

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20552

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19408

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIAL RADIATION PROTECTION SECTION
101 MARSHALL STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
798 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
811 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 710
WALNUT CREEK, CA 94598

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER 37-21345-01 MD
- C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Mallinckrodt, Inc.
Diagnostic Imaging Services
#19 Independence Court
Folcroft, PA. 19032

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:

SAME AS #2

8912060397 880730
REG 1 LIC 30
37-21345-01MD PDR

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Steven A. Spinosi

TELEPHONE NUMBER
(314) 895-2061

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3C AMOUNT ENCLOSED \$ 230.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

[Signature]

Carl E. Wood, Jr.

Director, Radiopharmacy
Operations

5-19-88

14. ANNUAL RECEIPTS

< \$250K	\$1M - 3.5M
\$250K - 500K	\$3.5M - 7M
\$500K - 750K	\$7M - 10M
\$750K - 1M	> \$10M

15. VOLUNTARY ECONOMIC DATA

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial - proprietary - information furnished to the agency in confidence)

YES

NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE

Mallinckrodt, Inc.

675 McDONNELL BLVD

P.O. BOX 5840

ST. LOUIS, MO 63133

(3

2000

May 19, 1988

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA. 19406

Re: NRC Lic. # 37-21345-01MD

Sirs:

The purpose of this request is to amend the NRC license of Mallinckrodt, Inc.: 19 Independence Court, Folcroft, PA, 19032 (License # 37-21345-01MD) for the following:

1. To Delete Todd Schmidt from the list of authorized users.
2. To change the listed name of Rebecca S. Kubic to Rebecca S. Brown. (Change in marital status of this user.)
3. To add the following individuals as authorized users:

Larry Horvath (training and experience attached) (attached item # 1).

Lori Devos (presently named on Texas Rad. Mat. Lic. No. L03008.) (attached item # 2).

Wayne Nye (presently named on Texas Rad. Mat. Lic. No. L03008.) (attached item # 3).

David Lutes (presently named on Texas Rad. Mat. Lic No. L03580.) (attached item # 4).

Lisa Lay (presently named on Georgia Rad. Mat. Lic. No. 877-1MD.) (attached item # 5).

Rajiv Rao (presently named on Maryland Rad. Mat. Lic. No MD-33-088-01.) (attached item # 6).

Barry Brown (presently named on California Rad. Mat. Lic. No. 3219-70.) (attached item # 7).

Dzung Tonthat (presently named on California Rad. Mat. Lic. No. 3219-70.) (attached item # 8).

Doug Petry (training and experience attached). (attached item # 9.)

Mallinckrodt

DIAGNOSTIC PRODUCTS DIVISION

*Application
6-21-88 5169*

*Reviewed
by Dr
Joseph Picone
337-5169
Control #
109006*

Rod Detrow (presently named on NRC License # 34-16654-01-MD (and California Rad. Mat. Lic. No. 2657-90.) (attached item # 10)

David McCord (presently named on NRC license # 34-16405-01-MD.)

4. To request authorization for the following materials:

<u>Element</u>	<u>Chemical/Physical Form</u>	<u>Activity</u>	<u>Use</u>
Uranium(depleted in the isotope U-235)	Metal enclosed in stainless steel	200 Kg.	Shielding for Mo-99
Any byproduct material listed in 31.11(a) of 10 CFR 31	Prepacked in-vitro diagnostic kits	20 mCi	Dispensing and or distribution of prepackaged in-vitro diagnostic test kits

5. To request authorization for this licensee to name authorized users via internal committee. (see item #11)

ITEM # 11

AUTHORIZED USER, INTERNAL COMMITTEE NAMED

The purpose of this amendment request is to permit the designation of authorized users to this NRC radioactive materials license via an internal committee. This procedure would facilitate the addition of qualified users to the Mallinckrodt radiopharmacy license, and would be in lieu of the present procedure of submission of training and experience to the Commission for review and approval.

Presently Mallinckrodt, Inc. maintains a "master-user" list of authorized users on the Folcroft, PA NRC license # 37-21345-01MD. This license is amended for each new hiree, requesting their addition to the list of authorized users.

A request is made to permit the naming of authorized users to this license by an internal committee who will maintain responsibility for review and approval of prospective user training and experience. This review process will be carried out by a committee made up of the following individuals:

- * General Manager: Radiopharmaceutical Business Unit
- * Director: DIS Radiopharmacy Operations
(presently named on NRC license # 37-21345-01MD)
- * Regional Manager: DIS Radiopharmacy
(presently named on NRC license # 37-21345-01MD)

The training and experience of each prospective user will be submitted to this committee for review, utilizing forms similar to that shown in Figures A-1 and A-2 of regulatory "Guide for Preparation of Applications for Nuclear Pharmacy Licenses". Should the prospective user have been named on a previous nuclear pharmacy license issued by the NRC or an Agreement State, a copy of the license that lists this user will be submitted.

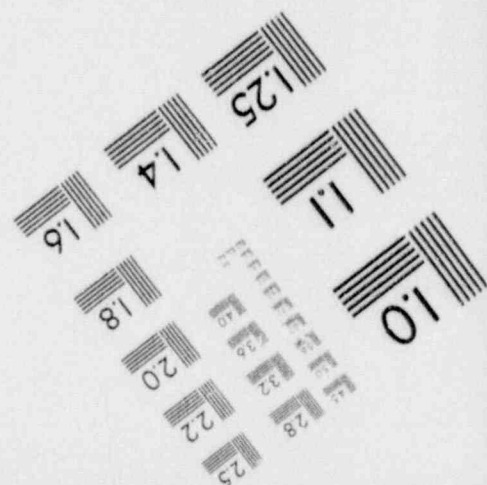
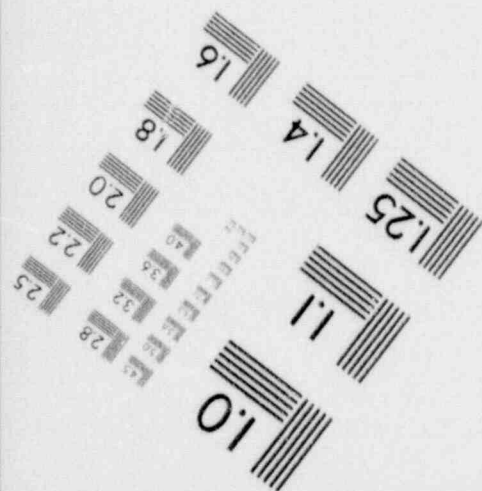
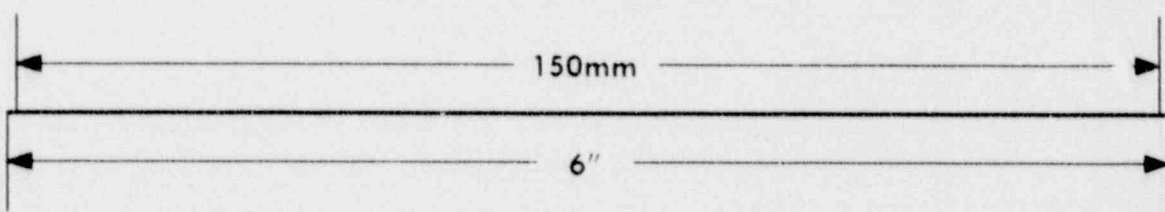
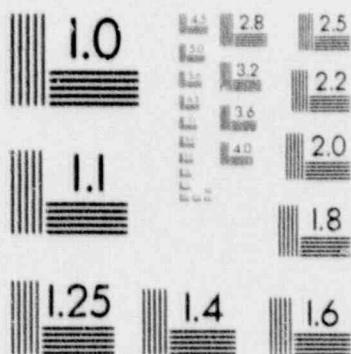
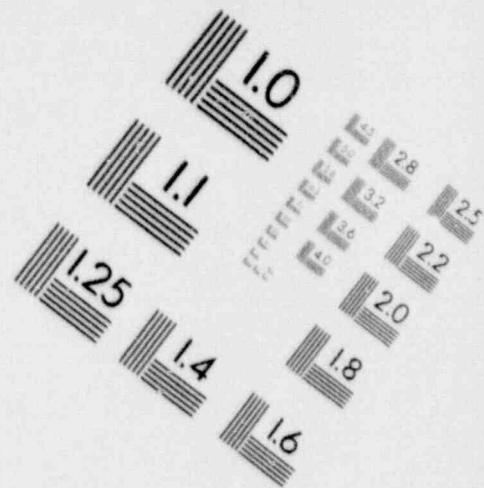
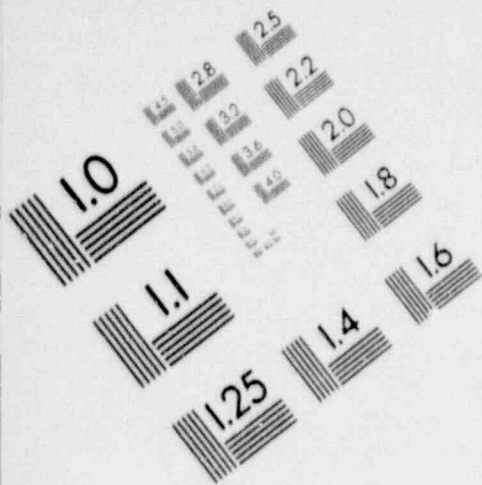
At least two members of this committee will review the submitted materials for compliance with training and experience recommendations as outlined in Appendix A of the regulatory "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" (dated August , 1985) (attachment A).

The committee will assure that the prospective users possess training and experience that minimally meet the recommendations as outlined in the above paragraphs. Should the candidate's training and experience meet fully the criteria, or the candidate has been named on a previous NRC or Agreement State license, he/she will be added to the list of authorized users that will be maintained on file. Copies of the submitted training and experience forms will be maintained on file for regulatory reference. In the case of a user that has been previously named on an NRC or Agreement State radioactive materials license, a copy of this license will be maintained on file for regulatory reference.

