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030-29675

KW 7/2/97

MALLINCKRODT

Improving Healthcare and Chemistry

Mallinckrodt Inc.
2252 E. 14 Mile Road
Warren, MI 48092

Telephone (810) 268-5300
Facsimile (810) 268-7190

June 16, 1997

U. S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Material License 24-04206-10MD

To Whom It May Concern,

Pursuant to 10 CFR 32.72(b)(5), I hereby notify the Commission that the following authorized nuclear pharmacist is working at this facility:

James D. Kauchak, R.Ph.

Mr. Kauchak, R. Ph., was previously listed as an authorized user at Gamma Rx, 141 Glen Bridge Road, Arden, NC 28704, under license No. 011-0780-3 which expires October 31, 2001. Mr. Kauchak, R.Ph., is currently licensed as a registered Pharmacist in the State of Michigan.

Copies of required documentation are enclosed for review.

Please contact me at (810) 268-5300 if additional information is needed regarding this matter.

Sincerely

Paul G. Lukas, R.Ph.

Paul G. Lukas, R.Ph.,
Radiation Safety Officer

1/1

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Pm 6-19-97

RADIOACTIVE MATERIALS SECTION
DIVISION OF RADIATION PROTECTION
N.C. DEPARTMENT OF ENVIRONMENT, HEALTH, AND NATURAL RESOURCES
RADIOACTIVE MATERIALS LICENSE

Pursuant to North Carolina Regulations for Protection Against Radiation and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import radioactive materials listed below; and use such radioactive material for the purpose(s) and at the place(s) designated below. This License is subject to all applicable rules and regulations of the North Carolina Department of Environment, Health, and Natural Resources now or hereafter in effect and to any conditions specified below.

Licensee	
1. **Name:** Gamma Rx	3. **License No.:** 011-0780-3
2a. **Mailing Address:** P.O. Box 1082, Arden, NC 28704	4. **Expiration Date:** October 31, 2001
b. **Physical Address:** 141 Glen Bridge Road, Arden, NC 28704	**AMENDS IN ITS ENTIRETY** 5. **Amendment No. 16**

6. **Radioactive Material (element and mass no.)**	7. **Chemical and/or Physical Form**	8. **Maximum Amount of Radioactivity and/or Quantity of Radioactive Material which Licensee may Possess at any one time.**
A. Molybdenum 99	A. Any Molybdenum 99/Technetium 99m generator authorized pursuant to 15A NCAC 11 .0321 (C)(2)(B).	A. 50 curies
B. Technetium 99m	B. Any form listed in Groups I through IV as defined in 15A NCAC 11 .0321	B. 50 curies
C. Any radioactive material listed in Group I, except for Iodine 131 and Technetium 99m.	C. Any form listed in Group I as defined in 15A NCAC 11 .0321.	C. 1000 millicuries
D. Any radioactive material listed in Group II, except for Iodine 131 and Technetium 99m.	D. Any form listed in Group II as defined in 15A NCAC 11 .0321.	D. 1000 millicuries
E. Any radioactive material listed in Group III, except for Iodine 131 and Technetium 99m.	E. Any form listed in Group III as defined in 15A NCAC 11 .0321.	E. 500 millicuries
F. Any radioactive material listed in Group IV, except for Iodine 131 and Technetium 99m.	F. Any form listed in Group IV as defined in 15A NCAC 11 .0321.	F. 500 millicuries
G. Iodine 131	G. Any form listed in Groups I through IV as defined in 15A NCAC 11 .0321, and as listed in a valid license issued by this agency, the NRC, or an Agreement State.	G. 1500 millicuries

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Supplementary Sheet

Radioactive materials (continued):

6H. Xenon 133	7H.	Unit dose containers of 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 the 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 the FDA.	8H. 1.5 curies
I. Strontium 89	I.	Metastron	I. 25 millicuries
J. Cobalt 57	J.	Any sealed sources manufactured, labeled, packaged and distributed in accordance with a specific license pursuant to 32.74 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent state regulations.	J. No single source to exceed 15 millicuries each.
K. Barium 133	K.	Any sealed sources manufactured, labeled, packaged and distributed in accordance with a specific license pursuant to 32.74 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent state regulations.	K. No single source to exceed 1 millicurie each
L. Cesium 137	L.	Any sealed sources manufactured, labeled, packaged and distributed in accordance with a specific license pursuant to 32.74 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent state regulations	L. No single source to exceed 2 millicuries.
M. Uranium (Deplated in Uranium 235)	M.	Uranium metal encased in stainless steel	M. 200 kilograms

9. Authorized Use:

A. To be used for production of Technetium 99m pertechnetate.

B. - G. To be used for dispensation and/or distribution of prepared radiopharmaceuticals to authorized recipients.

H. & I. To be distributed to authorized recipients.

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9. Authorized Use (continued):

J. - L. To be used for instrument calibration, and distributed to authorized recipients as calibration/reference sources for dose calibrator and gamma camera quality assurance tests.

M. To be used as shielding around Molybdenum 99/Technetium 99m generators.

Conditions:

10. Radioactive material may only be used at the licensee's address stated in Item 2b. above.

11. The licensee shall comply with the provisions of 15A NCAC 11 .1600, "Standards for Protection Against Radiation," and 15A NCAC 11 .1000, "Notices, Instructions, Reports and Inspections." (The North Carolina Regulations for Protection Against Radiation are contained in 15A NCAC 11.)

12A. Radioactive material shall be used by, or under the supervision and in the physical presence of Bruce Lewandowski, David L. Gilliland, George Kennedy Cawthorne, Lynette S. Richardson, R.Ph., Ray Holland, R.Ph., Stephen Bridges, R.Ph., Ray Courtney, R.Ph., Karen Dorn, R.Ph., Kevin Reynolds, Joseph M. Isaac, II, R.Ph., Susan G. Whitley, R. Ph., Orphas Dale Rusk, M.S., R.Ph., Mark D. Eitzman, R.Ph., Phillip F. Heim, R.Ph., Stephanie Smith, R.Ph., Peter Sagonias, R.Ph., and James Kauchak, R.Ph.

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

C. The Radiation Safety Officer for the activities authorized by this license shall be George Kennedy Cawthorne.

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

A. 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

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

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

A. In accordance with the directions provided by the sponsor of the IND, and

B. 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.

15. 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.

16. 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.

17. The licensee is required to keep on file a copy of the Sealed Source and Device Registration for each model sealed source distributed.

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Conditions (continued):

18A. Each sealed source containing radioactive material, other than Hydrogen 3, with a half life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested.

B. 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.

C. The test shall be capable of detecting the presence of 0.005 microcurie or radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency.

D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Agency regulations. A report shall be filed within five (5) days of the test with the Radioactive Materials Section, Division of Radiation Protection, Department of Environment, Health, and Natural Resources, 3825 Barrett Drive, Raleigh, NC 27609-7221 describing the equipment involved, the test results, and the corrective action taken.

E. Tests for leakage and/or contamination shall be performed by persons specifically authorized by the Agency to perform such services.

19. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.

20. The licensee may transport licensed material or deliver licensed material to a carrier for transport, in accordance with the provisions of Section 71.5, Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material For Transport."

21. Any proposed changes in packaging, shielding, or labeling shall be submitted for review to the North Carolina Radioactive Materials Section, Division of Radiation Protection, Department of Environment, Health, and Natural Resources, 3825, Barrett Drive, Raleigh, NC 27609-7221.

22. The licensee shall ensure that airborne concentrations of radioactive aerosols and gases are maintained low enough so as not to exceed the limits specified in 15A NCAC 11 .1604 and .1611(a).

23. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before release to the appropriate non-radioactive waste stream (biological, chemical, etc.), 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 with a calibrated radiation survey instrument to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated prior to disposal in the non-radioactive waste stream.

24A. The licensee shall survey with a calibrated radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

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Supplementary Sheet

Conditions (continued):

24B. The licensee shall survey for removable contamination once a week all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.

