Hittman
Nuclear Battery
Corporation
9190 Red Branch Road
Columbia, Maryland 21045
301/730-7800

Refer to:
74-N355

March 26, 1974

Mr. Bernard Singer
Chief, Materials Branch
Licensing, Fuels and Materials
U. S. Atomic Energy Commission
Washington, DC 20545

Subject: Cremation Temperature Profile Measurement

Dear Bernie:

Enclosed you will find three copies of the subject report concerning the test you witnessed on ~~13 March~~ 18, 1974. After processing the data, several interesting conclusions can be drawn which were not immediately apparent while the test was in progress.

If you or your staff have any questions concerning the test, please contact me.

Sincerely yours,

Thomas S. Bustard, Ph.D.
President

tb

Enclosures

cc: M. Shoup (AEC) - w/encl.
J. Bell (AEC) - w/encl.
T. Brown (AEC) - w/encl.
R. Mason (AEC) - w/encl.
I. Sopher (State of Md.) - w/encl.
R. Corcoran (State of Md.) - w/encl.
C. Crabtree (Loudon Park Cemetery) - w/encl.
W. B. Bradley (Md. Cremation Services Inc.) - w/encl.

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CREMATION TEMPERATURE PROFILE MEASUREMENT

The purpose of this test was to measure the time-temperature profile of an All Industrial Furnace Co., natural gas-fired crematorium, located at Loudon Park Cemetery on Frederick Avenue in Baltimore, Maryland. The test was performed on the afternoon of January 19, 1974. The following were in attendance:

Mr. Bernie Singer	USAEC
Mr. Mel Shoup	USAEC
Mr. Jay Brown	USAEC
Mr. Rod Mason	USAEC
Mr. Jack Bell	USAEC
Mr. Robert Corcoran	State of Maryland
Col. Chuck Crabtree	Loudon Park Cemetery
Mr. Dave Goslee	Nuclear Battery Corp.
Mr. Chuck Hopkins	Nuclear Battery Corp.
Dr. Tom Bustard	Nuclear Battery Corp.
Charlie	Deceased

As previously stated, the crematory was manufactured by the All Industrial Furnace Co. of Sacramento, California. It is a natural gas-fired furnace having only four on-off type controls. There are door open-closed, blower on-off, main burner on-off, and after burner on-off controls. No other controls, such as those for the purpose of adjusting gas or air flow exist. The furnace chamber consists of ordinary firebrick and measures 26.5 inches high by 35.5 inches wide by 120 inches deep. The main burner is located directly in the center of the door, recessed slightly below the floor of the furnace. A schematic of the furnace is shown in Figure 1.