Item # 11
Page 2 of 2
Prepared 5/19/88

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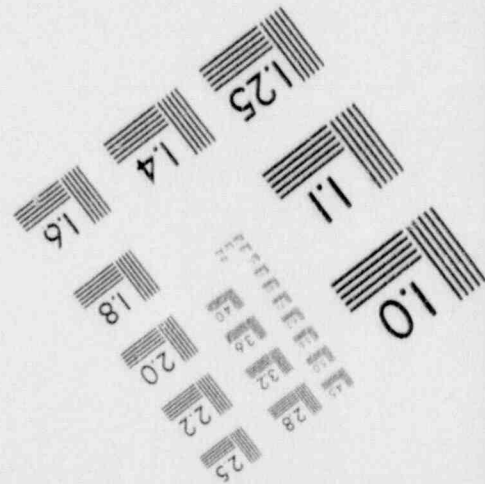
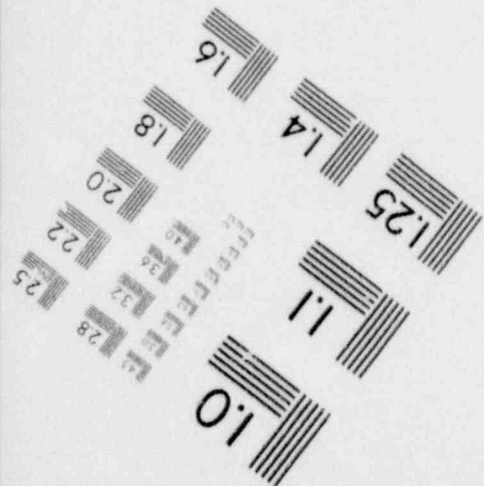
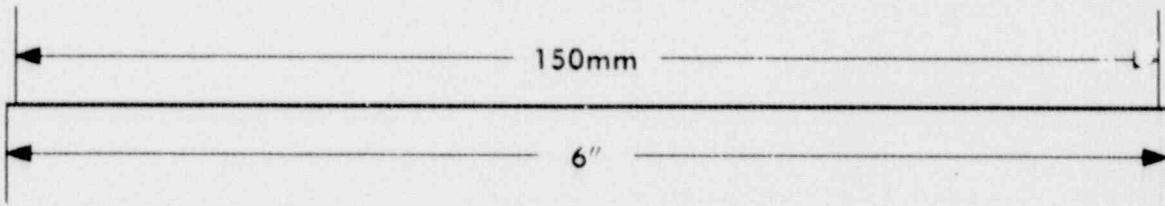
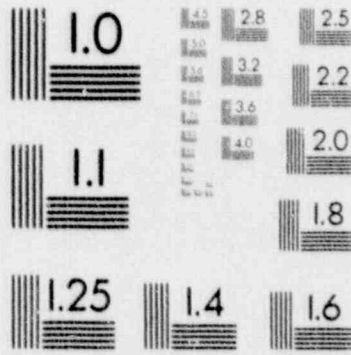
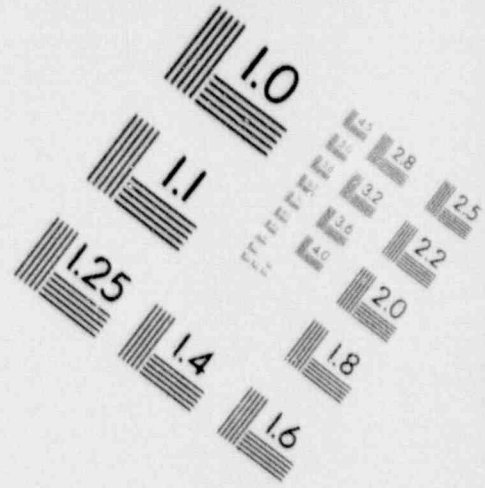
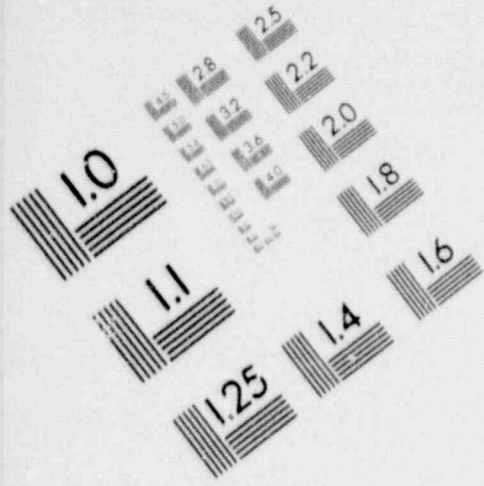
IMAGE EVALUATION TEST TARGET (MT-3)



PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

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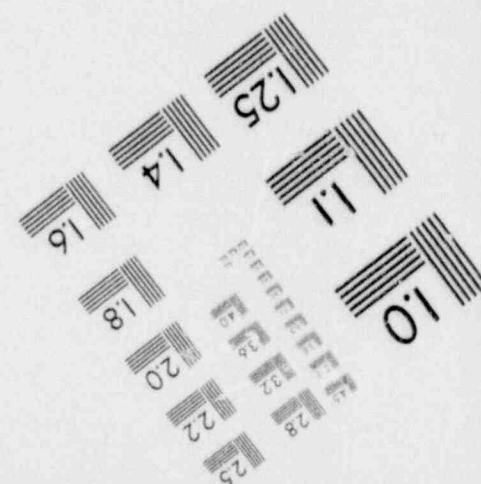
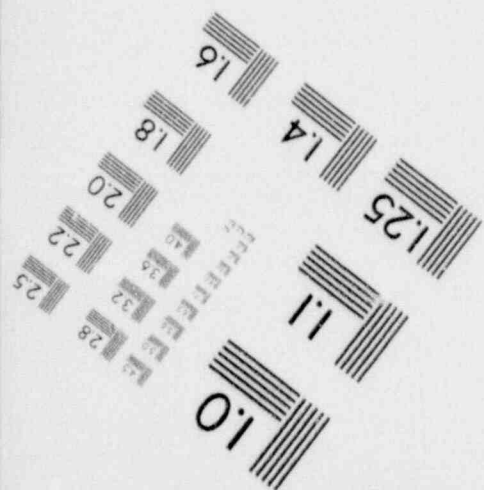
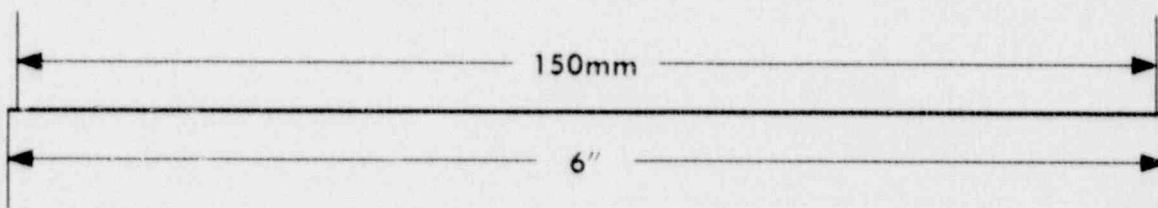
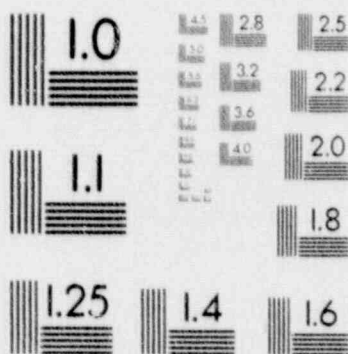
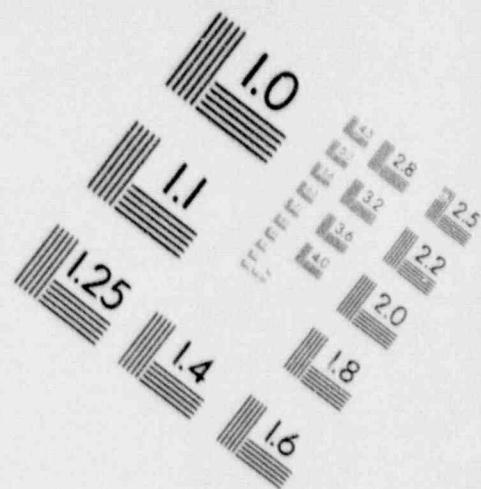
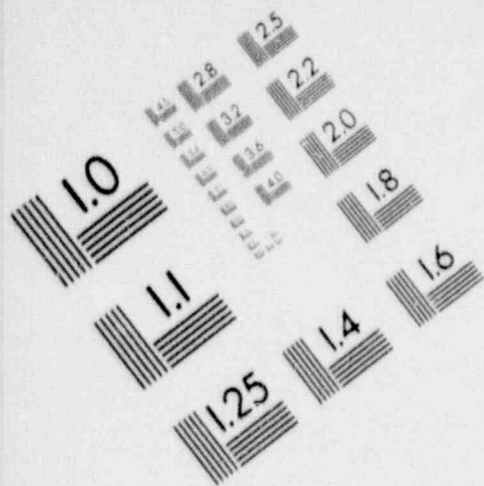
IMAGE EVALUATION TEST TARGET (MT-3)



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WEBSTER, NEW YORK 14580
(716) 265-1600

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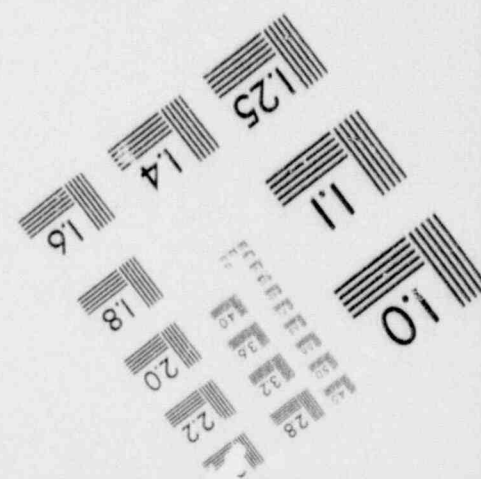
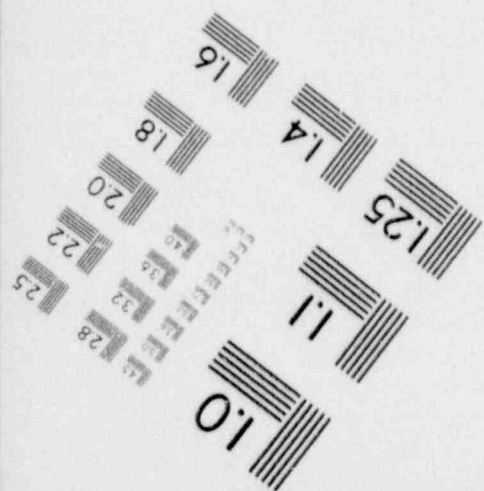
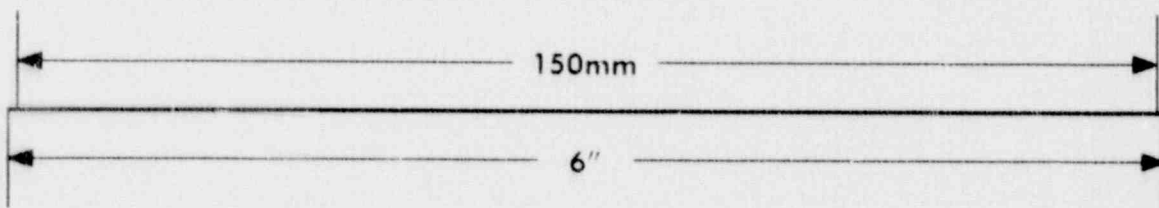
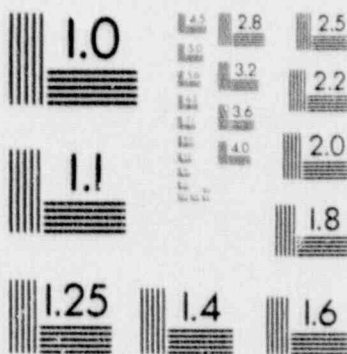
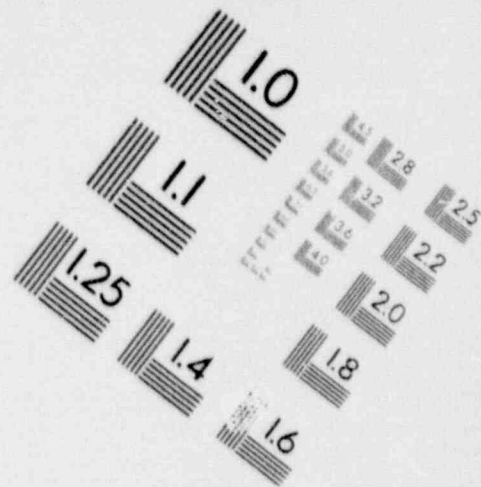
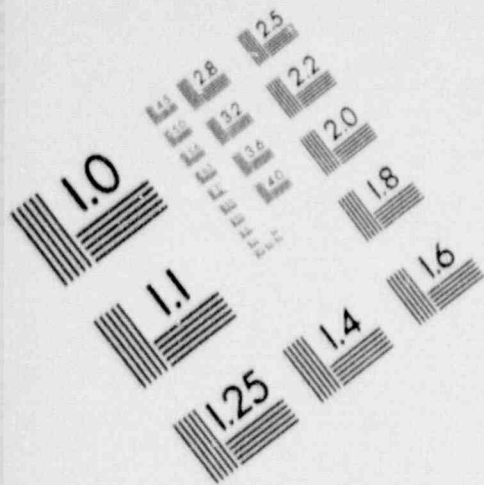
IMAGE EVALUATION TEST TARGET (MT-3)



