VOID SHEET

TO: License Fee Management Branch

FROM: RII

SUBJECT: VOIDED APPLICATION

Control Number: 255925

Applicant: Aetas Corp.

Date Voided: 6/8/94

Reason for Void: Licensee request
See letter dated 6/1/94

Diane O. Kern
Signature Date

1994 JUN 21 AM 11:37

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund Authorized and processed

☑ No Refund Due

☐ Fee Exempt or Fee Not Required

Comments: After Review

Log completed ☑

Processed by: Kim

200089

ML20

OFFICIAL RECORD COPY

JUN 08 1994

Mallinckrodt Medical, Inc.
ATTN: Mr. Warren Fadling, Director
Radiopharmacy Operations
P.O. Box 5840
St. Louis, Missouri 63134

Gentlemen:

SUBJECT: ABANDONMENT OF AMENDMENT REQUEST (REFERENCE: MAIL CONTROL NO. 255925; DOCKET NO. 030-33174)

As requested by your letter dated June 1, 1994, we have stopped work on the May 25, 1994 request for amendment to License No. 45-25251-01MD. The licensee is Aetos Corporation, Norfolk, Virginia. We shall also notify the licensee. Since technical evaluation of the amendment had begun, no refund of the fee paid is appropriate.

Thank you for your cooperation in this matter. Should you have questions, please contact me at 404-331-5624.

Sincerely,

ORIGINAL SIGNED BY
DAVID J. COLLINS.

David J. Collins
Health Physicist
Nuclear Materials Licensing Section

cc:
Aetos Corporation
ATTN: Mr. Barry Slaughter
President
3301 Colley Avenue
Norfolk, Virginia 23508-3016

bcc:
NMSS Reading File

SEND	OFC	RII:DRSS	RII:DRSS			
TO	NAME	DJCollins DJ Collins	JPPotter			
PDR?	DATE	06 / 07 /94	6/8 /94	/ /94	/ /94	/ /94
Yes No	COPY?	Yes No	Yes No	Yes No	Yes No	Yes No

OFFICIAL RECORD COPY DOCUMENT NAME: G:\DRSS\255925.DJC

MALLINCKRODT
Nuclear Medicine

June 1, 1994

Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
PO Box 5840
St. Louis, MO 63134
Telephone (314) 895 2000

David Collins
U.S. Nuclear Regulatory Commission, Region II
Nuclear Materials Safety Section
101 Marietta Street, N.W.
Suite 2900
Atlanta, GA 30323

RE: Material License #45-25251-01MD

Dear Mr. Collins:

Per your conversation with Chris Wagner today, please allow this letter to serve as notification to terminate a license amendment application submitted by Mallinckrodt Medical, Inc., dated May 25, 1994.

This application was intended to address Mallinckrodt's potential acquisition of certain Aetos Corporation, of Norfolk, VA, assets. A decision has been reached to discontinue negotiations for this purchase. As a result, the application submitted to your office is being withdrawn.

Mallinckrodt wishes to express its appreciation for the prompt and considerate response by NRC and you for being prepared to act upon this application in an expedited manner.

If you should have a further need to contact me, please feel free to do so at (314) 895-2200. Thank you.

Sincerely,

Warren Fadling
Director of Radiopharmacy Operations

cc: Scott Surovi

CONVERSATION RECORD

TIME | DATE

TYPE
☐ VISIT ☐ CONFERENCE ☐ TELEPHONE
☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Chris Wagner	Mallinckrodt	610 314 895-2588

SUBJECT: LICENSING DEFICIENCY TELEPHONE CALL

{ } New { } Renewal ☒ Amend

License | Docket | Control

SUMMARY

FAX

Cretos – purchase for Scott Sorovi

① deal will go thru – lease assets for 90 days for legal notifications

② Becky Fire will not move to Mallinckrodt

③ alternate RSO's listed on license

6/1/94 Withdraw application per Chris Wagner

today a letter will be sent!

SEE OVER - Yes No

Due Date

ACTION REQUIRED

Return papers?
Void action upon receipt of ltr

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
David J. Collins	DJCollins	6/1/94

ACTION TAKEN

SIGNATURE	TITLE	DATE

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 2B
EXP. DATE: 19980731
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: AETOS CORPORATION
RECEIVED DATE: 940527
DOCKET NO: 3033174
CONTROL NO.: 255925
LICENSE NO.: 45-25251-01MD
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 490 00
CHECK NO.: 067108

3. COMMENTS

SIGNED Diane Heim
DATE 5/31/94

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /-4-)

1. FEE CATEGORY AND AMOUNT: 3C 2B $490

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

3. OTHER

SIGNED Peter Mosier
DATE 6/7/94

NRC FORM 313
(3-92)
10 CFR 30, 32 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATION WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATION AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
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:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

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 JURISDICTIONS.

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

	A. NEW LICENSE
X	B. AMENDMENT TO LICENSE NUMBER 45-25251-01MD
	C. RENEWAL OF LICENSE NUMBER _____

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

Mallinckrodt Medical Inc.
Nuclear Medicine Division
P.O. Box 5840
675 McDonnell Boulevard
St. Louis, Missouri 63134

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

Mallinckrodt Medical Inc.
Diagnostic Imaging Services
3301 Colley Avenue
Norfolk, Virginia 23508-3016

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION — TELEPHONE NUMBER

Scott J. Surovi, Senior Consultant, NMA Medical Physics Consultation — (610) 532-0935

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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 $490.00

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 OFFICIAL	TYPED/PRINTED NAME	TITLE	DATE
Warren K. Fadling	Warren K. Fadling	Director, DIS/NMA Operations	5/23/94

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS
Amd	Jun 1 II	3C 2B	
AMOUNT RECEIVED	CHECK NUMBER		
490	009148		

APPROVED BY: Peter Mesler — DATE: 6/7/94

NRC FORM 313 (3-92)

MALLINCKRODT
Nuclear Medicine

May 25, 1994

Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
PO Box 5840
St. Louis, MO 63134
Telephone (314) 895 2000

Mr. David Collins
U.S. Nuclear Regulatory Commission. Region II
Nuclear Materials Safety Section
101 Marietta Street, N.W.
Suite 2900
Atlanta, GA 30323

PLEASE EXPEDITE LICENSING ACTION

RE: Material License 45-25251-01MD

Dear Mr. Collins:

Enclosed please find an amendment application for your review. As indicated during recent communication with your office, Mallinckrodt Medical, Inc. intends to acquire the nuclear pharmacy operations presently controlled by Aetos Corporation (3301 Colley Avenue, Norfolk, Virginia). The business transaction between Mallinckrodt Medical, Inc. and Aetos Corporation is scheduled for Thursday May 26, 1994 at 12:00. Therefore, it is requested that review of the application be considered a priority in order for Mallinckrodt Medical, Inc. to remain within current regulatory guidelines.

The following information addresses the items listed in "Guidelines for Material Licensing Cases Involving Change of Ownership" which was forwarded to our attention on May 20, 1994. These responses numerically correspond to this guide and should provide adequate information regarding our pending transaction with Aetos Corporation.

1. The name of the organization shall be changed from Aetos Corporation to Mallinckrodt Medical, Inc. The mailing address for this material license is identified in Item 2 of the attached application (NRC Form 313). The location of use shall remain the same: 3301 Colley Avenue, Norfolk, Virginia 23508-3016.

2. It is our intention to delete Leon J. Penny, Jr. and Nirupama Matani, R.Ph. as users from this material license. Rebecca M. Fire, R.Ph., Radwan Jaber, R.Ph. and David Askew, R.Ph. shall remain as authorized users as identified in Condition 11.

   In addition, it is our intent to name Amy Smith, R.Ph. as an authorized user at this time. Ms. Smith is presently listed on material license L03008 issued to Mallinckrodt Medical, Inc. by the Texas Department of Health. Additionally, documentation is included with this application identifying Ms. Smith's training and experience with radioactive materials. All licensing and training documentation may be referenced in Appendix A of the attached application.

3. Aetos Corporation will not remain as part of the nuclear pharmacy operations once the business transaction is completed.

4. Mallinckrodt Medical, Inc. shall acquire assets during the May 26, 1994 transaction. There will be no acquisition of Aetos Corporation stock. Confirmation of asset acquisition shall be provided following closure.

5. The location of use, facilities, equipment and established procedures shall remain the same as identified in the existing application. However, some of the commitments made by Aetos Corporation shall be modified in order to meet current Mallinckrodt Corporate and regulatory requirements. Please refer to the attached application for details regarding these proposed changes.

   As mentioned in response 2 of this document, Rebecca M. Fire, R.Ph., Radwan Jaber, R.Ph., David Askew, R.Ph. and Amy Smith, R.Ph. are to remain as authorized users. In addition, it is requested that consideration be given allowing Mallinckrodt Medical, Inc. to name users to this material license. Information is included in the attached application (Item 7.1) identifying our established program.

