NRC FORM 313M (9-81) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Centra-Pharm, Inc.
2937 Switzer Road
Columbus, Ohio 43219

TELEPHONE NO. AREA CODE( ) 614 - 253 - 3020

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same

30 -20858 02500 L&L 21491

2. PERSON TO CONTACT REGARDING THIS APPLICATION

W. Christopher Wagner, Consultant
Nuclear Medicine Associates, Inc.

TELEPHONE NO. AREA CODE (216) 641 - 5799

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

a. ☒ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Refer to Item #8

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Steven R. Lefevre, R.Ph. with consultation from Nuclear Medicine Assoc., Inc. Cleveland, Ohio 44125

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	20
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	X	2000

Oct -2 NW
Applicant
Check No. 1256
Amount Fee Category 3A) 3C
Type of Fee A
Date Check Rec'd 10/20 $3
Received By

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Mo-99	Mo-99/Tc-99m Generator	30 Ci	Elution of Tc-99m
Uranium (depleted in Uranium 235)	Metal encased in stainless steel	400Kg	Shielding for Mo-99/Tc-99m generators
Byproduct material as described in 10 CFR 35.14(d)(1-4) in quantities as needed for distribution to licensees authorized by license to receive them.			

C16

NRC FORM 313M

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REG3 LIC30
PDR

Fee paid. (See

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: Oct., 1980

7. MEDICAL ISOTOPES COMMITTEE N/A		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Names and Specialties Attached; and		Appendix G Rules Followed; or
	Duties as in Appendix B; or *(Check One)*	X	Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE			Appendix H Procedures Followed; or
X	see Item #8	X	Equivalent Procedures Attached
	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*	
9. INSTRUMENTATION *(Check One)*			Appendix I Procedures Followed; or
X	Appendix C Form Attached; or	X	Equivalent Procedures Attached
	List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*	
10. CALIBRATION OF INSTRUMENTS			Appendix J Form Attached; or
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	X	Equivalent Information Attached
X	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*		Appendix K Procedures Followed; or
X	Equivalent Procedures Attached	X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
X	Description and Diagram Attached		Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached		Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
			Detailed Information Attached
X	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached		Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Jr. & Sons	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Jr. & Sons	Weekly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Pocket Dosimeters	Victoreen	Annual Calibration
Bioassays as described in Item #19		As outlined in NRC Regulatory Guide 8.20.

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: 3B

(2) LICENSE FEE ENCLOSED: $ 190.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

X Steven Ray Lefevre, RPh BCNP

(1) NAME *(Type or Print)*

X Steven Ray Lefevre

(2) TITLE

X President

c. DATE

X 10-10-83

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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 313M. 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 30-36 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 used: (a) to provide records to State health departments for their information and use; and (b) to provide information 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 a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

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.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

We Will Be Distributing Generators and Reagent Kits:

a. We plan to redistribute generators and reagent kits obtained from manufacturers licensed or approved to distribute them in accordance with Section 32.73 of 10 CFR Part 32 or under equivalent regulations of an Agreement State.

b. We will not open or tamper with any part of the manufacturer's packaging of these generators.

We Will Be Distributing Radiopharmaceuticals That We Have Either:

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

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

We Will Obtain Prepackaged In Vitro Test Kits as Described in Section 31.11 (a) (1) - (6) for Redistribution to Specific Licenses.

We will receive and redistribute ampules and vials containing Xenon-133 gas or gas dissolved in saline. The ampules and vials will be received in unit dose size and will not be opened or divided prior to distribution.

We will receive and distribute instrument calibrations sources as described in 10 CFR 35.14(d). A minimum inventory of these sources will be kept on hand in order to fill orders as received. As far as sealed sources are concerned, the manufacturer's directions for safe use and storage, etc., and information regarding assay, leak test results, etc., will be supplied to the customer.

We intend to fill orders for quantities of Tc-99m greater than 30 mCi to customers whose dose calibrator activity linearity test requirements exceed this figure.

NAME OF AUTHORIZED USER	AUTHORIZATION
Steven R. Lefevre, R.Ph., B.C.N.P.	Groups I - V

34-18448-01MD
Agreement
Columbus
Ohio
2-24-84

For training and experience, refer to NRC license #34-18448-01 MD

George Hinkle, R.Ph., M.S., B.C.N.P. Groups I - V

For training and experience, refer to NRC licesne #34-00293-02

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AMEND TO ADD:

At least one authorized user will be physically present whenever licensed material is being used for the preparation or dispensing of radiopharmaceuticals. Trained ancillary personnel may work unsupervised at other tasks however.

Authorization is also requested to add to the above list as an individual user, any person meeting any one of the following criteria:

1. Any pharmacist qualified to dispense pharmaceuticals in Ohio and who is named on any NRC license as an individual user for the purpose of dispensing radiopharmaceuticals.

2. Any pharmacist qualified to dispense pharmaceuticals in Ohio and who is named on an Agreement State license as an individual user for the purpose of dispensing radiopharmaceuticals.

3. Any pharmacist qualified to dispense pharmaceuticals in Ohio who was named on an NRC or Agreement State license to dispense radiopharmaceuticals and who has had at least one year full time experience within the previous five years or at least one year of half time experience within the previous three years.

Prior to assuming duty, the qualifications of the prospective user will be examined by Steven R. Lefevre, President, or in his absence, by the Lab Manager and the Radiation Safety Officer. Documentation of this action will be maintained for five years.

Item #8
1 of 1 page
Prepared: 8/26/83

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name Ludlum

      Manufacturer's model number 2

      Number of instruments available 1

      Minimum range: 0 mR/hr to 0.5 mR/hr

      Maximum range: 0 mR/hr to 50 mR/hr

   b. Manufacturer's name Ludlum

      Manufacturer's model number 3

      Number of instruments available 1

      Minimum range: 0 mR/hr to 0.2 mR/hr

      Maximum range: 0 mR/hr to 200 mR/hr

2. Dose calibrator(s)

   Manufacturer's name Capintec

   Manufacturer's model number CRC-10R

   Number of instruments available 2

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Well detector	Nucleus, Inc.	2560

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

Dosimeters	Victoreen	Pocket
Number available	4	
Range	0-200mR	

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name Ludlum

      Manufacturer's model number 177

      Number of instruments available 1

      Minimum range: 0 cpm to 500 cpm

      Maximum range: 0 cpm to 500,000 cpm

   b. Manufacturer's name Atomic Products (Distributor)

      Manufacturer's model number 051-361 Digital Survey Meter

      Number of instruments available one

      Minimum range: 0.1 mR/hr to 200 mR/hr

      Maximum range: 10 mR/hr to ~~X~~error 20,000 mR/hr

2. Dose calibrator(s)

   Manufacturer's name _____

   Manufacturer's model number _____

   Number of instruments available _____

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

CALIBRATION OF INSTRUMENTS

A. Survey meters will be checked for operability prior to each use. This will be accomplished by holding the detector against an instrument check source or the dose calibrator sealed constancy source depending on the instrument or range to be tested. If any reading with the same geometry is not within ± 20% of the reading displayed after calibration, the instrument will be recalibrated. The reading obtained will be included on all recorded surveys.

The units will be calibrated after servicing and at least annually by the manufacturer or by Nuclear Medicine Associates, Cleveland, Ohio, in accordance with the procedure outlined in application for NRC license #34-16272-01. Records of these calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond the anniversary of its last successful calibration.

Arrangements will be made for the availability of at least one survey meter while a unit is away for calibration or repair.

B. The dose calibrator will be calibrated as follows:

1. Sealed sources will be used to establish accuracy. They will consist of:

Nuclide	Suggested Activity	Activity (mCi)	Accuracy
Co-57	3-5 mCi	1 mCi or more	Within ± 5%
Ba-133	0.1-0.5 mCi	100 uCi or more	Within ± 5%
Cs-137	0.1-0.3 mCi	100 uCi or more	Within ± 5%

2. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standard sources.

3. The calibration procedure will be as follows:

a. The dose calibrator will be checked for accuracy at annual intervals and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the dose calibrator is used. Nuclides that will be used are listed in Item 1 above.

The activity displayed by the dose calibrator must agree with the stated assay within ± 5% of the limits of the standard's calibration accuracy. If the unit displays readings with an error greater than ± 5%, arrangements will be made for immediate repair or adjustment.

b. The dose calibrator will be checked for constancy each day of use. This will be accomplished using a Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ± 5% of the predicted activity based on the value obtained at the time of the original accuracy test.

The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± 5% of the activity shown at the time of the most recent accuracy check. If variations greater than ± 5% are noted, arrangements will be made for immediate repair or adjustment.

c. The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the maximum amount of activity that will be assayed or the first elution from a new Mo/Tc generator. In the latter case, after assaying the entire elution vial, an aliquot will be drawn calculated to contain 200 mCi. The aliquot will be assayed for agreement with the calculated activity to within ± 5%. If 200 mCi cannot be spared for performance of linearity testing, an aliquot less than 200 mCi will be drawn and used. The reduced amount will then be established as the maximum activity to be employed for patient doses or kit preparation for the remainder of the quarter or until linearity testing can be repeated utilizing a greater activity. In this way, the accuracy of the unit will be assured in the measurement of activity from the maximum on hand to a quantity approximately the maximum amount drawn and assayed for kit preparation.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check may be used. An aliquot such as 0.5 to 1.0 ml will be withdrawn from the elution vial and assayed in a syringe. The concentration of the eluent can be determined by dividing the displayed activity by the volume in the syringe. A 200 mCi aliquot contained in the

proper volume can then be withdrawn from the elution vial and used for the linearity test. If 200 mCi cannot be used, the amount used may be less but the same restrictions as cited in the paragraph immediately preceding will apply. In this way, the accuracy of the dose calibrator will also be assured in the measurement of activities approximating the maximum quantities used for kit preparation.

The linearity test will be continued by repeating the assay of the test aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is approximately the minimum dose likely to be used in a patient study and also less than the activity displayed during the annual accuracy check utilizing the standard with the energy similar to that of Tc-99m. In this way, the accuracy of the dose calibrator will be assured in the measurement of individual doses throughout the entire ranges of doses drawn for kit preparation and patient studies.

The above linearity test data will be plotted as a function of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be ± 5%. If test result error exceeds ± 5%, arrangements will be made for immediate repair or adjustment. The unit may be used in the interim using predetermined correction factors.

As an alternative procedure, the linearity test can be performed with the use of the Calicheck kit from Calcorp, Inc. The manufacturer's instructions for use will be followed. The source used shall be the first elution of a new generator or the activity of the largest dose obtained from a Radiopharmacy if a Radiopharmacy is used. Limits of acceptability and corrective actions will be as described above.

d. The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or liner repair or replacement. This test will be performed using approximately 2 mCi of Tc-99m in a geometrical configuration approximating that of a point source. The source geometry will then be changed by dilution with assays performed at each step. A comparison will also be made to quantify the reduction in displayed activity caused by assaying sources in plastic versus glass containers.

The data will be analyzed relating the various readings to the reading acquired while the test source was in the geometry of the Co-57 accuracy standard. Correction factors will be used in clinical assays when geometry induced errors exceed ± 2%.

In the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the implementation of the following procedure:

1. A substitute dose calibrator will be acquired.

2. Eluents and/or doses will be assayed in a dose calibrator located at the nearest cooperating institutions having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be shielded with sufficient lead to reduce levels to 2.0 mR/hr or less on contact with the shield, wrapped in sufficient absorbant toweling to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned to this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of authorized use.

Method #2 will be depended upon only in cases of medical emergency and until a functional dose calibrator can again be acquired. If only the activity of the eluent is known, mathematical calculations will be used to determine activity needed for patient doses.