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IMAGE EVALUATION TEST TARGET (MT-3)



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WEBSTER, NEW YORK 14580
(716) 265-1600

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Larry Horvath

Date: April 26, 1988

Field of Training	Location & Date(s) of Training: Purdue University School of Pharmacy	Type and Length of Training Lecture/ Laboratory Courses (Hours)
A. Radiation Physics & Instrumentation	August 1981 through May 1987	105
B. Radiation Protection	" "	45
C. Mathematics Pertaining to the use & Measurement of Radioactivity	" "	30
D. Radiation Biology	" "	30
E. Radiopharmaceutical Chemistry	" "	50
TOTALS:		<u>260 hrs.</u>

Page 2. DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

Name: Larry Horvath

EXPERIENCE WITH RADIOACTIVE MATERIAL. (Actual Use of Radioisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours)	TYPES OF USE 1, 2, 3, 4, 5, 6 (see key below)
Tc-99m	20Ci	Mallinckrodt, Inc. Diagnostic Imaging Services Los Angeles, CA 7/9/87 to 4/22/88	600 hours	1 through 6
I-123	1Ci			
Ga-67	1Ci			
Tl-201	1Ci			
Xe-133	2Ci			
Se-75	250mCi			
Co-57	10mCi			
Cs-137	20mCi			
Ba-133	277uCi			
Co-60	1mCi			
In-111	10mCi			
I-131	1Ci			
Cr-51	10mCi			
I-125	5mCi			
Fe-59	5mCi			
P-32	35mCi			
			Total	600 hrs.

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrators, scintillation detectors, and survey meters.
3. Calculation dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the eluate for Molybdenum-99 contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

08795

Supplementary Sheet

LICENSE NUMBER	AMENDMENT NUMBER
L03008	15

CONDITIONS CONTINUED:

12. A. Radioactive material shall be used by, or under the supervision of, the following:

- | | |
|--------------------------|----------------------------|
| 1. Lori DeVos, R.Ph. | 5. Todd Schmidt, R. Ph. |
| 2. Frank M. Gwynn, R.Ph. | 6. Carl E. Wood, R.Ph. |
| 3. Richard A. Nickel | 7. Alice T. Worthen, R.Ph. |
| 4. Barbara D. Scavullo | |

Radiopharmaceuticals are to be dispensed only by a Texas licensed pharmacist.

B. Radioactive material for commercial and in-house leak test analyses may be used by, or under the supervision of, the following:

- | | |
|----------------------------|-----------------------|
| 1. Paul J. Early | 7. Steven Spinosi |
| 2. William H. Miller | 8. Raymond Kaczur |
| 3. Frank Eloe | 9. Samuel A. Pontillo |
| 4. Charles Anthony Giomuso | 10. Peggy Reilly |
| 5. W. Christopher Wagner | 11. Ronald J. Scala |
| 6. David Close | 12. Mark Beanblossom |

C. Radioactive material for commercial and in-house radiation survey instrument calibration may only be used by the individuals named in 12.B above.

13. Sealed sources containing radioactive material shall not be opened.

14. A. Sealed sources of radioactive material, Nickel 63 foil, and/or plated alpha-emitting sources shall be tested for leakage and/or contamination in accordance with the provisions of Texas Regulations for Control of Radiation 19.7.

B. The individuals listed in Condition 12.B above are authorized to perform leak test analyses in-house or as a commercial service using the commercial leak test kit approved for this license. The licensee shall maintain, for inspection by the Agency, records for verification of reported leak test results for three (3) years from the date of testing.

CONDITIONS CONTINUED ON PAGE 4



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

04110

Pursuant to the Texas Radiation Control Act and Texas Department of Health regulations on radiation, 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 radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Texas Department of Health now or hereafter in effect and to any conditions specified below.

LICENSEE

1. Name **Mallinckrodt, Inc.**
ATTN: Lloyd W. Nye, R.Ph.
2. Address
8078 El Rio
Houston, Texas 77054

This license issued pursuant to and in accordance with

APPLICATION LETTER

Dated: **March 1, 1988**

Signed By: **A. T. Worthen**

3. License Number **L03008** Amendment Number **16**

PREVIOUS AMENDMENTS ARE VOID

4. Expiration Date

May 31, 1991

8. Authorized Use

A. For receipt, storage, and preparation in accordance with applicable USFDA approved protocols, and dispensing upon prescription to authorized recipients.
B. Production of Tc-99m. Distribution of generators or eluate to authorized recipients.

RADIOACTIVE MATERIAL AUTHORIZED

5. Radioisotope	6. Form of Material	7. Maximum Activity*
A. Any radioactive material with Atomic Number less than 84	A. Any radio-pharmaceutical approved by the U.S. Food and Drug Administration (USFDA)	A. No single radionuclide to exceed 700 mCi except for Tc-99m which is not to exceed 45 Ci
B. Mo-99	B. USFDA approved Tc-99m generators	B. 45 Ci

CONTINUED ON PAGE 2, IF CHECKED.

CONDITIONS

9. Unless otherwise specified, radioactive material shall be used only at:

Sub-site Number	Location
000	Houston - 8078 El Rio

0. The licensee shall comply with the provisions of Parts 11, 12, 13, 21, 22, and 41 of the Texas Regulations for Control of Radiation (TRCR).

* Ci-Curies mCi-Millicuries μ Ci-Microcuries CONDITIONS CONTINUED ON PAGE 2

IRS:mr

FOR THE TEXAS DEPARTMENT OF HEALTH

Date **March 21, 1988**

Joseph C. Klein
Administrator, Licensing Division
Item #3
Page 1 of 6
Prepared: 5-19-88



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

10812

LICENSE NUMBER	AMENDMENT NUMBER
L03008	16

CONDITIONS CONTINUED:

5. Radio-isotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
C. Co-57 Cs-137, Ba-133, I-129	C. Sealed reference sources	C. No single source to exceed 10 mCi. Total: 15 mCi.	C. Reference sources for use, receipt, storage and distribution to authorized recipients.
D. Uranium	D. Depleted metal	D. 120 kilograms	D. Auxiliary shielding for Technetium generators.
E. Xe-127/ Xe-133	E. Any radio-pharmaceutical	E. 5 Ci	E. For receipt, storage, and preparation in accordance with applicable USFDA approved protocols, and dispensing upon prescription to authorized recipients.
F. Cs-137	F. Sealed source (Tech/Ops 77302)	F. 165 mCi	F. For use in a Tech/Ops 773 instrument calibrator for calibration of radiation survey meters.
G. Any radioactive material	G. Any solid	G. No single nuclide to exceed 6 mCi	G. As authorized by TRCR 41.26(b)(4), for transport to authorized licensees for calibration of instruments under the client's license authorization, and as leak test samples, to be returned for evaluation to the licensee's facility.

CONDITIONS CONTINUED:

- The individual designated to perform the functions of Radiation Safety Officer for activities covered by this license is Lloyd W. Nye, R.Ph. Designated as Alternate Radiation Safety Officer is Alice P. Worthen, R.Ph.

CONDITIONS CONTINUED ON PAGE 3

JRS:mr

March 21, 1988

Date _____

FOR THE TEXAS DEPARTMENT OF HEALTH

Item #3

Page 2 of 6

Prepared: 5-19-8

Joseph C. Kline



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

10813

LICENSE NUMBER	AMENDMENT NUMBER
L03008	16

CONDITIONS CONTINUED:

12. A. Radioactive material shall be used by, or under the supervision of, the following:

Lori DeVos, R.Ph.
Frank M. Gwynn, R.Ph.
Lloyd W. Nye, R.Ph.
Richard A. Nickel

Barbara D. Scavullo
Carl E. Wood, R.Ph.
Alice T. Worthen, R.Ph.

Radiopharmaceuticals are to be dispensed only by a Texas licensed pharmacist.

B. Radioactive material for commercial and in-house leak test analyses may be used by, or under the supervision of, the following:

Mark Beanblossom
Frank Bloe
David Close
Paul J. Early
Charles Anthony Giomuso
Raymond Kaczur

William H. Miller
Samuel A. Pontillo
Peggy Reilly
Steven Spinosi
Ronald J. Scala
W. Christopher Wagner

C. Radioactive material for commercial and in-house radiation survey instrument calibration may only be used by the individuals named in 12.B above.

3. Sealed sources containing radioactive material shall not be opened.

4. A. Sealed sources of radioactive material, Nickel 63 foil, and/or plated alpha-emitting sources shall be tested for leakage and/or contamination in accordance with the provisions of Texas Regulations for Control of Radiation 11.7.

B. The individuals listed in Condition 12.B above are authorized to perform leak test analyses in-house or as a commercial service using the commercial leak test kit approved for this license. The licensee shall maintain, for inspection by the Agency, records for verification of reported leak test results for three (3) years from the date of testing.

CONDITIONS CONTINUED ON PAGE 4

JRS:mr

FOR THE TEXAS DEPARTMENT OF HEALTH

Item #3
Page 3 of 6
Prepared: 5-19-88

March 21, 1988

Joseph C. Kleiniger
Administrator, Licensing Branch

Date _____



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

10814

LICENSE NUMBER	AMENDMENT NUMBER
L03008	16

CONDITIONS CONTINUED:

15. Radiation survey instruments used in the licensee's own radiation safety program shall be calibrated at intervals not to exceed twelve (12) months. Instruments routinely transported shall be so calibrated at intervals not to exceed six (6) months.
16. Radiopharmaceuticals that are procured shall be from another licensed nuclear pharmacy or from a supplier who distributes the radiopharmaceuticals under the New Drug Applications (NDA's) or Investigative New Drug Application (IND's) approved by the U.S. Food and Drug Administration.
17. The licensee shall report any irregularities to the Agency associated with identification, labeling, quality or assay of any radiopharmaceutical received or dispensed under the authority of this license.
18.
 - A. Technetium 99m Pertechnetate may be eluted and prepared from a Molybdenum 99/Technetium 99m generator provided the generator has been approved by the U.S. Food and Drug Administration for routine usage under an approved New Drug Application (NDA). Such elutions of the generator must be made in strict accordance with the manufacturer's instructions.
 - B. The licensee shall test each elution of Molybdenum 99/Technetium 99m generators to determine the concentration of Mo-99 activity in the Tc-99m preparation. Records of these tests shall be kept for inspection by the Agency and shall indicate the date, generator serial number, Mo-99 concentration in microcuries per millicurie of Tc-99m, and name of person performing the test.
 - C. The licensee shall not distribute any preparation which will contain more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m at the expiration time specified on the package label.
19. Radiopharmaceuticals authorized by this license which contain Technetium 99m may be prepared from kits, provided the kits used have been approved by the U.S. Food and Drug Administration (USFDA).

CONDITIONS CONTINUED ON PAGE 5

JRS:mr

March 21, 1988

Date _____

FOR THE TEXAS DEPARTMENT OF HEALTH

Joseph C. Kline

Item #3
Page 4 of 6
Prepared: 5-19-88



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

10815

LICENSE NUMBER	AMENDMENT NUMBER
L03008	16

CONDITIONS CONTINUED:

20. Radiopharmaceuticals are to be dispensed only upon the prescription of a specifically licensed physician who is authorized to possess and use such radiopharmaceuticals. Similarly, other radioactive materials are to be distributed only to licensees authorized to possess and use them. The licensee shall maintain a copy of the radioactive material license of each customer and shall verify that the customer is authorized to receive the radioactive material prior to dispensing or distributing them.
21. Radioactive material may be transferred to an unlicensed individual, for transport only, provided that written verification is first obtained to indicate that the individual is a designated transport agent of the licensee receiving the radioactive material.
22. Radioactive material which is transported by the licensee or delivered to a carrier or transport agent for transport shall be packaged, labeled and transported in accordance with U.S. Department of Transportation (DOT) Regulations.
23. The licensee shall use a calibrated dose calibrator to assay all single and multiple dose radiopharmaceuticals which are dispensed and shall provide appropriate assay data with each dose dispensed.
24. 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 inspection by the Agency for two (2) years from the date of the inventory and shall include the quantities and the kinds of radioactive material, location of sealed sources, and the date of the inventory.
25. The licensee shall maintain a record for inspection by the Agency of all radiopharmaceuticals dispensed. The record shall include the radiopharmaceutical, dosage, procedure, physician's name, patient's name, physician's radioactive material license number, the date and time the radiopharmaceutical is dispensed and the delivery method. Records of distribution of other radioactive material shall also be kept which include the type, quantities, form, customer name, license number, date and delivery method.

CONDITIONS CONTINUED ON PAGE 6

IRS:mr

March 21, 1988

Date _____

FOR THE TEXAS DEPARTMENT OF HEALTH

Joseph C. Kleininger
Administrator, Licensing Branch

Item #3
Page 4 of 6
Prepared: 5-19-88



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

16303

Supplementary Sheet

LICENSE NUMBER L03008	AMENDMENT NUMBER 16
--------------------------	------------------------

CONDITIONS CONTINUED:

26. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by license in accordance with statements, representations, and procedures contained in the following:

- application dated April 28, 1986
- letters dated August 8, 1986
 - September 24, 1986
- letter received October 27, 1986
- application dated November 14, 1986
- application and procedures received April 3, 1987
- letters dated June 2, 1987
 - June 22, 1987
 - June 29, 1987
- application dated October 14, 1987

The Texas Regulations for Control of Radiation shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

JRS:mr

FOR THE TEXAS DEPARTMENT OF HEALTH

March 21, 1988

Date _____

Item #3
Page 6 of 6
Prepared: 5-19-88

Joseph G. Blumson



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

07398

Supplementary Sheet

LICENSE NUMBER 5-3580	AMENDMENT NUMBER 6
--------------------------	-----------------------

CONDITIONS CONTINUED:

1. Radioactive material shall be used by, or under the supervision of the following:

- | | |
|----------------------------|--------------------------|
| 1. Todd Schmidt, R.Ph. | 5. Randal Watt, R.Ph. |
| 2. J. P. Minella, R.Ph. | 6. Alice Worthen, R.Ph. |
| 3. Denise L. Horner, R.Ph. | 7. David R. Lutes, R.Ph. |
| 4. Carl E. Wood | |

Individuals similarly listed on any of the licensee's other Texas licenses are also authorized to use radioactive material on a temporary basis provided they remain on site no longer than ninety (90) days per year, a copy of a Texas radioactive material license which authorizes their use is maintained at the licensed address, and records are kept of their dates of arrival and departure. Radiopharmaceuticals are to be dispensed only by a Texas pharmacist.

- 2. Sealed sources containing radioactive material shall not be opened.
- 3. Radiation survey instruments used in the licensee's own radiation safety program shall be calibrated at intervals not to exceed twelve (12) months. Instruments routinely transported shall be so calibrated at intervals not to exceed six (6) months.
- 14. Radiopharmaceuticals that are procured shall be from another licensed nuclear pharmacy or from a supplier who distributes the radiopharmaceuticals under the New Drug Applications (NDA's) or Investigative New Drug Application (IND's) approved by the U.S. Food and Drug Administration.
- 15. The licensee shall report any irregularities to the Agency associated with identification, labeling, quality or assay of any radiopharmaceutical received or dispensed under the authority of this license.
- 16. A. Technetium 99m Pertechnetate may be eluted and prepared from a Molybdenum 99/Technetium 99m generator provided the generator has been approved by the U.S. Food and Drug Administration for routine usage under an approved New Drug Application (NDA). Such elutions of the generator must be made in strict accordance with the manufacturer's instructions.

CONDITIONS CONTINUED ON PAGE 4

Item #4
Prepared: 5-19-88

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 1 PAGES

LICENSE NUMBER GA. 877-1M

Amendment No. .06

Mallinckrodt, Incorporated
Diagnostic Imaging Services
675 McConnell Boulevard
St. Louis, Missouri 63134

In accordance with letter dated October 26, 1987, signed by Carl E. Wood, Jr. Director, Diagnostic Imaging Services, and letter received January 29, 1988, signed by Wayne L. Toal Facility Manager, Georgia Radioactive Material License No. GA. 877-1MD is amended as follows:

Condition 12. is amended to read:

12. Radioactive material shall be used by or under the supervision of Stuart B. Herrick, R.Ph., Carl E. Wood, R.Ph., Wayne Toal, R.Ph., Michael P. Kevula, R.Ph., and Lisa Lay, R.Ph.

DATE February 23, 1988

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

BY Willard D. Ingram



DEPARTMENT OF THE ENVIRONMENT
 201 WEST PRESTON STREET
 BALTIMORE 21201

DIVISION OF RADIATION CONTROL
 RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

License No. MD-33-088-01	Amendment No. NEW
-----------------------------	----------------------

CONT'D

6. Radioactive material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
I. Any radioactive material listed in Sec. C.28(h) of Part C, COMAR 10.14.02.01	I. Prepackaged <u>in vitro</u> diagnostic kits	I. 20 millicuries
J. Cobalt-57	J. Sealed source (NEN Model NES-206)	J. 15 millicuries
K. Cesium-137	K. Sealed source (NEN Model 356 Type E vial)	K. 5 millicuries
L. Barium-133	L. Sealed source (NEN Model 358)	L. 5 millicuries

9. Authorized use

- I. Distribution of unopened prepackaged in vitro kits.
- J.-L. Distribution to authorized recipients and in-house use as calibration standards.

CONDITIONS

- 10. The authorized place of use is the licensee's address stated in Item 2.
- 11. A. The radiation protection program shall be under the supervision of Gregory Brooks, R.Ph.
- B. Radioactive material shall be used by, or under the supervision of Gregory Brooks, R.Ph.; Radwan C. Jaber, R.Ph.; and/or Rajiv Rao, R.Ph.

Date _____

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

RadPharm/S
637 South Lucas, Room 550
Los Angeles, CA 90017

Attention: Craig Minami, R.Ph.
Radiation Safety Officer

In response to the letter with attachments dated November 20, 1987,
signed by Craig Minami, R.Ph., License Number 3219-70 is hereby
amended in part as follows:

To add:

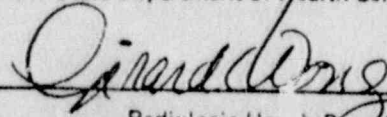
12. (g) Barry M. Brown, R.Ph.

Item #7 Prepared: 5-19-88

Date December 10, 1987

For the State Department of Health Services

by


Radiologic Use of Radioactive Materials

RADIOACTIVE MATERIAL LICENSE

License Number 3219-70

Supplementary Sheet

Amendment Number 18

Rad/Pharm
637 South Lucas, Room 550
Los Angeles, CA 90017

Attention: Craig Minami, R.Ph.
Radiation Safety Officer

In response to the letter with attachments dated July 28, 1987, signed by Craig Minami, R.Ph., License Number 3219-70 is hereby amended in part as follows:

To add:

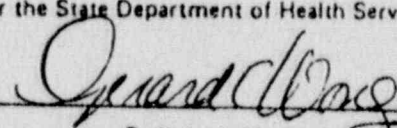
12. (f) Dzung Tonthat, R.Ph.

Item #8 Prepared: 5-19-88

Date August 18, 1987

For the State Department of Health Services

by



Radiologic Health Branch
714 P Street, Sacramento, CA 95814

Page 1. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Name: Doug Petry

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours*				
				Radiation Physics & Instrumentation (need total of 85)	Radiation Protection (need total of 45)	Math Pertaining to Radioactivity (need total of 20)	Radiation Biology (need total of 20)	Radiopharmaceutical Chemistry (need total of 30)
Purdue Univ.		Nuclear Pharmacy	47	25	6		7	9
		Nuclear Pharmacy Lab.	45	25	6	6	3	5
		Practicum in Nuclear Pharmacy	45	15	22	8		
		Special Problem in Nuclear Pharmacy	45					
		Total:	182	65	34	14	10	14

* Note: Show a breakdown of hours by institutions, dates, and subjects. List each hour only once (i.e., under the most applicable subject category).

TOTAL HOURS

MERCER

Southern School of Pharmacy
Department of Pharmacy Practice

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: DOUG PETRY

Date: February 5, 1988

Field of Training	Location & Date(s) of Training: Mercer Univ. Southern School of Pharmacy	Type and Length of Training	
		Lecture/ Laboratory Courses (Hours)	Supervised Lab. Experi- ence (Hours)
A. Radiation Physics & Instrumentation	January 4, 1988 thru February 5, 1988	38	17
B. Radiation Protection	" "	21	14
C. Mathematics Pertaining to the use & Measurement of Radioactivity	" "	16	4
D. Radiation Biology	" "	20	---
E. Radiopharmaceutical Chemistry	" "	30	---
TOTALS:		<u>125</u> hrs.	<u>35</u> hrs.