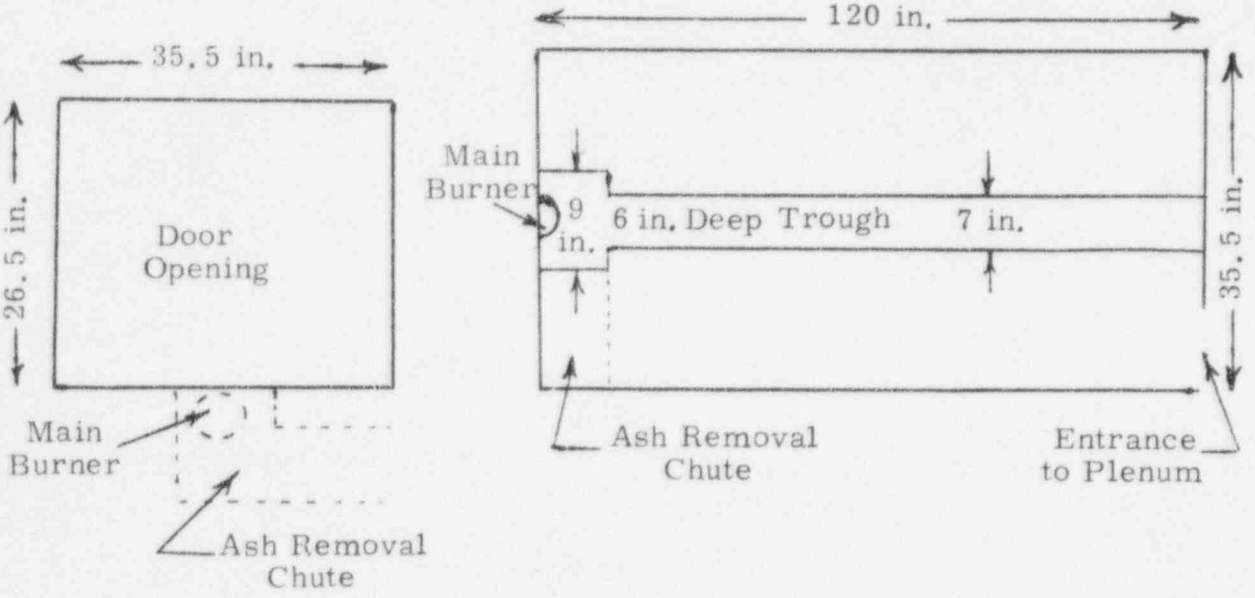


Figure 1. All Industrial Crematory Furnace Schematic

A cremation is normally carried out by placing the cadaver into the furnace, feet first, and the door closed. The apex of the head is usually located 12 to 16 inches from, and directly in line with, the main burner. The air blower is turned on and two minutes later, the after burner is activated. The main burner is then ignited. Approximately 90 minutes after igniting the main burner, the unit is shut down to check the cadaver. Heavy remains are then raked forward towards the main burner and the furnace restarted. Usually, another 30 minutes suffices to complete the process.

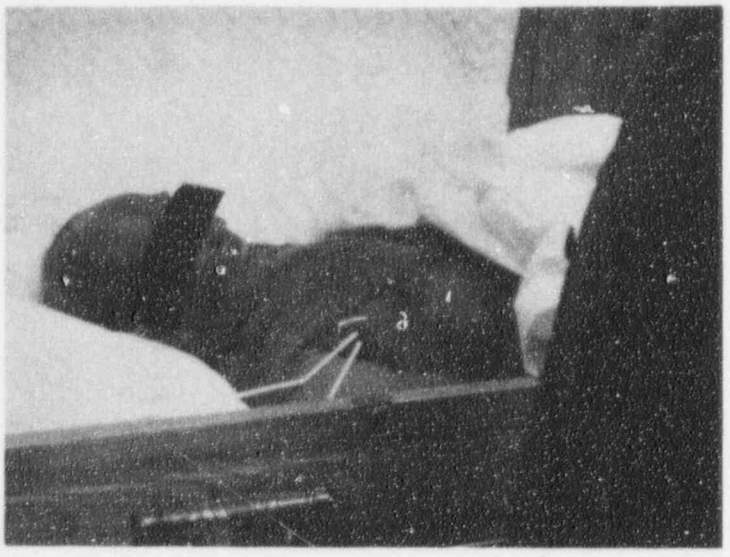
The furnace is allowed to cool and the remains are raked into the ash removal chute and then taken from the furnace. These are placed in a heavy grate sieve where a magnet is used to remove all metal pieces. The larger remains (i.e., bone pieces) are then placed through a crude grinder. After grinding, the remains are placed into a coffee-like metal can which is subsequently placed into a pasteboard box. This is delivered to the next of kin by the Funeral Director or by mailing.

Cremations are carried out in various type containers ranging from cardboard boxes to elaborate hardwood coffins. It is the practice at Loudon Park Cemetery to require a suitable container which is not opened unless specific instructions to that effect are received from the Funeral Director. This protects the cemetery and its employees, but also negates the possibility that a pacemaker would be discovered in a cadaver at the crematorium. No one is ever cremated at Loudon Park without specific approval from the next of kin or the Chief Medical Examiner of the State of Maryland.

