Atlantic Richfield Company

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April 3, 2019

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U.S. Nuclear Regulatory Commission, Region 1
ATTN: Director of Nuclear Materials Safety
2100 Renaissance Ave., Suite 100
King of Prussia , PA 19406

RE: License #SNM 1993 Condition 12 Report – 2018

I am writing you on behalf of ARCO Environmental Remediation LLC (ARCO).

Enclosed please find the report entitled "Radioisotope Powered Cardiac Pacemaker Program Technical Memorandum Report XLVIII on the Status of the Clinical Studies of the Nuclear Pacemaker Model NU-5 from the ARCO Medical Products Company." This report satisfies Condition 12 of ARCO's Special Nuclear Materials License.

If you have any questions or need additional information, please contact me.

Sincerely,

Cynthia D. Kezos
Liability Business Manager
Remediation Management Services Company
An affiliate of Atlantic Richfield Company

Enclosure

Cc: K. Paul Steinmeyer, Radiation Safety Associates

611852
RESEARCH MATERIALS-002

RADIOISOTOPE POWERED CARDIAC PACEMAKER PROGRAM

TECHNICAL MEMORANDUM

REPORT LI

ON THE STATUS OF THE CLINICAL STUDIES OF THE

NUCLEAR PACEMAKER MODEL NU-5

FROM THE

ARCO MEDICAL PRODUCTS COMPANY,

A SUBSIDARY OF ATLANTIC RICHFIELD

February 12, 2019

K. Paul Steinmeyer, RRPT
Radiation Safety Officer

Prepared By:
Radiation Safety Associates, Inc. for
Atlantic Richfield Company

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I. PROGRAM HISTORY

Arco Nuclear Model NU-5 pacemakers were implanted in humans from 1973 to 1978 as part of a clinical study to investigate their performance. The pacemaker power source is a sintered Pu-238 oxide fuel pellet from which heat from its decay flows through thermoelectric wires and is eventually converted to a DC voltage by normal thermocouple action. Extensive testing such as dog implantations, impact tests, crush tests, temperature and cremation tests, and capsule pressure considerations were completed to ensure pacemaker integrity in the unlikely event of an accident.

During the clinical study phase, reports were sent to the Nuclear Regulatory Commission with information as specified in both the "Research Protocol for clinical Investigation of the Arco Nuclear NU-5 Pacemaker" and attached "Contents of Sponsor's Periodic Report on Clinical Performance of Pacemaker" (Attachment A). The last full report during this study phase was submitted on October 15, 1980. After that, certain reporting requirements changed and semi-annual inventories were submitted to conform to the license. A copy of the latest inventory submittal is included as Attachment B.

In order to more fully update the Nuclear Regulatory Commission, per their verbal request, a report was submitted on January 15, 1988. This report, and all subsequent reports, will be submitted per Condition 12 of our material license and presents, in addition to the above:

- Implanted and explanted pacemaker tables with relevant information as specified in Attachment A, "Contents of Sponsors Periodic Report on Clinical Performance of Pacemakers" and presented in Tables I and II.

- Calculations of nuclear pacemaker failure rate and mode as required in Attachment A, Section IID, and included in Attachment C.

- A list of the pacemaker failure-related explants since the last reporting period and presented in Attachment D.

II. PURPOSE OF THE TECHNICAL MEMORANDUM

The purpose of this technical memorandum is to report upon and update the progress of the clinical study of the ARCO Medical Products NU-5 Model radioisotope powered cardiac pacemakers from January 26, 2018 to February 19, 2019 as specified in the "Contents of Sponsor's Periodic Report on Clinical Performance of Pacemakers." This is the fifty-second technical memorandum summarizing the clinical data to be submitted to the Materials Branch of the United States Nuclear Regulatory Commission, in compliance with license SNM-1993 that replaced #37-14916-01.

III. CLINICAL IMPLANT STATUS OF THE NUCLEAR PACEMAKERS

Tables I and II list nuclear pacemakers implanted and explanted, respectively. The pacemakers are listed in numerical order with the fixed rate units first, followed by the demand units.

Information listed on Tables I and II are the pacemaker identification and any follow-up information required in the "Contents of Sponsor's Periodic Report on clinical Performance of Pacemakers." Specifically, the follow-up information is listed in items A.1.J, and A.1.M through A.1.O. Items A.1.K and A.1.L are covered in the explanted pacemaker table. The information requested from items A.1.A to A.1.I is static and can easily be referenced from previous reports.

Information shown in Table II is also represented in the same format. Along with pacemaker identification are the implant service days and the reason for explantation corresponding to items B.1.J and B.1.K, respectively. Item B.1.K is depicted as a number, which must be referenced to the Table II Attachment. Items B.1.A to B.1.I are also static and can be easily referenced in Attachment B. Attachment D describes pacemakers explanted due to pacemaker failure.

IV. NUCLEAR PACEMAKER ACCOUNTABILITY AND FOLLOW-UP

Data from all investigators have been accounted for, except where patients have elected not to attend their semi-annual physician follow-up. The right hand column of Table I is entitled "Contact." A "yes" indicates a current physician/patient contact, "LTF" indicates the patient is lost-to-follow after numerous physician attempts to contact the patient, and "N/A" indicates the patient has left the United States permanently. A "-"in the "bracelet & ID present" column indicates no information was retrieved from physician follow-up correspondence, indicating the patients had the bracelets and wallet cards on their possession.

V. CLINICAL PERFORMANCE ANALYSIS

Five goals were outlined in Attachment A, Section II for program analysis, and listed as subsections "A" through "E." Subsection goals "A," "B," and "E" were completed by ARCO Biostatisticians on former reports. Thus, this and all subsequent reports will contain relevant information only on goals "C," and "D."

The pacemaker failure rate, as shown in Attachment C, has been calculated for the period from 10/15/80 to 02/12/19 and from program inception to date; columns "A" and "B" respectively. All calculations were based on data from 79 and 125 implants, due to one patient who left the United States resulting in no pacemaker service data. As can be seen in Attachment C, the pacemaker percent failure is 32.9% for the total program and 32.9% from 10/15/80 to 02/12/19. This yields an average monthly failure rate of 0.0016 and 0.0024 for the respective time periods.

Based on the data found in Attachments C and D, there is no evidence reported of any long-term adverse side effects or other unknown factors associated with the nuclear pacemakers. Additionally, there is no statistical evidence suggesting any deleterious failure rates or modes associated with the program.

TABLES

TABLE I
IMPLANTED PACEMAKERS
AS OF 2/19/19

PACEMAKER ID		PACEMAKER SERVICE INFORMATION						SUPPLEMENTAL	
MODEL#	PACER #	IMPLANT DATE	FOLLOW-UP DATE	IMPLANT DAYS+	TOTAL MONTHS	SERV DAYS++	SERV MONTHS	BRACELET & ID PRESENT	CONTACT
NU-5F	94	6/5/1973	2/11/2019[1]	16,511	543.04	13,403	440.85	-	
Total				16,511	543.04	13,403	440.85		

+ Implant days were calculated from the date the pacemaker was implanted, until end of the reporting period.
++ Service days were calculated from 10/15/80, until the end of the reporting period.

The average length of a month is $\frac{365.25\ days/yr}{12\ months/yr} = 30.4\ days\ in\ an\ average\ month$

$$\frac{383\ days}{30.4\ \frac{days}{month}} = 12.6\ months$$

[1] Patient expired on 2/11/19. Pacemaker was recovered by Jackson Memorial Hospital staff and is in safe storage. It will be transferred to Radiation Safety Associates, Inc., Hebron, CT within 6 weeks.

TABLE II
EXPLANTED PACEMAKERS 10/15/80 TO 02/19/18

MODEL#	PACER #	IMPLANT DATE	EXPLANT DATE	IMPLANT DAYS+	TOTAL MONTHS	SERV DAYS++	SERV MONTHS	EXPLANT CODE
NU-5F	70	4/10/73	7/9/90	6299	207.2	3554	116.9	13
NU-5F	74	5/12/73	4/1/89	5803	190.9	3090	101.6	36
NU-5F	80	2/19/74	1/5/91	6480	213.1	3734	122.8	03
NU-5F	83	4/10/73	8/1/86	4861	159.8	2116	69.6	03
NU-5F	85	4/9/73	10/29/91	6777	222.8	4031	132.5	02
NU-5F	86	4/10/73	9/19/91	6736	221.5	3991	131.2	11
NU-5F	90	4/10/73	4/15/2014	14,696	483.44	11,947	392.92	02
NU-5F	***94***	***6/5/73***	***2/11/19***	***16,511***	***543.04***	***13,402***	***440.85***	***03***
NU-5F	97	6/5/73	9/1/88	5504	181	2878	94.6	21
NU-5F	100	4/9/73	2/12/87	5057	166.3	2311	76	19
NU-5F	103	5/27/98	5/27/98	8083	265.8	6433	211.5	13
NU-5F	107	4/10/73	1/15/87	5028	165.3	2283	75.1	03
NU-5F	115	7/6/73	8/1/89	5870	193	3212	.6	03
NU-5F	120	7/24/73	9/1/88	1171	38.5	0	0	N/A
NU-5F	126	10/13/98	10/13/98	9254	304.3	6572	216.1105	2
NU-5F	128	6/12/73	2/9/88	5355	176.1	2673	87.9	03
NU-5F	131	6/13/73	9/19/93	7403	243.4	4722	155.3	03
NU-5F	138	12/10/73	12/17/82*	3294	108.3	793	26.1	36
NU-5F	140	6/13/73	10/15/81	3046	100.2	365	12	36
NU-5F	144	7/27/73	10/2/87	5180	170.3	2543	83.6	06
NU-5F	145	9/14/73	9/24/81*	2932	96.4	344	11.3	22**
NU-5F	149	8/7/73	6/26/97	8724	286.8	6098	200.5	22**
NU-5F	155	12/3/73	10/24/94	7630	250.9	5122	168.4	14
NU-5F	157	11/23/73	5/22/87	4928	162	2410	79.2	06
NU-5F	175	5/14/74	8/1/89	5558	182.7	3212	105.6	13
NU-5F	318	5/28/74	6/28/88	5145	169.2	2813	92.5	25
NU-5F	341	9/9/74	3/17/95	7494	246.4	5266	173.1	25
NU-5F	342	10/8/74	9/16/87	4726	155.4	2527	83.1	22**
NU-5F	361	10/29/74	12/21/81*	2610	85.8	432	14.2	36
NU-5F	362	10/25/74	12/3/91	6979	229.5	4797	157.7	02
NU-5F	363	10/10/75	8/1/89	5044	165.8	3212	105.6	21
NU-5D	408	7/5/74	1/15/82	2751	90.5	457	15	25
NU-5D	459	11/18/75	11/22/04	10,114	332.88	8500	289.42	03
NU-5D	460	3/6/75	4/13/90	5517	181.4	3467	114	13
NU-5D	462	3/3/75	1/25/91	5807	190.9	3754	123.4	13
NU-5D	465	3/24/75	7/28/92	6336	208.3	4304	141.5	02
NU-5D	467	6/4/75	3/21/80*	1752	57.6	0	0	36
NU-5D	474	11/23/73	9/30/88	5425	178.4	2907	95.6	25
NU-5D	476	1/27/75	11/29/89	5420	178.2	3332	109.6	13
NU-5D	477	5/16/75	11/19/81	2379	78.2	400	13.2	36
NU-5D	481	10/1/76	3/3/99	8188	269.2	6713	220.7	03
NU-5F	483	3/4/75	10/8/02	10,080	331.4	8028	263.93	02
NU-5D	490	3/15/75	8/18/03	10,380	341.26	8342	274.26	25
NU-5D	492	1/17/75	5/15/87	4501	148	2403	79	19

TABLE II (Continued)

PACEMAKER ID PACEMAKER SERVICE INFORMATION SUPPLEMENTAL

MODEL#	PACER #	IMPLANT DATE	EXPLANT DATE	IMPLANT DAYS+	TOTAL MONTHS	SERV DAYS++	SERV MONTHS	EXPLANT CODE
NU-5D	496	2/7/75	12/15/81*	2503	82.3	426	14	36
NU-5D	498	4/15/75	5/8/02	9885	324.99	7875	258.9	03
NU-5D	506	5/19/75	12/14/99	8975	295.1	6999	230.1	2
NU-5D	508	3/14/75	3/9/81	2187	71.9	145	4.8	25
NU-5F	509	6/12/98	6/12/98	8470	278.5	6449	212	3
NU-5D	513	10/10/97	10/10/97	8242	271	6204	204	3
NU-5D	515	7/16/75	10/8/88	4833	158.9	2915	95.8	6
NU-5D	519	5/22/75	9/20/88	4870	160.1	2897	95.3	6
NU-5D	523	11/13/76	2/6/02	9216	302.99	7784	255.90	36
NU-5D	524	2/12/76	11/20/94	6856	225.4	5149	169.3	3
NU-5D	525	5/30/75	9/19/95	7417	243.9	5452	179.3	02,05
NU-5D	527	5/14/75	11/19/04	10,390	351.59	8500	289.32	01
NU-5D	528	6/17/76	12/14/81	2006	66	425	14	36
NU-5D	529	3/13/76	11/6/04	10,460	371.07	8788	291.31	02
NU-5D	532	3/8/76	8/31/93	6385	209.9	4703	154.6	02
NU-5D	535	8/29/75	1/31/84	3077	101.2	1203	39.6	22**
NU-5D	537	6/4/97	6/4/97	7609	250.2	6076	199.8	02
NU-5D	539	10/24/75	8/18/06	11,260	366	9451	313.29	02
NU-5D	542	12/2/75	4/20/95	7079	232.8	5300	174.3	01
NU-5D	544	12/9/75	6/19/08	11,513	378.51	9741	320.26	03
NU-5D	545	2/5/75	10/2/82*	2796	91.9	717	23.6	36
NU-5D	549	11/15/75	6/12/87	4227	139	2431	79.9	21
NU-5D	562	11/19/76	5/15/05	10,344	340.39	8977	294.95	11
NU-5D	571	8/29/75	1/15/82*	2331	76.6	457	15	36
NU-5D	572	10/8/75	1/7/92	5935	195.1	4101	134.8	03
NU-5D	581	2/17/76	12/5/94	6866	225.8	5164	169.8	36
NU-5D	583	3/4/76	12/1/85	3559	117	1873	61.6	22**
NU-5D	585	1/23/76		3843	126.4	8865	69.6	L.T.F.
NU-5D	587	6/3/76	11/16/88	4549	149.6	2954	97.1	39
NU-5D	592	8/4/76	12/28/88	4529	148.9	2996	98.5	21
NU-5D	611	7/7/76	8/23/96	7352	241.7	5791	190.4	03
NU-5D	623	7/28/76	1/6/82*	1988	65.4	448	14.7	36
NU-5D	624	5/26/76	12/16/81*	2030	66.7	427	14	36
Totals	--	--	--	479,585	15802.52	323,778	10448.26	--

+ Implant days were calculated from the date the pacemaker was implanted, until end of the reporting period.
++ Service days were calculated from 10/15/80, until the date the device was explanted.
L.T.F.- lost to follow
N/A-left the USA permanently
Pacemakers explanted during this report year are indicated in bold italics. (See #97).