The above assay techniques will enable the measurement of Technetium-99m and its Molybdenum-99 contaminant to within $\pm$ 10% of the true assay. Every effort will be made to expedite repair and return of the dose calibrator.

General Description

The pharmacy is located in a light industrial area. As for security measures at this pharmacy, we have two outer doors, one garage door, and two fixed windows. These doors and windows will be equipped with a magnetic proximity switch security system. There is an additional infra-red motion detection security system located within the office area.

We will not allow radiation levels in unrestricted areas to result in a dose in excess of 100 millirems in any seven consective days or 2 millirems in any one hour. We will moniter this by surveying unrestricted areas adjacent to our generator room upon the first receipt of radioactive materials and upon each increase in the number of generators stored.

Building Description

Centra-Pharm, Inc. has leased office and garage space at 2937 Switzer Road, Columbus, Ohio 43219. The total area equals approximately 1200 square feet. This space is located in a single story building constructed of concrete block and steel. At the present time, there are unoccupied offices on each side of the leased space. Our office is separated from the other offices in the building by a fire wall that extends to the roof. We also have our own separate air conditioners and heating system. The garage area is heated by a propane furnace. There is an air conditioner/heater located in the front office, with electric baseboard heat in the restrooms. There is not any duct heating or cooling system.

Room Description

A sketch of the floor plan is included and may be referred to for the description.

A. Office area
B. Employee lounge
C. Storage area
D. Restroom
E. Fume Hood
F. Isotope storage; Mo-99, Tc-99m, Current generator area
G. Pharmaceutical compounding and dispensing/Quality control area
H. Refrigerator
I. Short and long lived radioactive waste storage
J. Receiving area
K. Prescription dispatch area
L. Garage area

Section A

This area will be utilized as offices and no radioactive materials will be permitted.

Section B

This area will be a lounge for employee use. No radioactive materials will be permitted in this area. This will allow food consumption in this area.

Section C

In this area will be stored office and dispensing supplies, such as syringes, cotton swabs and alcohol. No radioactive materials will be permitted in this area.

Section D

Each of the two restrooms contain one commode and one sink.

Section E

The fume hood is for storage and manipulation of volatile isotopes, such as Iodine-131 and Xenon-133, in their original lead containers. Additional shielding will be added if necessary.

Section F

This room will contain the fume hood, Isotope storage within a 24" x 12" x 1/2" lead castle and Mo-99/Tc-99m generators currently in use. In addition to the generator manufacturer's shielding, 1/2" lead sheets will be placed where needed for added protection.

Section G

This area will contain two drawing stations. The L shields for the drawing stations will consist of 1" lead and 1/2" leaded glass. Each station will contain a dose calibrator which will have at least 1/4" lead shielding around the well. If warranted, the back of the drawing stations will be shielded with at least 1/8" lead for added protection to the adjacent office suite. This section will also be used to evaluate the quality of the radiopharmaceuticals made in the pharmacy.

Section H

This refrigerator will be used for storage of temperature sensitive products, radioactive and non-radioactive. There will be no food stored in this refrigerator.

Section I

This area will be used for storage and decay of Mo-99/Tc-99m generators. In addition to the manufacturer's shielding, accessory lead sheet will be placed where indicated for added protection to other occupied offices.

This area will also be used for the storage and decay of long and short lived radioactive waste. The waste will be stored in 1/2" leaded drums (55 gal. equivalent) and then disposed of in accordance with our license.

Cleaning of returned doses from the hospitals and clinics will be completed in this area. The packages are monitored for excess levels of radiation before they are opened.

Section J

This is the receiving area for all radioactive shipments. All incoming radioactive packages will be monitored for leakage or external contamination.

Section K

This area consists of a counter where all prepared doses will be packaged for shipment. After preparation, each shipment will be monitored to determine the transport label category and where applicable, the transport index.

Section L

This indoor garage area will be used for loading and unloading of our transportation vehicles and also for storage of these vehicles.

DESCRIPTION OF FACILITIES

Diagram

Air Supply

Air Exhaust

Sink

Lead Castle

___ Scanner
___ Uptake
___ Well
___ Scaler
___ Camera
___ File
___ Lockable Door
___ Isotope Receipt Area
___ Generator
___ Kit preparation
___ Isotope Storage
___ Dose Preparation
___ Waste Storage
___ Dose Calibrator
___ Refrigerator

Adjacent Areas

A. Office
B. Employee Lounge
C. Storage Area
D. Restroom
E. Fumehood
F. Isotope/Generator
G. Compound/Dispensing
H. Refrigerator
I. Waste Storage
J. Receiving
K. Dispatch Area
L. Garage

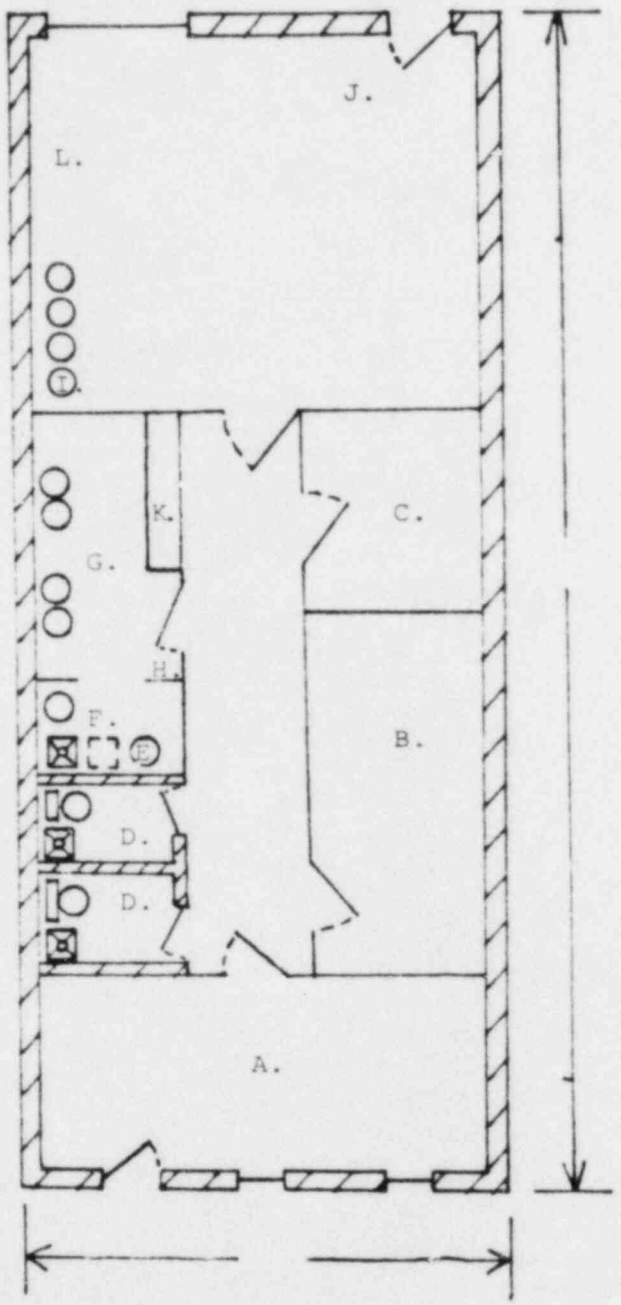
Lead Shielding

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T



Item #11
4 of 8 pages
Prepared 8/26/83

FACILITIES AND EQUIPMENT DESCRIPTION

All radioactive sources are stored in such a manner (lead, concrete, refrigerator) so as to not exceed 2 mR/hr at the surface of the barrier.

Mo-99/Tc-99m generator when used will be stored and eluted in the designated area. It will be shielded with lead sheets such that levels from all avenues of approach do not exceed 2.0 mR/hr. Spent generators will be stored in the location identified in the attached diagram.

During elution, the eluate will be collected, assayed, and stored in a vial held in a quarter inch lead pig except during brief periods of transfer. Transfer of the eluate or portions of the eluate will be made by the use of syringes retained in lead shields designed for this purpose.

Eluates and compounds made from eluates will be drawn, synthesized, assayed and stored in lead vials or syringes such that levels as measured at contact with a low level survey meter do not exceed 2.0 mR/hr except for brief periods during the actual transfer.

Radioactive materials obtained from the manufacturers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2 mR/hr or less.

Syringe shields will be used on all accessories requiring the transfer of radiopharmaceuticals from vial to vial and in drawing up patient doses.

Steps in the preparation of compounds requiring periods of heating, shaking, agitation or mixing will be performed utilizing lead shielding and/or mechanical or ultrasonic agitation equipment and/or remote handling devices (tongs, forceps, etc.) such that levels during the above period as measured by a low level survey meter do not exceed 2.0 mR/hr.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbent paper.

A decontamination kit will be maintained in the department. It will include the following items:

DECONTAMINATION KIT

ITEM	PURPOSE
1. Warning tape, chalk, & signs	posting of area
2. Plastic bags, small	shoe covers, wet containers
3. Disposable gloves	hand protection
4. Masking tape	fasten shoe covers, etc.
5. Forceps, tongs	safe handling
6. Large plastic bags	for contaminated material
7. Sponges, 4 x 4	sopping up
8. Paper towels	blotting & drying
9. Radiac wash or detergent	detergent
10. Scouring powder	friction
11. Tags	identification
12. Scissors	cut absorbent paper, etc.
13. Whatman #1 filter paper	taking swipes following decontamination
14. Chux	cover area following decontamination
15. G-M survey meter	monitoring

Facilities and Equipment
Diagram

Air Supply

Air Exhaust

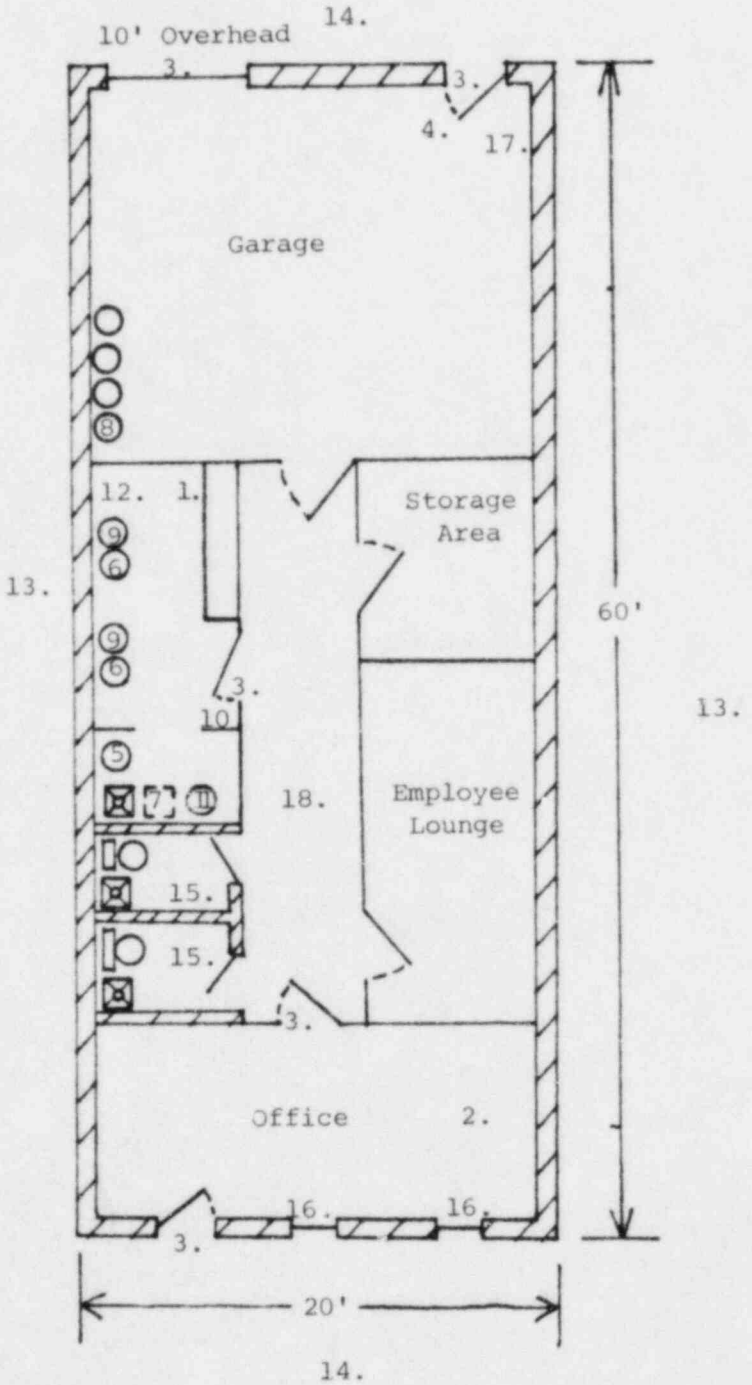
Sink

Lead Castle

N/A Scanner
N/A Uptake
1. Well
___ Scaler
N/A Camera
2. File/Desk
3. Lockable Door
4. Isotope Receipt Area
5. Generator
6. Kit preparation
7. Isotope Storage
6. Dose Preparation
8. Waste Storage
9. Dose Calibrator
10. Refrigerator