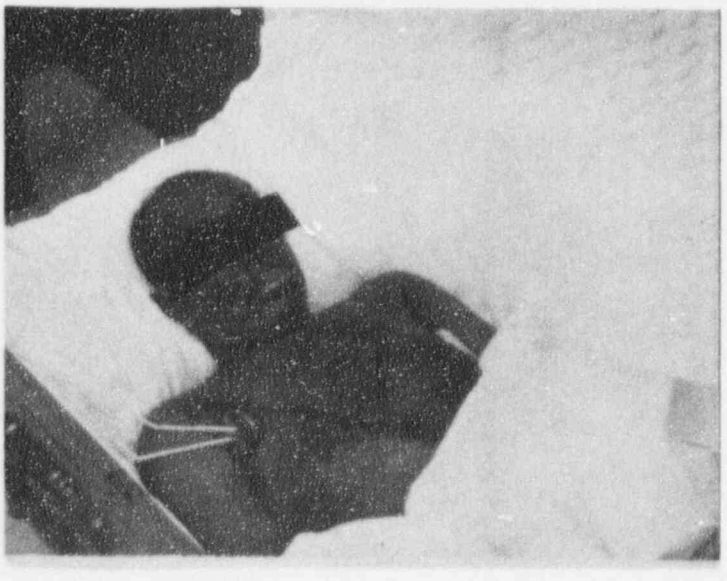
During this experiment, we wished to ascertain a worst case condition. We therefore procured a solid oak casket, which was approximately 1.5 inches thick. It was felt that conflagration of the hardwood casket would contribute to the severity of the thermal environment. A cadaver, obtained from the State of Maryland, was placed in the casket. A 17-mil thick, commercially pure titanium pacemaker can was placed under the right armpit of the cadaver. An alumina boat containing a piece of tantalum-10 percent tungsten was placed under the left armpit. These are shown in Figure 2. Two, platinum-13 percent rhodium thermocouples were spot welded to the can. Several pieces of copper as well as a piece of Hastelloy-C276 were placed on the chest of the cadaver.

The cremation was carried out in a normal fashion as previously described. Figure 3 shows the interior of the furnace and the remains after cremation as well as the metal pieces removed after the test. Figure 3 also shows the pacemaker can, now completely oxidized to titania, but still integral and easily discernible in the remains.

Figure 4 shows the most interesting data, the time-temperature profile. Note that the two thermocouples, which were separated by less than one inch distance, sometimes gave widely varying readings. In fact, each thermocouple was continually oscillating as much 300 to 400°C for the first 30 minutes and 100 to 200°C for the next 60 minutes. An attempt was made to read the maximum point of the oscillations which are indicated by the

