: None

5. Number of MedtronicTM Laurens-Alcatel Model 9000 re-
quested to be implanted annually during study:

25 to 30

(50 units)

6. Description of physical facilities and equipment at applicant:

1597

Modern operating suite is available for pacemaker implantation with general anesthesia as required. Equipment will be available for intra arterial blood pressure monitoring and electrocardiographic monitoring. Pacemaker implantation and other cardiovascular surgery is performed regularly. There is post operative intensive care unit and cardiac care unit with facilities available to monitor a total of 8 patients at one time. A pacemaker clinic has been established for the close follow up of patients with implanted pacemakers. Equipment includes: Standard electrocardiogram, portable electrocardiogram monitors or dynamic cardiogram, oscilloscope for measuring pulse width and equipment to vary pulse width of implanted pacemakers.

7. Description of Applicants present pacemaker implantation and follow up program:

Physicians and Technicians will be available at all times to follow and examine patients with implanted pacemakers. A 24 hour answering service is maintained by the Applicant and Physician responsible for study to establish close follow up care of patients with implanted pacemakers. Present pacemaker implantation and follow up program includes approximately 100 patients. The longest period of follow up is approximately 10 years. Patients with endocardial and myocardial leads are being followed at the present time.

The physician responsible for the study represents that he is familiar with Medtronic's Protocol and Technical Manual for the MedtronicTM Laurens-Alcatel Model 9000 and understands that the issuance of a license is conditioned upon the use of this Protocol and is conditioned on the following of the instructions in the Technical Manual regarding "Transporting, Handling and Sterilization of the Pulse Generator", and "Comments on Implantation Procedure (myocardial leads)".

Applicant will establish appropriate control procedures to insure that the pulse generators are not lost or stolen. These procedures will include keeping track by serial number of the location of each pulse generator and requiring that they be kept under lock when not being used. Applicant represents that it has adequate fire protection equipment in case of emergency and that all activities will be conducted in accordance with the regulations under 10 code of Federal Regulations, Part 70.

The Applicant agrees to continue the follow-up, reporting and

recovery procedures required under Medtronic's Protocol in the event the Physician Responsible for the Study or any other physician or surgeon participating in the study is no longer associated with Applicant.

Applicant hereby requests a license to receive, possess, store and implant the MedtronicTM Laurens-Alcatel Model 9000 Isotopic Pulse Generator in accordance with this application.

Signed:

Applicant: Mount Carmel Mercy Hospital
and Medical Center

by Thomas R. Donora Ph.D. Administrator

Physician Responsible for Study:
Joseph S. Bassett, M.D.

Joseph S. Bassett M.D.

U. S. ATOMIC ENERGY COMM.
REGULATORY
MAIL SECTION

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