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February 7, 2014

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

ATTN: Kathy Modes

RE: License #SNM 1993 Condition 12 Report – 2013

Dear Ms. Modes:

On behalf of the ARCO Environmental Remediation LLC (ARCO), enclosed please find the report entitled "Radioisotope Powered Cardiac Pacemaker Program Technical Memorandum Report XLVII 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 require any additional information, please call me at (714) 228-6708.

Sincerely,

Cynthia D. Kezos

Cynthia D. Kezos

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Cc: K. Paul Steinmeyer, Radiation Safety Associates

RADIOISOTOPE POWERED CARDIAC PACEMAKER PROGRAM

TECHNICAL MEMORANDUM

REPORT XLVII

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

January 23, 2014

K. Paul Steinmeyer, RRPT
Radiation Safety Officer

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

TABLE OF CONTENTS

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 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 24, 2013 to January 23, 2014 as specified in the "Contents of Sponsor's Periodic Report on Clinical Performance of Pacemakers." This is the forty-seventh 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 01/23/14 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 30.4% for the total program and 31.6% from 10/15/80 to 01/23/14. This yields an average monthly failure rate of 0.0017 and 0.0026 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 1/23/14

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	90	4/10/1973	1/24/2014	14,615	480.71	11,866	390.19	-	YES
NU-5F	94	6/5/1973	11/18/2011**	14,617	480.57	11,509	378.38	-	YES
Total				29,232	961.28	23,375	768.57		

+ 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.
*Explant date
** Patient is no longer checking in with her doctor. The doctor's staff is attempting to convince her to keep an appointment. She is in Florida. A letter has been sent to her from the RSO asking her to please contact her doctor.

TABLE II
EXPLANTED PACEMAKERS
10/15/80 TO 01/23/13

PACEMAKER ID | PACEMAKER SERVICE INFORMATION | SUPPLEMENTAL

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	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	105.6	03
NU-5F	120	7/24/73		1171	38.5	0	0	N/A
NU-5F	126	10/13/98	10/13/98	9254	304.3	6572	216.1	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

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-5F	499	3/6/98	3/6/98	7844	257.9	6351	208.8	3
NU-5D	501	4/17/78	4/14/87	3284	108	2372	78	36
NU-5D	504	4/20/77	10/11/00	8558	281.4	7284	239.5	36
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	--	--	--	464,889	15319.08	311831	10055.34	--

+ 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 this year are indicated in bold italics.

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

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.

ATTACHMENT C
Removal and Failure Rates for Nuclear Pacemakers

ATTACHMENT C

REMOVAL AND FAILURE RATES FOR NUCLEAR PACEMAKERS

		A 10/15/80-1/23/14	B PROGRAM TOTAL
A	# Of Implants	79	79
B	# Of Removals	77	77
C	# Of Failures	25	25
D	Average Months of Service/Patient	127.28	193.91
E	Percent Removals	97.98%	97.98%
F	Percent Failures	31.6%	30.4%
G	Average Monthly Removal Rate	0.0078	0.0051
H	Average Monthly Failure Rate	0.0026	0.0017

Calculations

A = 79
B = 77
C = 25

	IMPLANT DAYS[+]	PROG MONTHS	SERV DAYS[++]	SERV MONTHS
From Table II	464,889	15,319.08	311,831	10,055.34
Current	29,232	961.28	233.75	768.57
TOTAL	494,121	16,280.36	312,064.75	10,823.91

$$D = \frac{\text{total program months}}{\text{\# implants}} = \frac{16{,}280.36}{79} = 206.08$$

$$E = \frac{\text{\# removals}}{\text{\# implants}} = \frac{77}{79} = 0.9798 = 97.98\%$$

$$F = \frac{\text{\# failures}}{\text{\# implants}} = \frac{25}{79} = 0.316 = 31.6\% \text{ and } \frac{\text{\# failures}}{\text{\# implants}} = \frac{24}{79} = 0.304 = 30.4\%$$

$$G = \frac{\text{\# removals}}{\text{\# service months}} = \frac{77}{10{,}823.91} = 0.00471 \text{ and } \frac{\text{\# removals}}{\text{\# program months}} = \frac{77}{16{,}280.36} = 0.00473$$

$$H = \frac{\text{\# failures}}{\text{\# service months}} = \frac{25}{10{,}823.91} = 0.00231 \text{ and } \frac{\text{\# failures}}{\text{\# program months}} = \frac{25}{16{,}280.36} = 0.00154$$

ATTACHMENT D
Pacemaker-Related Explants

ATTACHMENT D

PACEMAKER RELATED EXPLANTS

There were no pacemaker explants between January 24, 2013 and January 23, 2014.

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 from Ms. Marian Villa 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.

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.

This is to acknowledge the receipt of your letter/application dated

2/7/14, and to inform you that the initial processing which includes an administrative review has been performed.

Notification (SNM-1993/07003078)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 583299.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader