030-13045

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

JUL 14 1995

Warren K. Fadling
Director, DIS/NMA
Mallinckrodt Medical, Inc.
Nuclear Medicine Division
P.O. Box 5840
675 McDonnell Boulevard
St. Louis, MO 63134

Dear Mr. Fadling:

In accordance with 10 CFR 32.72(b)(2), your letter received July 6, 1995 is accepted as notification that you have permitted the individual named in your letter referenced above to work as an authorized nuclear pharmacist. No further correspondence on this matter is required.

If you have any questions regarding fees please contact the NRC License Fee and Debt Collection Branch directly at (301) 415-6055 or 415-6096.

Your cooperation is appreciated.

Sincerely,

Francis M. Costello

Francis M. Costello, Chief
Medical Licensing Section
Division of Radiation Safety
and Safeguards

License No. 20-15215-02MD
Docket No. 030-13045
Control No. 122021

Enclosure:
Federal Register, Vol. 59, No. 231

cc:
License Fee and Debt Collection Branch



MUD

JUL 14 1995

Warren K. Fadling
Director, DIS/NMA
Mallinckrodt Medical, Inc.
Nuclear Medicine Division
P.O. Box 5840
675 McDonnell Boulevard
St. Louis, MO 63134

Dear Mr. Fadling:

In accordance with 10 CFR 32.72(b)(2), your letter received July 6, 1995 is accepted as notification that you have permitted the individual named in your letter referenced above to work as an authorized nuclear pharmacist. No further correspondence on this matter is required.

If you have any questions regarding fees please contact the NRC License Fee and Debt Collection Branch directly at (301) 415-6055 or 415-6096.

Your cooperation is appreciated.

Sincerely,

Original Signed By:

Francis M. Costello, Chief
Medical Licensing Section
Division of Radiation Safety
and Safeguards

License No. 20-15215-02MD
Docket No. 030-13045
Control No. 122021

Enclosure:
Federal Register, Vol. 59, No. 231

cc:
License Fee and Debt Collection Branch

DOCUMENT NAME: R:\WPS\MLTR\L2015215.02D
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

| OFFICE | DRSS/RI | N | DRSS/RI | N | | | | |
|---|---|---|---|---|---|---|---|---|
| NAME | JStambaugh:cmm | | FCostello | | | | | |
| DATE | 07/14/95 | | 07/ /95 | | 07/ /95 | | 07/ /95 | |

OFFICIAL RECORD COPY ML 10

MALLINCKRODT
*Nuclear Medicine*

030-13045

Lic No. 20-15215-02MD

Mallinckrodt Medical, Inc.
Diagnostic Imaging Services
P.O. Box 1349
Attleboro Falls, MA 02763
Telephone (508) 695-4600

Pamela J. Henderson
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards

Dear Miss Henderson:

This notice is intended to inform the NRC, pursuant to 10 CFR 35.14, that James Flynn is named as an authorized nuclear pharmacist to materials license 24-04206-19MD. Enclosed you will find a copy of the material license and a copy of Mr. Flynn's Pharmacists License.

