MAY 29 1985

License No. SNM-1319
Docket No. 070-01342
Control No. 23545

Coratomic, Inc.
ATTN: John R. Klingensmith
Patient Records Specialist
P. O. Box 431
Indiana, Pennsylvnaia 15701

Gentlemen:

This is in reference to your application dated May 2, 1985 to renew License No. SNM-1319. In order to continue our review, we need the following additional information:

1. Regarding your survey meters and counting equipment for alpha and neutrons, please submit the following information for each instrument.

   a. Manufacturers Name and Model No.
   b. Number available
   c. Sensitivity range
   d. Type of detector
   e. Type of radiation detected
   f. Method of calibration or determining counting efficiency

2. Please submit an outline of the subjects covered in your annual training lecture, the length of time involved for each subject, the name of the instructor, if other than your radiation safety officer (RSO), and the training and experience of the instructor if other than your RSO.

3. Please clarify your recovery/return program. Are the nuclear batteries ever removed from the explanted pacemakers returned to your from the licensed medical institution and placed in a new pacemaker?

4. Please clarify if the inventory/leaktest information given to our inspector during the August 17, 1984, inspection of your facility is the total number of sources you have on hand or does it include the sources which are implanted in patients. We note that this list contained 570 sources.

5. Exhibit X for your Model C-100 protocol (July 1, 1975), Exhibit X for your Model C-101 protocol (November 1, 1975), and Exhibit IX of your Model C-101-P protocol (March 2, 1983), indicate applications for pacemaker licenses should be sent to the USNRC, Washington, D.C. Please correct these

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exhibits to reflect submission of an application to the Region Office of the NRC which has jurisdiction over the state in which the applicant resides. It is our understanding that you are only manufacturing and transferring the Model C-101-P pacemaker and protocol, if so, it is only necessary to correct the March 2, 1983, protocol for the C-101-P pacemaker.

6. It appears from Attachment 1, "Fuel Capsule Assembly Procedure", that you are manufacturing the sealed source that is contained in your pacemakers, please clarify.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 23545.

Sincerely,

Original Signed By:
John E. Glenn

Jenny M. Johansen, M.S.
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

RI:DRSS
Johansen/djf
5/28/85

RI:DRSS
Glenn
5/06/85

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