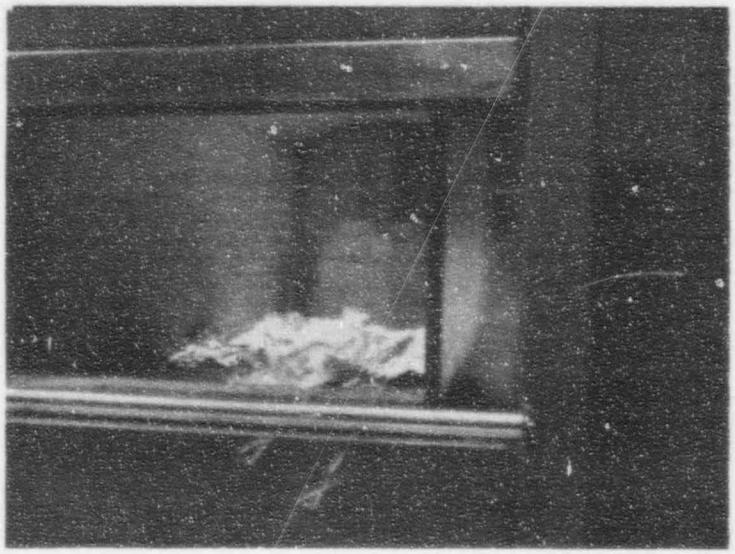


(a) Pacemaker Can Location

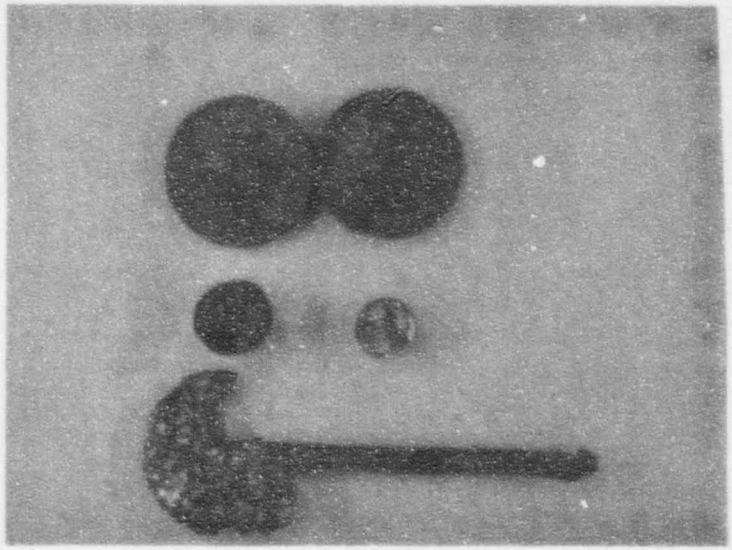


(b) Pacemaker Can and Alumina Boat Loacation

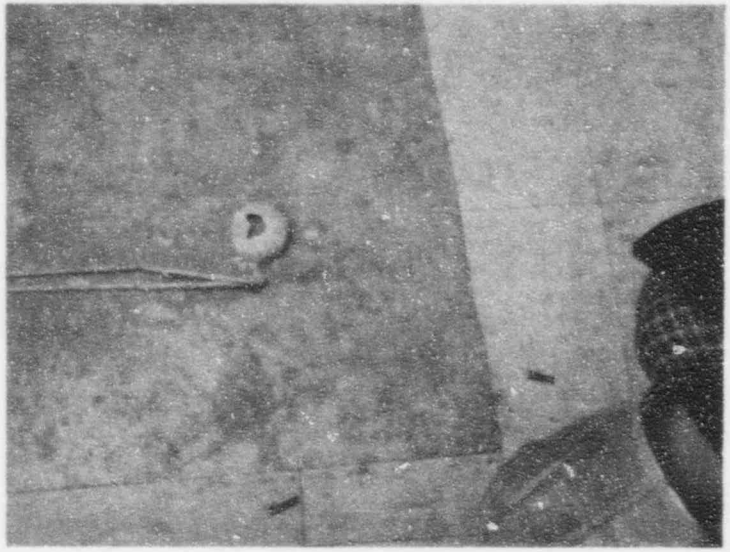
Figure 2



(a) Remains After Cremation



(b) Metal Removed After Test



(c) Pacemaker Can After Test

Figure 3

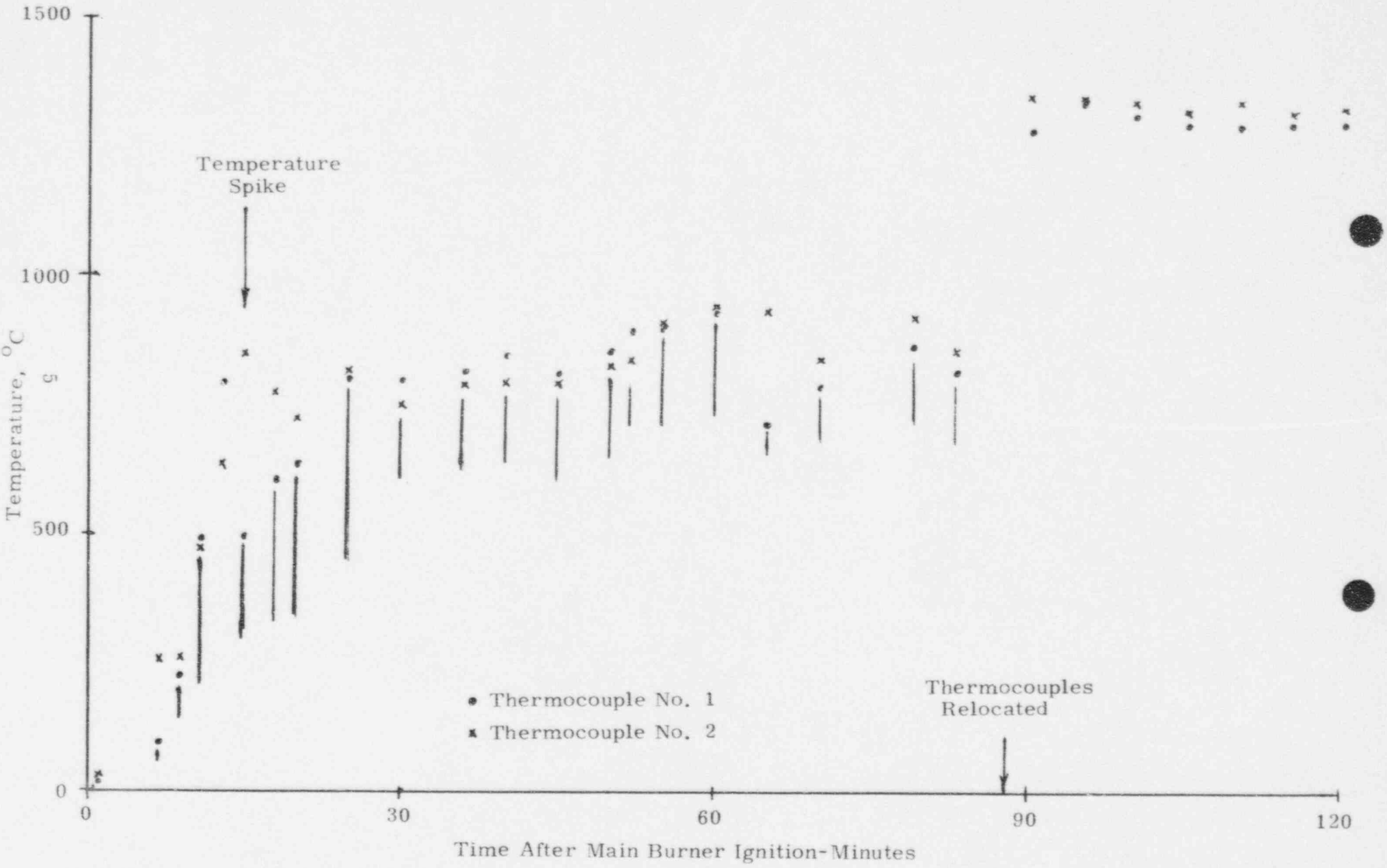


Figure 4. Cremation Temperature Profile

dots and x's in Figure 4. The temperature oscillation magnitude is roughly indicated by the vertical lines. The only explanation for the observed temperature oscillations is the main burner flame intermittently "licking" the thermocouples.

The initial heatup proceeded slower than expected with the temperature being less than 500°C after 10 minutes of operation. This is probably attributable to an insulating effect from the heavy oak coffin. Between 10 and 20 minutes after startup, a clear temperature spike occurred. This is probably attributable to conflagration of the coffin in the immediate vicinity of the thermocouples. After this, the temperature stabilized (not including the thermocouple oscillations) to between 750 and 950°C.

After 86 minutes of operation, the crematory furnace was shut down and the thermocouples, located approximately 24 inches and on a 45-degree angle from the main burner, were relocated directly in front of and 9 inches from the main burner. This is as close to the main burner as is possible. Any object coming closer to the main burner would fall into the ash removal chute.

