



Texas Department of State Health Services Radiation Safety Licensing Branch

REGULATORY GUIDE 3.8

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR USE OF NUCLEAR POWERED CARDIAC PACEMAKERS

I. Introduction

This guide describes the information the Department of State Health Services (DSHS or Agency) staff needs to evaluate license applications for the use of nuclear powered cardiac pacemakers. It is intended as general guidance and does not include all the information that may be required for a particular application.

II. License Fees

An application fee is required for all specific licenses and must be submitted with any NEW application. The applicant should refer to Title 25 Texas Administrative Code (TAC) Section (§) 289.204 to determine the amount of fee that should accompany the application. Review of the application will not begin until the proper fee is received by the Agency. The check or money order should be made payable to the Texas Department of State Health Services.

In the case of an application for renewal or amendment, a fee should NOT be submitted with the application. All current licensees will be billed according to the expiration month of their current license.

III. Completing the Application

BRC Form 252-2a, "Application for Radioactive Material License Human Uses," should be used to apply for this radioactive material license. All Items on the application should be completed. Because of limited space on the application, some information should be submitted on additional sheets of paper. Two copies of the completed application, including supplemental sheets, need to be submitted.

Regulatory Guides are issued to assist applicants and licensees/registrants in developing operational procedures acceptable to the Department of State Health Services, Radiation Safety Licensing Branch (agency), that are compliant with specific sections of Title 25 Texas Administrative Code Chapter 289. Regulatory Guides are NOT substitutes for regulations and compliance with them is not required. Methods for compliance with regulations different from those set out in guides will be acceptable if they are considered by agency staff to provide for public health and safety and demonstrate compliance with regulations.

Comments and suggestions for improvements in Regulatory Guides are encouraged. Letters containing comments and suggestions should be sent to the Manager, Radiation Safety Licensing Branch, Department of State Health Services, 1100 W. 49th Street, Austin, Texas 78756-3189. Regulatory guides may be reproduced or may be obtained by contacting the agency at (512) 834-6688 or accessing the agency web page at www.dshs.state.tx.us/radiation

Specific items of the application are listed and explained below.

Item 1 - The applicant is the hospital or institution where implants are to be performed.

Items 2-4 - Self-explanatory.

Item 5 - List the cardiologists whose patients will be implanted with the nuclear powered pacemakers.

Item 6 - The person designated as Radiation Safety Officer (RSO) is the person who administers the license and all associated correspondence. The RSO will be the primary contact with the Agency concerning the license and will be in charge of records, patient follow-up, pacemaker inventory, security of pacemakers, etc.

Item 7 - Provide information concerning the pacemaker to be used. For example:

5. Radioisotope A. Pu-238	6. Form of Material A. Nuclear powered pacemakers (Coratomic C-101-P)	7. Maximum Activity* A. Four pacemakers not to exceed 250 milligrams, each Total: 1 gram	8. Authorized Use A. Storage in patient; awaiting collection.
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Items 8-11 - Self-explanatory.

Item 12 The following information should be submitted on additional sheets of paper.

- A. Specify the pacemaker protocol(s) to be followed. Enclose a copy of each protocol to be used.
- B. Estimate the number of implantations to be performed in the first year and in the first five years.
- C. Describe the facilities for secure storage of the pacemakers and the posting of the storage area. Provide written confirmation that the hospital or institution will establish appropriate control procedures to ensure the physical security of the pacemakers while in the possession of the hospital. The applicant should also confirm that a current inventory will be kept indicating the location of each pacemaker, whether in storage or implanted in a patient.
- D. Describe how the records of implantation and patient follow-up will be kept separate from routine hospital records and available for inspection by the Agency. Include any special procedures for continuity of patient follow-up over the long term to ensure that patient contact is maintained. Specify who will be responsible for recovery of pacemakers due to replacement, routine removal, or patient death. Also, state who will be responsible for semi-annual reporting of patient/pacemaker status to the pacemaker manufacturer.
- E. For the physicians listed under Item 5 of the application, provide their previous experience in the clinical implantation of pacemakers. Each physician should also submit the following certification as a signed statement:

"As a result of experience and training, I am qualified to insert cardiac pacemakers. Community physicians use me as a consultant to perform this task and the applicant hospital's medical staff affords me this practice privilege. My medical liability insurance is adequate to perform pacemaker implants."

- F. Each physician named as an authorized user on the license should certify in writing that he or she is familiar with and will follow:
1. The administrative and radiation safety procedures submitted for licensure by the applicant institution.
 2. The specific manufacturer's protocol including the date issued.
 3. The manufacturer's technical manual for the make and model of the pacemaker desired.

Item 13 - Not applicable.

Item 14 - Financial Qualification and Financial Assurance - See 25 TAC §289.252(gg) to determine if financial assurance must be provided. Unless licensed authorizations include large amounts of long-lived radioactive material (i.e., half-lives of greater than 120 days), financial assurance is not required and financial qualification can be established via self-attestation on BRC Form 252-1, Business Information Form.

Item 15 - The application must be signed by the hospital or institution administrator. Please type or print the individual's name and title below the signature. On a separate sheet of paper, the administrator must certify the following:

" _____ (name of applicant) _____ agrees to continue the follow-up reporting and recovery procedures for each patient receiving an implant until all nuclear powered pacemakers are recovered and returned to the appropriate manufacturer. I am aware that this certification is binding whether or not the physician or physicians who performed the implantations continue their association with this hospital (institution)."

NOTE: The license must be maintained and the annual license fee paid until the final pacemaker is recovered. This may be long after the final pacemaker is implanted and long after the physician who implanted the pacemaker has left the hospital or institution.

Unsigned and undated applications will not be reviewed and will be returned to the applicant. Retain one copy for your files and mail the license applications and appropriate fee to:

Texas Department of State Health Services
Radiation Safety Licensing Branch
Medical and Academic Licensing Program
1100 West 49th Street
Austin, Texas 78756-3189