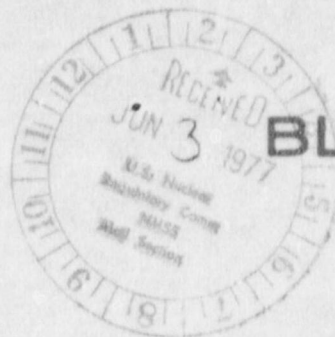


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# BLOOMINGTON HOSPITAL

605-625 WEST SECOND STREET · P.O. BOX 1149

BLOOMINGTON, INDIANA 47401

PHONE 336-6821 (AREA 812)

May 31, 1977

Radioisotopes Licensing Branch  
Office of Nuclear Material Safety  
and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

ATTENTION: Mr. Bernard Singer

RE: Application for license to implant Medtronic® Model 9000  
Isotopic Pulse Generator

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Gentlemen:

The following information is submitted in application for a license to implant the Medtronic Model 9000.

1. Applicant: Bloomington Hospital
2. Physician responsible for study:

Name: Dr. Frank Shahbahrami  
Office Address: 822 West First Street, Bloomington, IN 47401  
Telephone Number: (812) 336-7407  
State Licensed to Practice In: Indiana  
Specialty and Board Certification: Surgery  
Position with Hospital: Staff Surgeon

I implant approximately 30-40 pulse generators/year and use both endocardial and myocardial procedures. I am responsible for most of the implants at Bloomington Hospital and I have about four years experience in pacing.

3. Other physicians and surgeons participating:

Name: Dr. James Topolpus, Jr.  
Office Address: 403 North Walnut, Bloomington, IN 47401  
Telephone Number: (812) 336-4947  
State Licensed to Practice In: Indiana  
Specialty and Board Certification: Surgery  
Position with Hospital: Staff Surgeon

Dr. Topolpus implants from 5-10 pacemakers/year and has about two years of pacing experience.

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June 77-4

FREE EXEMPT

Name: Dr. Gene Creek  
Office Address: 419 West First Street, Bloomington, IN 47401  
Telephone Number: (812) 332-9331  
State Licensed to Practice In: Indiana  
Specialty and Board Certification: Cardiology  
Position with Hospital: Cardiologist

Dr. Creek follows 30-40 pacemaker patients and has been involved with pacing for the past five years.

4. Protocol to be followed: Medtronic® Model 9000 Isotopic Pulse Generator protocol dated March 1, 1973, revised October 1, 1975.

5. Number of Medtronic Model 9000 units requested to be implanted annually during study: Five

6. Description of physical facilities and equipment:

We have a Medtronic 5300 Pacing Systems Analyzer to take the threshold measurements required by the protocol. Bloomington Hospital contains approximately 315 beds and has a CCU with eight beds. We also have a nuclear medicine license.

7. Description of applicant's present pacemaker implantation and follow-up program:

We presently implant about 40-50 pacemakers/year. We have been implanting pacemakers for about four years and we follow patients in our pacemaker clinic which is part of the hospital.

8. Description of methods used to maintain separate records:

The records of the nuclear pacemakers patients will be kept separate from the records of the rest of the hospital and the rest of the pacemaker patients. They will be kept in specific folders with dates of return visits so that we can recognize when the patient has another follow-up appointment, and we will be able to tell if he does not show up for the appointment. We are also reminded of the patient's follow-up schedule by Medtronic's follow-up data forms which are sent on a regular basis. The folders and the separate files will also contain information on the patient's location and phone number where the patient can be reached if he does not show up for a follow-up exam.

9. Written Instruction for Telephone Operators:

See attachment.

We represent that we are familiar with the Medtronic Protocol and Technical Manual for the Medtronic? Model 9000 and understand that the issuance of a license is conditioned upon use of this protocol and the use of instructions in the technical manual on "transporting, handling and sterilization of the pulse generator." We agree to have the patient visit our clinic for the required follow-up examinations.

We will establish appropriate control procedures to ensure that the pulse generators are not lost or stolen. These procedures will include keeping track by serial number of the locations of each pulse generator and requiring that they be kept under lock when not being used. We represent that we have adequate fire protection in case of emergency, and we will conduct all activities in accordance with the NRC's regulations published in 10 CFR 70.

We agree 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 this hospital.

Bloomington Hospital hereby requests a license to receive, possess, store and implant Medtronic Model 9000 Isotopic Pulse Generators in accordance with this application.

Signed:

Applicant: by: Roland E. Kohr  
Roland Kohr, Hospital Administrator

Physicians Responsible for Study:

Frank Shahbahrani, M.D.

James Topoligis, Jr., M.D.

Gene Creek, M.D.

jfd

Attachment