

MAY 11 1982

Doylestown Hospital  
ATTN: Mr. J. Marek  
Administrator  
595 West State Street  
Doylestown, PA 18901

Soon you will receive a computer-generated notice reminding you that your license authorizing use of plutonium-238 nuclear-powered pacemakers is about to expire. We want to call your attention to some special conditions on these licenses and to explain how these conditions may affect your decision whether to renew the license.

In the United States anyone who possesses and uses plutonium must be covered by a license (10 CFR 70.3). Patients in whom you have implanted plutonium pacemakers are covered by the hospital's license; see Condition 11. of your license. In Conditions 15. and 16. of your license you are committed to following all patients with implanted plutonium pacemakers for the life of the patient or until the pacemaker is removed and returned to the manufacturer for proper disposal. Follow-up procedures must be in accordance with the protocol established by the manufacturer and approved by NRC.

I. TERMINATION

A. You can request termination of your license if:

- You do not want to implant plutonium pacemakers in the future AND
- You have never received any plutonium pacemakers OR
- All plutonium pacemakers that were received were returned to the manufacturer before implant in a patient AND/OR
- All plutonium pacemakers implanted in patients have been recovered and returned to the manufacturer.

B. To request termination of your license, please send a short letter, signed by the hospital administrator, addressed to Material Licensing Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Your letter should be received by NRC before your license expires. Your letter should specify your license number and should clearly explain the circumstances at your hospital that make termination appropriate.

- C. Please request termination of your license rather than simply allowing the license to expire. NRC expends a significant amount of effort in determining the status of materials authorized by expired licenses, their disposition, etc. and in making appropriate changes in our records; we would appreciate your help in this matter.

## II. RENEWAL

### A. Renewal of your license is appropriate if:

- You need to continue the follow-up procedures for patients with implanted plutonium pacemakers AND/OR
- You have one (or more) plutonium pacemakers in your possession (e.g., awaiting shipping instructions and materials from manufacturer) AND/OR
- You want to maintain the option of implanting plutonium pacemakers.

### B. To request renewal of your license, please send a letter, signed by the hospital administrator, addressed to Material Licensing Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Your letter should be received by NRC at least 30 days before your license expires and should contain the following information in support of your renewal request:

1. Number of your license that is to be renewed.
2. Your institution's name and mailing address as they should appear in Items 1 and 2 of your renewed license.
3. The number of plutonium pacemakers to be authorized. If you are authorized for more than one manufacturer's unit, specify the number of each manufacturer's pacemakers we should authorize. Be sure that the numbers you specify are sufficient to cover all patients with implanted plutonium pacemakers and any extra you may want for future implants.
4. Activities to be conducted under your license. The principal reasons for renewing a plutonium pacemaker license are: (1) to continue the authorized activities (i.e., receive and implant pacemakers, follow patients with implanted devices, return explanted pacemakers to manufacturer for proper disposal) and (2) to follow patients with implanted pacemakers and to return explanted pacemakers to manufacturer for proper disposal (but not to implant pacemakers in the future). Please explain exactly what you wish to do with plutonium pacemakers.

5. Update of the listing of physicians who are involved in your plutonium pacemaker program. The names of the physicians are found in correspondence listed in Condition 16. of your license. For each new physician to be added to your license, specify the physician's name, office address and telephone number, state in which licensed to practice medicine, specialty board certification, position with your institution, and describe the physician's previous experience with pacemakers (not necessarily plutonium pacemakers). You should also submit a statement signed by each new physician certifying that the physician is familiar with the manufacturer's NRC-approved protocol and agrees to follow that protocol.
6. Description of any changes in the commitments contained in the correspondence listed in Condition 16. of your license.

### III. FEES

- A. No fee is required for terminations.
- B. No fee is required for renewal of a plutonium pacemaker license if your hospital holds another NRC license.
- C. A renewal fee of \$150 is required by 10 CFR 170.31(7B) if your hospital does not hold another NRC license. (Renewal fee should accompany renewal request.)

### IV. QUESTIONS

If this letter does not answer all of your questions on pacemaker licenses, please call us at (301) 427-4232.

Sincerely,

Material Licensing Branch  
Division of Fuel Cycle and  
Material Safety

Enclosures: 10 CFR Parts 70, 170

*PMV*  
*5/10/82*