   Rebecca M. Fire, R.Ph. shall be replaced as Radiation Safety Officer to this material license. Amy Smith, R.Ph. shall serve as the Radiation Safety Officer as referenced in Item 7.2 of the attached application.

   Additionally, information is included with the attached application regarding limited authorized use by member of the NMA Medical Physics Consultation (Mallinckrodt Medical, Inc.) staff. This organization assists nuclear pharmacy

personnel with various radiation safety and regulatory compliance issues. A copy of the material license issued to NMA is provided in Appendix B of the attached application.

6. There shall be no changes implemented with respect to use and/or storage of licensed materials at this time. However, it is our intent to increase the existing possession limits of Technetium-99m, Molybdenum-99 and depleted Uranium (for shielding). Please refer to Item 5 and 6 of the attached application for details.

7. Information regarding Mallinckrodt's shipping and waste retrieval policies has been addressed in the attached application. Minor revisions shall be implemented in order to meet with current Mallinckrodt Corporate policy as well as revised regulations.

8. All surveillance items and records (radioactive inventory and accountability requirements) shall not be effected as a result of this business transaction. Required calibrations of instrumentation, sealed source inventory and leak testing, and area monitoring results will be current at the time of transfer.

9. Surveys shall be completed to ensure that contamination does not posse a threat to personnel nor the general public. In the event removable contamination is identified by nuclear pharmacy personnel, before or after the transfer, appropriate steps shall be taken to decontaminate in accordance with current license conditions and regulations. Records of surveys will be available for inspection upon request.

10. As stipulated in Condition 23 to material license 45-25251-01MD, "the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance." In addition, Mallinckrodt Medical, Inc. shall abide by Condition 24 to material license 45-25251-01MD regarding the decommissioning of the facility known as 3301 Colley Avenue, Norfolk, Virginia.

11. Mallinckrodt Medical, Inc. agrees to abide by all commitments and representations made by Aetos Corporation with exception to those items identified in the attached application. This includes financial assurance and decommissioning.

Additionally, Mallinckrodt Medical, Inc. accepts full liability for decommissioning the site with respect to the use of licensed materials (limited to radioactive materials) referenced in material license 45-25251-01MD.

12. Documentation identifying the transfer of ownership from Aetos Corporation to Mallinckrodt Medical, Inc. shall be forwarded upon closure.

13. Mallinckrodt Medical, Inc. shall abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license with exception to those items identified in the attached application. In addition, Mallinckrodt Medical, Inc. shall accept full liability for the site with respect to use of licensed materials identified in material license 45-25251-01MD prior to transfer.

As referenced previously, information is included with this document regarding proposed changes to be implemented by Mallinckrodt Medical, Inc. The attached application identifies these changes which allow for consistent operations throughout the Mallinckrodt nuclear pharmacy network.

I thank you in advance for your prompt attention regarding this matter. In the event additional information is required, please contact Scott Surovi at (610) 532-0935.

Sincerely,

Warren K. Fadling
Director DIS/NMA Operations

enclosure

MALLINCKRODT
Nuclear Medicine
Diagnostic Imaging Services

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 5 & 6 - Radioactive Materials/Uses

Byproduct Materials	Chemical/Physical Form	Possession Limit	Description of Use
D. Technetium-99m	Any form listed in Sections 35.100 and 35.200 of 10 CFR, Part 35.	200 Ci	Distribution and preparation of reagent kits and radiopharmaceuticals. Distribution and use as check, calibration, or reference source. Storage of contaminated vials syringes, and needles returned by customers.
F. Molybdenum-99	Any Mo-99/Tc-99m generator, manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR, Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations.	200 Ci	Elution of Tc-99m Pertechnetate. Redistribution of unused Mo-99/Tc-99m generators.
J. Uranium (depleted in the isotope U-235)	Metal encased in stainless steel.	600 kg	Shielding for Mo-99/Tc-99m generators.

MALLINCKRODT
Nuclear Medicine
Diagnostic Imaging Services

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 7 - Proposed Authorized Users and Radiation Safety Officer (RSO)

7.1 Authorized User, Internal Committee Named

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 users. This review process will be carried out by a committee made up of the following individuals:

- Director DIS and NMA Operations, Nuclear Medicine Division
- Manager, DIS Operations, Nuclear Medicine Division
- DIS Regional Manager, Nuclear Medicine Division

At least two members of this committee will review the submitted materials for compliance with training and experience recommendation.

Acceptance of proposed authorized users will be based upon guidelines outlined in:

> Appendix A, "Training and Experience for Authorized Users and day-to-day Radiation Safety Officer," Guide for the Preparation of Applications for Nuclear Pharmacy Licensees" (August 1985).

It will be assured that didactic training was provided to the prospective user in a formalized lecture format and will not consist of any form of home study nor on-the-job training.

A master list of authorized users will be compiled. Training and experience documentation for each on-site authorized user will be maintained for regulatory review.

Approval of this authorization request is in no way intended to exempt the licensee from the training requirements outlined in 10 CFR, Part 19.12.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 7 - Proposed Authorized Users and Radiation Safety Officer (RSO)

7.2 Radiation Safety Officer's (RSO) Duties

The RSO will spend a majority of his/her time fulfilling the following duties and responsibilities:

A. General surveillance over all activities involving radioactive material, including routine monitoring and special surveys.

B. Ensuring compliance with the rules, regulations and conditions of the NRC and/or applicable State regulations and license.

C. Monitoring the performance of fumehoods and/or glove boxes that are associated with radioisotope work.

D. Serving as the primary source of radiation protection information for facility personnel at all levels of responsibility.

E. Supervising the receipt, opening and storage of all shipments of radioactive material arriving at the nuclear pharmacy.

F. Supervising the preparation and packaging of all shipments of radioactive material leaving the nuclear pharmacy.

G. Supervising the distribution and processing of personnel monitoring equipment.

H. Conducting or supervising and coordinating the radiation safety training and instructional programs for facility personnel.

I. Supervising and coordinating the radioactive waste disposal program.

J. Supervising the safe storage of all radioactive materials not in current use.

K. Ensuring that sealed sources are inventoried and leak tested at proper intervals.

L. Maintaining an inventory of all radioisotopes and limiting the quantity of radionuclides at the facility to the amounts authorized by the license.

The remaining time will be spent in administering corporate policies, preparing and dispensing radiopharmaceuticals, and controlling purchasing and accounting procedures directly associated with the facility. In the absence of the RSO (i.e., in the early morning when only one authorized user is present, when the RSO is ill or on vacation, etc.), an authorized user will assume the duties of the RSO in order to ensure compliance with NRC and/or applicable State regulations and the terms and conditions of the license.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 7 - Proposed Authorized Users and Radiation Safety Officer (RSO)

7.3 Radiation Safety Officer

Amy Smith, R.Ph.

Refer to license L03008 issued by the Texas Department of Health for evidence of training and experience (Appendix A).

7.4 Limited Authorized Use

A request is made for authorization of individuals who are specifically named as users in Condition #12 of NRC License 34-16272-01, issued to Mallinckrodt Medical, Inc., NMA Medical Physics Consultation, to use licensed material for the calibration of survey instrumentation and to carry sealed sources to client facilities for intercomparison of dose calibrators for energy linearity and accuracy checks.

We also request authorization to perform leak/wipe testing of sealed sources with subsequent analysis for our client industries, hospitals, clinics and nuclear pharmacies. Refer to NRC License 34-16272-01 (Appendix B) for evidence of training, experience and methodologies that will be employed to perform the above-mentioned procedures.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

10.1 Personnel Monitoring Program

All individuals working in or frequenting restricted areas shall be issued and assigned a whole body badge (film or thermoluminescent-TLD dosimeter) in accordance with circumstances described in 10 CFR 20.1502. Also, ancillary personnel (i.e., clerical and drivers) shall be issued and assigned a whole body badge. This device shall be worn at all times when on duty.

All individuals who elute, prepare, assay or dispense millicurie quantities of radioactive material shall be issued at least one extremity monitor, such as a TLD ring badge, in addition to the whole body badge.

Both the whole body and ring badges will be exchanged for processing at intervals not to exceed one month. Processing of these personnel dosimetry devices will be conducted by a commercial personnel dosimetry service or a processor which is currently accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).

