

MATERIALS LICENSE

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, 36, 39, 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.

OFFICIAL RECORD COPY

Licensee		3. License Number	SNM-2003
1. Crozer-Chester Medical Center		4. Expiration Date	February 28, 2002
2. One Medical Center Boulevard Upland, Pennsylvania 19013-3995		5. Docket or Reference No.	070-03092/ SNM-1691
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 (principal radionuclide Pu-238)	A. Sealed source	A. 250 milligrams	
9. Authorized use			
A. As a component of a Coratomic Model C-101 nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated November 1, 1975, this authorization includes: follow-up, explanation, recovery, disposal, but not implantation.			

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at One Medical Center Boulevard, Upland, Pennsylvania.
11. The physician responsible for follow-up, explanation, and return of nuclear-powered pacemaker to the manufacturer for proper disposal is Howard P. Rothenberg, M.D.
12. The Radiation Safety Officer for this license is Diana Stockdale, M.S.
13. The specified possession limit for cardiac pacemakers includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.
14. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

SNM-2003

Docket or Reference Number

070-03092/ SNM-1691

17. 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. Letter dated January 9, 1997

Date

FEB - 5 1997

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By

Michelle Beardsley

Division of Nuclear Materials Safety
Region I

King of Prussia, Pennsylvania 19406

FEB - 5 1997

License No. SNM-2003
Docket No. 070-03092
Control No. 124116

Joseph Saunders
Vice President, Support Services
Crozer-Chester Medical Center
One Medical Center Boulevard
Upland, PA 19013-3995

Dear Mr. Saunders:

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Until your license is terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," 10 CFR Part 35, "Medical Use of Byproduct Material," and other applicable regulations.
2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:
 - a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and
 - b. you have notified the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 in writing, that activities authorized by the license will be initiated.
3. Notify NRC, in accordance with 10 CFR 35.14, no later than 30 days after:
 - a. the date that you permit any individual to work as an Authorized User or an Authorized Nuclear Pharmacist pursuant to 10 CFR 35.13(b)(1) through (4), and provide to the Commission a copy of the board certification, the

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Commission or Agreement State license, or the Permit issued by a licensee of broad scope identifying the individual;

- b. an Authorized User, Authorized Nuclear Pharmacist, Radiation Safety Officer, Teletherapy Physicist, or Medical Physicist permanently discontinues performance of duties under the license or has a name change; or
 - c. when the mailing address on the license changes (no fee is required if the location of byproduct material remains the same).
4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. when you decide to terminate all activities involving materials authorized under the license; or
 - b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.
5. In accordance with 10 CFR 35.13, request and obtain a license amendment before you:
 - a. receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. permit an individual, except as specified in 10 CFR 35.14(b)(1) through (4), to work as an Authorized User or Authorized Nuclear Pharmacist under the license;
 - c. change Radiation Safety Officer, Teletherapy Physicist or Medical Physicist;
 - d. order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or
 - e. add or change the areas of use, or address or addresses of use identified in the license application or on the license.
6. Receive written approval from the NRC prior to any change in ownership of your organization, in accordance with 10 CFR 30.34(b).
7. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances

J. Saunders
Crozer-Chester Medical Center

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where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than the Radiation Safety Officer or a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement actions will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Thank you for your cooperation.

Sincerely,

Original Signed By:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. SNM-2003
Docket No. 070-03092
Control No. 124116

Enclosures:

1. License No. SNM-2003
2. 10 CFR Parts 2, 19, 20, 30, 31, 35, and 170

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J. Saunders
Crozer-Chester Medical Center

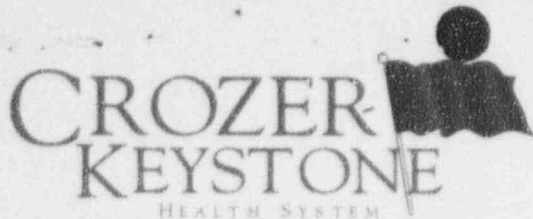
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DOCUMENT NAME: R:\WPS\MLTR\LSNM2003

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Beardsley MB						
DATE	01/17/97	01/ /97	01/ /97	01/ /97			

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CROZER
CROZER-CHESTER
MEDICAL CENTER

One Medical Center Blvd.
Upland, PA 19013-3995

Tel 610.447.2000

L 12240
070-03092
22160

January 9, 1997

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

ATTN: Michelle Beardsley

Dear Michelle:

We would like to apply for a Special Nuclear Material License to permit the follow-up of one (1) Coratomic Model C-101 nuclear-powered cardiac pacemaker containing 250 milligrams of Plutonium. (Previous license SNM-1691).