ATTACHMENT TO TABLE II

CODES USED FOR EXPLANTING DATA

01 Battery Depletion
02 Impending Pacemaker Wearout
03 Patient Death
04 Wound Dehiscence (Opening)
05 Infected Pocket (Pacemaker Bursa Infection)
06 Loss of Sensing Function, Pacer Not in Design Specifications
07 Competition
08 Electronics Failure
09 Lithium Battery Failure
10 Nuclear Battery Failure
11 Random Failure
12 Delaminated Capacitor
13 Lead Changed, Pace Removed
14 Patient Requires Faster Rate Pacer
15 Loss of Sensing, Patient or Lead Related, Pacer Normal on Return or Reimplanted
16 Electronics Damaged During Defibrillation
17 Pacemaker Erosion Reported
18 Pacer Reported Not in Spec. at Implant, or After Implant, Unit Normal on Return
19 Loss of Capture, Non-Pacer Related
20 Feedthrough Failure (Advisory Group)
21 Pacemaker Rate Change, Pacer Out of Specification
22 Pacer Explanted, Problem Reported Without Details, Pacer Not Returned
23 Lead Could Not Be Removed From Pacer
24 Muscle Stimulation
25 Elective Replacement, Not Pacer Related, Pacer Normal
26 Lead Could Not Be Inserted Into Pacer, or Set Screw Could Not Be Tightened
27 Pacer Rate Increase/Decrease Reported, Pacer Normal Upon Return
28 Pacer Rate Changed, Pacer in Specification
29 Loss of Capture, Non-Pacer Related (Plug Missing, Fluid in Terminal)
30 Pacer Returned Because of Cracked Epoxy
31 Automatic Rate Equals Magnetic Rate, Physiological Reasons
32 Non-Pacer Related Oversensing
33 Set Screw Head Stripped
34 Pacer in Spec., Explanted Due to Apparent Pacer Inhibition
35 Automatic Rate Equals Magnetic Rate, Electronic Failure
36 Pacer Returned Without Details; Pacer in Specification
37 Pulse Width Variation Due to Psuedofusion; Pacer in Specification
38 Advisory Return, Pacer in Electrical Spec. Upon Request
39 Loss of Capture, Pacer Related
40 Advisory Unit Not in Specification Upon Return, Non-Feedthrough Related; Pacemaker Still Functioning
41 Connection Problem
42 EMI Filter Capacitor Shunt; Results in Low Output Amplitude

ATTACHMENT A
Research Protocol for Clinical Investigation of the ARCO Nuclear NU-5 Pacemaker

RESEARCH PROTOCOL FOR CLINICAL INVESTIGATION OF THE ARCO NUCLEAR NU-5 PACEMAKER*

MARCH 25, 1974

*As of May 17, 1975, ARCO Nuclear Company became ARCO Medical Products Company.

ARCO Nuclear Company
Subsidiary of AtlanticRichfieldCompany
P O BOX 548 / LEECHBURG, PENNSYLVANIA 15656, U.S.A. / PHONE (412) 845-8111

I. Title of Study

Clinical Investigation of The ARCO Nuclear NU-5 Pacemaker.

II. Purpose

The purpose of this study is to clinically investigate the performance of the ARCO Nuclear NU-5 Radioisotope Powered Cardiac Pacemaker. This clinical investigation is based on sound biostatistical methods[1] and has five major goals which are:

A. Determine the random failure rate of the nuclear pacemaker and compare it to the conventional battery powered pacemaker. This determination will also include a characterization of "infant mortality" failure rates and modes.

B. Determine the failure rate distributions and which distributions apply in the statistical treatment of the reliability data. This will include a determination of the accuracy of the Poisson assumptions.

C. Confirmation that there are no long term adverse side effects or other unknown factors associated with nuclear pacemakers.

D. Determine nuclear pacemaker longevity by characterizing the "wear out" failure rate and mode.

E. Characterize the practicable aspects of the follow up, traceability and recovery of nuclear pacemakers.

III. Description of Pacemaker

The nuclear pacemaker to be implanted during the course of this study is the ARCO Nuclear Model NU-5. Complete technical data on the pacemaker including radiation levels, reliability tests and safety tests under conditions of normal use and conditions of credible accidents are on file with the U. S. Atomic Energy Commission. Due to the extensive amount of previous testing, the participating medical institutions are not required to perform radiation testing. Under this protocol, the Model NU-5 pacemaker contains a maximum of 0.45 grams of plutonium-238 (less than 8 curies). The resulting dose rate at the maximum point on the pacemaker surface is 5.64 millirads per hour and 0.37 millirads per hour at 5 centimeters from the surface along the maximum dose rate line. The Model NU-5 pacemaker is available in two types — fixed rate or demand (R-wave inhibited). Use of the magnet in this protocol applies only to the Model NU-5 demand type pacemaker.

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[1] The ARCO Nuclear Statistical Basis For Clinical Investigation of Radioisotopic Pacemakers - August 10, 1973

IV. Patient Selection

Patients may be of either sex with a maximum age of 65 or minimum age equal to the age of majority for the state of residence (special cases, however, may be considered on an individual basis by the appropriate licensing authority for older or younger patients) who:

A. Warrant replacement of their existing pacemaker or the insertion of a new pacemaker due to chronic heart block or other cardiac rhythm disturbances and

B. Have demonstrated emotional maturity, stability, that they are reliable patients who have a record of stable residence in the community such that they are willing to cooperate in, and are likely to remain available for the long term follow-up required a

C. Have no medical condition which in the physician's best judgement would limit life expectancy to less than 10 years.

Exclusions are the presence of a coexisting disease which may potentially limit life - e.g., potentially progressive heart disease, cerebrovascular disease, diabetes with any end organ manifestation or of greater than 10 years' known duration, renal disease, and neoplastic disease. Probability of lack of full cooperation, high mobility in the population, emotional disturbance, alcoholism, or other factors may also contra-indicate participation.

V. Duration of Study

It is anticipated that implantations of nuclear pacemakers under this study will continue for about two years and that the minimum time to achieve goals A, B and E under Section II is two-three years. Longevity studies and long term side effects studies may require much more time, perhaps in excess of ten years, due to the potentially long life capability of the nuclear pacemaker and its design characteristics.

Informed consent shall be obtained from all patients for participation in the program and for the ultimate removal of the pacemaker after its expected useful life is exceeded, its failure or the death of the patient, whichever occurs first. The study will continue throughout this period with follow-up by the clinics and reporting to ARCO Nuclear on implanted pacemakers.

VI. Control Group

In order to accurately compare the nuclear pacemaker with conventional pacemakers sound biostatistical practices require use of control groups. Therefore, a series of comparable control patients with conventional pacemakers of the same type (i.e., demand or fixed rate, bipolar or unipolar) will be followed. The control patients will be treated and followed using the same procedure for patient selection, medical procedures, follow-up, and reporting. The control group will be at least as large as the nuclear pacemaker study group.

VII. Implantation Procedures and Lead Systems

Fundamentally, conventional techniques of pacemaker insertion are to be utilized, but with particular attention to insuring that the electrodes and leads utilized have an expected life comparable to that of the pacemaker (in excess of 10 years) and that they have appropriate pacing thresholds. Because of the 10 or more year goal, it is vital that extreme care be taken to use the best available leads and to insure the best possible lead placement and configuration within the body. Since this is an investigational program, and not routine clinical use, it is preferable that a limited number of lead systems be used in order to limit the number of variables in the total pacing system and thus develop more meaningful data on longevity and reliability. Table 1 specifies the preferred leads to be used. It should be noted that the NU-5 pacemaker is of the monopolar type.