Visitors and subcontracted employees whose business or work requires entry to restricted areas shall be issued and assigned a self-reading pocket dosimeter. These devices shall be worn at all times when on site. The normal exchange frequency is as needed. All self-reading dosimeters will be calibrated at intervals not to exceed one year. A visitor's log book will be maintained in order to document any measured exposure as described in 10 CFR 20.1301 and 20.1502.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

10.9 Procedures for Retrieving Radioactive Waste from Customers

Mallinckrodt Medical, Inc. will pick up for disposal only those items which contain or are contaminated with radiopharmaceuticals supplied by Mallinckrodt Medical, Inc. The customer will be responsible for other waste generated within their facilities.

Customer. The following procedures must be followed for PACKAGING of radioactive waste for return to Mallinckrodt Medical, Inc.:

1. All vials and syringes must remain in their original, labeled lead shield.
2. All shipping containers must comply with D.O.T. regulations.
3. Containers must be sealed, labeled, and monitored (by the shipper).
4. A Radioactive Materials Transfer Record should accompany any package of radioactive waste returned to Mallinckrodt Medical, Inc. (An example copy is included on the next page)

Driver or Courier. The following procedures must be followed for PICK-UP of radioactive waste for return to Mallinckrodt Medical, Inc.:

1. Check all documents for completeness.
2. Ensure containers are properly sealed.
3. Ensure package is properly labeled (per D.O.T. regulations).
4. One copy of the transfer record is left with the customer and the original will be filed in the Mallinckrodt Medical, Inc. nuclear pharmacy as a permanent record of the transfer and disposal.
5. Radioactive waste will not be picked up if the packages are not properly labeled and sealed.
6. Material will be transported in an exclusive use vehicle.

Nuclear Pharmacy. The following procedures must be followed upon RECEIPT of the radioactive waste by the nuclear pharmacy:

1. The package shall be monitored for removable contamination.
2. The results of these tests will be recorded.
3. Returned waste shall be incorporated into the facility waste disposal system.
4. Syringe and vial shields recovered from clients will be surveyed to ensure no contamination prior to reuse. Contaminated shields will be decontaminated or held separately for decay while in temporary storage.

MALLINCKRODT
Nuclear Medicine
Diagnostic Imaging Services

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

Section 1: SHIPPED FROM	Section 2: SHIPPED TO:
Name	MALLINCKRODT MEDICAL, INC. Diagnostic Imaging Services Street Address City, State, Zip Code
Address	

Section 3: PACKAGE ACTIVITY FOR LIMITED QUANTITY SHIPMENTS

(Based on 10^{-4} A_2 values as stated in 10 CFR Title 49, Part 173.421)

Co-57	9	mCi	Mo-99	2	mCi
Co-58	2	mCi	P-32	3	mCi
Cr-51	60	mCi	Se-75	4	mCi
Fe-59	1	mCi	Tc-99m	10	mCi
Ga-67	10	mCi	Tl-201	20	mCi
I-123	5	mCi	Xe-127 (uncompressed)	7	mCi
I-125	7	mCi	Xe-133 (uncompressed)	100	mCi
I-131	1	mCi	Yb-169	8	mCi
In-111	2.5	mCi	Re-186	2	mCi

When shipping more than one type of radioactive material in the same package, the activity limit of the total package is determined by the smallest value assigned to the material.

Section 4: CERTIFICATION

A. THE TOTAL AMOUNT OF RADIOACTIVE MATERIAL IN THIS PACKAGE DOES NOT EXCEED THE SPECIFIED AMOUNT LISTED IN SECTION 3.

B. THE RADIATION LEVEL AT ANY POINT ON THE EXTERNAL SURFACE OF THE PACKAGE DOES NOT EXCEED 0.5 mR/hr (AS DETERMINED WITH A LOW LEVEL SURVEY METER).

C. EXTERNAL PACKAGE SURFACE WIPE TEST INDICATES NO REMOVABLE CONTAMINATION IN EXCESS OF 6600 dpm/300 cm^2.

SURVEY SURFACE: _____ mR/hr WIPE TEST: _____ dpm

SIGNED: _____ DATED: _____

BASED ON THE CERTIFICATION IN SECTION 4, THIS PACKAGE CONFORMS TO THE CONDITIONS AND LIMITATIONS SPECIFIED IN 49 CFR 173.421 FOR EXCEPTED RADIOACTIVE MATERIAL, LIMITED QUANTITY, N.O.S., UN 2910.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

10.6 Procedures for Safely Opening Packages Containing Radioactive Materials

1. Put on protective gloves to prevent hand contamination.

2. Visually inspect package for any sign of damage. If damage is noted, stop procedure and notify the Radiation Safety Officer (RSO).

3. Measure exposure rate at 1 meter from package surface and record. If > 10 mR/hr, stop and notify the RSO.

4. Measure surface exposure rate and record. If > 200 mR/hr, stop and notify the RSO.

5. Monitor surface of package for contamination and record. If > 6600 dpm/300 cm^2, stop and notify the RSO.

6. Open the package with the following precautionary steps and record receipt of the radioactive material:

   a. Open the outer package and remove packing slip.

   b. Verify that contents agree with those on packing slip. Compare purchase order, packing slip and label on product.

   c. Check that the shipment does not exceed possession limits.

   d. Monitor the packing material and packages for contamination before discarding.

      - If contaminated, treat as radioactive waste.
      - If not contaminated, obliterate the radiation labels before discarding.

7. If there is evidence of degradation of package integrity, wipe the external surface of the final source container. Check the wipe for contamination in a low background area using a G-M survey meter and take the necessary precautions against the spread of contamination.

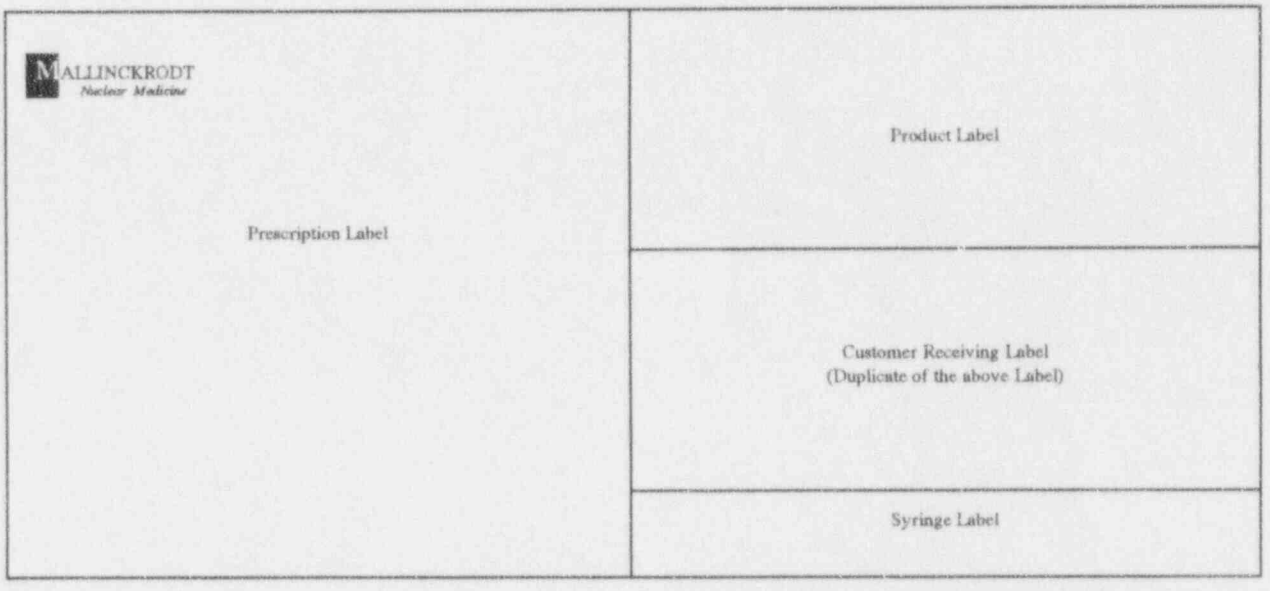
8. Records of exposure rate and contamination surveys in Items 3, 4, and 5 will be maintained for at least three (3) years. Records of receipt of byproduct material will be maintained for at least three (3) years.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

10.13 Product Labels

The product labels originate as a multiple part form consisting of four unique areas: a multi-layered prescription record on the left half and a single layer adhesive product container label, a single layer adhesive customer receiving book label (a duplicate of the product container label), and a single layer syringe label on the right half.



The label affixed to each final product container will contain information regarding the prescription dose such as the radiopharmaceutical name, quantity and expiration. If the radiopharmaceutical is tagged with Technetium-99m, it will specify the total activity or concentration of Molybdenum-99 and expiration date and time.

The prescription number will link the labeled syringe and/or product container to the prescription record should they be inadvertently separated. The product label will contain the appropriate designation of group number (35.100, 35.200, etc.), as needed.

