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

MS 16
P5

APPLICATION FOR RENEWAL OF LICENSE NUMBER SNM-1319

Coratomic, Inc.
300 Indian Springs Road
Indiana, Pennsylvania 15701

23545

"OFFICIAL RECORD COPY"

ML10

TABLE OF CONTENTS

ATTACHMENTS

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER SNM-1319

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Coratomic, Inc.
P. O. Box 434
Indiana, Pennsylvania 15701

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Coratomic, Inc.
300 Indian Springs Road
Indiana, Pennsylvania 15701

(additional information attached.)

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John R. Klingensmith

TELEPHONE NUMBER

(412)349-1811

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY
AMOUNT ENCLOSED $ previously submitted

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
David Purdy	David L. Purdy	President	May 2, 1985

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(Dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(10 CFR regulations permit it to protect confidential commercial or financial–proprietary information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY

AMOUNT RECEIVED	CHECK NUMBER		DATE

PRIVACY ACT STATEMENT ON THE REVERSE

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

The only location we are now using is:

Coratomic, Inc.
300 Indian Springs Road
Indiana, Pennsylvania 15701

We were formerly located at Old Route 119 South, Indiana, Pennsylvania, 15701, and North Plaza, Route 119 North, Indiana, Pennsylvania, 15701. We also had dogs with implanted pacemakers. The dogs were kept at Connie Winters Kennels, Airport Road, Indiana, Pennsylvania, 15701. We are no longer implanting pacemakers in dogs. All of the pacemakers were removed from the dogs and returned to Coratomic.

Only sealed sources were used at any of our locations. These sealed sources are capsules that are loaded and hermetically sealed by a qualified fabricator according to Coratomic Specification #1141 (see Attachment 1). Loaded capsules are delivered to Coratomic with a data sheet for each capsule that includes wipe test results, helium leak test results, quantity of fuel loaded, gamma and neutron dose measurement, capsule material certification numbers and welding parameters.

A close-out survey was performed at our old locations, and they are free of nuclear material.

One nuclear pacemaker was missing during the relocation from the old facility on Route 119 to the present facility on Indian Springs Road. A report on this matter is included as Attachment 2.

5. RADIOACTIVE MATERIAL

a. Element and mass number

Plutonium (Principal radionuclide Pu-238)

b. Chemical and/or physical form

Sealed sources

c. Maximum amount which will be possessed at any one time.

290 grams as sealed sources. Each sealed source contains 230 milligrams of Pu-238.

6. PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED.

a. As a component of Coratomic Model C-100 pacemakers for purposes of explantation and recovery from medical institution licensed by the Nuclear Regulatory Commission or an Agreement State to implant such pacemakers in humans under the Protocol entitled "Human Clinical Protocol for the Coratomic C-100 Series of Radioisotope Powered Cardiac Pacers" dated July 1, 1975 (see Attachment 3).

b. As a component of Coratomic Model C-101 pacemakers to be transferred to medical institutions licensed by the Nuclear Regulatory Commission or an Agreement State to implant such pacemakers in humans under the Protocol entitled "Human Clinical Protocol for the Coratomic C-101 Radioisotope Powered Cardiac Pacer" dated November 1, 1975 (see Attachment 4).

c. As a component of Coratomic Model C-101-P pacemakers to be transferred to medical institutions licensed by the Nuclear Regulatory Commission or an Agreement State to implant such pacemakers in humans under the Protocol entitled "Human Implantation Protocol for the Coratomic C-101-P Radioisotope Powered Cardiac Pacemaker" dated March 2, 1983 (see Attachment 5).

Coratomic shall collect and tally at six-month intervals data from all medical institutions with respect to the accountability, removal, and recovery of all implanted Coratomic Model C-100, Model C-101, and Model C-101-P pacemakers. Copies of these reports will be sent to the United States Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Material Licensing Branch, Washington, DC 20555. The reports referred to in the license renewal application request are on file at Coratomic, and copies have been mailed to the above address. These semi-annual reports will be prepared by Mr. John Klingensmith, Patient Records Specialist, and copies will be available for inspection in the Coratomic Data Center. The Coratomic Data Center also contains the patient records for each person who has a Coratomic isotopic-powered pacemaker implanted.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

SHIPKO, FREDERICK J. - RADIATION SAFETY OFFICER, VICE PRESIDENT, CORPORATE SECRETARY

Mr. Shipko received a B. A. degree in Chemistry from Syracuse University in 1950.