L.P.S.
Michael P. Kavula, Jr., Pharm.D.
Associate Professor of Pharmacy Practice

MERCER UNIVERSITY ATLANTA
345 Boulevard, NE
Atlanta, Georgia 30312
(404) 653-8829

Item #9
Page 2 of 4
Prepared: 5-19-88

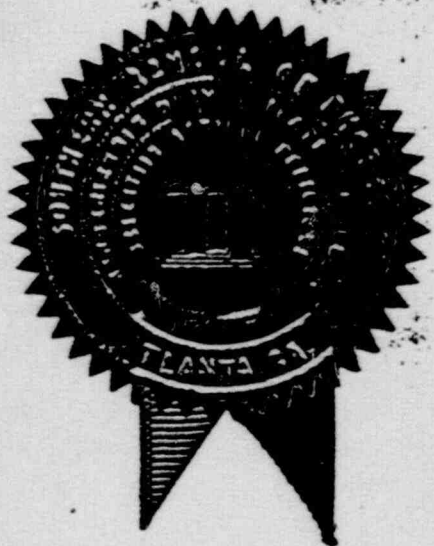
Mercer University

School of Pharmacy

Hereby certifies that

DOUG PETRY, R.Ph.

has successfully completed a five week
Training Program in Nuclear Pharmacy.
In witness thereof, we hereunto subscribe our
names this 5TH day of February 1988.



Dick R. Gourley
Dick R. Gourley, Pharm.D.
Dean, School of Pharmacy

Michael P. Kavala, Jr.
Michael P. Kavala, Jr. Pharm.D., BCNP
Course Director

Page 2. DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

Name: Doug Petry

EXPERIENCE WITH RADIOACTIVE MATERIAL. (Actual Use of Radfoisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours)	TYPES OF USE 1, 2, 3, 4, 5, 6 (see key below)
Tc-99m	20Ci	Syncor, Inc. Detroit, MI Chicago, IL May 1983 to Aug. 1983 May 1984 to Aug. 1984	600 hours	1 through 6
I-123	1Ci			
Ga-67	1Ci			
Tl-201	1Ci			
Xe-133	2Ci			
Se-75	250 mCi			
Co-57	10 mCi			
Cs-137	20mCi			
Ba-133	277 uCi			
Co-60	1mCi			
In-111	10mCi	Mallinckrodt, Inc. Cleveland, Ohio Dec. 1987 to May 1988.	Total 600hrs.	
I-131	1Ci			
Cr-51	10 mCi			
I-125	5mCi			
Fe-59	5mCi			
P-32	35mCi			

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrators, scintillation detectors, and survey meters.
3. Calculation dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the eluate for Molybdenum-99 contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Administrative Code, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any conditions specified in this license.

<p>1. Licensee RadPharm, Inc.</p> <p>2. Address 2330 Clay Street - Rm. 310 San Francisco, CA</p> <p>Attention: Clyde Cole, Director of Regulatory Affairs</p>	<p>3. License No. <u>2657-90</u> is hereby amended in its <u>entirety.</u> Amendment No. <u>8</u></p> <p>4. Expiration date January 29, 1989</p> <p>5. Inspection agency Radiologic Health Branch - N</p>
---	---

6. Nuclide	7. Form	8. Possession limit
A. Molybdenum 99 - Technetium 99m	A. Sterile generator(s)	A. 30 Curies
B. Any radionuclides with atomic numbers 3-83 inclusive except: (1) Strontium 90, and (2) Lead 210	B. Sealed source(s)	B. 15 Millicuries
C. Technetium-99m	C. Sodium pertechnetate, and products labeled in accordance with manu- facturers instructions.	C. Included with A
D. Xenon-133	D. Gas and/or saline, pharmaceutical	D. 3 Curies
E. Iodine-123, 125 and 131	E. Sodium Iodide and labeled compounds	E. 800 Millicuries
F. Any radionuclide with atomic numbers 3-83 inclusive except: (1) Strontium 90, (2) Lead 210 and (3) Nuclides itemized above	F. Pharmaceutical	F. 700 Millicuries

(cont'd)

RADIOACTIVE MATERIAL LICENSE

continued

Supplementary Sheet

9. Authorized use

- A. Source of Technetium-99m
- B. Calibration of instruments.
- C. - F. Processing, mixing or compounding of radiopharmaceuticals, and dispensing of prepared radiopharmaceuticals to authorized recipients pursuant to a prescription from a physician named in a Nuclear Medicine license. The name of each patient along with prescribed doses shall be a part of the labeling for each container. No more than 5 doses shall be dispensed in any one container.

10. Radioactive material may be used only at the following locations:

- (a) 2330 Clay Street, Rooms 308, 309 and 310.

11. This license is subject to an annual fee of one thousand two hundred sixty (1260) dollars due and payable on the anniversary of the date of issue of this license, January 29, 1975.

12. Radioactive material may be used by, or under the supervision and in the physical presence of the following individuals:

- (a) Rodney L. Detrow
- (b) Clyde N. Cole
- (c) Anne Irwin
- (d) Vincent Sharkey, Jr.
- (e) Lewis Lefkowitz

13. 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 the documents:

- ✓ (a) the application dated December 30, 1981, with attachments, signed by Clyde N. Cole.
- ✓ (b) the letter dated March 26, 1982, signed by Rodney L. Detrow, with attachments.
- ✓ (c) the two letters dated April 7, 1982 signed by Rodney L. Detrow, with attachments.
- (d) letter dated December 7, 1982, signed by Clyde N. Cole with attachments.
- (e) letter dated January 20, 1983, signed by Clyde N. Cole with attachments.

not avail.

(cont'd)

APPENDIX A

TRAINING AND EXPERIENCE
FOR AUTHORIZED USERS AND DAY-TO-DAY RADIATION SAFETY OFFICER

Paragraph 30.33(a)(3) of 10 CFR Part 30 requires that applicants be qualified by training and experience to use licensed material for the purpose requested in the application. In the case of a nuclear pharmacy operation, the NRC reviews the training and experience of the individuals who are to be listed as authorized users to determine whether they meet this requirement. Any individual who has sufficient training and experience to be named as an authorized user is also considered qualified to serve as the day-to-day radiation safety officer (RSO).

NOTE: An individual specifically listed as an authorized user on a previous nuclear pharmacy license issued by NRC or an Agreement State is considered to have adequate training and experience. In these cases, instead of documenting the individual's training and experience, simply specify the number of the NRC nuclear pharmacy license or submit a copy of the Agreement State license on which the proposed user was specifically listed as an authorized user.

This appendix lists the training and experience that the NRC finds acceptable for individuals who are to be named as authorized users or as RSO on licenses that involve the preparation and distribution of radiopharmaceuticals. These criteria evolved from NRC's guidelines for physicians in hospital nuclear medicine programs because the type of use and the degree of radiation hazard are quite similar. (See Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs.")

1. Training in basic radioisotope handling techniques specifically applicable to the use of unsealed sources (200 hours). This training should consist of lectures and laboratory sessions in the following areas:
 - a. Radiation physics and instrumentation (85 hours)
 - b. Radiation protection (45 hours)
 - c. Mathematics pertaining to the use and measurement of radioactivity (20 hours)
 - d. Radiation biology (20 hours)
 - e. Radiopharmaceutical chemistry (30 hours)

The hours listed above are suggested values; however, the training should emphasize radiation physics, instrumentation, and radiation protection, with no less than 130 hours total devoted to these subject areas.

On-the-job training may not count toward the hours listed above unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

on file

①

a. A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the NRC upon request.

b. Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to NRC upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.

c. A permanent record that the student successfully completed the course is kept at the institution.

2. Experience in handling unsealed radioactive material under the supervision of an authorized user (500 hours). This experience should cover the types and quantities of byproduct material requested in the application and should include:

a. Ordering, receiving, and unpackaging radioactive materials safely, including performing related radiation surveys,

b. Calibrating dose calibrators, scintillation detectors, and survey meters,

c. Calculating, preparing, and calibrating patient doses, including properly using radiation shields,

d. Following appropriate internal control procedures to prevent mislabeling errors,

e. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests,

f. Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing

the eluate with reagent kits to prepare technetium-99m-labeled radio-
pharmaceuticals.

You may use a format similar to that shown in Figures A-1 and A-2 for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes.

LICENSE NO. • 37-21345-01MD
DOCKET NO. 030-20537
CONTROL NO. 109006

NAME MALLINCKRODT, INC.
ATTN: CARL E. WOOD, DIR., NUC. PHARM
ADDRESS 19 INDEPENDENCE COURT
FOLCROFT, PA 19032-

GENTLEMAN,

THIS IS TO CONFIRM OUR TELEPHONE CONVERSATION ON July 22, 1988
WITH Mr. Steven Spinasi IN WHICH WE DISCUSSED THE INFORMATION
WE NEED TO CONTINUE REVIEW OF YOUR APPLICATION DATED May 19, 1988

THE ITEMS SPECIFIED BELOW ARE THOSE WE DISCUSSED.

1. Confirm the following points described in Appendix A of the "Guide for Preparation of Applications for Nuclear Pharmacy Licenses" in your review of the training and experience requirements of pharmacists:
 - (1) didactic training will be at least 200 hrs of student-teacher, contact in formal college-level or similar course;
 - (2) the 200 hrs will not include study/prep, homework or on-the-job training hours.
 - (3) you will confirm that the "formal" training meets the elements described in Appendix A;

IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE OF THIS LETTER, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION.

over →

SINCERELY,

Josephine M. Piccone, Ph.D.
NUCLEAR MATERIALS SAFETY SECTION A.
NUCLEAR MATERIALS SAFETY AND SAFEGUARDS BRANCH

CONCURRENCES: Piccone-----

2. Submit a copy of the Mercer College outline to illustrate your review of courses for the element described in Appendix A of Nuc. Pharm. Guide.
3. Clarify the discrepancies in the Mercer College presented hours between your amendment submittals of 3/2/88 and 5/19/88.
4. Confirm that a list of approved users will be kept at each Mallinckrodt facility.
5. Review the training received by Vito Deliso and Barbara Murray to satisfy the "formal" training requirement; Did Nuclear & Genetic Technology, Inc. have a formal course?; Did these individuals receive additional training from Mercer College.

APPLICATION FOR MATERIAL LICENSE

030-20537

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER 37-21345-01 MD
- C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Mallinckrodt, Inc.
Diagnostic Imaging Services
#19 Independence Court
Folcroft, PA. 19032

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:

SAME AS #2

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Steven A. Spinosi

TELEPHONE NUMBER

(314) 895-2061

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3C AMOUNT ENCLOSED \$ 230.00

13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Carl E. Wood, Jr.

Director, Radiopharmacy

5-19-88

14. VOLUNTARY ECONOMIC DATA

Operations

a. ANNUAL RECEIPTS

<\$250K	\$1M-3.5M
\$250K-500K	\$3.5M-7M
\$500K-750K	\$7M-10M
\$750K-1M	>\$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

107

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)

YES NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

APPROVED BY

AMD

Jun 10 1988

(3C) 3N

AMOUNT RECEIVED

CHECK NUMBER

DATE

\$230

A202270

6/19/88

109006

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

Mallinckrodt, Inc.