A sample of an actual label currently used is attached as Appendix C for reference.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

10.14 Product Shielding

Injectable radiopharmaceuticals are shipped in sterile pyrogen-free multiple dose vials or unit dose syringes. The individual vials and syringes are packaged inside lead containers which provide shielding and serve as a secondary container. The lead shields used for shipping vials and syringes range from 1/8-inch to 3/8-inch thickness.

The unit dose products will be shipped in reusable unit dose shipping containers. Absorbable foam inserts (either convoluted to hold any shape package or die cut to hold unit dose syringe shields) will be used in the shipping container. Shipping containers are closed by spring-type locking latches. A security seal will be placed through the latches to prevent tampering. Upon return from client, shipping containers will be surveyed before reuse.

Schematic drawing of lead shields for vials and syringes, as well as various shipping containers, can be referenced in Appendix D.

Shipping activities and radiation fields expected from shipping containers are also outlined within Appendix D.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

10.15 Procedures for Packaging and Transporting Radiopharmaceuticals

A. General Procedures for Packaging

After radiopharmaceutical doses are prepared, assayed, labeled, and placed within shielded containers, they will be packaged for shipment. Maximum radiation exposure for the package to be transported will not exceed the D.O.T. specifications for a Yellow-III label; the surface radiation exposure must be less than 200 mR/hr and the transport index less than 10 mR/hr.

D.O.T. diamond labels of White-I or Yellow-II will be used to label packages containing radioactive materials for transport. The D.O.T. specifications for marking packages containing radioactive materials for transport, such as Type A, Class 7, ID number (UN), upright arrows, etc., will be met.

A Bill of Lading for Radioactive Materials form will be used for packages shipped. This form conforms to D.O.T. standards. A bill of lading form will be filled out for each delivery of radioactive materials. A copy of the signed bill of lading will be returned to the nuclear pharmacy.

Delivery instructions will be obtained from customers for shipments of radioactive materials. The driver or courier will be instructed to leave the packages only in secured areas as designated by the customer.

Radioactive shipments will be carried in the cargo area of the delivery vehicle. Unauthorized passengers are not permitted to accompany the driver. Vehicles will be locked when unattended.

B. Instructions for Mallinckrodt Delivery Personnel.

1. Unauthorized passengers are not permitted in delivery vehicles.
2. Lock vehicle when it is left unattended.
3. Leave packages only in areas designated by the customer. Have the package signed for whenever possible.
4. In the event of an accident or emergency, notify the Radiation Safety Officer as soon as practical. If radioactive material has been spilled, obtain instructions from the RSO. Contain the spill if possible with the emergency spill kit stored in the passenger area of the vehicle. Wait for help or further instructions.
5. Attend annual refresher courses for radiation safety training.

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

10.15 Procedures for Packaging and Transporting Radiopharmaceuticals *(..continued)*

C. Emergency Kit and Instructions

The following information is a description of the Emergency Spill Kit which will be carried in the passenger area of each vehicle. Drivers will be trained in the use of this kit.

The emergency spill kit will be available in each vehicle. This kit will be a package that contains the following suggested materials:

A large manila envelope or box containing the following materials:

2 Pairs of protective gloves
2 Large garbage bags (plastic, heavy duty)
4 Chux (plastic-backed absorbent paper)
Paper towels
Heavy duty tape, tongs, small packet dry soap, small bottle of water
Radioactive warning labels or tape
Instructions on cleaning up a radioactive spill
Emergency phone numbers

The envelope or box should be sealed and placed within the passenger area of the vehicle. On the external surface of the envelope or box shall be an address label type the following:

Mallinckrodt Medical, Inc.
Diagnostic Imaging Services

* In case of emergency or if driver is unconscious, call the Radiation Safety Officer at: (xxx) xxx-xxxx

Mallinckrodt Medical: (facility phone #)
Facility Manager: (name and home phone #)

RADIOACTIVE MATERIALS LICENSE APPLICATION

Item 10 - Radiation Safety Program

10.16 Radiation Protection Surveys

Individuals employed by NMA Medical Physics Consultation (Mallinckrodt Medical, Inc.) will conduct quarterly surveys of the nuclear pharmacy Radiation Safety Program. The individuals currently employed by NMA that will conduct audits of the nuclear pharmacy are listed on NRC license 34-16272-01.

Please refer to the same license for the proof of training and experience.

The purpose of these surveys will be to assist in the maintenance of NRC regulatory and licensure compliance. Areas of non-compliance will be noted in a written report.

A copy of the quarterly survey results will be forwarded to the Facility Manager and Radiation Safety Officer (RSO) of the nuclear pharmacy,as well as the upper management personnel at Corporate headquarters.

APPENDIX A

TRC Form 12-1
7/90

Texas Department of Health
BUREAU OF RADIATION CONTROL

052813

RADIOACTIVE MATERIAL LICENSE

Pursuant to the Texas Radiation Control Act and Texas Health Department 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 Medical, Inc.
ATTN: Lori DeVos, R. Ph.
2. Address: 8078 El Rio
Houston, Texas 77054

This license is issued pursuant to and in accordance with a letter
Dated: February 7, 1994
Signed by: Lori DeVos, R.Ph.

3. License Number	Amendment Number
L03008	34

PREVIOUS AMENDMENTS ARE VOID

4. Expiration Date: May 31, 1996

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 radiopharmaceutical approved by the United States Food and Drug Administration (FDA)	A. No single radionuclide to exceed 700 mCi except: Tc-99m not to exceed 100 Ci; Tl-201 not to exceed 1.3 Ci	A. For receipt, storage, and preparation in accordance with applicable FDA approved protocols, and dispensing upon prescription to authorized recipients.
B. Mo-99	B. FDA approved Tc-99m generators	B. 100 Ci	B. Production of Tc-99m. Distribution of generators or eluate to authorized recipients.
C. Co-57, Cs-137, Ba-133	C. Sealed reference sources	C. No single source to use exceed 10 mCi. Total: 15 mCi	C. Reference sources for receipt storage and distribution to authorized recipients.
D. I-131	D. Solution or capsules	D. 5 Ci	D. For receipt, storage, preparation, and dispensing upon prescription to authorized recipients
E. Xe-127/ Xe-133	E. Any radiopharmaceutical	E. 5 Ci	E. For receipt, storage, and preparation in accordance with applicable FDA approved protocols and dispensing upon prescription to authorized recipients.
F. In-111	F. Oxine in non-pharmaceutical grades	F. 50 mCi	F. Pharmaceutical refinements labeling of leukocytes in accordance with FDA approved protocol and distribution upon prescription to authorized recipients.

TRC Form 12-1
7/90

Texas Department of Health
BUREAU OF RADIATION CONTROL

052814

RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
L03008	34

5. Radioisotope	6. Form of Material	7. Maximum Activity*	8. Authorized Use
G. Tc-99m	G. Tc-99m - HMPAO (Amersham: Ceretec)	G. No single prescription to exceed 10 mCi	G. For labeling autologous leukocytes in accordance with procedures dated March 25, 1992 and May 8, 1992, and dispensing upon presentation of a written directive, signed by an authorized user, to specifically authorized recipients.
H. Any radioactive material	H. Any solid	H. No single nuclide to exceed 6 mCi	H. As authorized by Texas Regulations for Control of Radiation (TRCR) 41.26(b)(4), for transport to authorized licensees for calibration of instruments under the client's license authorization.
I. H-3,C-14, Co-57/58/60, Fe-59,Se-75, I-125/131	I. As test kit reagents in FDA approved *in vitro* test kits	I. 100 mCi	I. For receipt, storage and redistribution to authorized recipients as *in vitro* test kits provided the kit packaging is not violated nor package inserts removed.

9. Radioactive material shall be used at:

Site Number	Location
000	Houston - 8078 El Rio

10. The licensee shall comply with the provisions of Parts 11, 12, 13, 21, 22, 40 and 41 of the TRCR.

11. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is Lori DeVos, R.Ph.

12. Radiation survey instruments used in the licensee's own radiation safety program shall be calibrated at intervals not to exceed 12 months. Instruments routinely transported shall be so calibrated at intervals not to exceed six months.

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Texas Department of Health
BUREAU OF RADIATION CONTROL

052815

RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
L03008	34

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

Quent Bosing, R.Ph.
Rodney L. Detrow, R.Ph.
Lori DeVos, R.Ph.
Allen Fazekas, R.Ph.
Kevin A. Grilley, R.Ph.
Dawn Renee Harris, R.Ph.
Scott Peter Knishka, R.Ph.
Tim Layne, R.Ph.
John P. Minella. R.Ph.
Thomas E. McKean, Jr., R.Ph.
Richard A. Nickel, R.Ph.
Lloyd W. Nye, R.Ph.
Barbara D. Scavullo, R.Ph.
Amy Smith, R.Ph.
Kenneth Williamson, R.Ph.
Alice T. Worthen, R.Ph.

