DCS

FEB 12 1991

License No. 37-14916-01 Docket No. 030-08247

ARCO Medical Products Company
ATTN: Edward J. Zenzola
President
3801 West Chester Pike
Newtown Square, Pennsylvania 19073

Gentlemen:

Subject: Pacemaker Reporting Requirement

Condition 12 of your current NRC License (copy enclosed) requires that you collect, tally and report to the Nuclear Regulatory Commission, Region I, at no more than 12 month intervals, data from all investigators as indicated in the "Research Protocol for Clinical Investigation of the ARCO Nuclear NU-5 Pacemaker" dated March 25, 1974.

The most recent report received by NRC is "Report XXI". Report XXI covers the six-month period from January to July 1989. A report for the twelve month period ending July, 1990 has not been received by the NRC. In addition, we would appreciate your clarification of Report XXI. From our review of previous ARCO reports and Tables I and II of Report XXI, we believe that you have provided information to show that a total of 126 units were implanted; 82 were removed from patients; 43 remained in patients as of August 1, 1989; and there were 14 failures. The sum of the number of units removed and the number remaining in patients does not equal your reported total of 126 units implanted. In addition, the number of removals and the number of failures does not correspond with the data reported in Attachment C of the report.

We would appreciate receiving copies of the report(s) issued after Report XXI and your explanation for the apparent discrepancies discussed above. Please forward the report(s) and your explanation to the attention of Teresa Darden at Region I.

Thank you for your cooperation in this matter.

Sincerely,
Original Signed By:
Jean Gresick-Schugsta
for Mohamed Shanbaky, Ph.D.
Chief, Nuclear Materials Section A
Nuclear Materials Safety Branch

Enclosure: Amendment No. 22

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REG1 LIC30
37-14916-01 PDR

OFFICIAL RECORD COPY LTR ARCO MEDICAL - 0001.0.0
01/31/91

Return Original to Region I IE:07

IE07

bcc: M. Shanbaky (w/concurrences)
T. Darden

RI:DRSS
Darden/vhd
2/15/91

RI:DRSS
Shanbaky
2/11/91

OFFICIAL RECORD COPY

LTR ARCO MEDICAL - 0002.0.0
01/31/91

MATERIALS LICENSE

Amendment No. 22

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93 - 438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. ARCO Medical Products Company	In accordance with letter dated June 1, 1988, 3. License number 37-14916-01 is amended in its entirety to read as follows:
2. 3801 West Chester Pike Newtown Square, Pennsylvania 19073	4. Expiration date February 29, 1992
	5. Docket or Reference No. 030-08247

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Plutonium 238	A. Sealed sources	A. 100 grams

9. Authorized use

A. For storage only

CONDITIONS

10. Licensed material shall be stored only at Roy F. Weston, Inc., One Weston Way, West Chester, Pennsylvania.

11. Licensed material shall be stored by, or under the supervision of, Stephan Gertz, John Janous, William Lee, Roy Peterson or Frank Melpolder, Radiation Safety Officer.

12. ARCO Medical Products Company shall collect, tally and report to the Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406, at no more than 12 month intervals, data from all investigators as indicated in the "Research Protocol for Clinical Investigation of the ARCO Nuclear NU-5 Pacemaker" dated March 25, 1974. The periodic reports shall contain information as indicated in the attached "Contents of Sponsor's Periodic Report on Clinical Performance of Pacemaker," except that data on the non-nuclear control of pacemakers is no longer required.

13. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".

"OFFICIAL RECORD COPY"

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 37-14916-01

Docket or Reference number: 030-08247

Amendment No. 22

(Continued) CONDITIONS

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated March 6, 1981
B. Letter dated March 7, 1983
C. Letter dated April 8, 1983
D. Letter dated May 2, 1983
E. Letter dated June 9, 1983
F. Letter dated October 13, 1983
G. Letter dated July 28, 1986
H. Letter dated August 28, 1986
I. Letter dated October 27, 1986
J. Letter dated June 1, 1988

For the U.S. Nuclear Regulatory Commission

Date 20 AUG 1988

By Original Signed By:
John D. Kinneman

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406