Experience and background summary of Mr. Shipko is as follows:

Coratomic, 1972 to Present - As Manager, Research and Development, Mr. Shipko has been responsible for the chemical and mechanical component development of pacemakers, heart catheters and other implantable medical devices. These included metal to ceramic seals, thermoelectric batteries for nuclear pacers, metal component fabrication and assembly techniques, hermetic sealing technology, development of potting and incapsulating techniques with polymers, fabrication of catheters and sterilization techniques.

Since mid-1980 he has been responsible for the mechanical components and assembly of an implantable and an external insulin dispenser. He developed low power solenoid-operated piston pumps for these systems which pump insulin in the range of .1 to .5 microliters per stroke. This necessitated an understanding of electromagnetism and fluid dynamics. The pumps required small precision metal components as well as injection-molded plastic parts which were fabricated at Coratomic under his direction. He developed a unique sterilization system in which the fluid flow path in these systems could be sterilized by ethylene oxide.

NUMEC, 1957 to 1972 - Staff Chemist - After joining this company, which was subsequently acquired by Atlantic Richfield (ARCO), he spent seven years in the development of processes for depositing coatings on spherical ceramic reactor fuel particles and other metal and ceramic shapes. The coatings included niobium, tungsten, vanadium, pyrolytic carbon, chromium, beryllium, beryllium oxide, molybdenum, nickel, copper, lead, aluminum, platinum, and gold. Methods for producing the deposits have included fluidized bed systems, electroplating, vaporization, and chemical immersion techniques. He also developed techniques for preparing high purity chemical compounds such as uranium mononitride, uranium triiodide, and beryllium halides.

In 1965 he was assigned as Supervisor of Hot Cell Operations at NUMEC. The work encompassed the encapsulation of gamma emitting sources such as Cobalt-60, Cesium-137, and Iridium-192, and the post-irradiation examination of plutonium-uranium oxide fuels.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. (continued)

SHIPKO, FREDERICK J. (continued)

In January, 1967 he transferred to the Energy Conversion Division of NUMEC and worked on developing chemical techniques and processes for nuclear-powered thermoelectric systems until November, 1971, and continued in this capacity when the division was acquired by ARCO Nuclear Company. This work encompassed the development of the AEC nuclear-powered cardiac pacemaker, radioisotope-powered artificial heart sponsored by the National Heart & Lung Institute, under-sea radioisotope thermoelectric generators for the Navy, and other microwatt and milliwatt thermoelectric devices.

KNOLLS ATOMIC POWER LABORATORY, 1951 to 1957 - During his tenure at Knolls, he was engaged in inorganic and physical chemical research and development, where he gained substantial experience in mass spectrometry and high vacuum techniques, corrosion problems, and radiation chemistry.

Publications -

"The Titanium-Hydrogen System", JACS 78, 5155 (1956)
"The Palladium-Tritium System at Low Temperatures", (KAPL-1097).
"Stability of Ferrous Hydroxide Precipitates", J. Phys. Chem 50, 1519 (2956).
"Thermal Stability of Hydrous Aluminum Oxides", (KAPL-1740).
"The Beta Paricle Radiolysis of Acetylene", JACS 77, 4723 (1955).
"Radiation Induced Exchange of Hydrogen Isotopes", J. Phys. Chem. 59, 1110 (1955).
"The Oxide Decomposition Process For Coating Uranium With Zirconium", (KAPL-876).
Co-Author "Post Examination of UO_2-5 w% PuO_2 Fuels", presented at the June, 1966 ANS meeting.

Patents -

1. Co-Inventor of a technique for the preparation of a solid source of beta radiation by the polymerization of tritiated acetylene (Patent 2,903,383).

2. Co-Inventor of Radio-Opaque Gloves (Patent 3,883,749).

3. Co-Inventor of Catheter (Patent 4,142,531) which attached to the internal surface of the heart.

4. Inventor of a Self-Sealing Set Screw for use with pacemakers (Patent 4,141,752).

5. Co-Inventor of method of potting of the internal components of pacemakers to provide shock resistance and low weight (Patent 4,041,956).