If you have any questions feel free to contact me at the above number

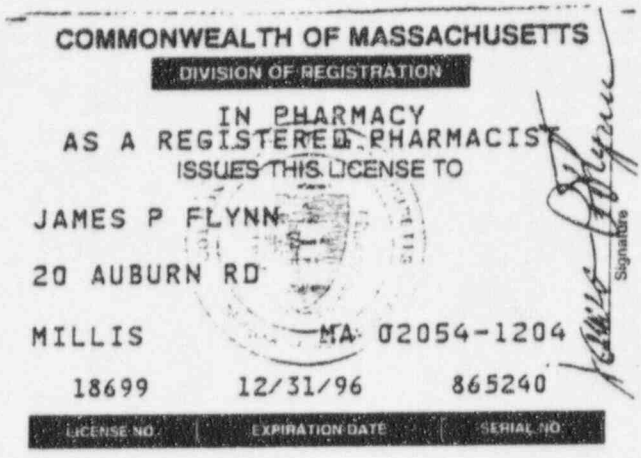
Sincerely,

Richard A. Hughes
Radiation Safety Officer

122021

OFFICIAL RECORD COPY ML 10

JUL - 6 1995



COMMONWEALTH OF MASSACHUSETTS

DIVISION OF REGISTRATION

IN PHARMACY
AS A REGISTERED PHARMACIST
ISSUES THIS LICENSE TO

JAMES P FLYNN

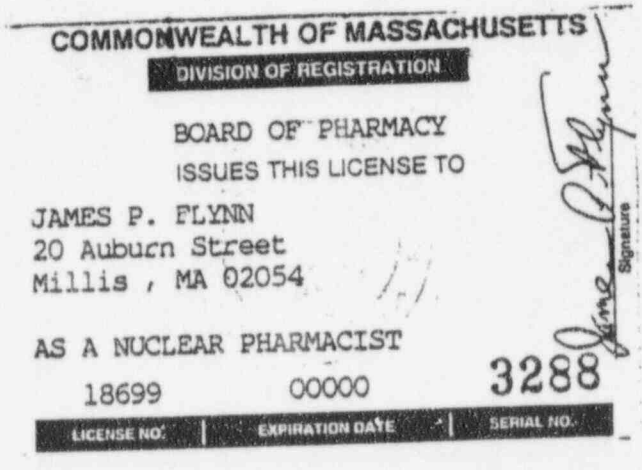
20 AUBURN RD

MILLIS MA 02054-1204

18699 12/31/96 865240

LICENSE NO. | EXPIRATION DATE | SERIAL NO.

Signature



COMMONWEALTH OF MASSACHUSETTS

DIVISION OF REGISTRATION

BOARD OF PHARMACY
ISSUES THIS LICENSE TO

JAMES P. FLYNN
20 Auburn Street
Millis , MA 02054

AS A NUCLEAR PHARMACIST

18699 00000 3288

LICENSE NO. | EXPIRATION DATE | SERIAL NO.

Signature

# MATERIALS LICENSE

Amendment No. 01

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.

| Licensee | |
|---|---|
| 1. Mallinckrodt Medical, Incorporated<br>Nuclear Medicine Division<br><br>2. P.O. Box 5840<br>675 McDonnell Boulevard<br>St. Louis, Missouri 63134 | In accordance with the application dated May 25, 1994,<br>3. License Number 24-04206-19MD is amended in its entirety to read as follows: |
| | 4. Expiration Date October 31, 1995 |
| | 5. Docket or Reference No. 030-33578/37-23326-01MD |

| 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 10 CFR 32.73 or equivalent regulations of any Agreement State | 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 |
| C. Any byproduct material identified in 10 CFR 35.57(a) | C. Any sealed source identified in 10 CFR 35.57(a) that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent regulations of any Agreement State | C. 30 millicuries |

**MATERIALS LICENSE**
SUPPLEMENTARY SHEET

License number: 24-04206-19MD
Docket or Reference number: 030-33578/37-23326-01MD
Amendment No. 01

| | | |
|---|---|---|
| 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. 1 curie |
| E. Iodine-131 | E. Any form identified in 10 CFR 35.100, 35.200 or 35.300 | E. 5 curies |
| F. Technetium 99m | F. Any form identified in 10 CFR 35.100 and 35.200 | F. 200 curies |
| G. Any byproduct material, except iodine 131 and technetium 99m, identified in 10 CFR 35.100 | G. Any form identified in 10 CFR 35.100 | G. 50 millicuries |
| H. Any byproduct material, except iodine 131 and technetium 99m, identified in 10 CFR 35.200 | H. Any form identified in 10 CFR 35.200 | H. 500 millicuries |
| I. Any byproduct material, except iodine 131, identified in 10 CFR 35.300 | I. Any form identified in 10 CFR 35.300 | I. 100 millicuries |
| J. Any byproduct material | J. Analytical samples | J. See item 9.J. |
| K. Technetium 99m | K. Any | K. 500 millicuries |
| L. Cesium 137 | L. Sealed sources (Tech/Ops Model 77302) | L. Not to exceed 165 millicuries per source and 330 millicuries total |
| M. Uranium depleted in isotope U-235 | M. Metal | M. 999 kilograms |

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 the application February 14, 1989.

B. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in the letter dated November 16, 1984.

C. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR 32.74, the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 35.14 and 35.100 of 10 CFR Part 35 (superseded) or 10 CFR 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) or under equivalent licenses of any Agreement State.

D. Distribution to authorized recipients.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 24-04206-19MD

Docket or Reference number: 030-33578/37-23326-01MD

Amendment No. 01

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. For possession incident to the performance of leak testing of customers' sealed sources.
K. For instrument calibration and testing for leakage and/or contamination.
L. For use in Tech/Ops survey meter calibration device for calibrating survey meters.
M. Shielding for Mo99/Tc99m generators.

Pursuant to 10 CFR 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 10 CFR 35.14 and 35.100 of 10 CFR Part 35 (superseded) or 10 CFR 35.100, 35.200, 35.300, 35.400 and 35.500 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 of 10 CFR 35.200.
D. Gas or gas in saline may be distributed to persons 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, 10 CFR 35.100 of 10 CFR Part 35 (superseded) or authorized by 10 CFR 35.100, 35.200, and 35.300 (effective April 1, 1987), may be distributed to persons licensed pursuant to 10 CFR Part 35 or under equivalent licenses of any Agreement State.

CONDITIONS

10. A. Licensed material may be used at the licensee's facilities located at 2722 Penn Avenue, Pittsburgh, Pennsylvania.

B. Licensed material in Items 7.I., 7.J. and 7.K. may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

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

A. In accordance with 10 CFR 32.72(b)(2)(i) or (4), pharmacists working as authorized nuclear pharmacists.

B. Authorized Nuclear Pharmacist Michael Hess and James Flynn.

C. At least one individual authorized by Paragraph A or B of this Condition shall be physically present at the authorized place of use whenever licensed material is being used.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 24-04206-19MD
Docket or Reference number: 030-33578/37-23326-01MD
Amendment No. 01

(11. continued)

D. Licensed material used for calibration of survey meters, calibration of dose calibrators, or for analysis of tests for leakage and/or contamination performed will be used by, or under the supervision of individuals who are specifically named as users in Condition 12 of NRC License Number 34-16272-01.

E. The Radiation Safety Officer for this license is Gary L. Spence, R.Ph.

12. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 24-04206-19MD

Docket or Reference number: 030-33578/37-23326-01MD

Amendment No. 01

(12 continued)

F. 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, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

14. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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

(i) repackaged from prepared radiopharmaceuticals that are the subject of U.S. Food and Drug Administration (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 reagent 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.

17. 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 24-04206-19MD

Docket or Reference number: 030-33578/37-23326-01MD

Amendment No. 01

18. 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. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

    B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.

20. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the statements, representations and procedures in the application dated December 5, 1983 and the letter dated March 19, 1984.

21. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

22. The licensee may use the Lineator device for doing linearity tests of its dose calibrator provided it follows the procedures in the Atomic Products Corporation Lineator Instruction Manual dated June 20, 1983.

23. 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 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

24. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 24-04206-19MD

Docket or Reference number: 030-33578/37-23326-01MD

Amendment No. 01

25. 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 February 14, 1989
B. Letter dated July 10, 1990
C. Letter dated November 9, 1990
D. Letter dated April 8, 1991
E. Letter dated February 3, 1992
F. Application dated May 25, 1994
G. Letter dated April 18, 1995
H. Letter dated May 31, 1995



For the U.S. Nuclear Regulatory Commission

Original Signed By:
Pamela J. Henderson

By _____

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

Date JUN 12 1995

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)

INFORMATION FROM LTS

PROGRAM CODE: 02511
STATUS CODE: 2
FEE CATEGORY: 3D
EXP. DATE: 19930331
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MALLINCKRODT MEDICAL, INC.
RECEIVED DATE: 950706
DOCKET NO: 3013045
CONTROL NO.: 122021
LICENSE NO.: 20-15215-02MD
ACTION TYPE: NOTIFICATIONS

2. FEE ATTACHED
AMOUNT: ---/---
CHECK NO.: ---/---

3. COMMENTS

SIGNED M. A. Perkins
DATE 7/12/95

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: _____

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE _____

3. OTHER _____
_____

SIGNED _____
DATE _____