

MATERIALS LICENSE

Amendment No. 11

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.

301714

Licensee

1. St. Mary's Hospital Ozaukee
2. 13111 N. Port Washington Rd.
Mequon, WI 53097

In accordance with letter dated
February 7, 1994

3. License Number 48-17393-01 is amended
in its entirety as follows:

4. Expiration Date June 30, 1998

5. Docket or
Reference No. 030-12682

6. Byproduct, Source, and/or
Special Nuclear Material

- A. Any byproduct
material identified
in 10 CFR 35.100
- B. Any byproduct
material identified
in 10 CFR 35.200
- C. Any byproduct
material identified
in 10 CFR 35.300

7. Chemical and/or Physical
Form

- A. Any
radiopharmaceutical
identified in 10 CFR
35.100
- B. Any
radiopharmaceutical
identified in 10 CFR
35.200 (excluding
xenon-133)
- C. Any
radiopharmaceutical
identified in 10 CFR
35.300

8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

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

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.

070072
9610070177 960925
PDR ADDCK 03012682
C PDR

COPY

ml.
234
SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

48-17393-01

Docket or Reference Number

030-12682

Amendment No. 11

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 13111 North Port Washington Rd., Mequon, WI 53097.
11. Radiation Safety Officer: Cynthia Rice, M.D.
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 UsersMaterial and Use

- A. Cynthia Rice, M.D. For material in 10 CFR 35.100, 35.200 (excluding xenon-133) and 35.300.
- B. John P. Whalen, M.D. For material in 10 CFR 35.100, 35.200 (excluding xenon-133) and 35.300.
- C. Frank Kreitzer, M.D. For material in 10 CFR 35.100, 35.200 (excluding xenon-133) and 35.300.
13. Pursuant to 10 CFR Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.
14. The licensee shall maintain records of information related to decommissioning at the location listed in Condition 10. of this license as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.
15. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
16. During the use of molybdenum-99/technetium-99m generators, the licensee shall perform the dose calibrator linearity test using a vial or syringe of Tc99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

48-17393-01

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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, 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 October 31, 1992; and
- B. Letters dated May 6, 1993 (with attachments) and February 7, 1994 (with attachments), April 26, 1994, and July 31, 1996 with attachment.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

Sept 25, 1996

By

Leticia M. Mackey
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: 02120
STATUS CODE: 0
FEE CATEGORY: 7C 2B
EXP. DATE: 20030630
FEE COMMENTS: CODE 21
DECOM FIN ASSUR REQD: N

R7
13

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ST. MARY'S HOSPITAL OZAUKEE
RECEIVED DATE: 960812
DOCKET NO: 3012682
CONTROL NO.: 301714
LICENSE NO.: 48-17393-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 430
CHECK NO.: 292869

3. COMMENTS

SIGNED
DATE

D. Hershey
8-15-96

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
DATE

LC
9/19/96

SEP 23 1996

Log	Aug 8 III
Remitter	
Check No.	96809 / 98110
Amount	430 #10
Fee Category	7C 2B
Type of Fee	Amo
Date Check Rec'd	8/15/96
Date Completed	9/19/96
By:	LC

1996 AUG 15 PM 3:30

St Mary's Hospital
O Z A U K E E

030-12682

July 31, 1996

Nuclear Regulatory Commission
Region III
Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

RE: Amendment to Radioactive Materials License #48-17393-01

Dear Sir or Madam:

The attached diagram outlines a room St. Mary's Hospital Ozaukee would like added to the above referenced Radioactive Materials License. This room will be used as a treadmill room as part of a stress test.

We hope this information is sufficient to grant our amendment request.

Sincerely,

Therese B. Pandl

Therese B. Pandl
Senior Vice President/COO

TBP:dss

Attachment

301714

AUG 12 1996

RECEIVED

AUG 12 1996

REGION III



Tm 8/9/96

N. MEDICINE
Room II

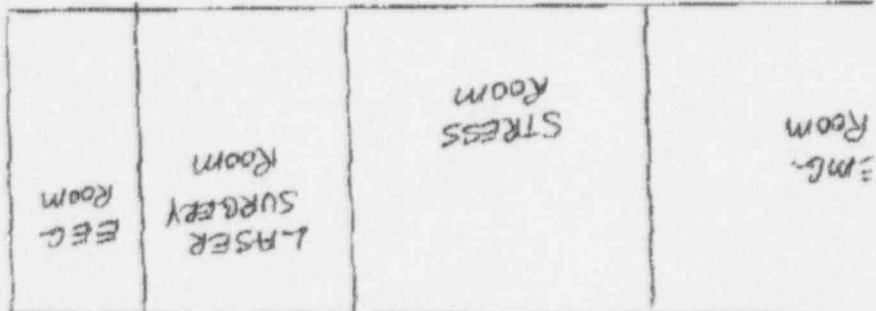
N. MEDICINE
Room I

HOT
LAB

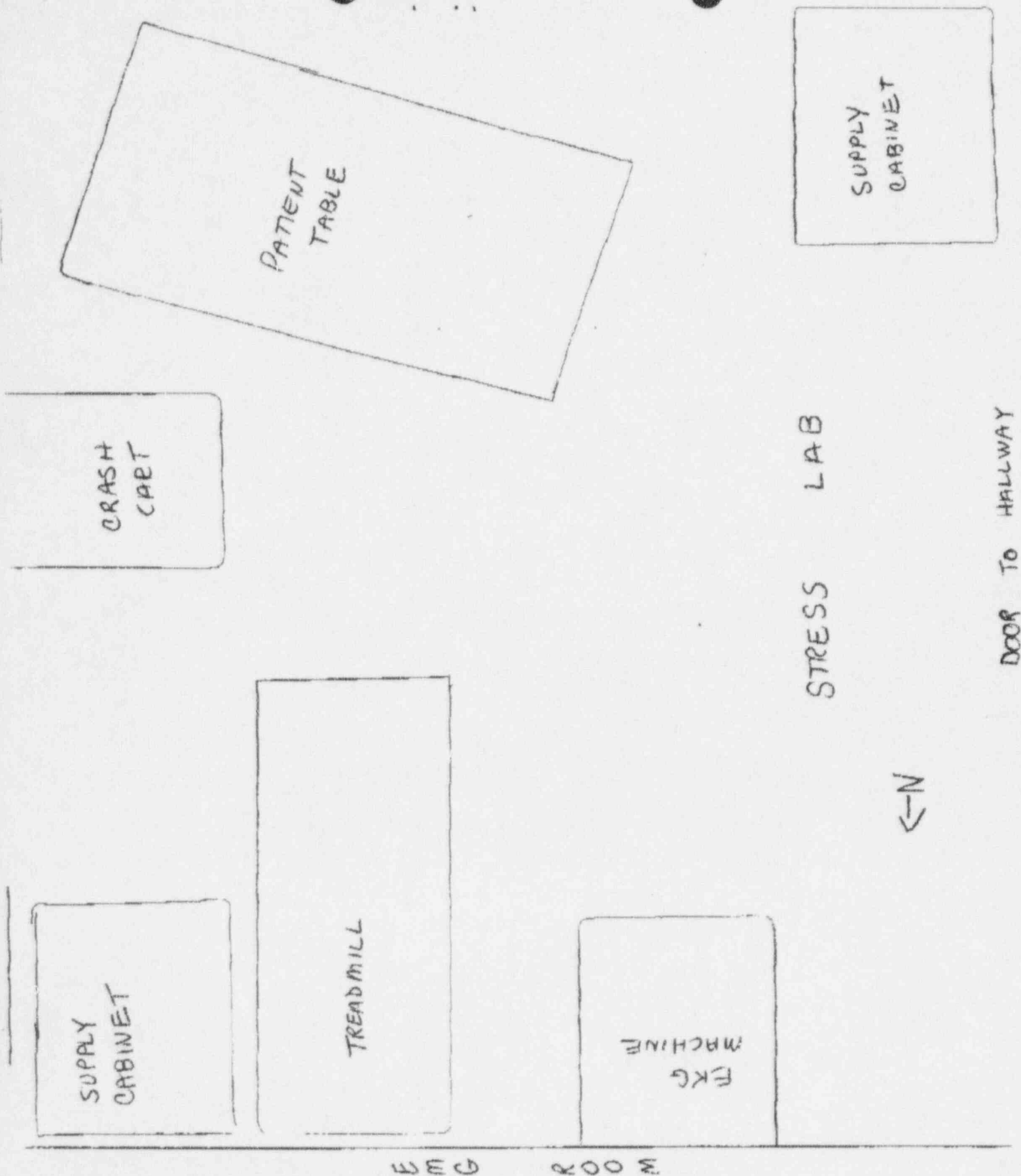
N →

E.R. AREA
TESTING & TREATMENT
WAITING AREA

Hallway



Outside



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 20555-0001ST. MARY'S HOSPITAL
ATTN: THERESE B. PANDL
SENIOR VICE PRESIDENT
13111 NORTH PORT WASHINGTON ROAD
MEQUON, WISCONSIN 53097

TYPE OF ACTION

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

REQUESTED DATE

7-31-96

LICENSE NUMBER

48-17393-01

CONTROL NUMBER

301714

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. 96809 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

SHIRLEY CRUTCHFIELD

8/26/96

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 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: OC/DAF/RF
Pending Fee File OC/DAF/SF(LF-3 2.7)
LFARB R/F (2) Region 3

DATE

Aug. 26, 1996

SEP 26 1996

Therese B. Pandl
Senior Vice President/COO
St. Mary's Hospital - Ozaukee
13111 North Port Washington Rd.
Mequon, WI 53097

Dear Ms. Pandl:

Enclosed is Amendment No. 11 to your NRC Material License No. 48-17393-0 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.

Note that we have extended your expiration date by five years in accordance with the NRC granting of a one-time five-year extension. Refer to our letter to you dated May 7, 1996 for details.

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:

301714

- 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

T. Pandl

-3-

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.: 48-17393-01
Docket No.: 030-12682

Enclosure: Amendment No. 11

DOCUMENT NAME: M:\03012682.CL6

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

OFFICE	DNMS/RIII								
NAME	PVACHERLON:jaw								
DATE	09/19/96 <i>PMM</i>								

OFFICIAL RECORD COPY