Adjacent Areas

11. Exhaust Hood
12. Monitoring Equipment
13. Unoccupied unit
14. Exterior
15. Restroom
16. Window
17. Propane Heater
18. Hallway



Lead Shielding

7
24" L x 12" W x 12" H x ½" T

___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T

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Facilities and Equipment Diagram

Air Supply
Air Exhaust
Sink
Lead Castle

___ Scanner
___ Uptake
1. Well
___ Scaler
___ Camera
___ File
3. Lockable Door
4. Isotope Receipt Area
5. Generator
6. Kit preparation
7. Isotope Storage
6. Dose Preparation
8. Waste Storage
9. Dose Calibrator
10. Refrigerator

Adjacent Areas

11. Exhaust Hood
12. Monitoring Equipment
13. Unoccupied Unit
14. Exterior
15. Restroom
___ _____
___ _____
18. Hallway

Lead Shielding

7.
24"L x 12"W x 12"H x ½"T

___
___L x ___W x ___H x ___T

___
___L x ___W x ___H x ___T

___
___L x ___W x ___H x ___T

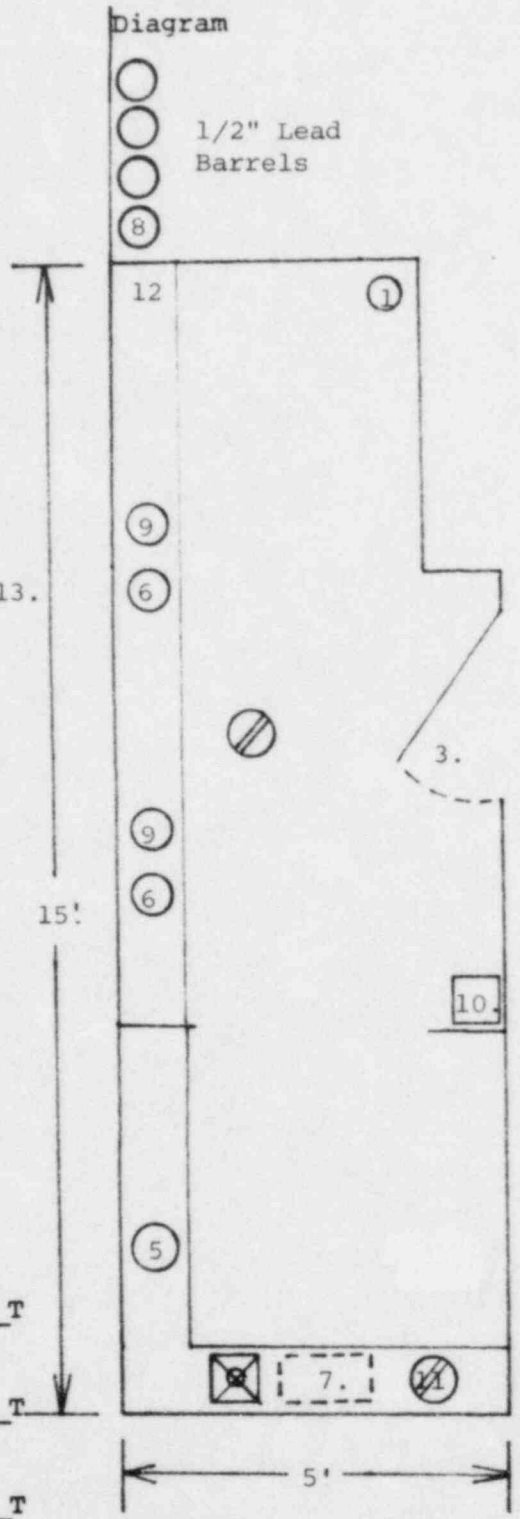

Diagram of Hot Lab Facilities

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PERSONNEL TRAINING PROGRAM

In accordance with Section 19.12 of 10 CFR, Part 19, the following is a description of the training required for all personnel who work with or in the vicinity of radioactive materials:

1. The radiopharmacy will be staffed by individuals who will be classified as occupational employees. These individuals will perform their duties from the radiation safety viewpoints under the direction of the Radiation Safety Officer named on the license.

2. Orientation of occupational personnel for a day or two by the Radiation Safety Officer named on the license and/or by his/her designee will include the following:

   a. Indicate areas where radioactive materials are used or stored.
   b. Potential hazards associated with radioactive materials.
   c. Radiological safety procedures appropriate to their respective duties.
   d. Pertinent NRC regulations.
   e. The rules and regulations of the license.
   f. The pertinent terms of the license.
   g. Their obligation to report unsafe conditions.
   h. Appropriate response to emergencies or unsafe conditions.
   i. Their right to be informed of their radiation exposure and bioassay results.
   j. Location where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR, Part 19.

3. Frequency on the training program shall be.

   a. Before assuming their duties with or in the vicinity of radioactive materials.

   b. During annual refresher course.

   c. Whenever there is a significant change in duties, regulations, or the terms of the license.

4. The Radiopharmacist staff will also receive the orientation training outlined above. As handlers, however, their orientation will include a one on one instruction and observational period by one

of the authorized users named on the license to assure safe handling techniques are employed. The period of observation and supervision will continue until sufficient time has elapsed in order to be named as a user on an NRC Radiopharmacy license. Those lacking sufficient didactic hours will be enrolled in a formal course for this purpose as soon as practicable.

5. Access into areas where radioactive material is stored or used will be restricted for nonoccupational personnel. When it is necessary for nonoccupational personnel to enter these areas, personnel so involved will be present under the direction of the radiopharmacist who will ensure that the exposure of these persons is held to the minimum required for the completion of the procedure. Further, all nonoccupational personnel will receive instruction as to the location and potential hazards associated with radioactive material during their orientation process and annually thereafter in the form of verbal instructions and/or memos.

PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL

1. A nuclear pharmacist will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the receiving area of the Nuclear Pharmacy.

3. Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials.

4. During off duty hours, delivery firms will have instructions to place packages in the receiving area of the Nuclear Pharmacy. If the carrier notices that the package is wet or appears to be damaged, he will be instructed to immediately contact the Nuclear Pharmacist on call (by calling the answering service) who then comes to the Nuclear Pharmacy to inspect the package. The carrier will be asked to remain at the Nuclear Pharmacy until it can be determined that neither he nor the delivery vehicle is contaminated. The letter on the next page will be posted in the receiving area.

5. The receiving area will be located such that radiation levels in the unrestricted areas do not exceed the limits specified in 20.105 of CFR Part 20.

   The following Radioactive Shipment Receipt Report Form will be used, or the equivalent information will be logged in the Radionuclide log book.

Radiation Safety Officer: Steven R. Lefevre, R.Ph., B.C.N.P.
Phone (Office):
Phone (Home) : (614) 475-0319

TO BE PLACED ON CENTRA-PHARM STATIONERY

TO: Any Courier Service delivering radioactive materials to Centra-Pharm, Inc.

FROM: Centra-Pharm, Inc.

RE: Delivery of packages containing Radioactive Materials

Any package containing radioactive materials that are to be delivered to our Nuclear Pharmacy after normal hours of operation are to be placed in the designated "receiving area". Be sure to lock the door upon leaving.

If the package is wet or appears damaged, immediately contact the Nuclear Pharmacist on call by calling our answering service at

Remain at the Nuclear Pharmacy until it can be determined that neither the carrier nor the delivery vehicle is contaminated.

RECEIVING

Date	Material	Lot #	Quant.	Wipe	Survey Surface	Survey 3 ft.	Survey Carton	GM Back	GM Source	By

Appendix F

Procedures For Safely Opening Packages
Containing Radioactive Material

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205 (a) (1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect package for sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure exposure rate at 3 feet (or 1m) from package surface and record. If > 10 mr/hr, stop procedure and notify Radiation Safety Officer.

   d. Measure surface exposure rate and record. If > 200mR/hr, stop procedure and notify Radiation Safety Officer.

   e. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition, † packing slip, and label on bottle.

      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

      (4) Check also that shipment does not exceed possession limits.

†In the case of special order (e.g., therapy doses) also compare with physician's written request.

f. Wipe external surface of final source container shield and remove wipe to low background area. Check wipes with a thin-end window G-M survey meter, and take precaution against the spread of contamination as necessary.

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

(1) If contaminated, treat as radioactive waste.

(2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package.

RADIOPHARMACY RULES FOR THE USE OF

RADIOACTIVE MATERIAL

1. Wear laboratory coats, or other protective clothing at all times in areas where radioactive materials are used.*

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

5. Assay each dose in the dose calibrator prior to dispensing. Do not dispense any doses that differ from the prescribed dose by more than 10%.

6. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.

7. Wear TLD finger badges during elution of generator and preparation, and assay of radiopharmaceuticals.

8. Dispose of radioactive waste only in specially designated receptacles.

9. Never pipette by mouth.

10. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

11. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level if applicable.

12. Always transport radioactive material in shielded containers.

13. Syringe shields will be used during radiopharmaceutical preparation and dispensing procedures.

14. Assay all radiopharmaceuticals in a dose calibrator prior to dispensing the radiopharmaceuticals to our customers.

15. Vials of Iodine-131 liquid will only be opened in a fume hood with the fan motor on.

16. Iodine-131 liquid will always be transferred with a bulb-aspirated pipet, or similar device. It will never be aspirated by mouth.

17. When transferring solution from one Iodine-131 oral solution container to another, replace caps on both containers immediately after making the transfer.

*Does not apply to delivery personnel

PACKAGING OF RADIOACTIVE MATERIAL FOR TRANSPORT
and
TRANSPORTATION OF RADIOACTIVE MATERIAL

The nuclear pharmacy will comply with applicable regulations for packaging and transportation of radioactive material as specified in Title 10, Part 71, Department of Transportation 49 CFR, Part 170-189, and 14 CFR, Part 103.

All of the radionuclides which the nuclear pharmacy will work with are in transport groups III and IV. The quantities are less than the Type A specification.