6. Co-Inventor of a Portable Insulin Infusion Pump (Patent pending).

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

The following is a list of persons who are qualified to handle our licensed material and assemble our pacemakers:

BABCO, JAMES
BERNINI, LINDA
BOARTS, GARY
CARNAHAN, ROGER
CUPP, JAMES
KALLAS, DAVID
KEISER, ROBERT
KLINGENSMITH, JOSEPH
OSWALT, NORMAN
PALANGIO, TIM
PURLY, DAVE
RAPACH, CHARLES
SEGNER, EDWARD
SHIPKO, FREDERICK
SPORY, DAVID
STILES, DARLENE
STILES, WAYNE
WARD, PATRICK
WIGGINS, BARRI
ZIMMERMAN, TERRY

All employees who handle nuclear material and/or pacemakers will receive yearly retraining consisting of lectures on radiation and radiation safety.

9. FACILITIES AND EQUIPMENT.

The following two pages show a diagram of the Coratomic facilities and a description of the rooms. These facilities are located at 300 Indian Springs Road, Indiana, Pennsylvania 15701.

The areas through which fuel will pass are indicated with an "f".

Storage areas are marked by an "s".

Areas in which records are kept are labeled with an "r".

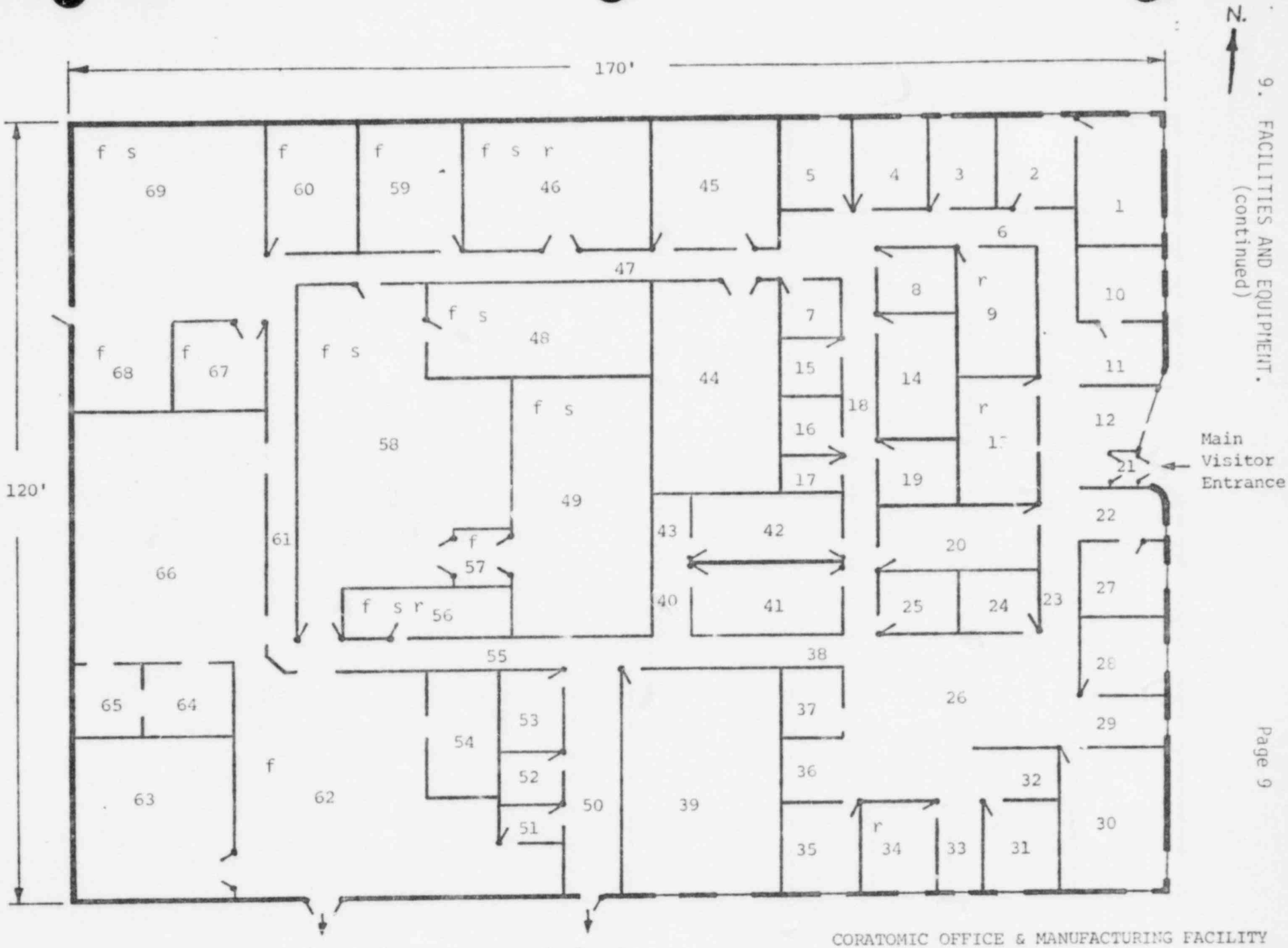
All fuel is contained in sealed sources. In a completed pacemaker there are four hermetic seals as follows:

