

MATERIALS LICENSE

Amendment No. 21

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.

302411

Licensee

1. The Monroe Clinic
2. 515 22nd Avenue
Monroe, WI 53566

In accordance with letter dated
February 26, 1997

3. License Number 48-16485-01 is amended in its entirety to read as follows:

4. Expiration Date April 30, 2001

5. Docket or Reference No. 030-11124

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 xenon-133)

- B. As needed

- C. Any byproduct material identified in 10 CFR 35.300

- C. Any radiopharmaceutical identified in 10 CFR 35.300

- C. As needed (not to exceed 1 curie of I-131)

- D. Any byproduct material identified in 10 CFR 31.11

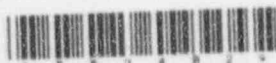
- D. Prepackaged Kits

- D. As needed

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
 - B. Medical use described in 10 CFR 35.200 (excluding xenon-133).
 - C. Medical use described in 10 CFR 35.300.

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COPY 230 50

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

48-16485-01

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030-11124

Amendment No. 21

9. Authorized Use (Continued)

D. Medical use described in 10 CFR 35.400.

E. In vitro studies.

CONDITIONS

10. Location of Use: 515 22nd Avenue, Monroe, Wisconsin.

11. Radiation Safety Officer: David D. Wisnfske, M.D.

12. Authorized Users:

- A. Ross L. Cline, M.D., for material in 10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 31.11.
- B. David D. Wisnfske, M.D., for material in 10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 31.11.
- C. John A. Jerisha, M.D., for material in 10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 31.11.
- D. Christopher J. Ostromecki, M.D., for material in 10 CFR 35.200 limited to cardiovascular clinical procedures.
- E. James T. Link, M.D., for material in 10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 31.11.
- F. Philip C. Eckstrom, M.D., for in material in 10 CFR 35.100, 35.200 (excluding xenon-133), 35.300 and 31.11.
- G. Shelley Falik, M.D., for material in 10 CFR 35.100 and 35.200 (excluding generators, xenon-133, and aerosols) limited to cardiovascular clinical procedures.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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13. 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 dated February 28, 1991 (excluding attachment 7.1.2); and
- B. Letters dated October 14, 1991, December 23, 1991, October 4, 1993, and October 28, 1993.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date APR 24 1997

By


Nuclear Materials Licensing Branch, Region III

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 02120
Status Code: 0
Fee Category: 7C 2B
Exp. Date: 20010430
Fee Comments:
Decom Fin Assur Req'd: N
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
Applicant/Licensee: MONROE CLINIC (THE)
Received Date: 970310
Docket No: 3011124
Control No.: 302411
License No.: 48-16485-01
Action Type: Amendment

2. FEE ATTACHED
Amount: 430
Check No.: 145713

3. COMMENTS

Signed D. Hershey
Date 3-17-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / ☒ /)

1. Fee Category and Amount: 7C 2B \$440

2. Correct Fee Paid. Application may be processed for:
Amendment ☒
Renewal ☐
License ☐

3. OTHER _____

Signed AC
Date 5/20/97

MAY 23 1997

MAY 23 1997

Log	<u>Mar 7 III</u>
Remitter	
Check No.	<u>147913</u> / <u>150756</u>
Amount	<u>\$430</u> / <u>410</u>
Fee Category	<u>7C 2B</u>
Type of Fee	<u>Amend</u>
Date Check Rec'd	<u>3/18/97</u>
Date Completed	<u>5/20/97</u>
By:	<u>AC</u>

1997 MAR 18 PM 1:04



The Monroe Clinic

A proud caring tradition

515 22nd Avenue
Monroe, Wisconsin 53566

February 26, 1997

US Nuclear Regulatory Commission
By-Product Material Licensing Section
801 Warrenville Rd.
Lisle, IL 60532-4351

RE: By-Product Material License #48-16485-01
Monroe Clinic/Hospital Division
Monroe, WI

Dear Sir/Madam:

We request that you amend our By-Product Material License to show the following change:

1. Please add Shelley Falik, M.D. as an authorized user for radiopharmaceuticals for diagnostic cardiac procedures only. A letter from the State of New York Department of Health indicating Dr. Falik having been added as an authorized user to New York State Department of Health Radioactive Material License 1022-2 is attached.

We authorize Mr. Ronald D. Edwards, Physicist, Radiation Protection Services, Ltd., 800 W. 5th Ave., Suite 103E., Naperville, IL 60563, to act on our behalf to answer any questions or provide any additional information you may require regarding this matter or other matters regarding the use of by-product material at our facility.

