

Junod, Rebecca

From: K. Paul Steinmeyer <kpstein@radpro.com>
Sent: Thursday, February 11, 2016 11:19 AM
To: Kezos, Cindy D; Lawyer, Dennis
Subject: [External_Sender] Re: FW: SNM-1993 Annual Report
Attachments: Annl Cond 12 Rprt 2015 XLVIII corrected page 7.pdf; Annual Cond 12 Report 2016 corrected page 34.pdf; kpstein.vcf

Question #1 (in reference to Report XLVIII)

"Table II, Explanted Pacemaker 10/15/80 to 01/23/13. Shouldn't this table be updated since the explanted pacemaker done between January 24, 2014 and January 23, 2015?"

Answer #1

Table II includes the pacemaker explanted on 4/15/2014. It is Pacer #90, 7th from the top of the list. The date range at the top of Table II, however, is incorrect. It should read 10/15/80 TO 01/23/15. The corrected page 7 is attached.

Question #2 (in reference to Report XLIX)

Attachment D – Pacemaker Related Explants .

Shouldn't this table reflect the number of pacemakers explanted in the previous year which I assume is 0 between January 23, 2015 to January 23, 2016?

Answer #2

Correct. There were no explants during this reporting year. A corrected page 34 is attached.

Paul

On 2/10/2016 3:35 PM, Kezos, Cindy D wrote:

Paul, the NRC located a small oversight on Attachment D. The dates needs to be updated. Will you please update and send Attachment D to me. I'll forward it to the NRC.

Thanks.

Cynthia Kezos

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From: Lawyer, Dennis [<mailto:Dennis.Lawyer@nrc.gov>]
Sent: Tuesday, February 09, 2016 12:52 PM
To: Kezos, Cindy D
Subject: SNM-1993 Annual Report

Ms. Kezos,

I am the license reviewer assigned to review 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." A couple of items that seem to need correction in the report.

Table II, Explanted Pacemaker 10/15/80 to 01/23/13.

Shouldn't this table be updated since the explanted pacemaker done between January 24, 2014 and January 23, 2015?

Attachment D – Pacemaker Related Explants

Shouldn't this table reflect the number of pacemakers explanted in the previous year which I assume is 0 between January 23, 2015 to January 23, 2016?

If so, please email me back and submit replacement pages for these tables. If not, please explain

Thank you,

Dennis Lawyer
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TABLE II (corrected)
EXPLANTED PACEMAKERS
10/15/80 TO 01/23/14

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	90	4/10/73	4/15/2014	14,696	483.44	11,947	392.92	02	
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	

ATTACHMENT D

PACEMAKER RELATED EXPLANTS

There were no pacemakers explanted between January 24, 2015 and January 23, 2016.