(a) incoming capsule

(b) TA - Fuel basket weld

(c) final battery closure weld

(d) pacemaker case.



CORATOMIC OFFICE & MANUFACTURING FACILITY
Indiana, Pennsylvania
1" = 20' PJ Ward 10/8/80

Coratomic Inc., 300 Indian Springs Road, Indiana, PA 15701
IDENTIFICATION OF SPACE - CORATOMIC OFFICE & MANUFACTURING FACILITY

(see plant layout drawing)

ROOM NO.	DESCRIPTION
1 thru 7	OFFICE AREA
8	REPRODUCTION CENTER
9 thru 11	OFFICE AREA
12	RECEPTION AREA (VISITOR ENTRANCE)
13	OFFICE AREA
14	DRAFTING ROOM
15 thru 16	OFFICE AREA
17	COMMUNICATIONS ROOM
18 thru 29	OFFICE AREA
30	EXECUTIVE CONFERENCE ROOM
31 thru 38	OFFICE AREA
39	EMPLOYEE CAFETERIA
40 thru 43	STORAGE & RESTROOMS
44	RESEARCH & DEVELOPMENT (Chemical)
45	RESEARCH & DEVELOPMENT (Electronics)... R-F Shielded
46	QUALITY CONTROL ... R-F Shielded
47	PASSAGEWAY
48	ELECTRONIC COMPONENT ASSEMBLY
49	STERILIZATION "CLEAN ROOM"
50	EMPLOYEE ENTRANCE AREA
51	SHIPPING & RECEIVING
52	PRODUCTION OFFICE
53	PRODUCTION CONFERENCE AREA
54 thru 56	PRODUCTION OFFICES
57	CLOTHING PREPARATION ROOM
58	MAIN ASSEMBLY ROOM
59	I.D. APPLICATION ROOM
60	FINISHING ROOM
61	PASSAGEWAY
62	STORAGE & RECEIVING AREA
63	POWER ENGINEERING & MAINTENANCE
64	TOOL ROOM
65	GRINDING ROOM
66	MACHINE SHOP
67	LASER WELDING ROOM
68 thru 69	CHEMICAL LABORATORY

10. RADIATION SAFETY PROGRAM.

All nuclear material is contained in sealed sources. Only capsules that are loaded and hermetically sealed by a qualified fabricator according to Coratomic Specification #1141 are used at Coratomic (see Attachment 1). Loaded capsules are delivered to Coratomic with a data sheet for each capsule that includes wipe test results, helium leak test results, quantity of fuel loaded, gamma and neutron dose measurement, capsule material certification numbers and welding parameters.

Upon receipt the capsules will be logged into the incoming capsule inspection log and also into the Isotopic Sources log.

Wipe tests, neutron counts, capsule identification, and leak checks are performed on the capsules according to the procedures given in Attachment 6.

All nuclear fuel capsules are stored in the safe in vials marked with I.D. number and radioactive tape around the vial.

Capsules are released from the safe by Quality Assurance and a record is kept of the disposition of each capsule (incoming inspection log and Isotopic Sources log).

Capsules stored in the safe for longer than six months must be wipe tested and information recorded in Isotopic Sources log before they can be released.

Capsules that are in completed batteries or pacers and kept by Coratomic must be checked for emissions every six months by wiping the outside of the battery or pacer or package it is contained in and by checking the battery or pacer output.

Wipe tests are performed by Quality Control using the procedures given in Attachment 6. Records of wipe tests are kept in areas 46 and 56 on the diagram of the Coratomic facilities (Item 9).

Only areas that are labeled with the trefoil are holding areas for devices with nuclear fuel.

Personnel are monitored with film badges. Results of the monitoring are contained in the monthly dosimetry reports, which are kept on file in Room 34 (Item 9).

Pacemakers are shipped only to licensed hospitals. These hospitals have agreed to follow the protocols corresponding to the models of pacemakers which they will receive. Results of the accountability in the field are given in the semi-annual reports prepared by the Coratomic Data Center and mailed to the U. S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Material Licensing Branch, Washington, DC 20555.

11. WASTE MANAGEMENT.

No waste is generated by this facility.

LIST OF ATTACHMENTS

Attachment 1 - Fuel Capsule Assembly Procedure

Attachment 2 - Loss of Plutonium-238

Attachment 3 - Protocol for C-100 Pacemakers

Attachment 4 - Protocol for C-101 Pacemakers

Attachment 5 - Protocol for C-101-P Pacemakers

Attachment 6 - Q. A. Incoming Inspection of Fuel Capsules
(Leak Test and Logging Procedures)

(Attachment 1)

FUEL CAPSULE ASSEMBLY PROCEDURE

1. Prepare Inner Capsule Components for Welding

Capsule parts are cleaned before shipping from Coratomic. If parts become contaiminated through handling, etc., they must be recleaned in boiling reagent grade trichloroethylene and then rinsed in reagent grade acetone. All capsule parts are to be handled with clean tweezers or clean rubber gloves and all chills, fixtures, etc., that come in contact with the capsule parts must also be cleaned in reagent grade trichloroethylene and acetone.

2. Load Specified Quantity of Fuel

Each source is to be loaded to 0.142 thermal watts (4.27 curies Pu-238, +0, -3%) using the 90% enriched Pu-238 powdered oxide specified in Coratomic Fuel Specification #B1-2044. The Pu-238 fuel shall be pressed into pellets of .156" diameter and of such length as is necessary to obtain the specified thermal loading. The maximum length is 0.133".

The fuel pellets shall then be loaded into a chamber, all air evacuated to 1×10^{-5} torr and back filled with oxygen-16. The pellets shall be heated in the presence of oxygen-16 to 700°C at the rate of 50°C per 2 minutes. When the temperature has reached 700°C, hold for 15 minutes, evacuate and backfill with oxygen-16, hold for 15 minutes and repeat this process until the oxygen-16 atmosphere has been exchanged 8 times. After the oxygen-16 atmosphere has been exchanged 8 times and the final 15 minute hold period has been completed, resume heating the pellets in oxygen-16 at the rate of 50°C per 2 minute intervals until a temperature of 1400°C has been reached. Hold at 1400°C for 1 hour so that complete sintering may occur. After sintering for 1 hour, reduce temperature at the rate of 50°C per 2 minutes until room temperature is reached. Pellets should be stored in sealed bottles under desiccant.

The pellet shall then be loaded into the fuel basket and the retaining tabs bent 90° to retain the pellet as tightly as possible.

3. Weld Inner Capsule

Welding is to be done in a high purity argon atmosphere that has a low water vapor and oxygen content. The argon must pass through a molecular sieve immersed in an acetone bath and which in turn is cooled by conduction through copper bars to a liquid nitrogen bath. Argon supply lines must be at a positive pressure of greater than 5 psig at all times. The molecular sieve must be reactivated each time the tank is changed. The molecular sieve (Linde 13X) is reactivated by heating the molecular sieve tube at 250°C to 275°C and holding at this temperature for one hour with a constant purge of high purity argon through the tube at a flow rate of about 100 cc per minute.

FUEL CAPSULE ASSEMBLY PROCEDURE (Con't)

Weld penetration must be 100%. The diameter of the welded inner capsule measured in the weld bead area must be 0.310" ±0.005".