The pacemaker was implanted in 1977 at Crozer Chester Medical Center. We will contact the physician group following the patient every six months to ensure that our information concerning her address and phone number remains current. We will continue follow-up for the life of the patient or until the pacemaker is recovered and returned to BioControl Technology, Inc.

This license request is for one patient follow-up only. Crozer Chester Medical Center does not intend to possess or implant other nuclear-powered pacemakers.

The authorized user for this license is Howard P. Rothenberg, M.D. who is currently an authorized user under our NRC License (37-12240-01).

The radiation safety officer for this license is Diana L. Stockdale, M.S. who is currently RSO under our NRC License (37-12240-01).

The application fee of \$1400.00 for a class 7C Special Nuclear Material License for human use is enclosed.

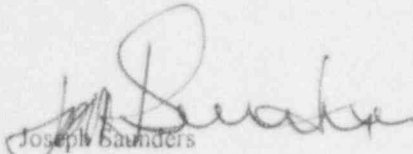
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124116
FEB - 3 1997

If you have any questions concerning this request you may contact our Radiation Safety Officer, Diana Stockdale at 610-447-2549. Thank you for your attention to this matter.

Sincerely,



Joseph Saunders
Vice President, Support Services
Crozer-Chester Medical Center
One Medical Center Boulevard
Upland, PA 19013

2010-03-11-22

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Crozer-Keystone Health System

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001CROZER-CHESTER MEDICAL CENTER
ATTN: DIANE L. STOCKDALE, M.S.
RADIATION SAFETY OFFICER
ONE MEDICAL CENTER BOULEVARD
UPLAND, PA 19013-3995*AS PER OUR TELEPHONE CONVERSATION OF FEBRUARY 3, 1997,
SINCE YOU ALREADY HAVE A NRC LICENSE, THE PACEMAKER
REQUEST DATED 1/9/97 IS FEE EXEMPT. NO FEE IS DUE.

TYPE OF ACTION

NEW LICENSE

RENEWAL OF LICENSE

AMENDMENT TO LICENSE

REQUESTED DATE

1-9-97

LICENSE NUMBER

NEW

CONTROL NUMBER

124116

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE \$

PAYMENT RECEIVED \$

AMOUNT DUE \$

- ☐ Your request was received without the prescribed application fee.
- ☐ We received your Check No. _____ in the amount of \$ _____. Payment of the additional fee noted above is required.
- ☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR
REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE
ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT
RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM
THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT
WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS
ACTION.

II. FEE NOT REQUIRED

☒ Enclosed is Check No. 228861 ^{\$1,400.00} which accompanied your request. The fee is not required because: *☐ We received your Check No. _____ in payment of the fee.☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____.

Control No. _____

☐ Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for☐ INSUFFICIENT FUNDS☐ ACCOUNT CLOSED☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____.

_____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section I of this form. Refer to Section 170.31 and Footnote 1(d)(2).

Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section I of this form.

SIGNATURE -- LICENSE FEE ANALYST

LFDCB

LFDCB

Distribution:

Region I

Pending

BBrown

LFARB R/F

OC/DAF R/F

OC/DAF S/F (LF-3.2.7)

DATE

BRENDA BROWN 301-415-6055

2/7/97

2-7-97

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 22160
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: _____

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: CROZER-CHESTER MEDICAL CENTER
RECEIVED DATE: 970113
DOCKET NO: 7003092
CONTROL NO.: 124116
LICENSE NO.:
ACTION TYPE: NEW LICENSE

2. FEE ATTACHED

AMOUNT: _____
CHECK NO.: _____

3. COMMENTS

SIGNED M. A. Perkins
DATE 1/13/97

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /V/)

1. FEE CATEGORY AND AMOUNT: EX 7C face maker

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT _____
RENEWAL _____
LICENSE _____

3. OTHER _____

SIGNED _____
DATE _____

Log	<u>Feb 4</u>
Remarks	
Check No.	<u>22861-227112</u>
Amount	<u>4400.00</u>
Fee Category	<u>EX7C</u>
Type of Fee	
Date Submitted	
Date Completed	
By	<u>BB</u>

63 + 07 for 2/3/97

Returned to
licensee. No fee due.
2/7/97
2/3/97
Already have
an existing license.
no charge for this
request. BB

2/3/97
I called RSO,
(Diana Prokache)
to advise, no fee
due since they
already have
a license w/NRL.
If we receive check
we will return it. BB