Enclosed please find a check for \$430.00 to cover the required amendment fee.

Thank you in advance for your cooperation in this matter.

Very truly yours,

Karen Thomas
Executive Vice President

RECEIVED
MAR 10 1997
REGION III

pm: 3-7-97

302411

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Center for Environmental Health

2 University Place

Albany, New York 12203-3389

Mark R. Chassin, M.D., M.P.P., M.P.H.
CommissionerPaula Wilson
Executive Deputy CommissionerOFFICE OF PUBLIC HEALTH
Lloyd F. Novick, M.D., M.P.H.
DirectorClara Jones Pitts
Executive Deputy Director
William H. Stashak, P.E., Ph.D.
Center Director

SEP 19 1994

W.C.A. Hospital
207 Foote Avenue
Jamestown, New York 14702-9975Attention: Donald Anderson, M.D.
Radiation Safety OfficerRE: NYS Dept. of Health Radioactive
Materials License No. 1022-2
DH No. 94-276

Dear Dr. Anderson:

Enclosed is Amendment No. 20 to New York State Department of Health Radioactive Materials License No. 1022-2, which adds Shelley Falik, M.D. to the list of authorized users of radiopharmaceuticals for diagnostic cardiology procedures only. In addition, Condition Numbers 6, 7, 8 and 9 have been modified to incorporate a more general authorization as described in 10 NYCRR 16.123(b).

If I may be of assistance, please contact this office at 518/458-6485 or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
Two University Place, Room 375
Albany, New York 12203

Sincerely,

Daniel J.P. Samson
Radiological Health Specialist

SG/DS:ks

Enclosure: Amendment No. 20

cc: John Galati, Administrator

DATE: 3-12-97

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: BJ HOLT
LICENSEE: MONROE CLINIC
LICENSE NUMBER: 48-16485-01

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

☐ Additional Information to Control No. _____
Process in as a new action, additional information, and no fee required.

☐ Process as new licensing action. Review has already been started on Control No. _____ and this information cannot be combined with current in-house action.

☐ Can be combined with Control No. _____. Review has not started.

☐ Appears to be information for the license file - file it.

☐ Licensee is adding Nuclear Pharmacists.

☐ Amendment is necessary _____. Amendment is not necessary _____.
(Information for license file)

☒ Licensee is adding authorized users.

☒ A check is included _____. No check is included _____.
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Amendment is necessary _____. Amendment is not necessary _____.
(This is a Notification)

☒ Process in as a new licensing action:

A. Amendment _____
B. Renewal _____
C. New License Application _____

☐ Other: _____

Thank You For Your Help!!!

10/16/96

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 20555-0001

MONROE CLINIC
ATTN: KAREN THOMAS
EXECUTIVE VICE PRESIDENT
515 22ND AVENUE
MONROE, WI 53566

TYPE OF ACTION

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

REQUESTED DATE

2-26-97

LICENSE NUMBER

48-16485-01

CONTROL NUMBER

302411

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. 147913 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

SHIRLEY CRUTCHFIELD

LFDCB

3/18/97

LFDCB

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 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.

Distribution:

Pending Fee File

LFARB R/F (2)

OC/DAF/RP
OC/DAF/SF(LF-3.2.7)
Region 2

DATE

Mar 18, 1997

MAY 27 1997

Karen Thomas
Executive Vice President
The Monroe Clinic
515 22nd Avenue
Monroe, WI 53566

Dear Ms. Thomas:

Enclosed is Amendment No. 21 to your NRC Material License No. 48-16485-01 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 at (630) 829-9887 so that we can provide appropriate corrections and answers.

We have extended your expiration date by five years. Please refer to our letter dated May 7, 1996 (attached) which discusses the recent regulatory change that grants a 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 mailing address listed on the license changes. (No fee is required if the location of byproduct material remains the same.)

302411

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
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 Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC

K. Thomas

-3-

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
James R. Mullauer, M.H.S.
Health Physicist
Nuclear Materials Licensing Branch

License No. 48-16485-01
Docket No. 030-11124

Enclosure: Amendment No. 21

DOCUMENT NAME: M:\03011124.CL7

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/RIH								
NAME	JRMullauer:brt								
DATE	04/24/97								

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 17, 1997

David D. Wisnepske, M.D.
Radiation Safety Officer
The Monroe Clinic
515 22nd Avenue
Monroe, WI 53566

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 02/26/97)

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)
☐ 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.

It appears that your request is routine (see 1-3 below, as applicable).

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 required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 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. 302411
License No. 48-16485-01