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030-29642

December 4, 1996

KN 12/17/96

United States Nuclear Regulatory Commission
Region III, Licensing
801 Warrenville Road
Lyle, IL 60532

MPI Pharmacy Services
Medi-Physics, Inc.
36937-39 Schoolcraft
Livonia, MI 48150

tel (313) 464-0888
fax (313) 464-3868

Amersham HEALTHCARE

RE: Radioactive Materials License No. 21-24828-01 MD

Gentlemen:

This letter is to inform you that starting November 25, 1996; Michael Grawburg has joined our staff as an Authorized Nuclear Pharmacist. He has been an Authorized User on NRC License 24-04206-11MD, and holds a Michigan Pharmacist License number 5302023.

If there are any additional questions, or if I can be of further assistance please contact me at (313) 464-0888.

Thank you,

Earl F. Hussett R.Ph.
Pharmacy Manager

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NRC
(5 84)

U.S. NUCLEAR REGULATORY COMMISSION

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, 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.

Licensee	
1. Mallinckrodt, Inc. Diagnostic Imaging Services 2. 675 McDonnell Blvd. St. Louis, MO 63134	3. License number 24-04206-11MD 4. Expiration date May 31, 1993 5. Docket or Reference No. 030-30262

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. Molybdenum-99	A. Any Molybdenum-99/ technetium-99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issed to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. 200 curies
B. Any byproduct material listed in paragraph 31.11(a) of 10 CFR Part 31	B. Prepackaged in vitro diagnostic test kits	B. 20 millicuries total possession limit

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 24-04206-11MD

Docket or Reference number: 030-30262

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
C. Any byproduct material authorized under paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987)	C. Any sealed source listed in paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) that has been manufactured, labeled packaged and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	C. 5 millicuries total for all sources authorized under Subitem 6.C.
D. Xenon-133	D. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a "New Drug" (IND) that has been accepted by FDA	D. 2.0 curies
E. Iodine-131	E. Any form listed in Groups I through V of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200, 35.300 of 10 CFR Part 35 (effective April 1, 1987)	E. 500 millicuries

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NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

License number: 24-04206-11MD

Docket or Reference number: 030-30262

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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
F. Technetium-99m	F. Any form listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100 and 35.200 of 10 CFR Part 35 (effective April 1, 1987)	F. 200 curies
G. Any byproduct material, except iodine-131 and technetium-99m, listed in group I of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 of 10 CFR Part 35 (effective April 1, 1987)	G. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) of Section 35.100 of 10 CFR Part 35 (effective April 1, 1987)	G. 50 millicuries total possession limit
H. Any byproduct material, except iodine-131 and technetium-99m, listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.200 of 10 CFR Part 35 (effective April 1, 1987)	H. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.200 of 10 CFR Part 35 (effective April 1, 1987)	H. 50 millicuries total possession limit
I. Any byproduct material except iodine-131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.300 of 10 CFR Part 35 (effective April 1, 1987)	I. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.300 of 10 CFR Part 35 (effective April 1, 1987)	I. 100 millicuries total possession limit
J. Uranium (depleted in the isotope Uranium 235)	J. Metal encased in stainless steel	J. 200 kilograms

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 24-04206-11MD

Docket or Reference number: 030-30262

9. Authorized use

A. Production of technetium-99m pertechnetate. Redistribution of unused generators to authorized recipients in accordance with statements, representations and procedures contained in application dated October 3, 1987.

B. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in application dated October 3, 1987.

C. Instrument calibration.

D. Distribution to authorized recipients.

E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

F. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

G. through I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

J. Shielding for Mo99/Tc99m generators.

Pursuant to Sections 32.72, 32.73 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Section 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200 and 35.300 of 10 CFR Part 35 (effective April 1, 1987) or under equivalent licenses of Agreement States, for the Groups or Sections indicated below:

A. Unused molybdenum-99/technetium-99m generators may be redistributed to persons licensed pursuant to Group III or Section 10 CFR 35.200.