An example weld on an empty (unfueled) inner fuel capsule shall be done before and after each production run. These capsules shall be sectioned and examined for 100% penetration, cracks and pores in the weld area. These sectioned capsules shall then be crushed between hardened steel surfaces with 1000 kg load to test for embrittlement of the capsule material. The crushed halves should not break up or show cracks.

Before each fueled capsule weld is accomplished, an arc shall be struck on a sample of .030" thick capsule material, or weld coupon, supplied by Coratomic. This shall be done in the same atmosphere and chamber and at the same time as the fueled capsule is welded. The fuel capsule shall then be welded without changing the atmosphere. After the capsule and sample are removed from the chamber, the sample shall be folded in half using a press to test for ductility. There shall be no cracks in the sample after bending. The weld chamber shall be capable of a vacuum of 2×10^{-6} torr before each weld. With vacuum valves closed after reaching 2×10^{-6} torr, the pressure shall not rise to greater than 1×10^{-4} torr in 3 minutes.

The weld chamber shall be capable of holding a pressure of 2 psig for 5 minutes. The chamber and argon supply lines shall be purged, the chamber evacuated and then backfilled to atmosphere pressure with argon before welding.

All inner capsule welds must be single pass. No rewelding or repair work is to be attempted on the inner capsule.

The welded capsules should not be removed from the weld chamber until the capsule temperature is below 200°C.

4. Visually Inspect Weld Using Magnification Greater Than 30X

a. uniform width of weld bead
b. no pores or void spaces in weld area
c. no discoloration
d. smooth surface
e. no high points

5. Alpha Wipe Test of Inner Capsule

Alpha wipe test on completed inner capsule must show less than 500 c/m of removable alpha contamination before proceeding.

6. Leak Check Inner Capsule Per Fuel Capsule Leak Check Procedure #B1-1102

a. Externally pressurize the capsule in a small chamber to 100 psig with helium for one hour.

FUEL CAPSULE ASSEMBLY PROCEDURE (Con't)

b. Remove capsule from pressurization chamber and immediately place it in a small clear glass beaker containing approximately 1" of distilled water at 90°C and observe any bubbles of helium coming from the capsule. No bubbles should occur in one minute.

c. Remove capsule from water and test for leaks using a mass spectrometer lead detector such as NRC, Model 925. Leak rate should be less than 1 x 10^{-8} std. cc/sec.

7. Prepare Outer Capsule for Welding

Outer capsule parts are supplied, cleaned, annealed and degassed. The welded inner capsule must be cleaned in boiling reagent grade trichloroethylene and rinsed in reagent grade acetone before being placed in the outer capsule shell. The weld chamber must be pumped down and checked for leaks as in the Inner Capsule Welding Procedure, Item 3 above. The test weld on a sample of outer capsule material is not done for the outer capsule weld. The welded outer capsule should not be removed from the weld chamber until the capsule temperature is below 200°C.

8. Visually Inspect Weld Using Magnification Greater Than 30X

a. uniform width of weld bead
b. no pores or void spaces in weld area
c. no discoloration
d. smooth surface
e. no high points

9. Alpha Wipe Test of Outer Capsule

Alpha wipe test on completed outer capsule must show less than 1 x 10^{-5} microcurie of removable alpha contamination before proceeding.

10. Leak Check Finished Capsule Assembly Per Fuel Capsule Leak Check Procedure #B1-1102

a. Externally pressurize the capsule in a small chamber to 100 psig with helium for one hour.

b. Remove capsule from pressurization chamber and immediately place it in a small clear glass beaker containing approximately 1" of distilled water at 90°C and observe any bubbles of helium coming from the capsule. No bubbles should occur in one minute.

c. Remove capsule from water and test for leaks using a mass spectrometer lead detector such as NRC, Model 925. Leak rate should be less than 1 x 10^{-8} std. cc/sec.

FUEL CAPSULE ASSEMBLY PROCEDURE (Con't)

11. Radiation Measurements

Measure and record on the assembly report the neutron radiation in neutrons per second and the gamma radiation in milliroentgens per hour at 4" distance of the finished capsule.