In patients with an existing lead, the following shall be done as a minimum, prior to implantation.

A. Appropriate chest films must be taken to assess the possibility of unduly sharp curves in leads.

B. The type of existing electrode must be ascertained and if it is not listed in Table I its use must be approved in advance by ARCO Nuclear. If doubt exists in the judgment of the responsible physician as to the reliability and/or compatibility of an existing lead, it should be replaced by a new one listed in Table 1. For existing leads, appropriate adapters may be used to fit the pacemaker; these should be of the type listed in Table 1 or approved in advance by ARCO Nuclear.

The threshold for pacing shall be tested for all electrodes whether old or new at the time of nuclear pacemaker implant prior to connecting the lead to the pacemaker. Only those leads may be utilized in which acceptable thresholds are demonstrated by these tests. Acceptable thresholds and test procedures are discussed elsewhere in this protocol.

It is important to note that certain information be obtained and recorded prior to and at the time of implantation. It is, therefore, necessary that the Accountability and Implant Data Form (a copy of which is Figure 1) be fully studied and understood prior to participating in this clinical study.

The NU-5 nuclear pacemaker is supplied sealed in gas permeable plastic double bags. Sterilization procedures prior to shipping are

TABLE I

Preferred Leads

Mfg.	Model	Type	System	Adapter
CORDIS	323-451	Myocardial	Monopolar	None
	322-256	Endocardial	Monopolar	None
	322-620	Endocardial	Monopolar	None
	322-251	Endocardial	Monopolar	None
	322-261	Endocardial	Monopolar	None
	322-281	Endocardial	Monopolar	None
MEDTRONIC	5814	Myocardial	Bipolar	Cordis 331-
	5819	Endocardial	Bipolar	Cordis 331-
	6901	Endocardial	Bipolar	Cordis 331-
	6907	Endocardial	Monopolar	Cordis 331-
	6909	Endocardial	Monopolar	Cordis 331-

NOTES:

1. To use a lead or adapter not listed, ARCO Nuclear approval is required.
2. For bipolar leads, use electrodes with lowest measured stimulation threshold of pair.
3. For the Cordis 322 series, leads 256 or 620 are preferred due to lower stimulation thresholds in general than leads 251, 261 or 281.

NUCLEAR POWERED CARDIAC PACEMAKER

PATIENT IDENTIFICATION

PACEMAKER

HEART LEAD

CLINICAL DATA

performed in gaseous ethylene oxide. If the bag is found to be opened or accidentally ruptured, the nuclear pacemaker may be re-sterilized in ethylene oxide gas at temperatures not to exceed 50°C. Following sterilization at least 72 hours should elapse prior to implantation to allow complete aeration. If a pacemaker is dropped, it should not be implanted but, instead, returned to AMCO Nuclear.

VIII. Threshold Specifications and Measurements

In order to determine if a particular lead can be used with the nuclear pacemaker, its stimulation threshold must be measured and found to be acceptable in addition to meeting all of the previously discussed requirements. The stimulation threshold must be measured at the time of nuclear pacemaker insertion but prior to connection to the pacemaker. It is important that both current and voltage stimulation thresholds be measured. It is also important that battery powered instruments be used in threshold measurements since the exposed lead represents a direct current path to the heart and even a minute amount of leakage current from power lines represents a potential fibrillation risk if entering the heart directly.

The stimulation threshold will be measured utilizing a battery operated pulse generator with adjustable amplitude and width. The calibrated accuracy should be at least ± 10% and the pulse duration should be adjusted to be in the range of 0.70 to 1.00 milliseconds. The pulse generator rate should be in the range of 65 - 80 ppm. The negative terminal of the pulse generator is connected to the lead whose threshold is being measured and the positive terminal of the pulse generator is connected to the indifferent lead which is placed in contact with subcutaneous tissue. With the output amplitude of the pulse generator initially set at approximately zero, the amplitude is gradually increased until consistent capture occurs. The amplitude at which consistent capture occurs is recorded as the stimulation threshold. Both current threshold and voltage threshold values shall be measured and recorded. It is suggested that an EKG recorder be used to observe consistent capture and that the output of the pulse generator set at threshold values be observed on an oscilloscope and recorded with a scope camera.

Only those electrodes may be utilized in which the measured threshold is no greater than 1.25 ma and 0.90 volts if newly implanted or 2.50 ma and 1.8 volts if chronically implanted (whether endocardial or myocardial).

IX. Accountability and Implant Data Form

In order to insure adequate data for this study if is vital that the Accountability and Implant Data Form (Figure 1) be completed promptly after each implantation and distributed within seven days after implantation as follows:

Orange	-	Operating Room Copy
Green	-	Surgeon's Copy
Blue	-	Patient's Medical Record
White	-	ARCO Nuclear Copy (Pre-addressed and Stamp

It should be noted that among other things the pulsing rate of th pacemaker shall be measured and recorded on the Accountability and Implant Data Form immediately upon implantation and 12 — 24 hours after implantation. The rates should be checked by a pulse interval measuring device accurate to ± 1 millisecond or ± 0.1 pulses per minute. It is recommended that the Accountability and Implant Data Form be reviewed in detail prior to participation in this clinical study to insure that all data requested is obtained and reported.

Examples of the type of information required are:

A. Pacemaker model, type and serial number

B. Date of implantation, surgical procedure and site of implantation

C. Lead identification by type, model and serial numbers, newly implanted or pre-existing, date of implantation, vein used and location of electrode

D. Threshold measurements and equipment used

E. Stimulation rate of the pacemaker both with and without magnet (if applicable)

F. History of previous implants, removals of pacemakers or leads, and reasons for such removals.

X. Follow-Up Data

At intervals of every three months during the first year and six months thereafter following nuclear pacemaker implantation each patient shall receive a follow-up examination and the resulting data shall be reported to ARCO Nuclear on the Follow-Up Data Form (a copy of which is Figure 2). Typical follow-up data includes:

A. Identification of patient, pacemaker, hospital, physician

B. Date of implantation and follow-up examination

C. Performance of pacemaker including stimulation rate (with and without magnet, if applicable)

D. Indication of any malfunction, modifications or replacements of pacemaker or lead system

ARCO Nuclear Company
Subsidiary of AtlanticRichfieldCompany
P O BOX 540 / CLEARBURG, PENNSYLVANIA 16602 U.S.A. / PHONE (412) 845-8111

FOLLOW-UP DATA FORM

(To be used each time patient is contacted and/or examined including telephone transmission of ECG.)

PATIENT IDENTIFICATION SHEET

Patient Name _____
Last First Initial

Patient Hospital Record No. _____

Pacemaker Serial No. _____

Date of Implantation _____

Date of Follow-Up _____

Name of Physician _____

Address _____

City _____ State _____ Zip _____

Area Code and Telephone No. _____

Patient has I.D. Card: Yes _____ No _____

Patient is wearing Bracelet or its Equivalent: Yes _____ No _____

Contact maintained with patient: Yes _____ No _____

PACEMAKER FUNCTION

Satisfactory _____

Unsatisfactory _____

Stimulation Rate: with Magnet _____ w/o Magnet _____

Change from previous rate _____

Change from initial rate _____

MEDICAL EXAMINATION

Summary: _____

_____

Reposition: Pacemaker/lead/both

Reason _____

_____

Explantation: Pacemaker/lead/both

Reason _____

_____

Autopsy Results (if applicable) _____

_____

Cause of Death (if applicable) _____

Title _____

Date _____

Signature _____

This form should be completed and returned to the manufacturer within 10 days of taking follow-up data.