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 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 licensed pharmacist.

14. Radiopharmaceuticals that are procured shall be from another licensed nuclear pharmacy or from a supplier who distributes the radiopharmaceutical under the New Drug Applications (NDA's) or Investigative New Drug Application (IND) approved by the FDA.

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. A written report shall be submitted to the Agency within 30 days of such an occurrence.

16. A. The Tc-99m pertechnetate may be eluted and prepared from a Mo-99/Tc-99m generator provided the generator has been approved by the FDA for routine usage under an approved NDA. Such elutions of the generator must be made in accordance with the manufacturer's instructions.

B. The licensee shall test each elution of Mo-99/Tc-99m generators to determine the concentration of Mo-99 activity in the Tc-99m preparation. Records of these tests shall be maintained for inspection by the Agency and shall indicate the date, generator serial number, Mo-99 concentration in μCi per mCi of Tc-99m, and name of person performing the test.

C. The licensee shall not distribute any preparation containing more than 0.15 μCi of Mo-99 per mCi of Tc-99m at the scheduled administration time.

TRC Form 12-1
7/90

Texas Department of Health
BUREAU OF RADIATION CONTROL

052816

RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
L03008	34

17. Radiopharmaceuticals authorized by this license which contain Tc-99m may be prepared from kits, provided the kits used have been accepted or approved for distribution by the FDA.

18. Radiopharmaceuticals are to be dispensed only upon the prescription of a specifically licensed physician who is authorized to possess and use such radiopharmaceuticals. 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.

19. 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.

20. 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 United States Department of Transportation (DOT) regulations.

21. The licensee shall use a properly calibrated dose calibrator to assay all single and multiple dose radiopharmaceuticals which are dispensed and shall provide appropriate assay data with each dose dispensed. However, when the product is distributed in the unopened manufacturer's container with the manufacturer's original assay label attached, additional assay by the licensee is not required. Any additional prescription accompanying the product shall reference the amount dispensed by stating "manufacturer's assay".

22. The licensee shall conduct a physical inventory every six 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 three years from the date of the inventory and shall include the quantities and the kinds of radioactive material, location of sealed sources, the name of the individual taking the inventory, and the date of the inventory.

23. 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.

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7/90

Texas Department of Health
BUREAU OF RADIATION CONTROL

052817

RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
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24. For radiopharmaceuticals where the beta emission is of primary interest, locally prepared or subdivided doses shall be assayed in a properly calibrated dose calibrator after preparation and before dispensing or use. Proper calibration of an ionization-type dose calibrator shall include participation in a standardization protocol with the National Institute for Standards and Technology (NIST), or the pharmaceutical manufacturer, which includes the use of appropriate standard solutions and containers for the radiopharmaceutical of interest. Documentation of such participation shall be retained by the licensee for the duration of the license.

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

application dated April 24, 1991, and
letters dated October 10, 1991, March 25, 1992 and May 8, 1992.

The TRCR shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

WMD:rd

FOR THE TEXAS DEPARTMENT OF HEALTH

Date May 3, 1994

Ralph D. Hoyer
Administrator, Licensing Branch

SUPPLEMENT A

SUPPLEMENT — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Amy Smith, R.Ph.	Texas

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: CLOCK HOURS IN LECTURE OR LABORATORY	TYPE AND LENGTH OF TRAINING: CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	200 Hour Basic Radioisotope Handling Techniques Course held by NMA in the following locations and on the following dates: January 16-20, 1991 Boston, Massachusetts February 11-15, 1991 Boston, Massachusetts March 18-22, 1991 Cleveland, Ohio April 15-19, 1991 Cleveland, Ohio	52	33
b. RADIATION PROTECTION	"	30	15
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	20	0
d. RADIATION BIOLOGY	"	20	0
e. RADIOPHARMACEUTICAL CHEMISTRY	"	18	12

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

Mallinckrodt

Mallinckrodt Medical, Inc.

DIAGNOSTIC IMAGING SERVICES 6078 EL RIO • HOUSTON, TX 77054 • (713) 741-9800

DOCUMENTATION OF HOURS WORKED UNDER THE DIRECT SUPERVISION OF LORI L. DEVOS, R.PH., R.S.O. FOR AMY SMITH, R.PH.

HOURS WORKED FOR THE WEEK ENDING	8/23/90	18
	9/30/90	47.5
	10/7/90	47.5
	10/14/90	47.5
	10/21/90	47.5
	01/20/91	17
	01/27/91	22.5
	02/03/91	47
	02/10/91	40.75
	02/24/91	44.5
	03/03/91	59
	03/10/91	49
	03/17/91	45
	03/31/91	61.5
	04/07/91	47.5
	04/14/91	44.5

TOTAL HOURS FOR TRAINING PERIOD 686.25.

Lori L DeVos, R.Ph.
Facility Manager

Internship Schedule

material, location of various instruments. This tour should conclude with the intern learning the proper method of exit monitoring.

WEEK ONE

View "Introduction to Nuclear Pharmacy" #1-5 — 10-2-18 / 2-19-91
"Transporting Radioactive Material" — 9-20-90
"DIS Driver Safety Orientation" — 9-20-90
"Back Facts" — 9-30-90
"Mallinckrodt Employee Education on AIDS" — 9-20-90

Discussion topics:
General Radiation Safety Overview — 9-20-90
Nuclear Pharmacy Practice Standards — 9-21-90
Mallinckrodt Safety Program — 9-21-90
Radioactive Materials License (worksheet) — 1-27-91

Pharmacy duties:
Learn how to perform a wipe test — 9-24-90
Learn how to close/heat shrink doses — 9-24-90
Learn how to perform out-going DOT procedures — 9-26-90
Ride with driver/make delivery — 9-27-90
Learn how to check in radioactive shipments — 10-1-90
Learn how to receive hospital returns — 10-5-90
Learn how to segregate radioactive waste — 10-1-90

WEEK TWO

Discussion topics:
Instrumentation — 9-27-90
Tc Generators (includes moly test for file) — 9-27-90
Tc Chemistry — 9-27-90
Decay Calculations (discussion, give problems) — 9-27-90

Pharmacy duties:*
Learn to perform dose set-up with drivers/tech (stats, and standing orders) — 1-28-91
Learn to perform daily area survey/wipe test — 2-4-91
Learn to perform daily MCA consistency — 2-4-91
Learn to perform daily dose calibrator constancy — 2-4-91
Learn to perform daily survey meter constancy — 2-4-91
Learn to elute a generator/ perform moly test — 1-28-91

** the intern should be assigned one or more of these duties to be performed daily. It should be their responsibility to make sure it get done every day. For example, they could set up the standing orders, or perform the daily survey. They should keep this responsibility for an extended period.

Internship Schedule

WEEK THREE

Discussion topics:

Review Dose Calculation problems	1-28-91
In-111 Leukocyte Labeling*	10-1-90
Radiopharmaceutical Quality Control	9-26-90
Dose Drawing Techniques (demonstration)	10-1-90
Tc-99m Imaging	9-26-90

Pharmacy duties:

Practice drawing doses with saline	9-25-90
Perform Dose Drawing exercise	9-26-90
Learn to draw floods	9-26-90
Learn to perform quality control	9-27-90

WEEKS FOUR THROUGH SIX

Discussion topics:

Bone Imaging	10-2-90
Brain Imaging	10-2-90
Renal Imaging	10-3-90
Liver Imaging	10-3-90
Lung Imaging	10-3-90
Cardiac Imaging	10-1-90
Thyroid Imaging and Therapy	10-2-90
Gallium Imaging	10-1-90
P-32, Sodium and Chromic, procedures	10-4-90
Hematology	10-1-90
Monoclonal Antibodies	10-1-90
PET Imaging	4-17-91

Pharmacy duties:

Learn to draw Thalliums	1-28-90
Learn to prepare Tc-99m RP kit	1-28-91
Learn to draw Tc-99m RP dose	1-28-91
Learn to place order with Maryland Hts.	1-28-91
Learn to take orders over phone	1-28-91

Special:

Begin lab research project (QC analysis, etc)	9-27-90
Research clinical question (use Prof. services)	9-27-90
Spend a couple days in hospital nuc. dept.	10-11-90

Internship Schedule

WEEKS SEVEN TO END

Discussion topics:	
Mallinckrodt Computer overview/demonstration	1-14-90
DIS Managerial overview	1-15-91
Pharmacy duties:	
Perform Dose Calibrator linearity test	NMA 4-18-91
Perform Dose Calibrator accuracy test	NMA 4-18-91
Perform Dose Calibrator geometry test	NMA 4-18-91
Setup and calculate Thyroid bioassay	10-1-90
Perform I-131 air monitoring	10-1-90
Work Morning run shift (1 week)	1-28-91 thru 2-1-91
Work a weekend shift	2-2-91
Assist pharmacist with Emergency call-in	4-1-91 thru 4-5-91
Special:	
Go on Sales calls with Sales representative	1-30-91
Present journal article review to pharmacists	10-3-90
Present safety topic to entire staff	10-3-90
Assist NMA consultant with audit (pharmacy or hospital)	4-10-91