1. Vehicle

   a. Appropriate placards will be displayed on front, rear, and each side of transport vehicles when any radioactive material package on board bears a "Radioactive Yellow-III" label.

   b. Packages will be blocked and braced so that they cannot change position during conditions normally incident to transportation.

   c. The number of packages of radioactive material in the vehicle will never exceed a transport index of 50.

   d. Packages of radioactive material bearing "Radioactive Yellow-II", or "Radioactive Yellow-III", will not be placed closer to passengers than is specified in 40 CFR, 177, para. 177.842.

2. Packaging of Radioactive Material for Transport by Carrier

   a. Unit doses of radiopharmaceuticals will be contained in unit dose containers (General Design Development, Model IC-008 or IC-004) composed of lead.

      There is less than 3% variation of thickness as noted when rotated through 90, 180, and 270 degrees. Nu Medico Associates, consultants in health physics, radiation physics, and nuclear medicine tested these containers to see what amount of radiation could be contained to give radiation levels of 2 mrem/hr. This criteria was chosen since it appears unlikely that these items would remain in any uncontrolled area for more than 1 hour during routine transit. The found the following:

MODEL IC-004

Safe Loading in Millicuries
(2 mrem/hr at _____ distance)

Isotope	6 inches	1 foot	1 meter
I-131	1.2 mCi	5 mCi	50 mCi
I-123	250 mCi	-----	------
Ga-67	150 mCi	-----	------

The energies of these isotopes represent most of the spectrum of energies of most isotopes used in nuclear medicine today. The unit dose containers will be positively sealed.

b. The unit dose containers will be labeled to include: Radioactive material sign and symbol, chemical form, radionuclide contained therein, time, concentration, total volume, total millicuries or microcuries, prescription number, physician's name, date, address of nuclear pharmacy. A duplicate copy of the prescription will also accompany the unit dose container.

c. The unit dose container will contain absorbent material or it will be wrapped in an absorbent material.

d. The sealed unit dose container will be put into a fiberboard box with packing to prevent movement. The fiberboard box (DOT-7A-Type A) will be sealed with fiber tape or its equivalent. The dimensions of the box will not be less than four inches on a side.

e. The appropriate radioactive label will be applied to the outside of the box. Determination of the transport index is accomplished by placing the package one meter distant from a calibrated G-M tube, then reading the transport index on the scaler in mR/hr. Determination of the radioactive White-I, radioactive Yellow-II, or radioactive Yellow-III, is accomplished by taking a surface reading of the package and using this criteria:

Radioactive White-I - less than 0.5mR/hr at surface of package

Radioactive Yellow-II - less than 50mR/hr at surface and less than 1 mR/hr at 3 ft. from surface

Radioactive Yellow-III - less than 200mR/hr at surface and less than 10mR/hr at 3 ft. from surface

f. A shippers certification for radioactive materials (two copies) will be effected and attached to the package.

g. Each package will show the name and address of the consignee if the package is to be transferred to a commercial carrier.

h. The outside of each package will incorporate a feature, such as a seal, which is not readily breakable and which, while intact, will be evidence that the package has not been illicitly opened.

3. Packaging of Radioactive Material for Transport to Immediate Area Hospitals

a. Unit dose containers will be positively sealed then put into transport cases designed specially for transport of unit doses to area hospitals.

b. These cases will be positively sealed when used to transport radioactive material and are certified as USA DOT-7A, Type A packages. See test results on following pages.

c. The inside of the transport cases contain an insert which has been cut to conform to the molded shape of the unit dose containers. This material will prevent movement of unit dose containers, will absorb a great amount of shock, and will act as an absorbent material in the event of an accident. A security seal will be present which is not readily breakable and which, while intact, will be evidence that the package has not been illictly opened.

Before transporting any radioactive material from the nuclear pharmacy, all packages will be checked to see that the above procedures have been carried out. It shall be the responsibility of the radiopharmacist in charge to see that this is done.

Therapy doses of Iodine-131 will be transported in the lead shielding containers utilized by the manufacturer of such a product, or heavier shielding.

4. Miscellaneous directives

a. All delivery personnel will be provided with instructions in proper handling of both the unit dose containers and the delivery packages. Radiation safety procedures will be emphasized. Exact instruction for delivery to each hospital (where to go within the institution, who to see, where to leave the delivered packages, etc.).

b. All carriers will be instructed to lock their vehicle whenever it is left unattended.

c. All carriers will be directed to ONLY leave package in a secure place previously designated by the client.

DOT SPEC 7A CERTIFICATION

1. COMMON NAME OF CONTAINER

Samsonite Brief Case Model No. 389903 or equivalent modified with internal packing. Tests were also performed on Model No. 389905 (or equivalent). The only difference being that the first model is 3" thick while the second is 5" thick.

2. AUTHORIZED CONTENTS

Type A quantities of radiopharmaceuticals contained in 2 to 5 cc syringes with end caps in place. These syringes are inserted in shielded syringe carriers of the 1C-004 screw-on top type as described in "Evaluation of Shielded Syringe Carriers for Transporting Radioactive Doses", Journal of Nuclear Medicine Technology, Volume 7, No. 4. A copy of the article should be included in this document as Appendix A.

3. DESCRIPTION OF CONTAINER

The containers tested were a Samsonite VIP attache case, Models 389903 and 389905 measuring 18" x 12 3/4" and 18" x 12 3/4" x 5", respectively. A shock resistant panel was added to one side of the 3" model to provide the minimum required 4" dimension. The interior of each container was modified by adding cushioning material, compartmentalized to receive the shielded syringe carriers referenced in Section 2. The case has a molded Absolite (ABS) body with a magnesium frame. NOTE - While the initial series of tests were done with both the slip fit and screw type syringe carriers the certification is applicable only for the screw type specified in Section 2.

4. TEST RESULTS

a) Heat - Direct sunlight at an ambient temperature of 130^{o}F in still air.

Passed. No loss of contents. No decrease in package effectiveness. The cushioning material provided an excellent insulating barrier.

b) Cold - An ambient temperature of -40^{o}F in still air and shade.

Passed. Same comments apply as in a) even when syringe and its contents were frozen there was no leakage.

c) Reduced Pressure - Ambient atmospheric pressure of 0.5 atmosphere (absolute)

Not applicable since this package breathes. Even a small differential cannot be maintained.

d) Vibration - Vibration normally incident to transport.

Passed. The inner syringe carrier has been subjected to vibration test. See Appendix A. The Samsonite Case with the cushioning material inside provides additional barriers to vibration effects.

e) Water Spray - Not applicable.

f) Free Drop - A free drop through a distance of 4 feet onto a flat essentially unyielding horizontal surface, striking the surface in a position for which maximum damage is expected.

Passed. The case was dropped onto the false side corner. The latches were not locked. One latch sprung open, but the catch mechanism did not release. No loss of contents.

g) Corner Drop - A free drop onto each corner of the package in succession from a height of one foot onto a flat essentially unyielding horizontal surface.

Passed.

h) Penetration - Impact of the hemispherical end of a vertical steel cylinder 1 1/4" diameter and weighing 13 pounds, dropped from a height of 40 inches onto the exposed surface of the package which is expected to be most vulnerable to puncture. The long axis of the cylinder shall be perpendicular to the package surface.

Passed.

i) Compression - A compressive load equal to either five times the weight of the package or two pounds per square inch multiplied by the maximum horizontal cross section of the package, which is greater. The load shall be applied during a period of 24 hours uniformly against the top and bottom of the package in the position in which the package is normally transported.

Passed. See Appendix B for calculations.

5. ADDITIONAL TESTS REQUIRED

Title 49 Part 173.393(g) calls for additional requirements when shipping Type A quantities of liquid radioactive materials. These requirements are as follows:

173.393(g) Liquid radioactive material in Type A quantities must be packaged in or within a leak resistant and corrosion resistant inner containment vessel. In addition:

1. The packaging must be adequate to prevent loss or dispersal of the radioactive contents from the inner containment vessel if the package were subjected to the 30 foot drop test and either.

2. Enough absorbent material must be provided to absorb at least twice the volume of radioactive liquid contents. The absorbent material may be located outside the radiation shield only if it can be shown that if the radioactive liquid contents were taken up by the absorbent material the resultant dose rate at the surface of the package would not exceed 1,000 millirem per hour; or

3. A secondary leak-resistant and corrosion-resistant containment vessel must be provided to retain the radioactive contents under the normal conditions of transport as prescribed in 173.398 (b), assuming the failure of the inner primary containment vessel.

Results

a. 30 foot drop - passed. Although the frame was damaged and there was some shifting of the contents there was not loss of contents and no damage to the main body of the case. NOTE: For the thirty foot drop a strong leather strap (tool pouch belt) was used to secure the package around its midpoint. This belt which is approximately 2" wide is a requirement for the use of this package. Any comparable strong belt is acceptable, but it must be tightly secured in place before transport.

b. With regard to the requirements of 173.393(g)(2) or (3), the cushioning material used to line the case was tested for absorbency. Water sat on top of the surface with little immediate penetration, therefore, 173.393(2) could not be met. However, the requirements for a secondardy leak resistant container are met by the syringe carrier. It was filled with liquid, simulating loss of contents from the primary container, the syringe. The carrier was subjected to vibration and left to set for 24 hours with no loss of contents. Therefore, 173.393(g)(3) is met.

6. ADDITIONAL 30 FT. DROP

To demonstrate the need for the securing belt a 5" thick case was loaded and dropped 30 ft. with the latches locked but without the securing belt.

The results show that although the case body was not damaged, the frame was broken allowing the top and bottom to separate and spill out all of the syringe carriers. One of the carriers was obviously damaged.

This test demonstrates the need for the securing belt.

7. CONDITIONS AND ADDITIONAL CERTIFICATIONS

The conditions include:

1. Only plastic type syringes are permitted and end caps must be in place.
2. Only the screw type syringe carriers are permitted.
3. The package must be secured with a leather belt around its midpoint and passing through the handle.

ADDITIONAL CERTIFICATION

During the 30 foot drop test on the 5" model there was no damage to the case body itself only to the frame. There is no difference in material or method of construction between the 5-inch and 3-inch model. The belt will secure the package. Therefore, the 5" model is authorized for use under the conditions of this certification.

Tests Conducted By:

R.K. Blauvelt

R. K. Blauvelt

Daniel R. Hopkins

D. R. Hopkins

Date: June 12, 1980

16016

Evaluation of Shielded Syringe Carriers for Transporting Radioactive Doses

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We evaluated four commercially available lead-lined syringe carriers typically used for transportation of radiopharmaceutical unit doses to determine their ability to safely contain radioactivity. The United States Department of Transportation (DOT) "performance criteria" were utilized as parameters to judge relative effectiveness. However, because specific design assessments are left to the user's discretion, we tested all four syringe carriers for: weight and thickness of lead; efficacy in attenuating radiation emitted from the most commonly shipped radiopharmaceuticals; effectiveness in prevention of leakage from the enclosed syringe; and compliance with DOT regulations. One syringe carrier model was found to safely contain radioactive emissions from both high- and low- energy radionuclides; while a second model was shown to provide adequate containment only when used for lower energy radionuclides (e.g., technetium products). Two other models were evaluated as less effective in several parameters including containment of fluids.