For urgent questions and for assistance concerning this pacemaker, please call 412-845-8111.

(MANUFACTURER'S COPY)

Seal Here After Folding

FIGURE 2

E. Physician's opinion and comments on pacemaker and lead system

F. Summary of medical examination

G. Indicate whether patient is carrying ID card and wearing bracelet and whether contact with patient has been maintained since last follow-up

The follow-up data shall include pulse interval measurements (using a device with a ± 1 millisecond or 0.1 ppm accuracy) and a recording of the electrocardiogram (with and without the magnet, if applicable). The Follow-Up Data form shall be completed and returned to ARCO Nuclear within 10 days of each examination. In addition, the Follow-Up Data form shall be used everytime the patient is examined even if such examinations take place more often than the specified frequency including telephone transmissions of ECGs.

The impulse rate of the pacemaker will vary in a predictable manner due to radioactive decay of the fuel and consequent decrease in voltage from the energy source to the electronic circuit or due to slight improvement in the nuclear battery efficiency brought about by gettering action and slight redistribution of thermal heat flow within the battery caused by vigorous patient physical activity which causes pulse rate to slightly increase after implant and then stabilize. If the measured pacemaker rate (either with or without the magnet) deviates from the initial rate recorded after implantation by more than 5 pulses per minute, ARCO Nuclear shall be notified immediately. If the pulse fails to capture (during non-refractory phases of the cardiac cycle), ARCO Nuclear shall be notified immediately, and the investigators shall seek to pursue the etiology, looking both to potential failures external to the pacemaker and to the pacemaker.

XC. Explantation

Pacemakers will be removed if clinically indicated due to failure, malfunction, development of "excessive" competition between the pacemaker and normal conducted beats, the death of the patient, the anticipated exhaustion of the unit or if the pacemaker rate changes by more than 10 pulses per minute. Whenever possible - i.e., whenever the patient's welfare is not compromised - ARCO Nuclear will be consulted prior to the removal of a pacemaker. Any pacemaker or lead which is explanted or repositioned for any reason shall be reported in writing within 1 week to ARCO Nuclear. The report shall include reasons for action taken, date of action, and associated tests performed. The pacemaker and, if possible, the intact lead system shall be removed upon death and returned to ARCO Nuclear for evaluation. If no autopsy is performed, the most probable cause of death shall be stated. Autopsy findings (if applicable) related to the pacemaker shall be reported and, if possible, the function of the pacemaker and lead system will be determined at autopsy.

All nuclear pacemakers that are explanted for any reason shall be returned to ARCO Nuclear as soon as possible in a shipping package

supplied by ARCO Nuclear and in accordance with labeling and shipping instructions also supplied by ARCO Nuclear. At explantatic the nuclear pacemaker rate shall be recorded (with and without the magnet, if applicable) and ARCO Nuclear shall be consulted, if possible, for additional tests to be performed.

XII. Notifications

ARCO Nuclear and the licensing agency shall be notified within 24 hours of the death of any nuclear pacemaker bearer, and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. ARCO Nuclear shall be notified within 10 days of loss of contact with a nuclear pacemaker bearer.

XIII. Records

Data and vital statistics pertaining to the nuclear pacemaker patients shall be maintained as individual files separately from routine hospital records. These records shall include:

A. The blue copy of the Accountability and Implant Data Form

B. Copies of all Follow-Up Data Form

C. A fully executed copy of the document "Informed Consent For Surgical Implantation Of Radioisotope Powered Cardiac Pacemaker" (a copy of which is attached)

D. Any additional information deemed important by the medical staff

XIV. Informed Consent

All patients shall sign the informed consent statement entitled "Informed Consent For Surgical Implantation Of Radioisotope Powered Cardiac Pacemaker" (a copy of which is attached). Using this document the patient, or his representative shall be informed and shall agree in writing to the following:

A. That nuclear pacemakers are under investigation, there are alternative treatments and the patient is willing to participate in the investigation

B. That after the patient's death, or if the useful life of the pacemaker is exceeded, or if it ceases to function effectively for the patient's medical needs, or if the patient requests to have the pacemaker removed, the nuclear pacemaker must be returned to ARCO Nuclear

C. The patient will always carry the ID card and bracelet on his person, and to notify the hospital of any change in his address or telephone number.

D. The patient will notify, through the hospital, and ARCO Nuclear the appropriate licensing authority prior to any travel outside the United States.

E. Acknowledgment that the patient has had the opportunity to ask questions pertaining to the surgical procedures, nuclear pacemaker, follow-up procedures, and possible alternate methods of treatment.

Copies of the signed consent form shall be given to the patient to ARCO Nuclear and placed in the patient's medical file.

IV. Patient Identification

All nuclear pacemaker patients shall carry credentials identifying them as nuclear pacemaker patients. These credentials will include an identification bracelet of the Medical-Alert type and a wallet size identification card. On the bracelet will be engraved the patient's name, the words "Radioactive Pacemaker", the trefoil radiation symbol, the word "Plutonium", and the words "In emergency hospitalization or death call collect (phone number of hospital)". A facsimile of the identification card is Figure 3 which contains the patient's name, the trefoil radiation symbol, the work "Radionuclide Statement that the patient is the implantee of a Radioisotope Powered Cardiac Pacemaker, manufacturer's name and phone number, pacemaker model number, amount and type of contained radionuclide, the words "In case of death from any cause or emergency or trauma involving pacemakers telephone collect (name and phone number of participating institution and doctor (s) in charge)", the words "Instruct phone operator call concerns Nuclear Pacemaker - Urgent!", and the words "Regulations require removal of pacer upon death."

Both the bracelet and identification card will be supplied to the participating institution by ARCO Nuclear following receipt of the Accountability and Implant Data Form. The institution will then give the bracelet and identification card to the patient and remind the patient to always carry them on his person. If the permanent bracelet and ID card are not available when the patient is discharged from the hospital, a temporary bracelet and ID card containing the same information shall be given to the patient until the permanent ones are supplied.

For each participating institution the telephone operators will be issued the following instructions:

A. Any collect calls concerning nuclear pacemakers will be accepted.

B. The operator should obtain as much information from the caller as possible including:

1. Caller's name and where to reach him

2. Patient's name, condition and where to reach him

URGENT

Medical Alert!

_____

is the implantee of a
Radioisotope Powered
Cardiac Pacemaker

Radionuclide is
Plutonium - 239 < 8 Curies

Made by
ARCO Nuclear Company
Model Number is NU-5

SEE OTHER SIDE
FOR EMERGENCY
INSTRUCTIONS

Regulations require removal of pacemaker upon death.

URGENT

Medical Alert!

(Continued from reverse side)

In case of death from any cause or emergency or trauma involving pacemakers telephone, collect, the:

_____
(HOSPITAL)

_____
(PHONE NUMBER)

_____
(DOCTOR)

_____
(DOCTOR)

OR telephone, collect, the
ARCO NuclearCompany
(412) 843-8111
Lewistown, Pa. 17044

Instruct phone operator call concerns
Nuclear Pacemaker – Urgent!
Regulations require removal of pacemaker upon death.

FIGURE 3

3. If any physician is present, and if so, his name and where he can be reached.

4. Condition of pacemaker, if known (i.e., expelled or still implanted).

5. Information on patient's ID card, if available.

C. Such calls represent potentially severe emergencies and the operator should immediately contact the institution's Radiation Safety Officer and responsible doctor while keeping the caller on the line and standing by.