12. Final Dimensional Check

All completed fuel capsules are to be checked for dimensional acceptability by placing in the Coratomic provided go-no-go fixture. The capsule should fit in the fixture and the two halves of the fixture mate without interference.

13. A final assembly report will be completed and sent with each capsule when shipped to Coratomic. The Final Assembly Report is Form #B1-2045.

FUEL CAPSULE ASSEMBLY PROCEDURE (Con't)

A. A Production Run is Defined as:

1. A lot not to exceed 20 capsules
2. A lot that shall not extend over fifteen (15) calendar days.

B. Parameters

1. A sample shall be done prior to the production run and examined immediately to assure acceptance.
2. A sample shall be done immediately after a production run to assure current production.
3. A sample at the end of a production run should be used as the start of the next production run if the following criteria is satisfied:
   a. No change in welder set-up (including use for other job or associated material change).
   b. Next production run originated prior to fifteen (15) calendar day period.
4. Allowable stoppage (will not terminate production run)
   a. Normal day-end shutdown
   b. Normal weekend or holiday shutdown
5. Non-allowable stoppages (production run to be terminated)
   a. Change in welder set-up
   b. Change in associated material (include argon tank change, fixture, etc.)
   c. Capsule test failure

REVISION											
	CR# Date 2/21/77		CR# Date		CR# Date		CR# Date		CR# Date		
	CR# Date		CR# Date		CR# Date		CR# Date		CR# Date		
	CR# Date		CR# Date		CR# Date		CR# Date		CR# Date		
	CR#		CR#		Dc						

FUEL CAPSULE ASSEMBLY REPORT

Source No._____ Date:_____

Purchase Order No._____ Drawing No._____

Material Certification No.

Part #3, 4 (Inner)_____ Part #1, 2 (Outer)_____

Part #5 (Basket)_____

Welding Data: Welder Make Hobart Model TG-201 Serial No. 8RT-4105

Inner Capsule	Outer Capsule
Plutonium:	
Batch No._____Wt. % Isotope_____	
Powder wt._____grams	
Green Pellet wt._____grams	
Sintered wt._____grams	
Pu-238	
Factor ( )_____grams	
ci/g (17.2)_____curies	
Current_____Voltage_____	Current_____Voltage_____
Arc Gap_____Rotation(s/r)_____	Arc Gap_____Rotation(s/r)_____
Electrode Size 0.125"	Electrode Size 0.060"
Electrode Type 3% Thoria Tungsten	Electrode Type 1% Thoria Tungsten
Welder Operator_____	Welder Operator_____
Welding Atmosphere Argon	Welding Atmosphere Argon
Alpha Wipe Test_____C/M	
_____uci	
Leak Test:	
Alcohol Bubbles: yes_____no_____	Alcohol Bubbles: yes_____no_____
Leak tester_____std.cc/sec	Leak tester_____std.cc/sec

Finished Source: Neutron Radiation_____Gamma Radiation_____at 4"

Alpha wipe test_____uci

REMARKS:

Coratomic®
P.O. BOX 434, INDIANA, PENNSYLVANIA 15701
PHONE (412) 349-1811 TELEX 86-6658

LOSS OF PLUTONIUM-238

License No. SNM-1319

On June 27, 1978, a Coratomic, Inc. C-100 nuclear pacemaker, serial number 23, was noted as missing from inventory. Loss occurred during the relocation of Coratomic into its new facility. The following is a detailed report of the nuclear material burial.

1. Description of the nuclear material:

Material - Pu-238 (See Attachment I)	
Amount - <0.250 grams	
Fuel Capsule - Serial Number 24	
Encapsulation (pacer form) -	5 separate encapsulations all leak checked to $<1x10^{-8}$ std. cc sec^{-1}
Leak Check - March 18, 1974	$<1x10^{-8}$ std. cc sec^{-1}
Wipe Test - June 2, 1978	<.0005μci

2. Description of the circumstance which which the burial occurred (as documented from interviews with certain Coratomic personnel on June 30, 1978).

INTERVIEW - JIM CUPP (Chemistry Dept. Supervisor)

Jim Cupp received the nuclear pacer on June 7th or 8th with instructions to remove the epoxy head using an epoxy stripper. Jim labelled the beaker with a tri-foil radiation sysbol and the words "Dog Implant" using a black marking pen.