Special shielded carriers have been developed for syringes containing radioactive doses in order to safely transport the doses from one location to another (e.g., from centralized radiopharmacies to area hospitals). These doses are usually delivered by radiopharmacy-owned vehicles or by common carrier (*1*). The transportation of radiopharmaceuticals by common carrier is regulated by DOT under the "Hazardous Materials Regulations" (*2–4*). Regulatory bodies that routinely govern operation of vehicles owned by centralized radiopharmacies are both DOT and NRC (or its equivalent in Agreement States). In addition, some state, county, and local agencies may also regulate vehicle operation (e.g., placarding of vehicle). Standards for hazardous materials containers and their transport are outlined in Tariff No. 31, effective March 31, 1977. However, because regulations prescribe the "performance criteria", but do not provide specific regulatory approval of design, the shipper must make his own assessment of the effectiveness of a particular shielded carrier relative to federal performance requirements (*2–4*).

This project was conducted so that the general nuclear medicine community could have a basis for determining the relative ability of typical syringe carriers to attenuate radioactivity and contain internal fluid leakage should it occur during dose transportation.

We evaluated commercially available shielded syringe carriers for: (a) weight and thickness of lead, (b) efficacy in attenuating radiation emitted from the most commonly shipped radiopharmaceuticals, (c) effectiveness in preventing any leakage from the enclosed syringe, and (d) compliance with DOT regulations.

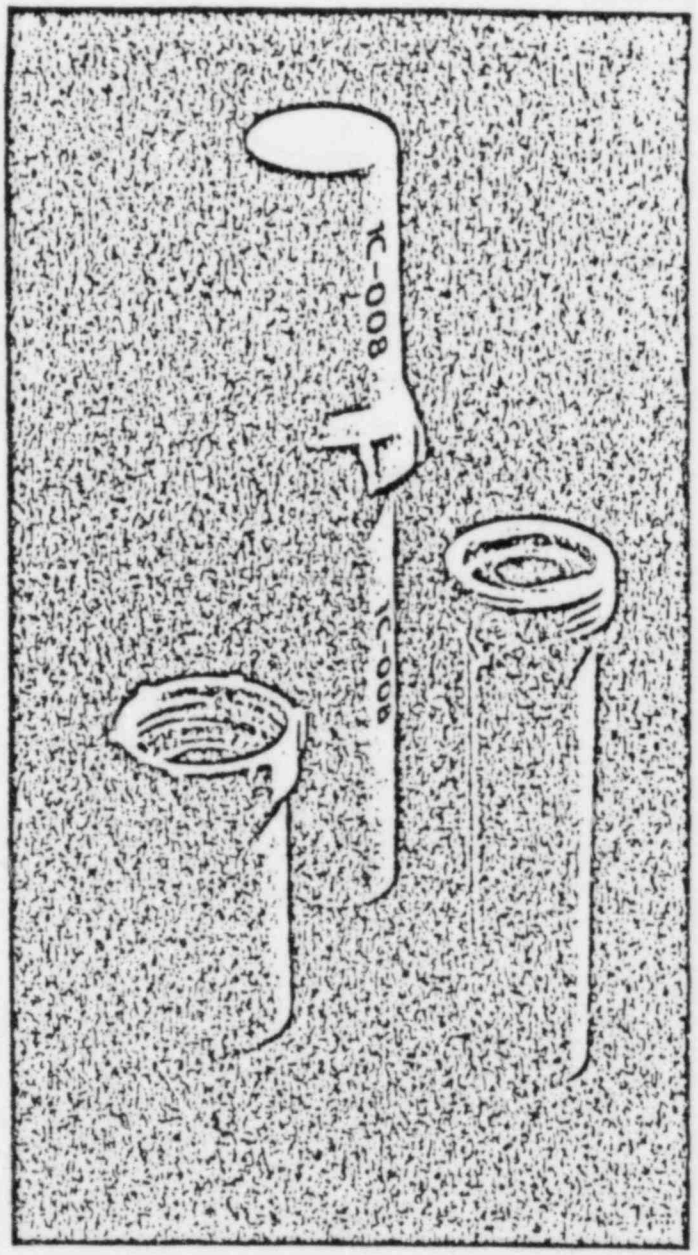


FIG. 1. Syringe carrier shield, 1 C-008 with screw-on top and continuous plastic coating.

For reprints contact: Norman B. Levit, UNM Radiopharmacy, College of Pharmacy, Albuquerque, NM 87131.

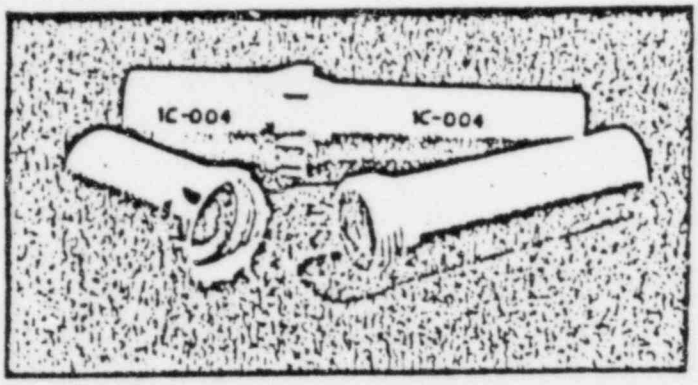


FIG. 2. Syringe carrier shield, 1C-004 with screw-on top, continuous plastic coating.

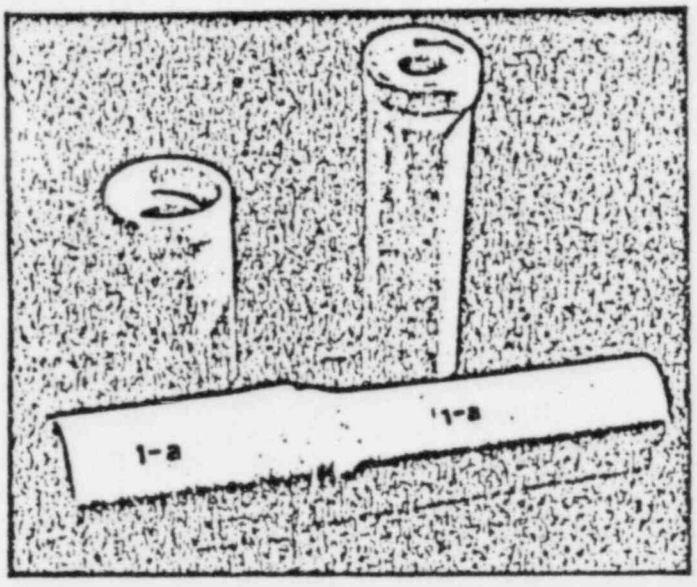
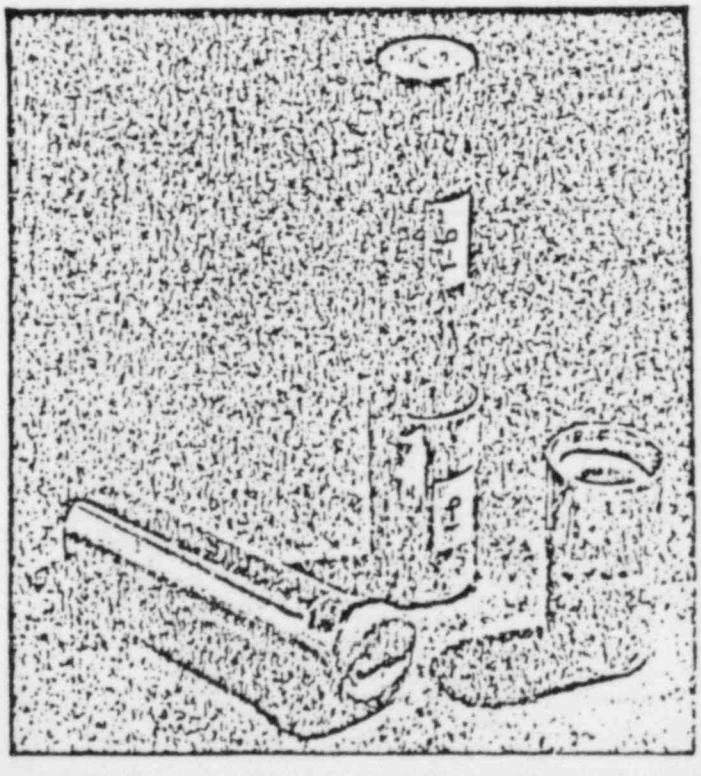


FIG. 3. Syringe carrier shield, 1a with slip-on top, plastic coating.



Materials and Methods

Four different syringe carriers were evaluated: the I C-008 (Fig. 1) and the I C-004 (Fig. 2) (General Design Development, Albuquerque, NM), and the Ia (Fig. 3) and Ib (Fig. 4), both formerly made by Ainsworth Co. (Albuquerque, NM). The General Design models are made of no less than 95% lead, and the top and bottom interlock by means of threads molded into the plastic housing. The top and bottom of the Ainsworth carriers slide together and the junction is usually sealed with masking tape. In the Ainsworth models, the covering is not continuous. Neither Ainsworth model is currently in production, but since many of these carriers are still in use, we felt they should also be evaluated.

In all following tests, six of each type of carrier were tested and the average results reported. Each carrier was weighed and the thickness at critical points was measured (Table 1). Attenuating effectiveness of the carriers (both surface and transport index readings) was evaluated with syringes containing: (a) approximately 350 μCi of I-131 (Table 2), (b) 7 mCi of Ga-67 (Table 3), and (c) 100 mCi of Tc-99m (Table 4). Transport index is defined as the highest radiation dose measured in mrem/hr at 1-m distance from any accessible surface of the container.

Leakage of liquid was tested by placing 2.0 ml of a nonradioactive rose bengal solution in each carrier, sealing the carrier, wrapping it in absorbent paper, and subjecting it to conditions at least as strenuous as those normally associated with transportation. Syringe carriers were transported for a full day in the UNM radiopharmacy truck on its usual delivery route. The carriers were then packed in a DOT box and transported by common carrier to and from a client 200 miles from the radiopharmacy (*2–4*). The carriers and surrounding absorbent paper were then examined for evidence of leakage, which would be indicated by stains on the outside of carriers and absorbent paper.

At this time, we felt that placing a very thin rubber gasket between upper and lower parts of carriers might increase their ability to contain internal fluid leakage. This was done and all subsequent testing of the carriers was accomplished with the gasket in place. The gasket improved containment characteristics and did not change attenuation characteristics. It is now an integral part of the General Design carriers (Table 5).

Further tests for leakage were performed by filling the carriers with 2.0 ml of rose bengal solution, wrapping them in absorbent paper, placing them horizontally in an Eberbach shaker, and shaking for 5 min at a rate of 120 strokes per min (Table 6). A drop test was performed by filling the carriers with 2.0 ml of rose bengal solution, wrapping them in absorbent paper, and subjecting them to a free drop of 6 ft onto concrete. They were allowed to remain on the concrete for 30 min to allow for seepage and then examined (Table 7).

Compliance of each carrier with applicable DOT regulations was evaluated by comparing test results with these

Results

As shown in Table 1, carrier I C-004 contains 50% (by weight) more lead then model I C-008, 11% more than model Ia, and approximately the same amount as Ib. The tops of I C-004 and I C-008 are 35% thicker than those of Ia and Ib, and the bottoms have 43% greater thickness. With the exception of I C-008, carrier walls are essentially equal in lead thickness.

TABLE 1. Measurements of Weights and Thickness of Lead.

Carrier No.	Total Weight (g)	Lead Thickness (cm)				
		Syringe Carrier Cover		Syringe Carrier Body		
		Side	Top	Carrier Wall at Top	Carrier Wall at Bottom	Base
I C-008	780	0.31	1.19	0.83	0.39	1.11
I C-004	1536	0.83	1.11	0.95	0.83	1.27
Ia	1364	0.79	0.71	0.79	0.63	0.63
Ib	1516	0.71	0.79	0.95	0.83	0.71

Table 2 indicates that carrier I C-004 attenuates gamma rays of I-131 as well as or better than other carriers when measured at the top, bottom, and junction. It has 27% more attenuating properties for this isotope than either Ia or Ib, and 74% more than I C-008. The same carrier (I C-004) also attenuates gamma rays of Ga-67 better than any of the other carriers measured at all points tested, as seen in Table 3, with the most notable differences being the reading at the middle of the carrier's body. At this point, I C-004 attenuates these emissions 69% better than I C-008 and 53% better than either Ia or Ib.