After relocation of the thermocouples, the door was closed and the main burner re-ignited. The temperature readings immediately elevated to the 1300°C vicinity. No thermocouple oscillations were observed lending credence to the postulate that the previous oscillations observed were due to a flame "licking" effect. Another interesting observation is that the initial temperature readings after thermocouple relocation were slightly higher than the latter ones. We believe this is due to the fact that air was let into the furnace at the time the thermocouples were relocated. As this excess air was consumed and the burner returned to a fuel rich condition, the temperature decreased.

Conclusions

The test was very worthwhile from several standpoints. Several points were uncovered concerning the possible cremation of nuclear pacemakers that were not immediately obvious previously.

- There is little possibility that a cadaver bearing a nuclear pacemaker could be identified at the crematorium. The containers are not opened at that point so tatooing or other means of identification would not help.

- The container in which the cremation occurs will contribute to the thermal environment somewhat. The heavier hard wood coffins will probably burn hotter but will also provide an initial insulating effect. A cardboard container will probably burn cooler but will provide less initial insulation. The effects are probably counter balancing.

- A "licking" effect from the flame will cause a wide oscillation of temperature in objects possessing slight thermal inertia and located in the vicinity of the main burner.

- A severe thermal gradient occurs within the crematory chamber running from the 1300 to 1340°C range nine inches from the main burner to the 800 to 950°C range 24 inches from the main burner. This is about 25°C per inch. Therefore, in stating the temperature within a crematory, one must be very careful to specify the point of measurement as it is hardly an isothermal chamber.

- Should a cadaver be cremated still bearing a titanium encased nuclear pacemaker, it is highly improbable that it would be overlooked. The can utilized in this experiment was easily discernible after the test. Further, the remains are sieved and the larger pieces placed in a crude grinder. Care is taken to remove all metal pieces such as coffin nails, clasps and hinges prior to grinding. These metal pieces are placed into the trash and the pacemaker would probably end up in a municipal dump. The personnel at Loudon Park profess never to have found the remains of a pacemaker. They have recovered artificial bones and joints, heart valves, etc.

- It is highly unlikely that the source from a nuclear pacemaker would ever be exposed to 1300°C for 90 minutes as is being specified in the new Interim Guide if this crematory is typical. Most probably its exposure would be in the 800 to 950°C temperature range for two hours.

The evidence uncovered in this experiment would seem to negate most of the results published by ARCO-Nuclear in their crematory study. Without knowing the location of the Tempil pellets within the crematory, the results are meaningless. Further, the temperature measured at the main burner could explain the isolated instance of melting Inconel in their experiments. The holder was probably very close to the main burner.

It would be most interesting to repeat this experiment with a large number of thermocouples located throughout the chamber so that a complete thermal profile could be obtained. It would further be desirable to have these connected to a recorder rather than the Thermo-Electric Model 31101 potentiometer utilized here. While the recorders would be less accurate, they would record the wide oscillations observed.

Further, while an indication was obtained in this experiment that the main burner was running fuel rich, it would be desirable to be able to sample the atmosphere within the chamber. This would be difficult to accomplish.

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

June 24, 1980

Food & Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, MD 20910

RE: 510(k) Submission
Coratomic C-101-P
Cardiac Pacemaker

Dear Sirs:

In a telephone conversation with Glenn Rahmoeller on June 20, 1980, Mr. Rahmoeller suggested that a 510(k) on the C-101-P be submitted.

The C-101-P pacemaker is essentially equivalent to pacemakers existent and being implanted prior to May 28, 1976. A drawing of the C-101-P is shown as Exhibit 1, Drawing D-4101-144. The isotopic battery used in the C-101-P is identical to that used in Coratomic's C-101 pacemaker described in Exhibit 2, Drawing D-4101-101. It uses the electronics from the Ovalith-P pacemaker shown in Exhibit 3, and the case of the L-500 pacemaker described in Exhibit 4.

The C-101, Ovalith-P and L-500 pacemakers were all in use or judged "essentially equivalent" to pacemakers implanted prior to May 28, 1976.