Physicians Course
, Jan. 16-20, 1991
Andover, Massachusetts

Prepared: 10/18/90

Day & Date / Time	Wednesday	Thursday	Friday	Saturday @ Medic Warehouse	Sunday Lawrence General
	Jan. 16	Jan. 17	Jan. 18	Jan. 19	Jan. 20
8:00 - 10:00	Radiation Safety: Licensing D. Close	Radiation Safety: Regulations Parts 19-33 D. Close	Radiation Safety: Regulations Parts 19-33 D. Close	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane
10:00 - 12:00	Radiation Safety: Time, Distance & Shielding S. Pontillo	Radiation Safety: Radiation Accidents D. Kane	Radiation Safety Exam D. Close	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane
12:00 - 1:00	L U N C H				
1:00 - 3:00	Radiation Safety: Therapy D. Close	Radiation Safety: Therapy D. Close	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane
3:00 - 5:00	Instrumentation: Scintillation Detectors T. Dickinson	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane
5:00 - 7:00	Instrumentation: Scintillation Detectors T. Dickinson	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation: Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation Scintillation Cameras T. Dickinson/ S. Pontillo/D. Kane	Instrumentation & Exam T. Dickinson/ S. Pontillo/D. Kane

Physicians Course

, Feb. 11-15, 1991
Andover, Massachusetts

Prepared: 10/18/90
Revised: 1/21/91

Day & Date / Time	Monday	Tuesday	Wednesday	Thursday	Friday
	Feb. 11	Feb. 12	Feb. 13	Feb. 14	Feb. 15
8:00 - 10:00	Radiation Biology II R. Weed	Radiation Biology II R. Weed	Radiation Biology II Radioactive gases R. Weed	Instrumentation: PET P. Early	Radiation Biology II & Exam R. Weed
10:00 - 12:00	Radiation Biology I P. Early	Radiation Biology I P. Early	Radiation Biology II R. Weed	Radiation Biology I & Exam P. Early	Radiation Safety: D.O.T. C. Brady
12:00 - 1:00	L U N C H				
1:00 - 3:00	Radiation Safety: Personnel Monitoring C. Brady	*Camera Review Instrumentation: SPECT Tips for SPECT imaging T. Dickinson	Radiation Safety: Radioactive Gases C. Brady	Radiation Biology II R. Weed	Radiation Safety Exam C. Brady
3:00 - 5:00	Physics P. Early	Radiation Biology I P. Early	Instrumentation: SPECT P. Early	Radiation Safety: Regulations Part 35 T. Dickinson	Instrumentation T. Dickinson
5:00 - 7:00	Instrumentation: Cameras T. Dickinson	Radiation Safety: Surveys, Signs, Disposal C. Brady	Instrumentation: SPECT P. Early	Radiation Safety: Regulations Part 35 T. Dickinson	Instrumentation & Exam T. Dickinson

Physicians Course
, March 18-22, 1991
Cleveland, OH

Prepared: 3/4/91

Day & Date / Time	Monday	Tuesday	Wednesday	Thursday	Friday
	March 18 25	March 19 26	March 20 27	March 21 28	March 22 29
8:00 - 10:00	Physics P. Early	Physics P. Early	Math D. Close	Math D. Close	Math & Exam D. Close
10:00 - 12:00	Physics P. Early	Physics P. Early	Physics & Exam P. Early	Instrumentation: Scintillation Detectors F. Bloe	Radiopharmacy R. Chandler
12:00 - 1:00	L U N C H				
1:00 - 3:00	Math D. Close	Math D. Close	Instrumentation: Gas Detectors D. Close	Instrumentation: Gas Detectors D. Close	Radiopharmacy & Exam R. Chandler
3:00 - 5:00	Radiopharmacy R. Chandler	Instrumentation: Chart of Nuclides F. Bloe	Radiopharmacy R. Chandler	Radiopharmacy R. Chandler	Instrumentation: Scintillation Detectors F. Bloe
5:00 - 7:00	Radiopharmacy R. Chandler	Instrumentation: Scintillation Detectors F. Bloe	Radiopharmacy R. Chandler	Radiopharmacy R. Chandler	Instrumentation & Exam F. Bloe

Physicians Course
, April 15-19, 1991
Cleveland, Ohio

Prepared: 3/4/91

Day & Date / Time	Monday	Tuesday	Wednesday	Thursday	Friday
	April 15	April 16	April 17	April 18	April 19
8:00 - 10:00	Math D. Close	Math D. Close	Math D. Close	Math D. Close	Math & Exam D. Close
10:00 - 12:00	Physics P. Early	Physics P. Early	Physics P. Early	Physics P. Early	Physics & Exam P. Early
12:00 - 1:00	L U N C H				
1:00 - 3:00	Radiopharmacy R. Chandler	Instrumentation: Scintillation Detectors F. Bloe/D. Weimer	Instrumentation: Scintillation Detectors F. Bloe/ D. Weimer	Radiopharmacy R. Chandler	Radiopharmacy & Exam R. Chandler
3:00 - 5:00	Instrumentation: Scintillation Detectors F. Bloe/D. Weimer	Radiopharmacy R. Chandler	Radiopharmacy R. Chandler	Instrumentation: Scintillation Detectors F. Bloe/ D. Weimer	Instrumentation: Scintillation Detectors F. Bloe/ D. Weimer
5:00 - 7:00	Instrumentation: Scintillation Detectors F. Bloe/D.Weimer	Radiopharmacy R. Chandler	Radiopharmacy R. Chandler	Instrumentation: Scintillation Detectors F. Bloe/ D. Weimer	Instrumentation & Exam F. Bloe/ D. Weimer

APPENDIX B

NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 21

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Mallinckrodt Medical Inc. NMA Medical Physics Consultation	In accordance with application dated November 26, 1986, 3. License number 34-16272-01 is amended in its entirety to read as follows:
2. 9457 Midwest Avenue Cleveland, Ohio 44125	4. Expiration date: September 30, 1994
	5. Docket or Reference No: 030-10703

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with Atomic Nos. 3-83, inclusive	A. Leak test samples	A. See Item 9.A. below
B. Cesium-137	B. Sealed sources (New England Nuclear Model Nos. NES-356, NES-360, or NES-367)	B. No single source to exceed 250 microcuries. Total possession limit not to exceed 2.0 millicuries.
C. Barium-133	C. Sealed sources (New England Nuclear Model Nos. NES-358 or NES-367)	C. No single source to exceed 250 microcuries. Total possession limit not to exceed 2.0 millicuries.
D. Cobalt-60	D. Sealed sources (New England Nuclear Model Nos. NES-354, NES-360, or NES-367)	D. No single source to exceed 50 microcuries. Total possession limit not to exceed 1.0 millicurie.
E. Technetium-99m	E. Any	E. 500 millicuries.
F. Any byproduct material with Atomic Nos. 3-83, inclusive	F. Sealed sources (which have been evaluated and approved by the Commission in accordance with Section 32.10 of 10 CFR Part 32 or equivalent Agreement State requirements).	F. No single source to exceed 1.0 millicurie. Total possession limit not to exceed 20 millicuries.

COPY 5

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 34-16272-01

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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
G. Cesium-137	G. Sealed sources (Tech/Ops Model 77302)	G. Two sources not to exceed 165 millicuries each.

9. Authorized Use:

A. Possession incident to the performance of tests for leakage and/or contamination on sealed sources containing licensed material specified in Item 6 of application dated November 25, 1986.

B. through F. To be used for instrument calibration and testing.

G. To be used in Tech/Ops Model 773 instrument calibrator for commercial survey instrument calibrations.

CONDITIONS

10. A. Tests for leakage and/or contamination shall be performed only at temporary job sites of the licensee anywhere in the United States where the Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material. Analysis of leak test samples may be performed at the licensee's facilities at 9457 Midwest Avenue, Cleveland, Ohio 44125. Licensed material in Subitems 6.B through 6.G shall be used only at the licensee's facilities at 9457 Midwest Avenue, Cleveland, Ohio 44125, and at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of the licensed material.

B. Licensed material listed in Subitems 6.B, 6.C, 6.D, 6.E. and 6.G may be used and/or stored at the licensee's facilities located at 9455 Midwest Avenue, Garfield Heights, Ohio.