TABLE 2. Gamma-Ray Penetration with Syringe Containing 362 μCi of Iodine-131 in 2 ml of Volume. (Measured in mR/h on the surface.)

Carrier No.	Top	Junction	Middle	Bottom	at 1 m (T.I.)
I C-008	0.20	6.5	25.0	0.50	0.05
I C-004	0.20	2.0	6.5	0.35	0.05
Ia	0.25	3.5	9.0	0.65	0.05
Ib	0.30	2.0	9.0	0.45	0.10

Table 4 shows all external survey readings to be very low (measured in mR/hr). Attenuation of gamma-ray emissions from Tc-99m is considered essentially complete for all four of the carriers tested.

TABLE 3. Gamma-Ray Penetration with Syringe Containing 7.47 mCi of Gallium-67 in 3 ml of Volume. (Measured in mR/h.)

Carrier No.	Top	Junction	Middle	Bottom	at 1 m (T.I.)
	Surface Readings				
I C-008	0.45	8.0	55.0	1.00	0.15
I C-004	0.30	2.5	11.6	0.75	0.08
Ia	0.40	3.0	25.0	2.00	0.10
Ib	0.40	5.5	25.0	1.00	0.10

Tests for containment of internal fluid leakage under these different experimental conditions are shown in Tables 5, 6, and 7. When these results are examined, it is evident that both models I C-008 and I C-004 (when equipped with gaskets) prevented external fluid leakage in 100% of the tests, whereas Ia prevented external leakage in 16.67%, 33.3%, and 33.3%, respectively, in the trials in which it was subjected. Model Ib prevented external leakage in 0%, 33.3%, and 33.3% of its trials (i.e., transportation test, shake test, and drop test).

TABLE 4. Gamma-Ray Penetration with Syringe Containing 100 mCi of Tc-99m in 1.0 ml. (Measured in mR/h.)

Carrier No.	Top	Junction	Middle	Bottom	at 1 m (T.I.)
	Surface Readings				
I C-008	0.10	0.20	0.40	0.04	0.04
I C-004	0.06	0.40	0.05	0.04	0.04
Ia	0.07	0.50	0.10	0.09	0.05
Ib	0.04	0.065	0.09	0.04	0.04

Conclusion

Syringe carrier I C-008 and I C-004 both adequately contained internal fluid leakage. Federal regulations require that absorbent material sufficient to absorb twice the volume of liquid contained be incorporated into the packaging of each individual container. Under certain conditions, this material may be on the outside of the carrier (*2–4*). All four carriers tested attenuated I-131 and Ga-67.

The I C-004 carrier complied with all DOT regulations all of the radionuclides tested. The I C-008 carrier attenuated technetium as well as the I C-004. However, since the I C-008 is lighter in weight and less expensive than model I C-004, it is preferred for Tc-99m doses.

We recommend that a rubber or plastic gasket be inserted in both of the older types of carriers (Ia and Ib). The newer screw-capped carriers were evaluated and found to be superior to the older slip-on cap models with respect to attenuation of radiation, containment of fluids, and ease in handling.

TABLE 5. Containment of Internal Fluid Leakage by Carriers after Being Filled and Transported.

Syringe Carrier No.	Without Gasket Leakage	With Gasket
1 C-008	1 of 6	In all six leakage was prevented
1 C-004	1 of 6	In all six leakage was prevented
1a	5 of 6	No change
1b	6 of 6	No change

TABLE 6. Containment of Internal Fluid Leakage after Shake Test.*

Syringe Carrier No.	Leakage
1 C-008	0
1 C-004	0
1a	5 of 6
1b	4 of 6

*All syringe carriers were fitted with gaskets.

TABLE 7. Containment of Internal Fluid Leakage after a Drop Test.

Syringe Carrier* No.	Leakage
1 C-008	0 of 6
1 C-004	0 of 6
1a	4 of 6
1b	4 of 6

*All syringe carriers were fitted with gaskets.

References

1. Rhodes BA, Croft B: Operating a radiopharmacy. In *Basics of Radiopharmacy*. St. Louis, CV Mosby, 1978, pp 148-154

2. Graziano RM: Tariff No. 31, *Hazardous Materials Regulations of the Department of Transportation*, Washington, DC, 1977, pp 18-260

3. DOT: *A Review of the Department of Transportation (DOT) Regulations for Transportation of Radioactive Materials*, Washington, DC, DOT, Materials Transportation Bureau, Office of Hazardous Materials Operations, 1977, pp 12-35.

4. *The Federal Register, 49CFR, Dept. of Transportation Materials Transportation Bureau Part IV*. Washington, DC, The National Archives of the United States; parts 171-177, 1976

5. *All about radioactive packages, a guide for supervisors at cargo terminals*. Washington, DC, DOT, NRC; 1978, pp 1-10

Appendix B

Compression Test Criteria

a. Authorized gross weight of package is 20 lbs.

5 x 20 lbs = 100 lbs

b. Cross section area

18 in x 13 in = 234 in^2

$\frac{2 \text{ lbs}}{in^2} \times 234 \ in^2 = 468$ lbs.

Therefore, apply at least 468 lbs in compression to the package.

Emergency Procedures

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.
2. PREVENT THE SPREAD: Cover the spill with absorbent paper.
3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands and clothing for contamination.
5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills: Activity >1 mCi and T ½ >20 hrs. or activity >30 mCi and T ½ <20 hrs.

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.
6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Steven R. Lefevre, R.Ph., B.C.N.P.
OFFICE PHONE: x
HOME PHONE: (614) 475-0319

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

George Hinkle, R.Ph., M.S.,B.C.N.P.
Home Phone:

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Prepared:

EMERGENCIES INVOLVING MOTOR VEHICLES

ACTING AS CARRIERS OF RADIOACTIVE MATERIALS

Because of the nature of these kinds of emergencies, the following is a completely self-contained set of instructions which will be carried in every vehicle used while transporting radioactive substances. These instructions are to be read and followed by all personnel in the event of an emergency.

a. Driver is to take the following immediate action:

1. Do not touch any open or broken containers.
2. Call the pharmacy immediately, using a two-way radio if at all possible. If you must use a telephone to notify the pharmacy, have someone maintain security over the vehicle and radioactive material and keep bystanders away while calls are being made.
3. Keep all people away from the radioactive material.
4. Stay at the scene until a Centra-Pharm representative arrives.

b. Pharmacist is to take the following immediate action:

1. Notify Radiation Safety Officer of the accident.
2. Dispatch car with qualified person to assist the driver. Take emergency kit including monitor, use car with mobile radio if at all possible.
3. Notify State Highway Patrol to have police on the scene for traffic and crowd control.
4. Notify Ohio Department of Public Health, Division of Radiological Health between 0830 - 1700 Monday through Friday at number below. All other times, they can be reached through the State Highway Patrol.
5. If the spill meets the criteria in CFR Title 10 Section 20.403, notify the NRC, Region III at (312) 932-2500 anytime.

Phone Numbers

State Highway Patrol:		(614) 406-2660	anytime
Dept. of Pub. Health, Dept. Rad.		(614) 466-3543	0830 - 1700 M-F
Nuclear Pharmacist (Radiation Safety Officer)	B	( )	
	H	(614) 475-0319	anytime
Region III NRC		(312) 932-2500	anytime

c. All traffic should be detoured around the scene of an accident. If this is not possible, vehicles should be moved the shortest distance necessary to clear the right-of-way. If radioactive material is spilled, passage through areas should be prevented

unless absolutely necessary. If the right-of-way must be cleared before assistance has arrived, the spill should be washed to shoulders of right-of-way with minimum dispersal of wash water, or covered with at least four inches of earth or sand.

d. The nearest Nuclear Regulatory Commission Office should be notified as soon as possible. See phone numbers above.

e. If the accident involves wreckage and a person is believed to be alive and entrapped, every possible effort should be made to rescue him/her.

f. The area of the accident should be restricted. The public should be kept as far from the scene as is practicable. Local authorities should make only necessary entries and investigations into the accident area. No attempt should be made to open or examine contained material. No attempt should be made to clean up any debris or material involved in the accident prior to the arrival of experienced help.

g. Any persons who have had possible contact with the radioactive material should be segregated and confined until they can be examined further. The names and addresses of those involved should be obtained.

h. The injured should be removed from the area of the accident with as little contact as possible and held at a transfer point. All life-saving measures should be performed promptly, but elective first aid and surgical procedures should be delayed until advice or help can be obtained from a physician familiar with radiation medicine. Except in extreme emergency, patients should not be moved to local hospital or doctor's office before a radiological survey has been made.

i. If the accident involves fire, attempt to extinguish it should be made from as great a distance as possible. The fire should be treated as one involving toxic chemicals. Suspended material should not be handled until it has been monitored and released by monitoring personnel. Clothing and tools used at the fire should be segregated until they can be checked by the monitoring teams.

j. Eating, drinking, or smoking in the area of the accident should be prohibited. Food or drinking water which may have been in contact with material from the accident should not be used.

k. Careful attention and consideration should be given in matters of public relations to:

1. Transmission of information to the public by press, radio, and television, and

2. Tactful handling of volunteers and crowds of curious onlookers.

SURVEY PROCEDURES

A. All elution, preparation and injection areas will be surveyed daily with a G-M survey meter and decontaminated, if necessary.

B. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be monitored monthly, via wipe test.

C. All other laboratory areas will be surveyed weekly.

D. The weekly and monthly survey will consist of:

   1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   2. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm.

E. A permanent record will be kept of the weekly or monthly survey results, including negative results. The record will include:

   1. Location, date, and type of equipment used.

   2. Name of person conducting the survey.

   3. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   4. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).

   5. Detected contamination levels, keyed to locations on drawing.

   6. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

F. Area will be cleaned if the contamination level exceeds 200 dpm/100cm^2, except in the case of some Tc-99m spill where less radiation exposure would be received by personnel if the area is secured and contamination is allowed to decay.

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APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate).

__X__ In the sanitary sewer system in accordance with 20.303 of 10 CFR,Part 20.

__X__ Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.

_____ By commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

2. Mo-99/Tc-99m generators will be (check as appropriate).

__X__ Returned to the manufacturer for disposal.

__X__ Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate).

__X__ Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be:

_____

(Name) (City, State)

NRC/Agreement State License No. _____

5. Gaseous waste will be (check as appropriate).

X Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

____ Disposed of by commercial waste disposal service (see Item #4).

REQUEST FOR AUTHORIZATION TO COLLECT RADIOACTIVE WASTE

We submit the following information to permit the pick up of radioactive wastes from our customers. The only radioactive waste that will be picked up will be that which was distributed by Centra-Pharm, Inc., to our customers. We will not pick up radioactive waste which was not initially distributed by Centra-Pharm, Inc.

I. Packaging and pick up from customers.

A. Type of radioactive waste

Radioactive waste picked up will be comprised of plastic syringes, needles, needle covers, and vials which have been used by Nuclear Medicine Departments serviced by Centra-Pharm, Inc. These items will represent solid waste which has contained radiopharmaceutical substances, which are listed in Groups I, II, III, and IV of 10 CFR, Part 35.100.

