

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.

301723

<p>Licensee</p> <p>1. The Heart Center of Northeastern Ohio, Inc.</p> <p>2. 250 Debartolo Place, Suite 2750 Youngstown, Ohio 44512</p>		<p>In accordance with letter dated August 9, 1996</p> <p>3. License Number 34-26273-01 is amended in its entirety to read as follows:</p>	
		<p>4. Expiration Date March 31, 2001</p>	
		<p>5. Docket or Reference No. 030-32051</p>	
<p>6. Byproduct, Source, and/or Special Nuclear Material</p> <p>A. Any byproduct material identified in 10 CFR 35.200</p>	<p>7. Chemical and/or Physical Form</p> <p>A. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding generators and xenon-133)</p>	<p>8. Maximum Amount that Licensee May Possess at Any One Time Under This License</p> <p>A. As needed</p>	
<p>9. Authorized Use:</p> <p>A. Medical use described in 10 CFR 35.200 (limited to cardiovascular clinical procedures).</p>			

CONDITIONS

10. Location of Use: 250 Debartolo Place, Suite 2750, Youngstown, Ohio.
11. Radiation Safety Officer: Steven L. Ballas, M.D.
12. Authorized User:
Steven L. Ballas, M.D., for material in 10 CFR 35.200 (limited to cardiovascular
clinical procedures).
13. The license shall follow the Leak-Testing procedures as outlined in Appendix H of
Regulatory Guide 10.8, Revision 2, 1987.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

34-26273-01

Docket or Reference Number

030-32051

Amendment No. 06

14. The licensee shall follow the Worker Dose from Aerosols procedures as outlined in Appendix O of Regulatory Guide 10.8, Revision 2, 1987.
15. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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 received February 7, 1991; and
- B. Two letters dated September 16, 1991 and letters dated October 29, 1991, November 22, 1991, May 29, 1996, June 6, 1996 and June 10, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

Sept. 20, 1996

By

Patricia Macchubon
Nuclear Materials Licensing Branch, Region III

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(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 02200
STATUS CODE: 0
FEL CATEGORY: 7C
EXP. DATE: 20010331
FEE COMMENTS:
DECOM FIN ASSUR REQDT N
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LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: HEART CENTER OF NE OHIO, INC. (THE)
RECEIVED DATE: 960813
DOCKET NO: 3032051
CONTROL NO.: 301723
LICENSE NO.: 34-26273-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 0
CHECK NO.: 2

3. COMMENTS

SIGNED S. Hersey
DATE 8-15-96

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

1. FEE CATEGORY AND AMOUNT: 7C \$440
2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ☒
RENEWAL ☐
LICENSE ☐
3. OTHER

SIGNED SC
DATE 9/10/96

SEP 16 1996

Log	<u>Aug 9 III</u>
Remitter	
Check No.	<u>13618</u>
Amount	<u>\$440</u>
Fee Category	<u>7C</u>
Type of Fee	<u>AMD</u>
Date Check Rec'd	<u>9/10/96</u>
Date Completed	<u>9/10/96</u>
By:	<u>SC</u>

1996 AUG 20 AM 10:47



The Heart Center
of Northeastern Ohio

Arthur V. Whittaker, M.D., F.A.C.C.

Keith H. Kuppler, M.D., F.A.C.C.

Steven L. Ballas, M.D., F.A.C.C.

Mark D. Fildes, M.D., F.A.C.C.

Michael L. Scavrona, M.D., F.A.C.C.

Edmund O. Fiksinski, M.D.

August 9, 1996

U. S. N. R. C.
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Re; NRC License #34-26273-01

To whom it may concern:

Recently we have submitted an application to add Dr. Steven L. Ballas to our license as and authorized user. In addition, we wish to add Dr. Ballas as the Radiation Safety Officer at the Heart Center of Northeastern Ohio, Inc. Documentation of training and experience was included with the above referenced application.

Please delete reference to Stephen M. Barolsky, M. D. as RSO and authorized user. Dr. Barolsky is no longer affiliated with the Heart Center of Northeastern Ohio, Inc.

Best regards,

Arthur V. Whittaker, M.D., F.A.C.C.
Chairman/President

Southwoods Commons
250 DeBartolo Place
Suite 2750
Youngstown, OH 44512
(330) 758-7703 Fax (330) 758-4930

500 Gypsy Lane
Youngstown, Ohio 44501
(330) 747-1200 Fax (330) 747-1502

1534 E. Market Street
Warren, Ohio 44483
(330) 393-3355 Fax (330) 399-2448

1995 E. State Street
Salem, Ohio 44460
(330) 332-7656

RECEIVED

AUG 13 1996

REGION III

SEP 16 1996

AUG 13 1996

301723

pm: 8-9-96

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 20555-0001THE HEART CENTER OF NORTHEASTERN OHIO
ATTN: ARTHUR V. WHITTAKER, M.D., F.A.C.C.
CHAIRMAN/PRESIDENT
SOUTHWOODS COMMONS
250 DEBARTOLO PLACE SUITE 2750
YOUNGSTOWN, OHIO 44512

TYPE OF ACTION

- ☐ NEW LICENSE
☐ RENEWAL OF LICENSE
☒ AMENDMENT TO LICENSE

REQUESTED DATE

8-9-96

LICENSE NUMBER

34-26273-01

CONTROL NUMBER

301723

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
7C	\$	\$	\$ 440.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	440.00
PAYMENT RECEIVED	\$	0.00
AMOUNT DUE	\$	440.00

☒ 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.

SIGNATURE - LICENSE FEE ANALYST

LFDCB

LFDCB

SHIRLEY CRUTCHFIELD

8/26/96

Distribution:

Pending Fee File OC/DAF/SF(LF-3.2.7)
FARB R/F (2) Region 3

DATE

Aug. 26, 1996

SEP 23 1996

Arthur V. Whittaker, M.D.
Chairman/President
The Heart Center of
Northeastern Ohio
250 DeBartolo Place, Suite 2750
Youngstown, OH 44512

Dear Dr. Whittaker:

Enclosed is Amendment No. 06 to your NRC Material License No. 34-26273-01 in accordance with your request.

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 III office 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. Unless your license has been 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," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. 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

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- b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
4. 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 anyone, except individuals described in 10 CFR 35.13(b) to work as an authorized user under the license;
 - c. Change Radiation Safety Officers;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - f. Change ownership of your organization.
5. 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 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 certifying official rather than a consultant.

You will be periodically inspected by 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 Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply

A. Whittaker

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with NRC requirements, prompt and vigorous enforcement action 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.

Sincerely,

Original Signed By
Patricia M. Vacherlon
Nuclear Materials Licensing Branch

License No.: 34-26273-01
Docket No.: 030-32051

Enclosure: Amendment No. 06

DOCUMENT NAME: M:\03032051.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" =
Copy with attachment/enclosure "N" = No copy

OFFICE	DRSS/RIII								
NAME	PVacherlon/jaw								
DATE	09/19/96 <i>pm</i>								

OFFICIAL RECORD COPY