11. Licensed material shall be used by, or under the supervision of:

Paul J. Early	William H. Miller	David W. Close
Steve A. Spinosi	W. Chris Wagner	Frank T. Bloe
Samuel A. Pontillo	Ronald Scala	Margaret M. Reilly
Mark Beanblossom	Daniel Patrick	Amy Sakaluk

MATERIALS LICENSE
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11. (Continued)

Colleen Rose Brady	Thomas W. Dickinson	Andrew Williams
Robert K. Carlson	Danny H. Harris	Edward Johnston
Daniel F. Kane	Scott Surovi	Anthony Montagnese
Rebecca Louise Watson-Kirchner		

12. The Radiation Protection Officer for the activities authorized by this license is Paul J. Early.

13. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicting that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

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

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

C. Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

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

13. (Continued)

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action taken.

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

15. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.

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

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

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

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

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Applications dated November 25, 1985 and February 16, 1989; and

B. Letter dated December 1, 1986.

For the U.S. Nuclear Regulatory Commission

Date: August 2, 1989

Original Signed
By Patricia J. Pelke
Materials Licensing Section, Region III

APPENDIX C

APPENDIX D

MALLINCKRODT
Nuclear Medicine
Diagnostic Imaging Services

VIAL SHIELDS

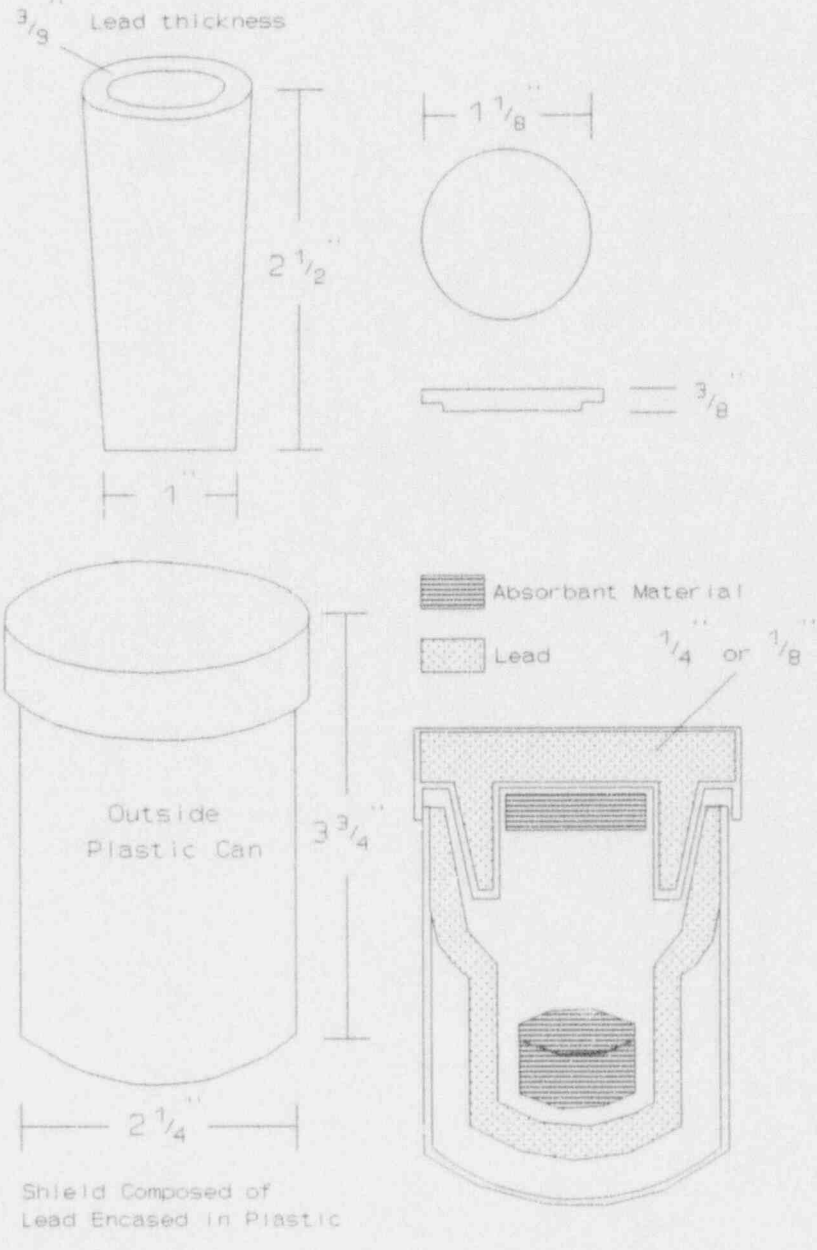
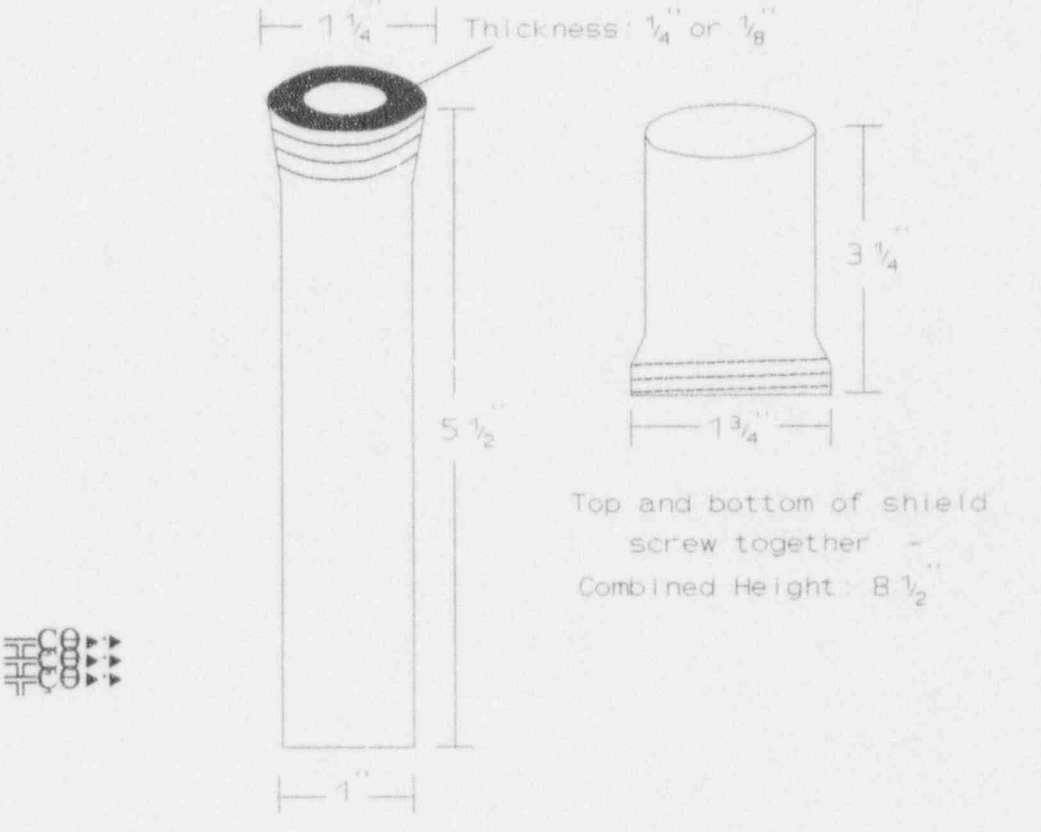