B. Step-by-step procedures for the safe handling of radioactive waste material.

1. It must be emphasized that unit dose material represents very low level radioactive waste. With the exception of vials, which have contained radiopharmaceuticals, the syringes will have been flushed out with patient blood in the process of injecting the patient. Also because of the routine of a Nuclear Pharmacy, these materials will be retrieved 24 hours after use; therefore, the Tc-99m products will have decayed at the user's site for at least three half-lives. Those vials retrieved as waste represent a very small portion of the waste in this system. Examples of vial waste would be I-131 oral therapy vials, Yb-169 DTPA vials, Cr-51 vials, Xenon-133 vials, and I-131 IHSA vials. This represents 5% of the waste retrieved from the customer. It must also

be pointed out that each unit dose syringe or vial is identified by prescription number and radiopharmaceutical. This is required by state pharmacy regulations. Therefore, returned, used materials are easily identifiable.

2. The following procedure will be provided to the Nuclear Medicine Technologists in charge of departments serviced by Centra-Pharm Inc.:

PROCEDURE FOR RETURNING USED UNIT DOSE CONTAINERS TO CENTRA-PHARM, INC.

Centra-Pharm has been licensed by the Nuclear Regulatory Commission to pick up those materials which after use represent radioactive waste. Only those materials supplied to you by Centra-Pharm may be returned to the pharmacy as waste.

A. Syringes, needles and needle covers.

1. After injection, return the needle cover to the needle, remove the syringe from the syringe shield and return the syringe to the unit dose shield provided. Make sure that the needle cover is firmly seated on the needle.

2. Place the unit dose shield in the case provided for return to the pharmacy.

B. Unit dose vials.

1. After use, return the vial to its original shipping container and place in the case provided.

2. In those situations (usually I-131 therapy doses) that material has been delivered to you in appropriate D.O.T. packaging, return the vial to its container, replace in packaging, and seal.

II. The following is the procedure for receiving waste at Centra-Pharm, Inc.

A. Returned unit dose shilds may contain used syringes and/or vials, therefore, it is necessary for the individual checking in this material to wear disposable rubber gloves.

1. Survey the case. If levels on contact exceed 0.5mR/hr:

a. Open the case.

b. Examine carefully for the presence of "long-lived" dose residues (by syringe carrier color) or unused

Tc-99m doses (by the presence of a double prescription label). If none, or if there is an unshielded syringe, vial, alcohol swab, wetness, etc., call the RSO or a member of the professional staff.

c. Remove "long-lived" and unused doses and set aside for disposal by a professional staff member.

d. Open "short-lived" carriers and dump contents into the properly labeled disposal container.

e. Survey the empty case and empty carrier. If levels above background are detected, set aside for evaluation by a member of the professional staff or place in storage for decay.

f. Recycle non-contaminated carriers and cases.

2. If original case survey reveals levels less than 0.5 mR/hr:

a. Open the case

b. Follow steps a - f above.

B. Centra-Pharm uses a unit dose shield developed by General Design and Development Company of Albuquerque, New Mexico. It is comprised of a top and bottom lead cylinder which is threaded together to form a safe and effective lead shield for syringes containing radiopharmaceuticals. All multiple dose containers are transported in their original containers or the equivalent. These lead shields are then placed in our specially designed cases which have polystyrene foam inserts that accommodate the exact size of the shield. These cases are positively sealed when used to transport radiopharmaceuticals.

All radiopharmaceuticals will be transported to our vehicles by delivery personnel employed by Centra-Pharm, Inc. The waste material will be handled just like the original material is transported to the customer. Only waste syringes, needles, needle covers, and vials will be accepted for pick up, if they have been returned to their original containers after use, and placed in the cases for return to the Nuclear Pharmacy.

C. The individual handling the radioactive waste will be a trained Nuclear Technologist at the hospital or clinic. The individual handling the radioactive waste at the Nuclear Pharmacy will meet that criteria for training established in Item 12 of this application. Drivers will also be trained in accordance with Item 12 of this application.

THERAPEUTIC RADIOPHARMACEUTICALS

Since we will be dispensing I-131 in both capsular and liquid form, the following precautions will be taken:

1. Open and dispense therapeutic quantity of I-131 in the fume hood.

2. Wear disposable gloves when handling such sources.

3. Immediately close all vials and bottles containing I-131 after dispensing.

4. Use the remote pipetter for measuring liquid I-131.

5. Use tongs for handling capsules.

6. Participate in the Bioassay Program.

Bioassay Program:

We will follow the recommendations, as applicable, outlined in U.S. NRC Regulatory Guide 8.20, as amended in September, 1979, "Applications of Bioassay for I-125 and I-131".

Thyroid uptake measurements will be supervised by the Radiation Safety Officer. Equipment used will be a Nucleus, Inc. Model 256D multi-channel analyzer. This equipment will be calibrated prior to use using a Cs-137 source and adjusting high voltage until the count rate is at a maximum. We will use a low level activity I-131 NaI capsule from a Radiopharmaceutical manufacturer and count it in a lucite thyroid neck phantom. Then the person being evaluated will place his/her neck in the same geometric position as the lucite thyroid neck phantom for counting purposes. By using a ratio of phantom counts to known activity, the unknown activity can be determined from known counts of the thyroid.

$$\text{Activity (uCi) of I-131 in thyroid} = \frac{\text{CPM of thyroid} \times \text{act. (uCi) of cap.}}{\text{CPM of phantom}}$$

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

In accordance with the Guide for Supporting Documentation for Xenon-133 use, please accept the following information:

I. Quantities to be received and dispensed.

The desired possession limit is two curies of Xenon-133 in gas and/or saline form. The only forms of Xenon-133 we are requesting are sealed glass vials of the New England Nuclear, Diagnostic Isotopes, Medi-Physics type of glass vial containing gas, or the Mallinckrodt cartridge or Diagnostic Isotope vial of Xenon-133 in saline. The rubber septums of these vials will not be punctured nor the contents of the vials altered in any way. These vials will be shipped from the nuclear pharmacy in the same containers and form in which they are shipped to the pharmacy, reducing the possibility of Xenon-133 leaks, spills or contamination essentially to zero.

II. Use and Storage Areas

When the pharmacy receives shipments of Xenon-133, the gas or gas in saline will be in sealed glass vials which will be shipped to authorized users without being opened or without the septum being punctured by anyone in the pharmacy. The sealed vials will be stored in a fume hood, nevertheless, and will remain inside the lead containers used by the manufacturer for shipment of the Xenon-133. Please see attached floor plan diagram for the location of the fume hood.

Xenon-133 is not to be used in the pharmacy. It will be stored and dispensed in the fume hood only. The exhaust system consists of a vent in the hot lab room and the fume hood. The ducts from these two exhausts meet before reaching the roof. There is a common duct for these vents from this juncture to the roof. The exhaust rate from the hot lab vent is 800 cfm. The exhaust rate from the front of the fume hood is 100 cfm. This is a direct exhaust to the roof only, no recirculation. The nearest point of re-entry is at least 35 feet from the nearest window, door or intake vent.

These exhaust rates will be checked semi-annually with a velometer to determine if the fume hood is operating according to specifications in this license.

III. Procedures for routine use

The vials will be stored in the original shipping containers composed of lead, and they will be stored in the fume hood

at all times. When an authorized user orders a quantity of Xenon-133 gas or gas in saline, the vials will be dispensed in their original containers to the physician. Dispension will be preceded by an assay of the vial in the dose calibrator.

IV. Emergency Procedures

The worst occurance possible will be the accidental release of the contents of a Xenon-133 unit dose vial(s). This could happen through breakage or a cracked vial.

In the event there is an accidental loss of Xenon into the room, the exhaust system will clear the room to levels less than 1×10^{-5} uCi/ml in less than 4 minutes:

For the Hot lab room:

Activity per loss (A) $= 25 \text{ mCi} = 2.5 \times 10^{4} \text{ uCi}$

Room Volume (V) $= 15' \times 5' \times 8'$

$= 600 \text{ ft.}^{3}$

$= 1.7 \times 10^{7} \text{ml}$

Clearance rates (λ) $= \frac{900 \text{ cfm}}{600 \text{ ft.}^{3}}$

$= 1.5 \text{ min.}^{-1}$

Initial Concentration (C_o) $= \frac{2.5 \times 10^{4} \text{ uCi}}{1.7 \times 10^{7} \text{ ml}}$

$= 1.47 \times 10^{-3} \text{ uCi/ml}$

Evacuation time (t) $= 4 \text{ min.}$

Final Concentration (C) $= C_o e^{-\lambda t}$

$= (1.47 \times 10^{-3}) e^{-1.5 \times 4}$

$= 3.6 \times 10^{-6} \text{ uCi/ml}$

This value is less than 1×10^{-5} uCi/ml

All unnecessary personnel will evacuate the room. The hot lab room door will be guarded against inadvertant entry during this time period.

A survey meter will be placed on the floor so it can be observed from the door. When background levels are reached, the room may be re-entered.

V. Air Concentration of Xenon-133 in Restricted Areas

A. The maximum amount of Xenon in possession per year will be:

Activity = 2000 mCi x 52 weeks

= 104,000 mCi/yr

B. For storage of Xenon in the hot lab it is assumed that up to 5% of the gas may be lost due to leakage.

Activity = 104,000 mCi/yr x 5% x 10^3 uCi/mCi

= 5.2×10^6 uCi (A)

C. Air flow per year is (V):

V = 900 cfm x 1.484×10^{10} ml/yr/cfm

V = 1.34×10^{13} ml/yr

D. The average concentration of Xenon in the hot lab is(C):

$$C = \frac{A}{V}$$

$$= \frac{5.2 \times 10^6 \text{ uCi}}{1.34 \times 10^{13} \text{ ml/yr}}$$

$$= 3.88 \times 10^{-7} \text{ uCi/ml/yr}$$

This value is less than required for restricted areas (1×10^{-5} uCi/ml).

