

## MATERIALS LICENSE

Amendment No. 19

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

**"OFFICIAL RECORD COPY"**

Licensee

In accordance with application dated  
May 2, 19853. License number SNM-1319 is amended in its  
entirety to read as follows:

4. Expiration date September 30, 1990

5. Docket or  
Reference No. 070-013426. Byproduct, source, and/or  
special nuclear material7. Chemical and/or physical  
form8. Maximum amount that licensee  
may possess at any one time  
under this licenseA. Plutonium (Principal  
radionuclide Pu-238)A. Sealed sources  
(Plutonium batteries)A. Not to exceed 250  
milligrams of Pu-238 per  
sealed source; 290 grams  
total

## 9. Authorized use

- A. (1) For use as a component in assembled Coratomic Model C-101 pacemakers and as a component in the assembly (manufacturing) of Coratomic Model C-101-P pacemakers; for distribution to medical institutions authorized to receive pacemakers pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.
- (2) For recovery as a component of explanted Coratomic Model C-100, C-101 and C-101-P pacemakers transferred from specific licensees.
- (3) For storage or disassembly and re-furbishing of the battery source from Coratomic Model C-100, C-101 and C-101-P pacemakers.

## CONDITIONS

10. Licensed material shall be used only at the licensee's facilities, 300 Indian Spring Road, Indiana, Pennsylvania.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions, and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
12. Licensed material shall be used by, or under the supervision of, individuals who have completed the training program as outlined in the letter dated August 19, 1985 and have been designated by Frederick J. Shipko, Radiation Safety Officer.

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**MATERIALS LICENSE**  
**SUPPLEMENTARY SHEET**

License number

SNM-1319

Docket or Reference number

070-01342

Amendment No. 19

(continued)

**CONDITIONS**

13. As six month intervals Coratomic, Inc. shall collect and tally data from all medical institutions with respect to: (a) accountability, removal and recovery, (b) duration of satisfactory performance or the time of service before malfunction, and (c) nature of malfunction (if appropriate) of all implanted Coratomic Model C-100, C-101, and C-101P nuclear-powered pacemakers. Within ninety (90) days of the six month period ending February 28 or August 31, one copy of the report shall be sent to the U.S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Material Licensing Branch, Washington, D.C. 20555. A second copy of the report shall be sent to the U.S. Nuclear Regulatory Commission, Region I, Nuclear Materials Safety Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406.
14. Coratomic, Inc., shall maintain records of the medical institutions approved by the FDA for participation in IDE G 810104/A2 and the date of FDA's approval of each institution.
15. This license does not authorize the implantation of pacemakers into humans or animals.
16. A. Each plutonium source shall be tested for leakage at intervals not to exceed six (6) months. In the absence of a certificate from a transfer indicating that a test has been made within six (6) months prior to the transfer, a sealed source received from another person shall not be put into use until tested.  
B. The test shall be capable of detecting the presence of 0.005 microcurie of alpha contamination on the test sample. The test sample shall be taken from the source or from appropriate accessible surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.  
C. If the test reveals the presence of 0.005 microcurie or more of removable alpha contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired by a person appropriately licensed to make such repairs or to be disposed of in accordance with the Commission regulations. Within five (5) days after determining that any source has leaked, the licensee shall file a report in duplicate with the U. S. Nuclear Regulatory Commission, Region I, Nuclear Materials Safety Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406, describing the source, the test results, the extent of contamination, the apparent or suspected cause of source failure, and the corrective action taken.  
D. The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six (6) months prior to the date of use or transfer.

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(continued)

**CONDITIONS**

17. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."
18. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of licensed material, location of sealed sources and the date of the inventory.
19. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated May 2, 1985 and letter dated August 19, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.



For the U.S. Nuclear Regulatory Commission

Original Signed By:

By Jenny M. Johansen

Nuclear Materials Safety and  
Safeguards Branch, Region I  
King of Prussia, Pennsylvania 19406

Date SEP 25 1985