FIGURE 1

MALLINCKRODT
Nuclear Medicine
Diagnostic Imaging Services

SYRINGE SHIELD



Shield composed of lead encased in plastic

FIGURE 2

CARDBOARD BOXES

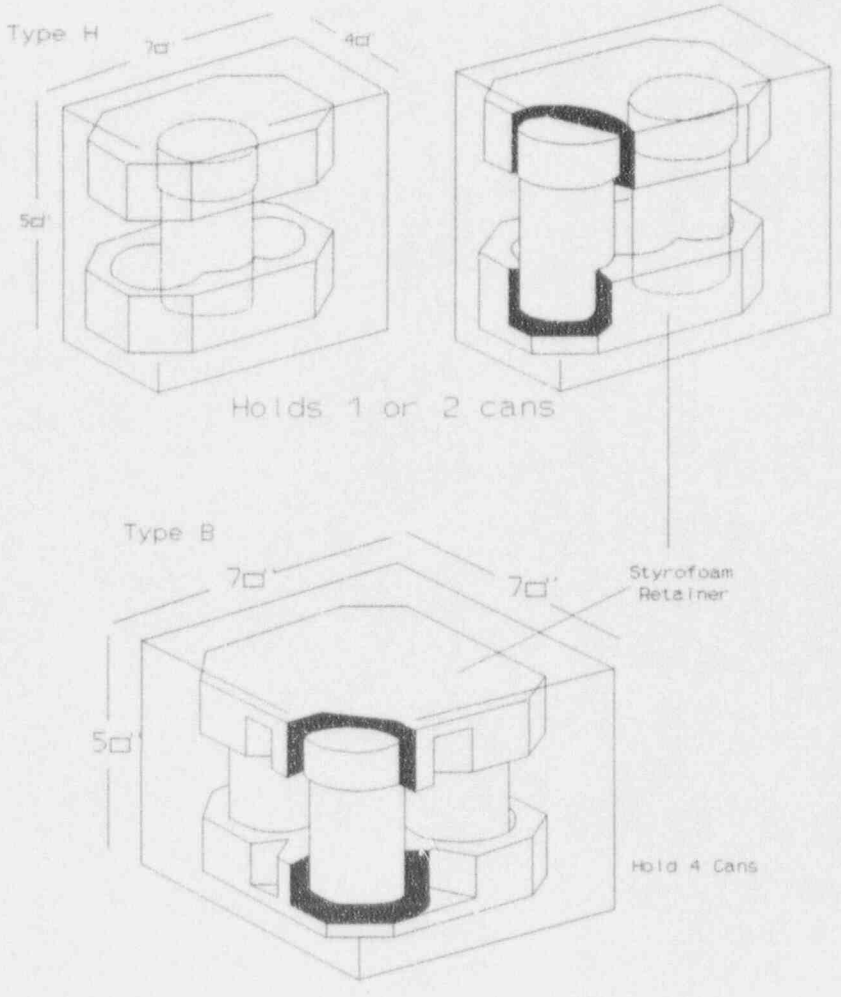


FIGURE 3

MALLINCKRODT
Nuclear Medicine
Diagnostic Imaging Services

CARDBOARD BOX

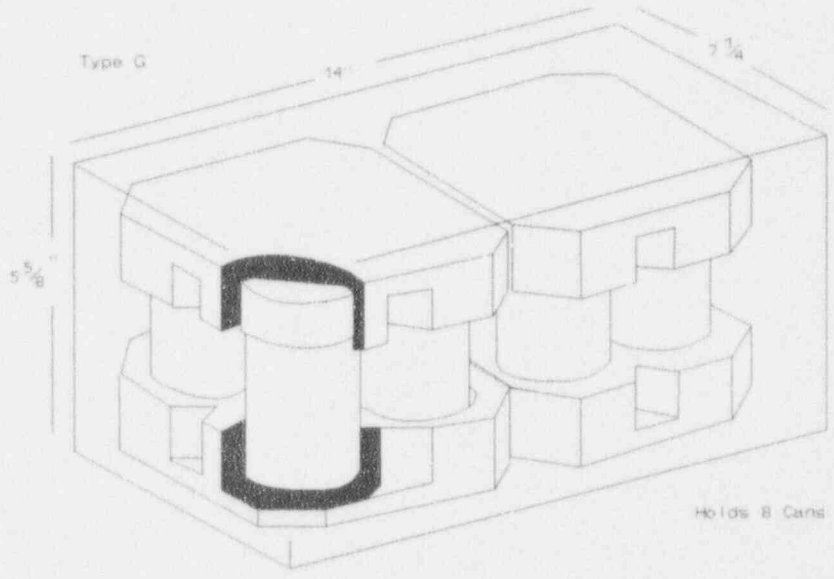


FIGURE 4

UNIT DOSE SHIPPING CONTAINER

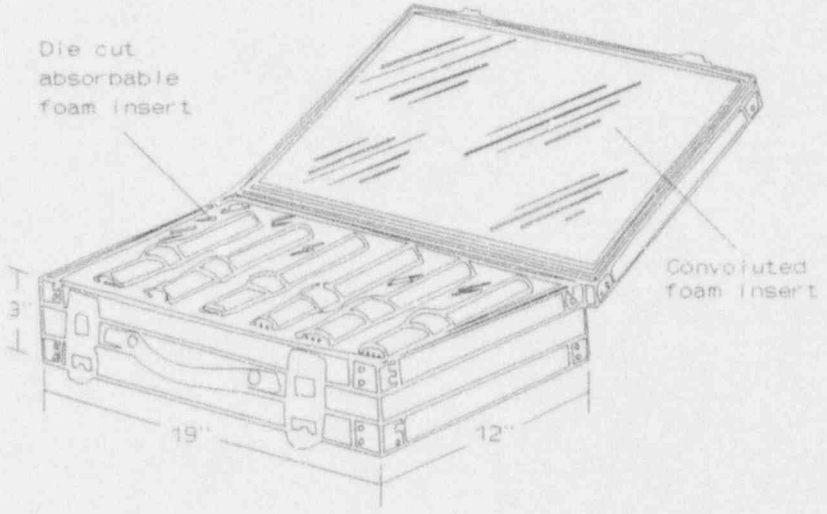


FIGURE 5

MALLINCKRODT
Nuclear Medicine
Diagnostic Imaging Services

PRODUCT SHIELDING

Shipping Activities and Radiation Fields

Nuclide/Activity (Maximum Dose/Carrier)	Lead Shield	Carrier	Maximum Radiation Field @ Surface of Shield (mR/hr)
Tc-99m (100 mCi)	Syringe Shield*	Syringe	0.5
Tc-99m (500 mCi)	Vial Shields	Vial	1.5
Ga-67 (9 mCi)	Syringe Shield**	Syringe	24
Ga-67 (12 mCi)	Vial Shields	Vial	20
Tl-201 (2 mCi)	Syringe Shield	Syringe	1.1
I-131 (0.35 mCi) (Hippuran or Albumin)	Vial Shields**	Vial	13

Other doses ordered will be shipped out from the nuclear pharmacy in the original lead container supplied by the manufacturer. Greater shielding may be provided if necessary. These products include:

I-131 Hippuran (1 mCi)	Supplied by Mallinckrodt Medical, Inc. or Squibb
Xe-133 (10 or 20 mCi)	Supplied by Mallinckrodt Medical, Inc., Amersham/Medi-Physics, or Dupont
P-32 (1.5 mCi)	Supplied by Mallinckrodt Medical, Inc.
Cr-51 (100 - 300 uCi)	Supplied by Mallinckrodt Medical, Inc., or Squibb
I-125 (5 - 500 uCi)	Supplied by Mallinckrodt Medical, Inc.
I-123 (100 - 200 uCi)	Supplied by Mallinckrodt Medical, Inc., Amersham/Medi-Physics, or Squibb
Se-75 (250 uCi)	Supplied by Mallinckrodt Medical, Inc.
Fe-59 (125 uCi)	Supplied by Mallinckrodt Medical, Inc.
Co-58/Co-60	Supplied by Amersham/Medi-Physics

* See Syringe Shield Schematic
** See Vial Shield Schematics

MALLINCKRODT
Nuclear Medicine
Diagnostic Imaging Services

Product Label

MALLINCKRODT MEDICAL, INC.

MALLINCKRODT
Nuclear Medicine

HOSPITAL

PROCEDURE

RADIOPHARMACEUTICAL

DATE	℞ NUMBER
LOT NUMBER	ASSAY
DOSE REQUESTED	AT (CAL. TIME)
VOLUME DISPENSED	ACTIVITY DISPENSED
DOCTOR	PRICE $
FILLED BY	MISCELLANEOUS CHARGES $
PATIENT	PURCHASE ORDER NUMBER

Caution: To be used under the direct supervision of a physician

SPECIAL INSTRUCTIONS

WARNING: The U.S. Nuclear Regulatory Commission has approved distribution of the radiopharmaceutical to persons licensed to use by-product material listed in paragraphs at 10 CFR Part 35, and to persons holding an equivalent license issued by an agreement state.

ORIGINAL

Diagnostic Imaging Services

DATE	℞ NO.
CAL. TIME	VOL.
EXP. TIME	ACTIVITY
DOCTOR	
HOSPITAL	
ADDRESS	
PATIENT	

DIRECTIONS: Per Physician's Orders

CAUTION: Federal law prohibits dispensing without a prescription

MALLINCKRODT MEDICAL, INC. Diagnostic Imaging Services Pharmacy

CAUTION
RADIOACTIVE MATERIAL

Diagnostic Imaging Services

DATE	℞ NO.
CAL. TIME	VOL.
EXP. TIME	ACTIVITY
DOCTOR	
HOSPITAL	
ADDRESS	
PATIENT	

DIRECTIONS: Per Physician's Orders

CAUTION: Federal law prohibits dispensing without a prescription

MALLINCKRODT MEDICAL, INC. Diagnostic Imaging Services Pharmacy

CAUTION
RADIOACTIVE MATERIAL

CAUTION
RADIOACTIVE MATERIAL