D. If the Radiation Safety Officer or the responsible physician or designated alternate cannot be reached, contact Cardiac Care Unit physician on duty and advise of the situation and what information is available.

XVI. Participating Institution Requirements

During the investigational phase of nuclear pacemaker use, licenses are being issued only to medical institutions that can assure continuity of follow-up of patients with implanted pacemakers rather than to individual physicians. A license issued to a medical institution authorizes a specified implantation limit in terms of number of plutonium fueled pacemakers and requires the licensed institution to be responsible for the follow-up and recovery of the nuclear pacemakers implanted in patients under the license. The physicians designated as the responsible investigators by the medical institution should have substantial experience with pacemakers in the specialities of cardiology and thoracic surgery. The medical institution is expected to have an established program and appropriate facilities for the implantation and follow-up of cardiac pacemakers.

Each application from a medical institution should include:

A. Identification of the institution as the applicant.

B. Incorporation of this research protocol by reference with a commitment to follow it.

C. For each physician on the study team, his name, specialty board certification, previous experience in the implantation and follow-up of implantable pacemakers including specific information on the duration and number of pacemakers implanted and/or followed, a breakdown of how many of the implants used myocardial leads and endocardial leads, and position of the physician with the applicant.

D. A description of the applicant's present pacemaker implantation and follow-up program including size, duration and types of implantations.

E. Description of the physical facilities and equipment available for implantation and follow-up. This should include specific test equipment required to carry out the tests discussed in this protocol.

F. A description of the applicant's procedures for accountability and security against loss or theft of pacemakers before implantation and after removal from patients.

G. A description of the applicant's procedures to assure notification of appropriate individuals within the licensed medical institution upon receipt of a report or inquiry concerning a pacemaker bearer. Include written instruction given to telephone operators (as outlined in Section IV of this protocol).

H. A procedure for periodically reviewing all implantation and follow-up records on nuclear pacemaker patients and follow-up as necessary to verify that loss of contact with the patient has not occurred.

I. An acknowledgment from the institution administration of their long-term commitment and responsibility for the follow-up and recovery of nuclear pacemakers.

A standardized application form will be provided by ARCO Nuclear to qualified institutions that wish to apply to participate in this study. This form will facilitate rapid processing of such applications placing the above required information in a compact standard format.

INFORMED CONSENT FOR SURGICAL IMPLANTATION OF RADIOISOTOPE POWERED CARDIAC PACEMAKER

I understand that for the treatment of my cardiac condition - a disturbance of normal cardiac conduction - a cardiac pacemaker is to be implanted in me. I also understand that the surgical procedure (may/will require the placement of a new electrode and lead into or onto the surfac of my heart and the implantation of a new cardiac pacemaker, and I understand that while the surgical procedure is not of unreasonable risk, the possibility of complications or even death exists. The procedure has been explained to me, in a manner that I could understand, and I have had the opportunity to ask any questions which I would like.

It is my understanding that a radioisotope powered cardiac pacemaker which is now undergoing its initial clinical use in approximately 400 persons, will be utilized for the implantation. I have been told that the pacemaker design has been extensively tested over a period of several years. I have been told that on the basis of these experiments in animals and in the laboratory, units of this type are predicted to have a reliable life expectancy comparable to (and hopefully considerably in excess of) that of current standard cardiac pacemakers. However, I understand that it is impossible to be certain of the pacemaker's actual reliability, and no guarantee has been given to me concerning the results which may follow. I understand that the pacemaker does produce radiation, but I have been told by my attending physician that it is the medical judgment that this radiation presents a negligible hazard to me and the members of my household.

I understand that in consenting to the implantation of this pacemaker I am authorizing, as well, all standard operating procedures, including the administration of anesthetics which may be incident to the operation. For the purpose of advancing medical and scientific knowledge, I consent to the admittance of observers to the operating room.

Ultimately - after my death or earlier, if the useful life of the pacemaker is exceeded, if it ceases to function effectively for my medical needs, or if I request to have it removed - the pacemaker must be removed and returned to ARCO Nuclear Company or to its designee, _____ _____(Clinic). Accordingly, I agree to contact _____ _____(Clinic) at regular intervals of no less than three months during the first year and every six months thereafter and whenever I change my residence. I will always carry the appropriate identification card on my person and will at all times wear the standard identification bracelet.

Notwithstanding my contacting the implanting clinic following the insertion of a cardiac pacemaker of any sort, I agree to remain in periodic contact with my personal physician. I will also instruct all members of my household and inform those who have extended contact with me that I have received a radioisotope powered cardiac pacer implant.

I understand that the radioisotope powered cardiac pacemaker is an experimental unit. In order to assess the effectiveness of the device, and to monitor my personal well-being, _____(Clinic) is interested in collecting data upon the device. Accordingly, I agree to visit _____(Clinic) in person or to transmit by telephone (with the aid of a device supplied to me and applied to the surface of my skin) my electrocardiogram and an indication of the functioning of the pacemaker. I agree to permit this monitoring to be performed at least once every three months for the first year and every six months thereafter. I further agree to provide information on my clinical condition as it pertains to the pacemaker at no less than six month intervals. Furthermore, I consent to disclosure by the clinic of any information acquired by the clinic in regard to the implantation of the radioisotope powered cardiac pacemakers; provided, however, in no event shall such disclosures include my identification without my specific written approval.

I understand and agree that I must notify _____(Clir prior to any travel outside of the United States.

I have had the opportunity to ask any questions pertaining to the surgical procedure, the radioisotope powered cardiac pacemaker, and the mandatory follow-up procedure, and these questions have been answered to my satisfaction. The possible alternate methods of treatment, including the use of conventional chemical battery powered pacemakers, have been called to my attention, and I have been given an opportunity to ask any questions about these alternative methods.

With these facts in mind and with the intent of being legally bound, I release any right to claim that the implantation of a radioisotope powere cardiac pacemaker was not properly authorized, and I agree to the follow-up procedures and the ultimate return of the unit as detailed above. I agree to assume the risk of the implantation of a radioisotope powered pacer and release and discharge ARCO Nuclear, the implanting clinic and my physician from failures not caused by their fault or negligence.

Witness (preferably a relative)		Date
Date	Patient's signature or two persons authorized to consent for the patient.	Date

_____

_____

Relationships to the patient signing if other than the patient.

I certify that I have explained the above procedure.

CONTENTS OF SPONSOR'S PERIODIC REPORT ON
CLINICAL PERFORMANCE OF PACEMAKERS
(FOR NUCLEAR PACEMAKERS AND CONVENTIONAL PACEMAKER CONTROLS)

A. For pacemakers in satisfactory service:

1. Tabulate each implanted nuclear and control pacemaker identif by serial or other assigned number. For each pacemaker inclu the following:

   a. Date of manufacture
   b. Date of implant.
   c. Indicate whether fixed rate or demand.
   d. Age of patient (at implant)
   e. Implanting institution (can be coded).
   f. Type of leads (make and model).
   g. Indicate bi-polar or unipolar.
   h. Indicate myocardial or endocardial.
   i. Date of lead implant.
   j. Duration (in days at time of report) of pacemaker servic
   k. Indicate the nature and date of any additional related s relocations, or post implantation complications.
   l. Indicate whether any lead was replaced, repaired, or rel and date(s) thereof.
   m. Date of most recent follow-up examination.
   *n. Indicate whether patient was carrying I.D. card and wear I.D. bracelet.
   o. Indicate whether effective contact was being maintained with patient.

