

MATERIALS LICENSE

Amendment No. 02

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.

301655

Licensee		In accordance with letter dated July 23, 1996	
1. Greater Cincinnati Cardiovascular Consultants, Inc.		3. License Number 34-26461-01 is amended in its entirety to read as follows:	
2. 415 Straight Street Suite 300 Cincinnati, OH 45219-1098		4. Expiration Date January 31, 2003	
		5. Docket or Reference No. 030-33017	
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. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed	
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding generators, xenon- 133 and aerosols)	B. As needed	
9. Authorized Use:			
A. Medical use described in 10 CFR 35.100.			
B. Medical use described in 10 CFR 35.200 (excluding generators, xenon-133 and aerosols).			

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 415 Straight Street, Suite 300, Cincinnati, Ohio, and 2990 Mack Road, Fairfield, Ohio.
11. Radiation Safety Officer: James K. O'Donnell, M.D.

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PDR ADOCK 03033017
C PDR

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SD

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

34-26461-01

Docket or Reference Number

030-33017

Amendment No. 02

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

James K. O'Donnell, M.D. 35.100 and 35.200 (excluding generators, xenon-133 and aerosols)

13. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:

1. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and
2. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Section, 801 Warrenville Road, Lisle, IL 60137 has been notified that activities authorized by the license will be initiated.

15. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.

16. 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 U.S. 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 November 9, 1992; and

B. Letters dated June 29, 1995, September 20, 1995, and October 9, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

August 13, 1996

By

Patricia M. Beckwith

Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02201
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20030131
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: GREATER CINCINNATI CARDIOVASCULAR
RECEIVED DATE: 960726
DOCKET NO: 3033017
CONTROL NO.: 301655
LICENSE NO.: 34-26461-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 430.00
CHECK NO.: 12432

3. COMMENTS

SIGNED
DATE

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
DATE

AUG 26 1996

Log	Aug 1 III
Remitter	
Check No.	12432 2153
Amount	430.00 410
Fee Category	7C
Type of Fee	AmD
Date Check Rec'd	8/2/96 8/23/96
Date Completed	8/23/96
By:	sl

AUG 26 1996

Greater
Cincinnati Cardiovascular Consultants

Byron W. Gustin, M.D., FACC • F. Thomas Jenike, M.D., FACC • John S. Held, M.D., FACC
David G. Babbitt, M.D., FACC • Lester E. Suna, M.D., FACC

23 July 1996

U.S. N.R.C.
Region III
801 Warrensville Road
Lisle, Illinois 60532-4351

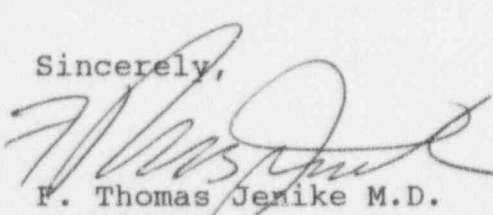
Re: NRC License # 34-26461-01

To Whom it may concern:

We are requesting an amendment to our existing NRC License to reflect a change in the Radiation Safety Officer. Please delete reference to Shirley T. Small, M.S. We wish to add James K. O'Donnell, M.D. as Radiation Safety Officer of our location.

We have affixed a check in the amount of \$430.00 payable to the NRC. Should there be any questions regarding this amendment, please feel free to contact me at 513-751-4222. We would appreciate if you could please expedite this request as soon as possible. Thank you for your time and attention to this matter.

Sincerely,


F. Thomas Jenike M.D.
President
Greater Cincinnati Cardiovascular Consultants, Inc.

FTJ/jis

OFFICES:

Enclosure

Cincinnati (Clifton) • Fairfield/Hamilton • Eastgate • Landen • Hillsboro • Oxford • Wetherington (West Chester)

BUSINESS OFFICE:

415 Straight Street, Suite 300, Cincinnati, Ohio 45219-1098 • 513-751-GCCC (4222) • Fax: 513-751-4353

RECEIVED

7:24-96
JUL 26 1996

REGION III
GCCC

301655

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 20555-0001GREATER CINCINNATI CARDIOVASCULAR
CONSULTANTS
ATTN: F. THOMAS JENIKE, M.D.
415 STRAIGHT STREET STE 300
CINCINNATI, OHIO 45219-1098

TYPE OF ACTION

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

REQUESTED DATE

7-23-96

LICENSE NUMBER

34-26461-01

CONTROL NUMBER

301655

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	\$	430.00
AMOUNT DUE	\$	10.00

☐ Your request was received without the prescribed application fee.

☒ We received your Check No. 12432 in the amount of \$ 430.00. 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
<i>Shirley Crutchfield</i>		
SHIRLEY CRUTCHFIELD	8/2/96	

II. FEE NOT REQUIRED

- ☐ Enclosed is Check No. _____ 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 1 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 1 of this form.

Distribution: *OC/DAF/RF*
Pending Fee File: *OC/DAF/SF(LF-3 2 7)*
LFARB R/F (2) Region *3*

DATE

Aug. 5, 1996

AUG 27 1996

F. Thomas Jenike, M.D.
President
Greater Cincinnati Cardiovascular
Consultants, Inc.
415 Straight Street, Suite 300
Cincinnati, OH 45219-1098

Dear Dr. Jenike:

Enclosed is Amendment No. 02 to your NRC Material License No. 34-26461-01 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.

In addition to changing your radiation safety officer, we have extended your expiration date by five years. Please refer to our letter dated May 7, 1996 which discusses the one-time five year extension for certain licenses.

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).

301655

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
 - 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 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. 34-26461-01
Docket No. 030-33017

Enclosures: Amendment No. 02

DOCUMENT NAME: M:\03033017.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	DNMS/RIII								
NAME	PMVacherlon:brt								
DATE	08/13/96 <i>PMV</i>								

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

July 29, 1996

James K. O'Donnell, M.D.
Radiation Safety Officer
Greater Cincinnati Cardiovascular
Consultants, Inc.
415 Straight Street, Suite 300
Cincinnati, OH 45219-1098

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(☒ Letter ☐ Application ☐ Dated July 23, 1996)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License ☒ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required) ☐ QMP Revision
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information, technical issues that require additional information, or policy/technical issues that require coordination with headquarters or other NRC regional offices.

It appears that your request is nonroutine and has been assigned to Patricia M. Vacherlon for an expedited review. If you should have any questions please contact Ms. Vacherlon at (708) 829-9811.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (708) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301655
License No. 34-26461-01