675 McDONNELL BLVD.

P.O. BOX 5840

ST. LOUIS, MO. 63134

(314) 695-2000

May 19, 1988

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA. 19406

Re: NRC Lic. # 37-21345-01MD

Sirs:

The purpose of this request is to amend the NRC license of Mallinckrodt, Inc.: 19 Independence Court, Folcroft, PA, 19032 (License # 37-21345-01MD) for the following:

1. To Delete Todd Schmidt from the list of authorized users.
2. To change the listed name of Rebecca S. Kubic to Rebecca S. Brown. (Change in marital status of this user.)
3. To add the following individuals as authorized users:

Larry Horvath (training and experience attached)
(attached item # 1).

Lori Devos (presently named on Texas Rad. Mat. Lic. No. L03008.) (attached item # 2).

Wayne Nye (presently named on Texas Rad. Mat. Lic. No. L03008.) (attached item # 3).

David Lutes (presently named on Texas Rad. Mat. Lic. No. L03580.) (attached item # 4).

Lisa Lay (presently named on Georgia Rad. Mat. Lic. No. 877-1MD.) (attached item # 5).

Rajiv Rao (presently named on Maryland Rad. Mat. Lic. No. MD-33-088-01.) (attached item # 6).

Barry Brown (presently named on California Rad. Mat. Lic. No. 3219-70.) (attached item # 7).

Dzung Tonthat (presently named on California Rad. Mat. Lic. No. 3219-70.) (attached item # 8).

Doug Petry (training and experience attached). (attached item # 9.)

Mallinckrodt

DIAGNOSTIC PRODUCTS DIVISION

Rod Detrow (presently named on NRC License # 34-16654-01-MD (and California Rad. Mat. Lic. No. 2657-90.) (attached item # 10)

David McCord (presently named on NRC license # 34-16405-01-MD.)

4. To request authorization for the following materials:

<u>Element</u>	<u>Chemical/Physical Form</u>	<u>Activity</u>	<u>Use</u>
Uranium(depleted in the isotope U-235)	Metal enclosed in stainless steel	200 Kg.	Shielding for Mo-99
Any byproduct material listed in 31.21(a) of 10 CFR 31	Prepacked in-vitro diagnostic kits	20 mCi	Dispensing and or distribution of prepackaged in-vitro diagnostic test kits

5. To request authorization for this licensee to name authorized users via internal committee. (see item #11)

ITEM # 11

AUTHORIZED USER, INTERNAL COMMITTEE NAMED

The purpose of this amendment request is to permit the designation of authorized users to this NRC radioactive materials license via an internal committee. This procedure would facilitate the addition of qualified users to the Mallinckrodt radiopharmacy license, and would be in lieu of the present procedure of submission of training and experience to the Commission for review and approval.

Presently Mallinckrodt, Inc. maintains a "master-user" list of authorized users on the Folcroft, PA NRC license # 37-21345-01MD. This license is amended for each new hiree, requesting their addition to the list of authorized users.

A request is made to permit the naming of authorized users to this license by an internal committee who will maintain responsibility for review and approval of prospective user training and experience. This review process will be carried out by a committee made up of the following individuals:

- * General Manager: Radiopharmaceutical Business Unit
- * Director: DIS Radiopharmacy Operations
(presently named on NRC license # 37-21345-01MD)
- * Regional Manager: DIS Radiopharmacy
(presently named on NRC license # 37-21345-01MD)

The training and experience of each prospective user will be submitted to this committee for review, utilizing forms similar to that shown in Figures A-1 and A-2 of regulatory "Guide for Preparation of Applications for Nuclear Pharmacy Licenses". Should the prospective user have been named on a previous nuclear pharmacy license issued by the NRC or an Agreement State, a copy of the license that lists this user will be submitted.

At least two members of this committee will review the submitted materials for compliance with training and experience recommendations as outlined in Appendix A of the regulatory "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses"(dated August , 1985)(attachment A).

The committee will assure that the prospective users possess training and experience that minimally meet the recommendations as outlined in the above paragraphs. Should the candidate's training and experience meet fully the criteria, or the candidate has been named on a previous NRC or Agreement State license, he/she will be added to the list of authorized users that will be maintained on file. Copies of the submitted training and experience forms will be maintained on file for regulatory reference. In the case of a user that has been previously named on an NRC or Agreement State radioactive materials license, a copy of this license will be maintained on file for regulatory reference.

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Larry Horvath

Date: April 26, 1988

<u>Field of Training</u>	<u>Location & Date(s) of Training:</u>	<u>Type and Length of Training</u>
	Purdue University School of Pharmacy	<u>Lecture/ Laboratory Courses (Hours)</u>
A. Radiation Physics & Instrumentation	August 1981 through May 1987	105
B. Radiation Protection	" "	45
C. Mathematics Per- taining to the use & Measurement of Radioactivity	" "	30
D. Radiation Biology	" "	30
E. Radiopharma- ceutical Chemistry	" "	50
TOTALS:		<u>260 hrs.</u>

Page 2. DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

Name: Larry Horvath

EXPERIENCE WITH RADIOACTIVE MATERIAL. (Actual Use of Radioisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours)	TYPES OF USE 1, 2, 3, 4, 5, 6 (see key below)
Tc-99m	20Ci	Mallinckrodt, Inc. Diagnostic Imaging Services Los Angeles, CA 7/9/87 to 4/22/88	600 hours	1 through 6
I-123	1Ci			
Ga-67	1Ci			
Tl-201	1Ci			
Xe-133	2Ci			
Se-75	250mCi			
Co-57	10mCi			
Cs-137	20mCi			
Ba-133	277uCi			
Co-60	1mCi			
In-111	10mCi			
I-131	1Ci			
Cr-51	10mCi			
I-125	5mCi			
Fe-59	5mCi			
P-32	35mCi			
			Total	600 hrs.

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrators, scintillation detectors, and survey meters.
3. Calculation dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the eluate for Molybdenum-99 contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

08795

Supplementary Sheet

LICENSE NUMBER	AMENDMENT NUMBER
L03008	15

CONDITIONS CONTINUED:

12. A. Radioactive material shall be used by, or under the supervision of, the following:

- | | |
|--------------------------|----------------------------|
| 1. Lori DeVos, R.Ph. | 5. Todd Schmidt, R. Ph. |
| 2. Frank M. Gwynn, R.Ph. | 6. Carl E. Wood, R.Ph. |
| 3. Richard A. Nickel | 7. Alice T. Worthen, R.Ph. |
| 4. Barbara D. Scavullo | |

Radiopharmaceuticals are to be dispensed only by a Texas licensed pharmacist.

B. Radioactive material for commercial and in-house leak test analyses may be used by, or under the supervision of, the following:

- | | |
|----------------------------|-----------------------|
| 1. Paul J. Early | 7. Steven Spinosi |
| 2. William H. Miller | 8. Raymond Kaczur |
| 3. Frank Bloce | 9. Samuel A. Pontillo |
| 4. Charles Anthony Giomuso | 10. Peggy Reilly |
| 5. W. Christopher Wagner | 11. Ronald J. Scala |
| 6. David Close | 12. Mark Beanblossom |

C. Radioactive material for commercial and in-house radiation survey instrument calibration may only be used by the individuals named in 12.B above.

13. Sealed sources containing radioactive material shall not be opened.

14. A. Sealed sources of radioactive material, Nickel 63 foil, and/or plated alpha-emitting sources shall be tested for leakage and/or contamination in accordance with the provisions of Texas Regulations for Control of Radiation 11.7.

B. The individuals listed in Condition 12.B above are authorized to perform leak test analyses in-house or as a commercial service using the commercial leak test kit approved for this license. The licensee shall maintain, for inspection by the Agency, records for verification of reported leak test results for three (3) years from the date of testing.

CONDITIONS CONTINUED ON PAGE 4



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

04110

Pursuant to the Texas Radiation Control Act and Texas Department of Health regulations on radiation, 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 radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Texas Department of Health now or hereafter in effect and to any conditions specified below.

LICENSEE		This license issued pursuant to and in accordance with	
1. Name Mallinckrodt, Inc. ATTN: Lloyd W. Nye, R.Ph.		<input type="checkbox"/> APPLICATION <input checked="" type="checkbox"/> LETTER <input type="checkbox"/> _____ Dated: March 1, 1988 Signed By: A. T. Worthen	
		2. Address 8078 El Rio Houston, Texas 77054	
		3. License Number	Amendment Number
		L02008	16
		PREVIOUS AMENDMENTS ARE VOID	
		4. Expiration Date	
		May 31, 1991	

RADIOACTIVE MATERIAL AUTHORIZED

5. Radioisotope	6. Form of Material	7. Maximum Activity*	8. Authorized Use
A. Any radioactive material with Atomic Number less than 84	A. Any radio-pharmaceutical approved by the U.S. Food and Drug Administration (USFDA)	A. No single radionuclide to exceed 700 mCi except for Tc-99m which is not to exceed 45 Ci	A. For receipt, storage, and preparation in accordance with applicable USFDA approved protocols, and dispensing upon prescription to authorized recipients.
B. Mo-99	B. USFDA approved Tc-99m generators	B. 45 Ci	B. Production of Tc-99m. Distribution of generators or eluate to authorized recipients.

CONTINUED ON PAGE 2, IF CHECKED.

CONDITIONS

9. Unless otherwise specified, radioactive material shall be used only at:

Sub-site Number	Location
000	Houston - 8078 El Rio

10. The licensee shall comply with the provisions of Parts 11, 12, 13, 21, 22, and 41 of the Texas Regulations for Control of Radiation (TRCR).

* Ci-Curies mCi-Millicuries μ Ci-Microcuries CONDITIONS CONTINUED ON PAGE 2

JRS:mr

FOR THE TEXAS DEPARTMENT OF HEALTH

March 21, 1988

Date _____

Item #3

Page 1 of 6

Prepared: 5-19-88

Joseph C. Blinn
Administrator, Licensing Branch



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

10812

LICENSE NUMBER	AMENDMENT NUMBER
L03008	16

CONDITIONS CONTINUED:

5. Radio-isotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
C. Co-57 Cs-137, Ba-133, I-129	C. Sealed reference sources	C. No single source to exceed 10 mCi. Total: 15 mCi.	C. Reference sources for use, receipt, storage and distribution to authorized recipients.
D. Uranium	D. Depleted metal	D. 120 kilograms	D. Auxiliary shielding for Technetium generators.
E. Xe-127/ Xe-133	E. Any radio-pharmaceutical	E. 5 Ci	E. For receipt, storage, and preparation in accordance with applicable USFDA approved protocols, and dispensing upon prescription to authorized recipients.
F. Cs-137	F. Sealed source (Tech/Ops 77302)	F. 165 mCi	F. For use in a Tech/Ops 773 instrument calibrator for calibration of radiation survey meters.
G. Any radioactive material	G. Any solid	G. No single nuclide to exceed 6 mCi	G. As authorized by TRCR 41.26(b)(4), for transport to authorized licensees for calibration of instruments under the client's license authorization, and as leak test samples, to be returned for evaluation to the licensee's facility.