Thus, the C-101-P is also "essentially equivalent" to pacemakers implanted prior to May 28, 1976.

The following information is submitted to clearly delineate the characteristics and status of the devices listed which substantiate the essential equivalency of the C-101-P with pre-enactment devices.

Ovalith-P

A 510(k) notification was received on the Ovalith-P on October 22, 1979. This notification is attached as Exhibit 5. A brochure describing the pacer and the programmer are enclosed as Exhibit 6, and a Physician's Manual enclosed as Exhibit 7.

L-500

The L-500 pacemaker was first implanted in February of 1976. Most recently a reliability and performance update was prepared for this device and a copy of this reliability performance update is enclosed as Exhibit 8. This analysis compares the performance of the L-500 with that of the C-100 Series pacemakers, composed of the C-100 and C-101 pacers.

The Coratomic C-100 Series Pacers

The first Coratomic isotopic pacemaker, the C-100, was developed in 1972 and 1973. The first two implants of the C-100 occurred on October 3, 1974. The first two initial C-100 implants continue to pace the patients satisfactorily and each has accumulated a unit implant time of 1,974 days (64.9 months). The implants were performed under license number SNM-1319 from the U. S. Atomic Energy Commission (now the U. S. Nuclear Regulatory Commission). This license has been amended thirteen times, the most recent amendment being issued on October 29, 1979 for the continuation of the C-100 Series implants. The C-100 pacer was modified by widening its bandpass in the Spring of 1975 in order that the pacer would accurately sense a larger number of patients R-waves. The model number was changed from the C-100 to the C-101 and implants continued under a Human Clinical Protocol issued November 1, 1975 and attached as Exhibit 9. A description of the pacer is seen in Exhibit 10 and a Physician's Manual may be found as Exhibit 11. This isotopic pacer has far exceeded the objectives established by the Nuclear Regulatory Commission for its implantation. It has achieved a level of reliability three times higher than anticipated and twice that of the control group of conventional pacers established for the C-100 Series in 1974. Its performance has far exceeded that of lithium pacemakers and other nuclear pacers as reported in Exhibit 8.

The isotopic pacer utilizes the same amount of fuel used as the model for the "Draft Generic Environmental Statement on the Wide Scale Use of Plutonium Powered Cardiac Pacemakers" issued in January, 1975, and the "Final Generic Environmental Statement on Routine Use of Plutonium Powered Cardiac Pacemakers dated July 1976" (NUREG 0060) and the "Final Generic Environmental Statement Supplement on the Routine Use of Plutonium Powered Cardiac Pacemakers" issued in May 1979 (NUREG 0060, Supplement 1). A copy of the new NUREG 0060, Supplement 1 is enclosed as Exhibit 12. All of these environmental statements prepared by the staff of the Nuclear Regulatory Commission have resulted in an unconditional recommendation that the routine use of plutonium powered cardiac pacemakers be permitted. To date, however, Coratomic continues to implant the C-101 as part of a clinical study as described in Exhibit 9.

As part of the requirement of the SNM-1319 license, Coratomic issued a bi-annual report on the study. A copy of the March 1, 1980 Investigational Program is enclosed as Exhibit 13.

The Physician's Technical Manual for the C-101-P programmable isotopic powered pulse generator is attached as Exhibit 14.

Coratomic hereby requests that a 510(k) application be approved to allow Coratomic to implant the C-101-P subject to the nuclear safety provisions provided in its SNM-1319 license.