B. For pacemakers no longer satisfactorily pacing the patient:

1. Tabulate each nuclear and control pacemaker identified by seri or other assigned number and include the following:

   a. Date of manufacture
   b. Date of implant.
   c. Indicate whether fixed rate or demand.
   d. Age of patient (at implant).
   e. Implanting institution (can be coded).
   f. Type the leads (make and model).
   g. Indicate bi-polar or unipolar.
   h. Indicate myocardial or endocardial.
   i. Date of lead implant.
   j. Duration (in days) of satisfactory pacemaker service befo removal or replacement.
   k. For each removed or replaced pacemaker or lead system, ex in detail the reasons therefore and date thereof.

*not applicable for control patients with conventional pacemakers.

k. In case of death of the patient give: date and caus death, autopsy findings related to the pacemaker, de mination at autopsy (if possible) of whether pacemak and lead system were still operable, post-removal ev tion by sponsor of pacemaker and lead operability, a final disposition of pacemaker.

C. Accountability

1. Have all implanted nuclear pacemakers been accounted for reporting period? If not, explain in detail.

2. Has adequate follow-up contact with any patient been lost the reporting period? If yes, explain in detail.

ATTACHMENT B
Copy of ARCO Authorization to Ship/Relinquishment of Ownership Form

No pacemakers were shipped from Radiation Safety Associates, Inc. since the last report. The final pacer recovered from this program became available only recently. A report of its disposition will be made to ARCO and the U.S.N.R.C. in the near future.

ATTACHMENT C
Removal and Failure Rates for Nuclear Pacemakers

ATTACHMENT C

REMOVAL AND FAILURE RATES FOR NUCLEAR PACEMAKERS

		A (Service)$^{++}$ 10/15/80-1/25/18	B PROGRAM TOTAL
A	# Of Implants	79	79
B	# Of Removals	79	79
C	# Of Failures	26	26
D	Average Months of Service/Patient	200.03	206.75
E	Percent Removals	98.73%	98.73%
F	Percent Failures	32.9%	32.9%
G	Average Monthly Removal Rate	0.00718	0.00478
H	Average Monthly Failure Rate	0.0024	0.0016

Calculations

A = 79

B = 78

C = 26

	SERV DAYS^{++}	SERV MONTHS^{++}	IMPLANT DAYS^{+}	TOTAL MONTHS^{+}
From Table II (prev. yr.)	336,017	11,291.49	494,932	16,307.09
Current	382	12.6	382	12.6
TOTAL	**336,399**	**11,304.09**	**494,314**	**16,319.69**

$$D = \frac{total\ program\ months}{\#\ implants} = \frac{15{,}815.12}{79} = 200.19 \text{ and } \frac{total\ months}{\#\ implants}\ \frac{15{,}802.52}{79} = 200.03$$

$$E = \frac{\#\ removals}{\#\ implants} = \frac{79}{79} = 1.00 = 100\%$$

$$F = \frac{\#\,failures}{\#\,implants} = \frac{26}{79} = 0.329 = 32.9\% \text{ and } \frac{\#\,failures}{\#\,implants} = \frac{26}{79} = 0.329 = 32.9\%$$

$$G = \frac{\#\ removals}{\#\ service\ months} = \frac{79}{10{,}460.86} = 0.00755 \text{ and } \frac{\#\ removals}{\#\ program\ months} = \frac{79}{10{,}460.86} = 0.00755$$

$$H = \frac{\#\ failures}{\#\ service\ months} = \frac{26}{10{,}850.64} = 0.0024 \text{ and } \frac{\#\ failures}{\#\ program\ months} = \frac{26}{10{,}460.86} = 0.002485$$

+ Implant days were calculated from the date the pacemaker was implanted, until end of the reporting period.
++ Service days were calculated from 10/15/80, until the date the device was explanted.

ATTACHMENT D

PACEMAKER RELATED EXPLANTS

The final pacemaker in the program explanted on February 11, 2019 upon the death of the subject. We do not have specific information regarding the patient's cause of death, but it is known that she had been in declining health for some time.

She passed away on Monday, February 11, at 0644.

Explanted Pacemakers

X-1	Died, 1 January 1987. Pacer #107-NU-5F(A-102). Death not pacemaker related, but by renal failure and mitral valve disease.
X-2	Explanted 12 February 1987. Failure to capture- broken wire. Pacer #100-NU-5F(A-095), implanted 4/9/73.
X-3	Died, 5/14/87. Not pacemaker related. Pacemaker #501-NU-5D(B-169). Implanted 4/17/78.
X-4	Explanted 5/22/87. Failure of sensing with occasional non-sensed beats and spikes in T-wave. Pacemaker #157-NU-5F(A-039). Implanted 11/23/73.
X-5	Explanted 6/12/87. Decrease in pulse rate. Pacemaker #549-NU-5D(B-200). Implanted 11/15/75
X-6	Explanted 5/15/87. Lead wire break. Pacemaker #492-NU-5D(B-159). Implanted 1/17/75.
X-7	Explanted 2/9/88. Pacemaker #128-NU-5F(A-060). Not pacemaker related & died of a myocardial infarction.
X-8	Pacemaker #318-NU-5F(B-004). Explanted 6/22/88. Pacer operating properly but patient needed a dual chamber device.
X-9	Pacemaker #97-NU-5F(A-064). Explanted 9/1/88. Upon implantation, pacemaker initially dropped then leveled off to 68 bpm. A recent bpm drop to 66 prompted Doctor to explant the pacemaker.
X-10	Explanted 9/20/88, Pacemaker #519-NU-5(B-156). Pacemaker malfunction; intermittent failure to sense.
X-11	Died, 9/30/88. Cardiac arrest. Pacemaker #474-NU-5D(B-124), implanted 11/23/73.
X-12	Explanted 11/16/88. Pacemaker #587-NU-5D(B-246). Pacemaker failure- failure to capture.
X-13	Pacemaker #592-NU-5D (B-251). Explanted on 12/28/88. Pacemaker was experiencing a "runaway phenomenon" (i.e., went up 150 bpm and then down to a very low bpm.).
X-14	Pacemaker explanted 10/08/88 due to sensing failure. Pacer #515-NU-50(B-154).
X-15	Pacemaker #175-NU-5F(A-067) was explanted August 1989 due to lead fracture.
X-16	Pacemaker returned 5/29/89 without any explant information. Pacer #NU5-074(A-042).
X-17	Pacemaker #363-NU-5F(A-048). Explanted 8-01-89. Patient experienced a decrease in pulse rate.
X-18	Pacemaker #476-NU-5(B-060). Explanted 11-29-89. Patient expired due to causes unrelated to the pacemaker.
X-19	Pacemaker #460-NU-5D(B-117) explanted 04-13-90. Pacer functioning properly but a lead fracture prompted physician to implant a new pacer.
X-20	Pacemaker #70-NU-5F(A-027) explanted 07-09-90 due to lead fracture.
X-21	Died approximately 1/05/91. Cardiac arrest. Pacemaker #80-NU-5F(A-084), implanted 2-19-74.
X-22	Pacer #462-NU-5D(AN-1-55), implanted 3/3/75, was explanted on 01/25/91 due to a lead fracture.
X-23	Pacemaker #86-NU-5F(A-088) explanted 9/19/91. Hospital reprted sudden failure of pacemaker without additional detail.
X-24	Pacemaker #85-NU-5F(A-087) explanted 10/29/91. Pacemaker was removed due to end of pacemaker life parameter.
X-25	Pacemaker #362-NU-5F(B-046) explanted 12/3/91. Hospital reported that magnet reading started to decrease and pacemaker was running out of power.
X-26	Pacemaker #572-NU-5D(B-201) explanted on 1/7/92. Pacemaker was removed after patient died of congestive heart failure.
X-27	Pacemaker #083-NU-5(A-086) returned.