VI. Methods for Xenon-133 Disposal:

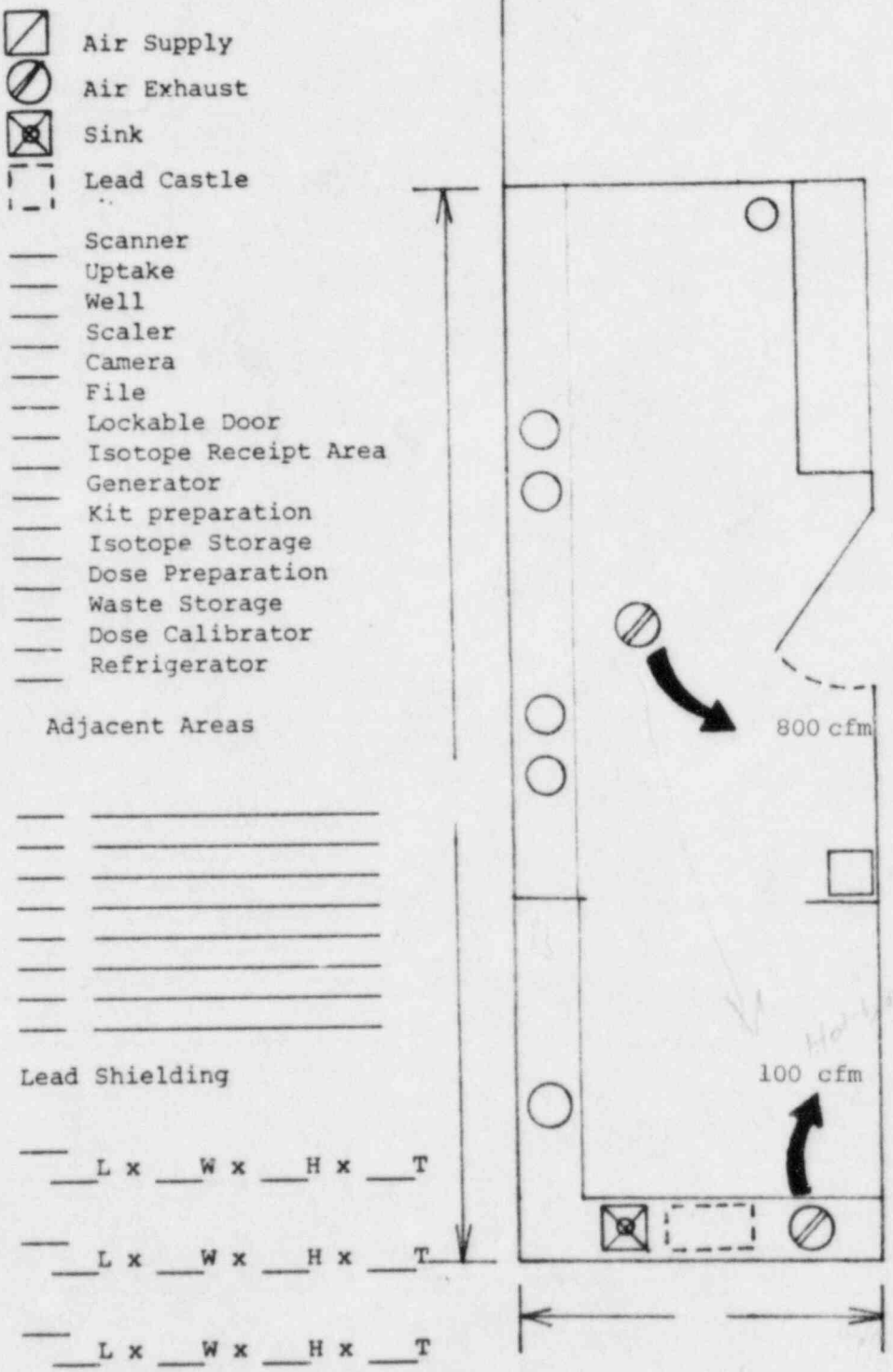
A. All Xenon acquired will be disposed of by dispensing to clients, or by decay in storage. Containers and vials will be surveyed unshielded with the low level survey meter held on contact. If levels are the same as background, the containers will be disposed of after defacing the labels.

All escaped Xenon will be vented through the exhaust system.

B. For average Concentration of Xenon to the environment through the exhaust system in the hot lab, due to leakage, the same calculations would apply as contained in V (D). This value does not exceed the value for unrestricted areas of 3.0×10^{-7} uCi/ml per 10 CFR 20.106.

Facilities and Equipment

Diagram



Hot Lab
Ventilation
Flow Rates

Item #21

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Prepared 8/26/83

GUIDE FOR THE PREPARATION OF A NUCLEAR PHARMACY LICENSE

Referring to paragraph III of the NRC Radiopharmacy Licensing Guide requesting information relating to 10 CFR 32.72-32.74:

A. Referencing 10 CFR 32.72 (a)(2):

1. See enclosed.

2. Radiopharmaceuticals that we dispense and/or distribute for human use will be either:

   a. Radiopharmaceuticals that are the subject of an active "New Drug Application" (NDA) approved by FDA or an active "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA, or

   b. Radiopharmaceuticals prepared from generators and reagent kits that are the subject of an active NDA approved by FDA or an active IND that has been accepted by FDA.

3. We intend to distribute IND radiopharmaceuticals and radiopharmaceuticals prepared from generators or reagent kits that are under IND status, and we will:

   a. Dispense these drugs in accordance with the directions provided by the sponsor of the IND.

   b. Distribute these drugs only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

   c. Notify the participating physician in writing that the physician is responsible to the sponsor of the IND for use of the drug in accordance with the protocol established by the sponsor and for reporting the clinical information obtained through the use of the drug.

4. We intend to redistribute reagent kits obtained from other manufacturers and we will:

   a. Obtain the reagent kits from manufacturers approved to distribute them in accordance with Section 32.73 of 10 CFR Part 32 or under equivalent regulations of an Agreement State, and

   b. Redistribute the reagent kits as received from the manufacturer in the "kit sleeve" (e.g., cardboard enclosure holding Styrofoam container with multiple reaction vials) and accompanied by the manufacturer's approved package insert.

B. Referring to the information requested under 10 CFR 32.72 (a)(3):

1. Syringe carrier shields having a minimum wall thickness of 0.39 cm lead will be used for transporting Tc-99m sources up to 200 mCi may be in one carrier.

   Syringe carriers having minimum wall thicknesses of 0.63 cm lead will be used for all higher energy radionuclide distributions. Up to 10 mCi may be distributed.

   Distribution of greater amounts of the higher energy radionuclides will be accomplished through the use of the manufacturers original shipping shield or its equivalent.

   See the attached reprint from the Journal of Nuclear Medicine Technology.

2. See the attached syringe carrier shield diagram.

3. See the attached JNMT article, Item #15, Appendix A.

C. Referring to the requirement given in CFR 32.72(a)(4) see the attached photo copy of labeling to be used.

IV. As to procedures for packaging and transporting radiopharmaceuticals to customers, see Item #12.

Hospital

Rt.

Doctor Date

Radionuclide

Pharmaceutical

Procedure

Lot Number

Assay as of

Activity: Needed Dispensed

Volume Dispensed

Dispensed By Rx.

Patient Name

Comment:

P.O.# Use as directed by physician.

Special Charge Charge Code

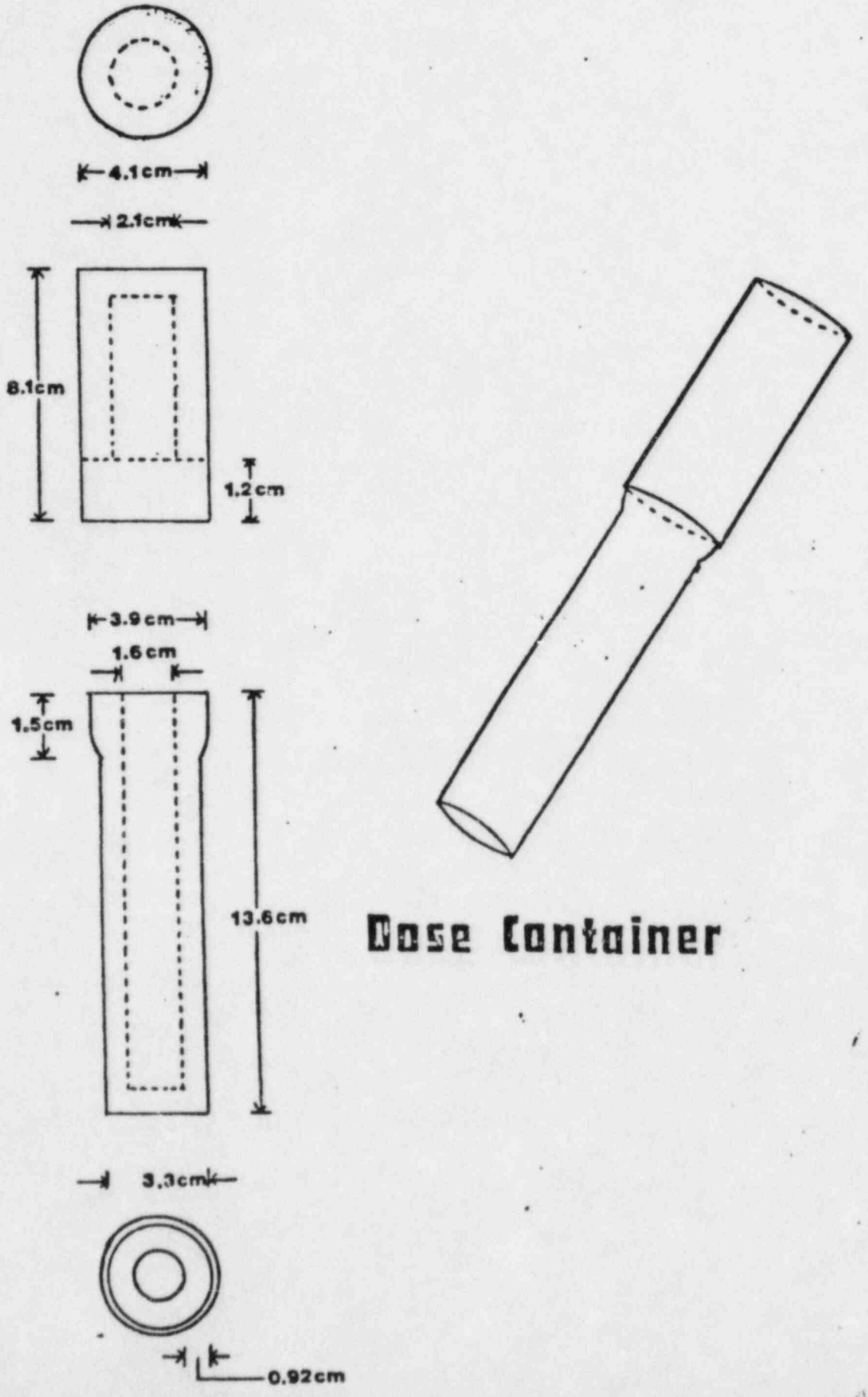
Rx

Rx

Warning: This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group I or Group II of 10 CFR part 35. Syringe containing drug should be kept in this container or within heavier shield.

Warning: This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group ____ of 10 CFR part 35. Syringe containing drug should be kept in this container or within heavier shield.

Whenever this label is used, we will be certain to fill in the blank space with the appropriate group, so that it reads group I, II, IV, or V in compliance with 10 CFR 32.72 subsection (a.) (4).



Dose Container

18C16

Model Program for Maintaining Occupational
Radiation Exposures at Medical Institutions ALARA

Centra-Pharm, Inc.
(Licensee's Name)

10-10-83
(Date)

I. Management Commitment

a. We, the management of this (medical facility, hospital, etc.) are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)[1] and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

1 Private practice physician licenses do not include a RSC.

II. Radiation Safety Committee (RSC)[2]

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

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[2] The RSO on private practive physician licenses will assume the responsibilities of the RSC under Section II.

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see paragraph VI).[3]

3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC and the RSO are committed to implementing the ALARA concept.

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[3]The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection", serve as check points above which the results are considered sufficiently important to justify further investigation.

c. Cooperative Efforts for Development of ALARA Procedures

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

2. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and encourage the the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he surpervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

b. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

VI. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practive) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

TABLE 1

		Investigational levels - (mrems per calendar quarter)	
		LEVEL I	LEVEL II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, §20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

a. Quarterly exposure of individuals to less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form MRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed in Table I.

In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.

VII. Signature of Certifying Official[4]

I hereby certify that his institution (or private practice), has implemented the ALARA Program set forth above.

Steven Ray Lefevre, RPh, BCNP
Signature

Steven Ray Lefevre
Name (print or type)

President
Title

Institution (or Private Practice) Name and Address:

[4]The individual who is authorized to make commitments for the administration of the institution (e.g., hospital administrator, etc.) or, in the case of private practice the licensed physician.

NOTE TO: License Fee Management Branch, ADM

FROM: Region III

SUBJECT: VOIDED APPLICATION

Control Number 16016

Applicant Centra Pharm

Date Voided 8/27/85

Reason for Void Licensee withdrew application - after review

Signature ADAM

Attachment:
Application

OK LFMB
no refund due

HJ 9/9