Sincerely,

David L. Purdy
Chairman of the Board

DLP:mb

Enclosures

cc: Mr. Joseph Brown, Nuclear Regulatory Commission
Congressman John P. Murtha
Senator Lawton Chiles
Congressman Earl Hutto
Mr. David Mica, Aide to Senator Chiles
Ms. Mary Ann Williams, Aide to Congressman Hutto
Ms. Peggy Parker, Aide to Senator Schweiker
Senator Richard Schweiker
Mr. William Allan, Aide to Congressman Murtha
Senator John P. Heinz, III
Mr. David Diesley, Aide to Senator Heinz

EXHIBIT 5

OCT 24 1979

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

OCT 22 1979

Mr. David L. Purdy
President
Coratomic
P.O. Box 434
Indiana, Pennsylvania 15701

Ref: K790566 - Ovalith-P Cardiac Pacemaker

Dear Mr. Purdy:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

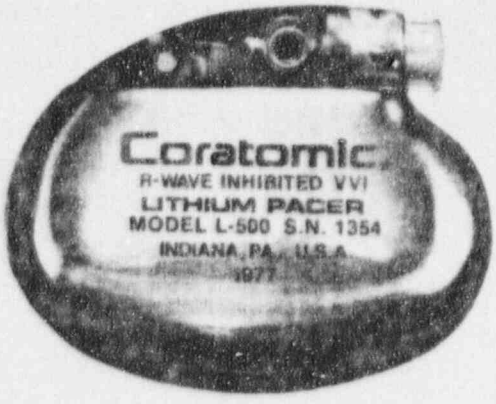
Sincerely yours,

David M. Link

David M. Link, Director
Bureau of Medical Devices

Coratomic L-500

lithium pacer . . . a quality product



INTRODUCTION

The Coratomic Model L-500 is an R-wave inhibited (VVI) unipolar lithium pacer. This pacer, introduced in February, 1976, utilized discrete electronic circuitry and a mulitple redundant solid-state Mallory lithium battery.

FEATURES

Biocompatibility The patented ovaloid shape, small size, and light weight of the L-500 provide minimum pacer bulge and maximum comfort for even the thinnest patient.

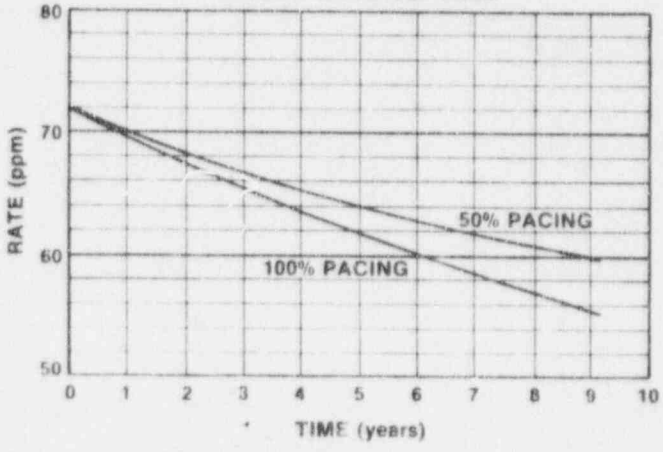
Patient Safety For maximum patient safety, Coratomc selected Mallory's unique, multiple redundant solid-state lithium battery and combined it with a simple discrete circuit utilizing JAN-TX and S-level components of the finest available quality. In addition, each production pacer is 100% acceptance tested prior to shipment.

Coratomic Service Coratomic stands behind every product with fully trained Pacer Specialists in the field to answer technical inquiries and a corporate Applications Engineering Department to assist in pacer problem management. You can expect a prompt and knowledgeable response to all technical inquiries from your Coratomic representatives.

CHARACTERISTICS

Implanted rate	72 ½ppm
Magnetic rate and noise rate	93 ±5 ppm
Pulse width	0.5±0.1 msec
Pulse current	10.5±0.5 ma
Pulse voltage	5.4 v, nominal
Sensitivity	2.5 ±1.0 mv
Refractory period	200-300 msec.
Current drain (pacing)	10 μa
Circuitry	discrete, constant voltage output
Power source	Mallory LSA-900-6, Series II solid-state lithium battery
Size	6.4 × 5.1 × 1.9 cm
Weight	69 gm
Volume	39 cc
Specific gravity	1.77 gm/cc
End-of-life indicator	rate decrease with time

PACER RATE VS. TIME



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

PW0680

EXHIBIT 4