CONDITIONS CONTINUED:

- The individual designated to perform the functions of Radiation Safety Officer for activities covered by this license is Lloyd W. Hye, R.Ph. Designated as Alternate Radiation Safety Officer is Alice P. Worthen, R.Ph.

CONDITIONS CONTINUED ON PAGE 3

RS:mr

FOR THE TEXAS DEPARTMENT OF HEALTH

Item #3

March 21, 1988

Page 2 of 6

Date _____

Joseph C. Kline

Prepared: 5-19-88



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

10813

LICENSE NUMBER	AMENDMENT NUMBER
L03008	16

CONDITIONS CONTINUED:

12. A. Radioactive material shall be used by, or under the supervision of, the following:

- | | |
|----------------------------|-------------------------|
| Lori DeVos, R.Ph. | Barbara D. Scavullo |
| Frank M. Gwynn, R.Ph. | Carl E. Wood, R.Ph. |
| Lloyd W. Nye, R.Ph. | Alice T. Worthen, R.Ph. |
| Richard A. Nickel | |

Radiopharmaceuticals are to be dispensed only by a Texas licensed pharmacist.

B. Radioactive material for commercial and in-house leak test analyses may be used by, or under the supervision of, the following:

- | | |
|-------------------------|-----------------------|
| Mark Beanblossom | William H. Miller |
| Frank Bloe | Samuel A. Pontillo |
| David Close | Peggy Reilly |
| Paul J. Early | Steven Spinosi |
| Charles Anthony Giomuso | Ronald J. Scala |
| Raymond Kaczur | W. Christopher Wagner |

C. Radioactive material for commercial and in-house radiation survey instrument calibration may only be used by the individuals named in 12.B above.

3. Sealed sources containing radioactive material shall not be opened.

4. A. Sealed sources of radioactive material, Nickel 63 foil, and/or plated alpha-emitting sources shall be tested for leakage and/or contamination in accordance with the provisions of Texas Regulations for Control of Radiation 11.7.

B. The individuals listed in Condition 12.B above are authorized to perform leak test analyses in-house or as a commercial service using the commercial leak test kit approved for this license. The licensee shall maintain, for inspection by the Agency, records for verification of reported leak test results for three (3) years from the date of testing.

CONDITIONS CONTINUED ON PAGE 4

JRS:mr

March 21, 1988

Date

FOR THE TEXAS DEPARTMENT OF HEALTH

Item #3
Page 3 of 6
Prepared: 5-19-88

Joseph C. Bluminger
Administrator, Licensing Branch



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

10814

LICENSE NUMBER	AMENDMENT NUMBER
103008	16

CONDITIONS CONTINUED:

15. Radiation survey instruments used in the licensee's own radiation safety program shall be calibrated at intervals not to exceed twelve (12) months. Instruments routinely transported shall be so calibrated at intervals not to exceed six (6) months.
16. Radiopharmaceuticals that are procured shall be from another licensed nuclear pharmacy or from a supplier who distributes the radiopharmaceuticals under the New Drug Applications (NDA's) or Investigative New Drug Application (IND's) approved by the U.S. Food and Drug Administration.
17. The licensee shall report any irregularities to the Agency associated with identification, labeling, quality or assay of any radiopharmaceutical received or dispensed under the authority of this license.
18. A. Technetium 99m Pertechnetate may be eluted and prepared from a Molybdenum 99/Technetium 99m generator provided the generator has been approved by the U.S. Food and Drug Administration for routine usage under an approved New Drug Application (NDA). Such elutions of the generator must be made in strict accordance with the manufacturer's instructions.
 B. The licensee shall test each elution of Molybdenum 99/Technetium 99m generators to determine the concentration of Mo-99 activity in the Tc-99m preparation. Records of these tests shall be kept for inspection by the Agency and shall indicate the date, generator serial number, Mo-99 concentration in microcuries per millicurie of Tc-99m, and name of person performing the test.
 C. The licensee shall not distribute any preparation which will contain more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m at the expiration time specified on the package label.
19. Radiopharmaceuticals authorized by this license which contain Technetium 99m may be prepared from kits, provided the kits used have been approved by the U.S. Food and Drug Administration (USFDA).

CONDITIONS CONTINUED ON PAGE 5

JRS:mr

March 21, 1988

Date _____

FOR THE TEXAS DEPARTMENT OF HEALTH

Joseph C. Blinger
Administrator

Item #3
Page 4 of 6
Prepared: 5-19-88



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

10815

LICENSE NUMBER	AMENDMENT NUMBER
L03008	16

CONDITIONS CONTINUED:

20. Radiopharmaceuticals are to be dispensed only upon the prescription of a specifically licensed physician who is authorized to possess and use such radiopharmaceuticals. Similarly, other radioactive materials are to be distributed only to licensees authorized to possess and use them. The licensee shall maintain a copy of the radioactive material license of each customer and shall verify that the customer is authorized to receive the radioactive material prior to dispensing or distributing them.
21. Radioactive material may be transferred to an unlicensed individual, for transport only, provided that written verification is first obtained to indicate that the individual is a designated transport agent of the licensee receiving the radioactive material.
22. Radioactive material which is transported by the licensee or delivered to a carrier or transport agent for transport shall be packaged, labeled and transported in accordance with U.S. Department of Transportation (DOT) Regulations.
23. The licensee shall use a calibrated dose calibrator to assay all single and multiple dose radiopharmaceuticals which are dispensed and shall provide appropriate assay data with each dose dispensed.
24. 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 inspection by the Agency for two (2) years from the date of the inventory and shall include the quantities and the kinds of radioactive material, location of sealed sources, and the date of the inventory.
25. The licensee shall maintain a record for inspection by the Agency of all radiopharmaceuticals dispensed. The record shall include the radiopharmaceutical, dosage, procedure, physician's name, patient's name, physician's radioactive material license number, the date and time the radiopharmaceutical is dispensed and the delivery method. Records of distribution of other radioactive material shall also be kept which include the type, quantities, form, customer name, license number, date and delivery method.

CONDITIONS CONTINUED ON PAGE 6

JRS:mr

FOR THE TEXAS DEPARTMENT OF HEALTH

March 21, 1988

Date _____

Item #3
Page 4 of 6
Prepared: 5-19-88

Joseph C. Blum
Administrator, Licensing Branch



TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

16303

Supplementary Sheet

LICENSE NUMBER L03008	AMENDMENT NUMBER 16
--------------------------	------------------------

CONDITIONS CONTINUED:

26. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by license in accordance with statements, representations, and procedures contained in the following:

- application dated April 28, 1986
- letters dated August 8, 1986
 - September 24, 1986
- letter received October 27, 1986
- application dated November 14, 1986
- application and procedures received April 3, 1987
- letters dated June 2, 1987
 - June 22, 1987
 - June 29, 1987
- application dated October 14, 1987

The Texas Regulations for Control of Radiation shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

JRS:mr

March 21, 1988

Date _____

FOR THE TEXAS DEPARTMENT OF HEALTH

Joseph C. Blum
Administrator, Licensee Dept

Item #3
Page 6 of 6
Prepared: 5-19-88

TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

07398

Supplementary Sheet

LICENSE NUMBER	AMENDMENT NUMBER
5-3580	6

CONDITIONS CONTINUED:

1. Radioactive material shall be used by, or under the supervision of the following:

- | | |
|----------------------------|--------------------------|
| 1. Todd Schmidt, R.Ph. | 5. Randal Watt, R.Ph. |
| 2. J. P. Minella, R.Ph. | 6. Alice Worthen, R.Ph. |
| 3. Denise L. Horner, R.Ph. | 7. David R. Lutes, R.Ph. |
| 4. Carl E. Wood | |

Individuals similarly listed on any of the licensee's other Texas licenses are also authorized to use radioactive material on a temporary basis provided they remain on site no longer than ninety (90) days per year, a copy of a Texas radioactive material license which authorizes their use is maintained at the licensed address, and records are kept of their dates of arrival and departure. Radiopharmaceuticals are to be dispensed only by a Texas pharmacist.

2. Sealed sources containing radioactive material shall not be opened.
3. Radiation survey instruments used in the licensee's own radiation safety program shall be calibrated at intervals not to exceed twelve (12) months. Instruments routinely transported shall be so calibrated at intervals not to exceed six (6) months.
14. Radiopharmaceuticals that are procured shall be from another licensed nuclear pharmacy or from a supplier who distributes the radiopharmaceuticals under the New Drug Applications (NDA's) or Investigative New Drug Application (IND's) approved by the U.S. Food and Drug Administration.
15. The licensee shall report any irregularities to the Agency associated with identification, labeling, quality or assay of any radiopharmaceutical received or dispensed under the authority of this license.
16. A. Technetium 99m Pertechnetate may be eluted and prepared from a Molybdenum 99/Technetium 99m generator provided the generator has been approved by the U.S. Food and Drug Administration for routine usage under an approved New Drug Application (NDA). Such elutions of the generator must be made in strict accordance with the manufacturer's instructions.

CONDITIONS CONTINUED ON PAGE 4

Item #4

Prepared: 5-19-88

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 1 PAGES

LICENSE NUMBER GA. 877-1MD

Amendment No. .06

Mallinckrodt, Incorporated
Diagnostic Imaging Services
675 McConnell Boulevard
St. Louis, Missouri 63134

In accordance with letter dated October 26, 1987, signed by Carl E. Wood, Jr. Director, Diagnostic Imaging Services, and letter received January 29, 1988, signed by Wayne L. Toal Facility Manager, Georgia Radioactive Material License No. GA. 877-1MD is amended as follows:

Condition 12. is amended to read:

12. Radioactive material shall be used by or under the supervision of Stuart B. Herrick, R.Ph., Carl E. Wood, R.Ph., Wayne Toal, R.Ph., Michael P. Kavula, R.Ph., and Lisa Lay, R.Ph.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

BY

Willard D. Ingram

DATE February 23, 1988



DEPARTMENT OF THE ENVIRONMENT
201 WEST PRESTON STREET
BALTIMORE 21201

**DIVISION OF RADIATION CONTROL
RADIOACTIVE MATERIAL LICENSE**

Supplementary Sheet

License No.	MD-33-088-01	Amendment No.	NEW
-------------	--------------	---------------	-----

CONT'D

6. Radioactive material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
I. Any radioactive material listed in Sec. C.28(h) of Part C, COMAR 10.14.02.01	I. Prepackaged <u>in vitro</u> diagnostic kits	I. 20 millicuries
J. Cobalt-57	J. Sealed source (NEN Model NES-206)	J. 15 millicuries
K. Cesium-137	K. Sealed source (NEN Model 356 Type E vial)	K. 5 millicuries
L. Barium-133	L. Sealed source (NEN Model 358)	L. 5 millicuries

9. Authorized use
I. Distribution of unopened prepackaged <u>in vitro</u> kits.
J.-L. Distribution to authorized recipients and in-house use as calibration standards.

CONDITIONS

- 10. The authorized place of use is the licensee's address stated in Item 2.
- 11. A. The radiation protection program shall be under the supervision of Gregory Brooks, R.Ph.
- B. Radioactive material shall be used by, or under the supervision of Gregory Brooks, R.Ph.; Radwan C. Jaber, R.Ph.; and/or Rajiv Rao, R.Ph.

Date _____

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

RadPharm/S
637 South Lucas, Room 550
Los Angeles, CA 90017

Attention: Craig Minami, R.Ph.
Radiation Safety Officer

In response to the letter with attachments dated November 20, 1987,
signed by Craig Minami, R.Ph., License Number 3219-70 is hereby
amended in part as follows:

To add:

12. (g) Barry M. Brown, R.Ph.

Item #7 Prepared: 5-19-88

For the State Department of Health Services

Date December 10, 1987

by *Quardong*

Radiologic Health Branch

RADIOACTIVE MATERIAL LICENSE

License Number 3219-70

Supplementary Sheet

Amendment Number 18

Rad/Pharm
637 South Lucas, Room 550
Los Angeles, CA 90017

Attention: Craig Minami, R.Ph.
Radiation Safety Officer

In response to the letter with attachments dated July 28, 1987, signed by Craig Minami, R.Ph., License Number 3219-70 is hereby amended in part as follows:

To add:

12. (f) Dzang Tonthat, R.Ph.

Item #8 Prepared: 5-19-88

Date August 18, 1987

For the State Department of Health Services

by *Quard Wong*

Radiologic Health Branch
714 P Street, Sacramento, CA 95814

Page 1. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Name: Doug Petry

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours*				
				Radiation Physics & Instrumentation (need total of 85)	Radiation Protection (need total of 45)	Math Pertaining to Radioactivity (need total of 20)	Radiation Biology (need total of 20)	Radiopharmaceutical Chemistry (need total of 30)
Purdue Univ.		Nuclear Pharmacy	47	25	6		7	9
		Nuclear Pharmacy Lab.	45	25	6	6	3	5
		Practicum in Nuclear Pharmacy	45	15	22	8		
		Special Problem in Nuclear Pharmacy	45					
		Total:	182	65	34	14	10	14

* Note: Show a breakdown of hours by institutions, dates, and subjects. List each hour only once (i.e., under the most applicable subject category).

TOTAL HOURS

MERCER

Southern School of Pharmacy
Department of Pharmacy Practice

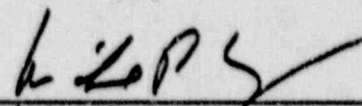
TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: DOUG PETRY

Date: February 5, 1988

Field of Training	Location & Date(s) of Training: Mercer Univ. Southern School of Pharmacy	Type and Length of Training	
		Lecture/ Laboratory Courses (Hours)	Supervised Lab. Exper- ience (Hours)
A. Radiation Physics & Instrumentation	January 4, 1988 thru February 5, 1988	38	17
B. Radiation Protection	" "	21	14
C. Mathematics Pertaining to the use & Measurement of Radioactivity	" "	16	4
D. Radiation Biology	" "	20	---
E. Radiopharmaceutical Chemistry	" "	30	---

TOTALS: 125 hrs. 35 hrs.


Michael P. Kavula, Jr., Pharm.D.
Associate Professor of Pharmacy Practice

MERCER UNIVERSITY ATLANTA
345 Boulevard, NE
Atlanta, Georgia 30312
(404) 653-8829

Item #9
Page 2 of 4
Prepared: 5-19-88

Mercer University

School of Pharmacy

Hereby certifies that

DOUG PETRY, R.Ph.

has successfully completed a five week
Training Program in Nuclear Pharmacy.

In witness thereof, we hereunto subscribe our
names this 5TH day of February 1988.



Dick R. Gourley
Dick R. Gourley, Pharm.D.
Dean, School of Pharmacy

Michael P. Kavula, Jr.
Michael P. Kavula, Jr. Pharm.D., BCNP
Course Director

Page 2. DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

Name: Doug Petry

EXPERIENCE WITH RADIOACTIVE MATERIAL. (Actual Use of Radioisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours)	TYPES OF USE 1, 2, 3, 4, 5, 6 (see key below)		
Tc-99m	20Ci	Syncor, Inc.,	600 hours	1 through 6		
I-123	1Ci	Detroit, MI				
Ga-67	1Ci	Chicago, IL				
Tl-201	1Ci	May 1983 to				
Xe-133	2Ci	Aug. 1983				
Se-75	250 mCi	May 1984 to				
Co-57	10 mCi	Aug. 1984				
Cs-137	20mCi					
Ba-133	277 uCi	Mallinckrodt, Inc.				
Co-60	1mCi	Cleveland, Ohio				
In-111	10mCi	Dec. 1987 to				
I-131	1Ci	May 1988.				
Cr-51	10 mCi					
I-125	5mCi					
Fe-59	5mCi					
P-32	35mCi					
Total					600hrs.	

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrators, scintillation detectors, and survey meters.
3. Calculation dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the eluate for Molybdenum-99 contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Administrative Code, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any conditions specified in this license.

<p>1. Licensee RadPharm, Inc.</p> <p>2. Address 2330 Clay Street - Rm. 310 San Francisco, CA</p> <p>Attention: Clyde Cole, Director of Regulatory Affairs</p>	<p>3. License No. <u>2657-90</u> is hereby amended in its <u>entirety</u>. Amendment No. <u>8</u></p> <p>4. Expiration date January 29, 1989</p> <p>5. Inspection agency Radiologic Health Branch - N</p>
---	---

6. Nuclide	7. Form	8. Possession limit
A. Molybdenum 99 - Technetium 99m	A. Sterile generator(s)	A. 30 Curies
B. Any radionuclides with atomic numbers 3-83 inclusive except: (1) Strontium 90, and (2) Lead 210	B. Sealed source(s)	B. 15 Millicuries
C. Technetium-99m	C. Sodium pertechnetate, and products labeled in accordance with manu- facturers instructions.	C. Included with A
D. Xenon-133	D. Gas and/or saline, pharmaceutical	D. 3 Curies
E. Iodine-123, 125 and 131	E. Sodium Iodide and labeled compounds	E. 800 Millicuries
F. Any radionuclide with atomic numbers 3-83 inclusive except: (1) Strontium 90, (2) Lead 210 and (3) Nuclides itemized above	F. Pharmaceutical	F. 700 Millicuries

(cont'd)

RADIOACTIVE MATERIAL LICENSE

License Number 2657-90

continued

Supplementary Sheet

Amendment Number 8

9. Authorized use

- A. Source of Technetium-99m
- B. Calibration of instruments.
- C. - F. Processing, mixing or compounding of radiopharmaceuticals, and dispensing of prepared radiopharmaceuticals to authorized recipients pursuant to a prescription from a physician named in a Nuclear Medicine license. The name of each patient along with prescribed doses shall be a part of the labeling for each container. No more than 5 doses shall be dispensed in any one container.

10. Radioactive material may be used only at the following locations:

- (a) 2330 Clay Street, Rooms 308, 309 and 310.

11. This license is subject to an annual fee of one thousand two hundred sixty (\$260) dollars due and payable on the anniversary of the date of issue of this license, January 29, 1975.

12. Radioactive material may be used by, or under the supervision and in the physical presence of the following individuals:

- (a) Rodney L. Detrow
- (b) Clyde N. Cole
- (c) Anne Irwin
- (d) Vincent Sharkey, Jr.
- (e) Lewis Lefkowitz

13. 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 the documents:

- ✓ (a) the application dated December 30, 1981, with attachments, signed by Clyde N. Cole.
- ✓ (b) the letter dated March 26, 1982, signed by Rodney L. Detrow, with attachments.
- ✓ (c) the two letters dated April 7, 1982 signed by Rodney L. Detrow, with attachments.
- (d) letter dated December 7, 1982, signed by Clyde N. Cole with attachments.
- (e) letter dated January 20, 1983, signed by Clyde N. Cole with attachments.

not avail.

(cont'd)

APPENDIX A

TRAINING AND EXPERIENCE
FOR AUTHORIZED USERS AND DAY-TO-DAY RADIATION SAFETY OFFICER

Paragraph 30.33(a)(3) of 10 CFR Part 30 requires that applicants be qualified by training and experience to use licensed material for the purpose requested in the application. In the case of a nuclear pharmacy operation, the NRC reviews the training and experience of the individuals who are to be listed as authorized users to determine whether they meet this requirement. Any individual who has sufficient training and experience to be named as an authorized user is also considered qualified to serve as the day-to-day radiation safety officer (RSO).

NOTE: An individual specifically listed as an authorized user on a previous nuclear pharmacy license issued by NRC or an Agreement State is considered to have adequate training and experience. In these cases, instead of documenting the individual's training and experience, simply specify the number of the NRC nuclear pharmacy license or submit a copy of the Agreement State license on which the proposed user was specifically listed as an authorized user.

This appendix lists the training and experience that the NRC finds acceptable for individuals who are to be named as authorized users or as RSO on licenses that involve the preparation and distribution of radiopharmaceuticals. These criteria evolved from NRC's guidelines for physicians in hospital nuclear medicine programs because the type of use and the degree of radiation hazard are quite similar. (See Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs.")

1. Training in basic radioisotope handling techniques specifically applicable to the use of unsealed sources (200 hours). This training should consist of lectures and laboratory sessions in the following areas:

- | | |
|---|------------|
| a. Radiation physics and instrumentation | (85 hours) |
| b. Radiation protection | (45 hours) |
| c. Mathematics pertaining to the use and measurement of radioactivity | (20 hours) |
| d. Radiation biology | (20 hours) |
| e. Radiopharmaceutical chemistry | (30 hours) |

The hours listed above are suggested values; however, the training should emphasize radiation physics, instrumentation, and radiation protection, with no less than 130 hours total devoted to these subject areas.

On-the-job training may not count toward the hours listed above unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

- a. A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the NRC upon request.
 - b. Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to NRC upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.
 - c. A permanent record that the student successfully completed the course is kept at the institution.
2. Experience in handling unsealed radioactive material under the supervision of an authorized user (500 hours). This experience should cover the types and quantities of byproduct material requested in the application and should include:
- a. Ordering, receiving, and unpackaging radioactive materials safely, including performing related radiation surveys,
 - b. Calibrating dose calibrators, scintillation detectors, and survey meters,
 - c. Calculating, preparing, and calibrating patient doses, including properly using radiation shields,
 - d. Following appropriate internal control procedures to prevent mislabeling errors,
 - e. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests,
 - f. Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing

the eluate with reagent kits to prepare technetium-99m-labeled radio-pharmaceuticals.

You may use a format similar to that shown in Figures A-1 and A-2 for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02500
STATUS CODE: 0
FEE CATEGORY: 3C
EXP. DATE: 19880831
FEE COMMENTS: -----

(also 3V)
not
added yet

LICENSE FEE TRANSMITTAL

4. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: MALLINCKRODT, INC.
RECEIVED DATE: 880601
DOCKET NO: 3020537
CONTROL NO.: 109006
LICENSE NO.: 37-21345-01MD
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: 230.00
CHECK NO.: 10203270

3. COMMENT

SIGNED BP
DATE 6/8/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1-75)

1. FEE CATEGORY AND AMOUNT: 3C 3V \$ 230

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED S. Kimberley
DATE 2/17/89