X-28	Pacemaker #138-NU-5(A-078) returned.
X-29	Pacemaker #140-NU-5(A-026) returned.
X-30	Pacemaker #361-NU-5(B-044) returned.
X-31	Pacemaker #408-NU-5(B-069) returned.
X-32	Pacemaker #467-NU-5(B-121) returned.
X-33	Pacemaker #477-NU-5(B-138) returned.
X-34	Pacemaker #496-NU-5(B-161) returned.
X-35	Pacemaker #508-NU-5(B-062) returned.
X-36	Pacemaker #528-NU-5(B-213) returned.
X-37	Pacemaker #545-NU-5(B-196) returned.
X-38	Pacemaker #571-NU-5(B-170) returned.
X-39	Pacemaker #623-NU-5(B-290) returned.
X-40	Pacemaker #624-NU-5(B-271) returned.
X-41	Pacemaker #513-NU-5D(B-142) returned.
X-42	Pacemaker #465-NU-5D(B-065) was explanted on 28 July 1992. Pacemaker had reached its end of use parameter.
X-43	Pacemaker #532-NU-5D(B-083) explanted on 8/31/93. Hospital reported pacemaker was not operating properly. Pacemaker returned.
X-44	Pacemaker #131-NU-5F(A-100) explanted on 9/19/93. Cause of death was renal failure, not related to pacemaker. Pacemaker returned.
X-45	Pacemaker #NU5-499 was returned on 6 March, 1998
X-46	Pacemaker #NU5-103 explanted on 5/27/98. The pacemaker was removed because the lead was broken. Pacemaker returned.
X-47	Pacemaker #NU-509 explanted on 12 June, 1998. Cause of death was renal failure, not related to pacemaker.
X-48	Died, 9/16/87. Not pacemaker related. Cardiac arrest. Pace #342-NU-5F (B-016), implanted 10/8/74. Pacemaker not retrieved.
X-49	Explanted 10.2.87. Not sensing patient's own beats and firing on T-waves, causing ventricular tachycardia. Pacemaker #144-NU-5F(A-091). Implanted 7/27/73. Pacemaker not retrieved.
X-50	Died 8/01/89. Pacemaker 115-NU-5F(A-109) not retrieved from Elmhurst General Hospital. Cause of death uncertain.
X-51	Pacemaker #145-NU-5(A-093) buried with patient.
X-52	Pacemaker #535-NU-5(B-179) buried with patient.
X-53	Pacemaker #583-NU-5(B-240) not returned by funeral home.
X-54	Pacemaker #581-NU-5D(B-237) explanted on 5 December 1994. No reason was given for removal. Pacemaker returned.
X-55	Pacemaker #155-NU-5F(A-031) explanted on 24 October 1994. Pacemaker was working fine, but doctor recommended a different type. Pacemaker returned.
X-56	Pacemaker #341-NU-5F(B-002) explanted on 17 March 1995 for an upgraded pacemaker.
X-57	Pacemaker #542-NU-5D(B189) explanted on 20 April 1995. Cause of death uncertain.
X-58	Pacemaker #525-NU-5D (B-190) explanted on 19 September 1995 Surgeon said pacemaker was failing and there was an infection in area of the pacemaker. Pacemaker returned.
X-59	Pacemaker #611-NU-5D(B-269) explanted on 23 August 1996.Patient died in her sleep and cause of death is unknown. Pacemaker returned.
X-60	Pacemaker #537-NU-5D(B-184) explanted on 4 June 1997. Cardiologist said removal was for "end of life pacemaker."

X-61	Pacemaker # 126-NU-5F(A-028) was explanted from patient by a physician who indicated the unit was removed due to the end of the pacemaker life parameter.
X-62	Pacemaker #NU-5D-481 was explanted from patient by an undertaker on 22 February 1999. The pacemaker was removed upon patient's death. The cause of death is unknown.
X-63	Pacemaker #506-NU-5D was explanted on 14 December 1999, as reported by the NJ Pacemaker and Defibrillator Evaluation Center. The pacemaker was removed due to a fluctuation in the rate.
X-64	Pacemaker #504-NU-5D(B-174) explanted on 10/11/00. Pacemaker explanted due to patient disease. Pacemaker working fine according to Dr.'s office.
X-65	Pacemaker #523-NU-5D B-172 explanted on February 6, 2002 at New Jersey Pacemaker and Defibrillator Center, Newark, NJ. Pacemaker returned.
X-66	Pacemaker #498-NU-5D B-162. Patient died May 8, 2002, pacemaker explanted on that date. Pacemaker returned.
X-67	Pacemaker #481-NU-5D, explanted October 8, 2002. Device reached recommended replacement time. Pacemaker returned.
X-68	Pacemaker # 490-NU-5D B-157, explanted August 18, 2003. Device reached recommended replacement time. Pacemaker returned.
X-69	Pacemaker # 459-NU-5D, B-113. She passed away on November 12, 2004 while confined to a nursing home. The funeral director recovered the pacemaker and returned it to ARCO.
X-70	Pacemaker #529-NU-5D, 529-NU-5D, explanted in 2004 and returned to Los Alamos by the hospital.
X-71	Pacemaker # 527-NU-5D, B-211. Pacemaker was not functioning when it was checked in November 2004. It was returned to ARCO.
X-72	Pacemaker # 562-NU-5D, B-183. Pacemaker stopped functioning ands was replaced in May 2005. It was returned to ARCO.
X-73	Pacemaker #539-NU-5D was explanted August 18, 2006 and was returned to NSSI/LANL by the hospital.
X-74	Pacemaker #544-NU-5D was explanted a few days after the death of the patient on June 19, 2008. It was returned to NSSI/LANL by the pacemaker clinic in New Jersey.
X-75	Pacemaker #090-NU-5F (A-092) was explanted on April 15, 2014. It was retrieved from the Newark Beth Israel Pacemaker Center and is in safe storage in Hebron, CT.
X-76	Pacemaker #094-NU-5F. Patient expired on 2/11/19. Pacemaker was recovered by Jackson Memorial Hospital staff and is in safe storage. It will be transferred to Radiation Safety Associates, Inc., Hebron, CT within 6 weeks

Explanted Pacemakers Not Retrieved

NR-1	Died 8/01/89. Pacemaker 115-NU-5F(A-109) not retrieved from Elmhurst General Hospital. Cause of death uncertain.
NR-2	Pacemaker #145-NU-5(A-093) buried with patient.
NR-3	Pacemaker #535-NU-5(B-179) buried with patient.
NR-4	Pacemaker #583-NU-5(B-240) not returned by funeral home.
NR-5	Pacemaker #524-NU-5D(B-185) buried with patient. Cause of death unknown. Died on 11/20/94
NR-6	Pacemaker #149-NU-5F(A-063) buried with patient. Cause of death unknown. Died on May 10, 1998.

Pacemakers Whereabouts Unknown

U-1	Pacemaker #585-NU-5D (B-245). Implant date 1/23/76. Last contact with Patient was 8/1/86.
U-2	Pacemaker #120-NU-5F (A-074). Moved to Belgium in 1982.

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

ARCO Environmental Remediation, LLC
ATTN: Cynthia D. Kezos, Liability Business Manager
c/o Atlantic Richfield Company
4 Centerpointe Drive, Suite 200
La Palma, CA 90623

Date
April 10, 2019

License Number(s)
SNM-1993

Mail Control Number(s)
611852

Licensing and/or Technical Reviewer or Branch
Commercial, Industrial, R&D, & Academic Branch Notification

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 04/03/2019

The initial processing, which included an administrative review, has been performed.

☐ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
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