D. Gas or gas in saline may be distributed to person licensed pursuant to 10 CFR 35.200 effective April 1, 1987).

E. through I. Any form listed in each group, Groups I, II, IV and V of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or authorized by Sections 35.100, 35.200, 35.300 (effective April 1, 1987), may be distributed to persons licensed pursuant to that Group or Section.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2795 Universal Drive, Saginaw, Michigan.

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11. Licensed material shall be used by, or under the supervision of, individuals who are specifically named as users in Condition 11. of NRC Byproduct Material License No. 37-21345-01MD. The licensee shall verify that each individual selected as a user is specifically named in Condition 11. of NRC Byproduct Material License No. 37-21345-01MD and shall maintain, for inspection by the Commission, copies of License Number 37-21345-01MD.

12. At least one individual named in Condition 11. shall be physically present at the authorized place of use whenever licensed material is being used.

13. The Radiation Protection Officer for the activities authorized by this license is Michael Grawburg, R.Ph.

14. A. (1) The source(s) specified in Item(s) 7.C. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. 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.

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15. Sealed sources containing licensed material shall not be opened.

16. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.

17. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".

18. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or

(ii) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or regent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(i) In accordance with the directions provided by the sponsor of the IND, and

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall information in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

19. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

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21. Reagent kits may be redistributed to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR part 35, or under equivalent licenses of Agreement States, for Group III.

22. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or

(ii) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or regent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(i) In accordance with the directions provided by the sponsor of the IND, and

(ii) Only to physicians who Have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

23. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in application dated October 3, 1987.

24. 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. Application dated October 3, 1987; and

B. Letter dated February 29, 1988.

For the U.S. Nuclear Regulatory Commission

Original Signed
By William J. Adam, Ph.D.
Materials Licensing Section, Region III

Date: March 24, 1988

COPY

MALLINCKRODT MEDICAL INC.

AUTHORIZED USERS LIST

AS OF FEBRUARY 12, 1992

Steven Alvey
David Askew
William Barkowiak
Quent Besing
John Briggs
Gregory Brooks
Roger Brown
Daniel Casey
Robert P. Chandler
Harold Cleveland
Cheryl Cordum
Marcia Cohen
Michael Conway
Debbie Davis
Debra Dabrowiak
Rod Detrow
Lori Devos
Thomas Donia
Gary Edquist
Thomas Firmin
Genevieve Gamboa
Rudolph Gilliam
Bonnie Gindling
Margaret E. Glennon
Michael Grawburg
David Hartter
Elaine Haynes
Betsy Holak
Radwan Jaber
Homan Jarrar
Michael Klug
Tracy Knollhoff
Raymond Komosinski
Karen Kuchinskas
Lynn Kuchinskas
Tim Layne
David Lutes
John Manzi
John Martin
Thomas McKean
John Minella
Joseph M. Mladinov
Richard Nickel
Vincent Nizza
Michael Palmer
Amit Parikh
Rudy Parola
Monique Piontek
Dave Poydence
Mark Przekop
Charles Reid
Warren Salomon
Barbara Scavullo
Richard Schafer
David Schmitt
Steve Schultz
Pankaj Shah
Aly A. Sharaf
Amy Smith
James Sorensen
Gary Spence
Jeffrey K. Steffey
David Suski
Wayne Toal
Dzun Tonthat
Todd Warren
Randall Watt
Henry Wielgosz
Ken Williamson
Michael Whyte
Jeff Williams

**New addition: Gary Edquist

JOHN ENGLER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF COMMERCE

I 162491

BOARD OF PHARMACY

REGISTERED PHARMACIST
LICENSE

MICHAEL J GRAWBURG
600 REDMOND RD APT J-3
ROME GA 30165

PERMANENT I.D. NO.	EXPIRATION DATE	
5302023140	06/30/98	3540990

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN.

DATE: 12-13-96

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: BJ HOLT

LICENSEE: TROY

LICENSE NUMBER: 21-24828-01MD

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 X. (Information for license file) KN

☐ Licensee is adding authorized users.

A check is included _____. No check is included _____.

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