C. The licensee shall maintain a record for each survey required in subitems A. & B. above and retain these records for a period of three (3) years.

25. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 15A NCAC 11 .0353 for establishing decommissioning financial assurance.

26. The licensee shall annually review its Radiation Protection Program for content and implementation [Ref. 15A NCAC 11 .1603(c)]. Documentation of the Radiation Protection program reviews shall be retained for inspection by the agency [Ref. 15A NCAC 11 .1636].

27. The licensee shall institute the provisions of 15A NCAC 11 .1610 when an occupationally exposed woman voluntarily informs her supervisor, in writing, of her pregnancy and the estimated date of conception.

28. The licensee shall ensure that no individual "member of the public" [Reference: 15A NCAC 11 .0104(64)] receives a radiation dose in excess of the limits specified in 15A NCAC 11 .1611(a) while conducting licensed operations.

29A. The licensee shall establish written procedures for performing the following tests on dose calibrator(s) used to determine the quantity and quality of radiopharmaceuticals:

1. Geometric variation to be performed upon installation and following relocation and repair.

2. Accuracy to be performed upon installation and at intervals not to exceed one (1) year.

3. Linearity to be performed upon installation and at intervals not to exceed three (3) months.

a. The dose calibrator shall be tested for linearity over the full range of normal use. (i.e. eluant range down to the lowest administered patient dose.)

b. Licensee may use a Calicheck or Lineator device for performing linearity tests of his dose calibrator provided that the current manufacturers instructions are followed.

4. Constancy to be performed daily.

B. Records of the results of the tests outlined in Condition No. 29A above shall be maintained for inspection by the agency.

C. Records described in Condition No. 29B above shall be maintained for two (2) years following the performance of the tests.

30. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7 and 8 of this license in accordance with statements, representations and procedures contained in:

A. Application with attachments dated September 27, 1996, signed by G.K. Cawthorne, Manager; letter with attachments dated March 24, 1997, signed by G.K. Cawthorne, Manager; and, letter dated April 2, 1997, signed by David Gilliland, Ph.D., President.

Date of Issuance: April 21, 1997

For: R.M. Fry
Acting Director
Division of Radiation Protection

(Rev. 04/97)

DEPARTMENT OF CONSUMER & INDUSTRY SERVICES
OFFICE OF HEALTH SERVICES - COMPUTER/EXAMINATION SECTION
PO BOX 30670, LANSING, MI 48909
sb 517-335-0930

PHARMACY JURISPRUDENCE EXAMINATION RESULTS
JUN 10, 1997

JAMES DAVID KAUCHAK
14865 ATWATER
STERLING HEIGHTS, MI 48313

SSN# 305-66-2803
CANDIDATE # 01158

The Michigan Board of Pharmacy is pleased to inform you that you have achieved a passing score on the Jurisprudence Examination held on 6/05/97.

If your application is complete, a computer generated license will be mailed to you in approximately three to four weeks to the address currently on file. Under the Michigan Public Health Code, you must report any changes in the name and/or mailing address in writing to this office within thirty (30) days from the date the change occurred.

Your license will expire on the first renewal date following the original date of registration. You must comply with Continuing Education requirements, refer to General Rules #338.3041. A renewal card will be mailed to you at the address on file approximately ninety (90) days prior to the expiration date of the registration.

If you were advised that specific documents were necessary to complete your application file, then your license will be issued upon receipt of those documents.

JOHN ENGLER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF CONSUMER & INDUSTRY SERVICES

I 537905

BOARD OF PHARMACY

REGISTERED PHARMACIST
LICENSE

JAMES DAVID KAUCHAK
14865 ATWATER
STERLING HEIGHTS MI 48313

PERMANENT I.D. NO.	EXPIRATION DATE	
5302031316	06/30/1998	3902143

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

DATE: 7/1/97

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: ~~BJ HOLT~~ Null

LICENSEE: Mallinckrodt

LICENSE NUMBER: 24-04206-02MD

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)

☒ 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