On June 16th, the Friday before the move, Jim removed the nuclear and and a few other lithium pacers from their respective beakers. Upon examination he found that the nuclear pacer had not dissolved and he replaced it back into the stripper solution.

On June 19th, which was moving day, Bob Schickler asked Jim Cupp what should be done with the pacer. Jim instructed him to leave it on the shelf explaining that they would pick it up after the material had all been moved to the new building.

On Wednesday, June 28, while locating a pacer Quality Assurance had requested, Jim remembered that the "dog pacer" had been left in the old building. When he looked for it, the old chemistry room had been stripped bare and cleaned out.

Jim indicated that they finished packing the room before lunch on Monday, June 17.

INTERVIEW - ROBERT SCHICKER (Precision Assembler - Chemistry Dept.)

The last time Schickler handled the pacer was Wednesday, June 14th. On that day he put it back into the stripper because the head was dissolving

slowly. The last place Schickler recalls seeing the pacer was on the shelf soaking in stripper solution.

Schickler recalls leaving the old building about 1:30 on Monday, June 19th at about 1:00 or 1:30 p.m.

INTERVIEW - CLIFF HENDERSON (Maintenance Tradesman)

Cliff indicated he cleaned the old chemistry room on Wednesday, June 21. There was a log of old papers and paper towels and scrap. Using a 3' x 2' box about 2' high, Cliff gathered all this trash and discarded it in the trash bin in back of the old building. He specifically remembers discarding the beaker and two others which were sitting above the sink at that time. When asked if he had checked any of the beakers, he responded that he thought everything left in the room was trash to be discarded. (The stripper solution turns a yellow-brown as it dissolves the epoxy and the contents are not visible.) Cliff said he placed the aluminum foil covered beaker upright in the trash so the liquid would not spill. The garbage bin was full Thursday, June 22 at 3:30 and had been emptied by the following afternoon. (Pellegrene Sanitation Service indicated this trash was picked up late in the afternoon on Thursday.)

3. Actions taken to recover the nuclear material:

A thorough search of all Coratomic facilities, both new and old plant, including garbage of both facilities was conducted on June 28, 1978.

On June 29, 1978, the Pelligrene land fill facility was completely searched by J. Cupp and K. Munz using a Varian Survey Meter, Model No. 490, Serial No. 2341. Assistance in moving refuse material was provided by two Pelligrene operators at the land fill. Material was moved five times by the operators and a complete search of the area was conducted after each movement of material. Material was dug out approximately 18 inches each time. No radiation was detected by the survey meter at any time when sweeping the area.

4. Statement of disposition and radiation exposure to individuals:

Pellegrene Sanitary Service subsequenty buried the nuclear pacemaker at a depth of six to eight feet in their sanitary land fill. Due to the location and depth of the pacer and the multiple hermeticity of its design, there could be no personal injury or ecological damage from this source.

5. Subsequent report:

Mr. Larry Lesnak, Manager of Quality Assurance and Control, reported the burial to the regional office of the Nuclear Regulatory Commission in Philadelphia within 24 hours of the burial. He was told that the verbal reporting was sufficient since the location of the burial source was known, and it had been disposed of in a safe manner with no threat to the biosphere. He was told that no formal written report was necessary.

6. Procedures and measures adopted to prevent a recurrence of loss of licensed material:

Coratomic, Inc. will continue the current accountability system with an additional safeguard to keep company personnel cognizant of regulatory requirements. An audit of each department will be frequently and randomly conducted to assure proper accounting of nuclear material. The Coratomic accountability chart will be improved.

Mine Valley
Fidelity File

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
631 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

Docket No. 70-01342

16 APR 1981

Coratomic, Inc.
ATTN: Mr. David Purdy
President
P. O. Box 434
Indiana, Pennsylvania 15701

Gentlemen:

Subject: Loss of Source

Thank you for your letter which forwarded a final report pursuant to 10 CFR 20.402 regarding the subject matter.

This matter was reviewed by our inspector during an inspection conducted on January 28, 1981.

Your cooperation with us is appreciated.

Sincerely,

John D. Kinneman

John D. Kinneman, Chief, Materials
Radiological Protection Section,
Technical Inspection Branch

1P.