MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Spectrum Pharmacy, Inc.	3. License number 13-26367-01MD
2. 1301 Milburn Boulevard Mishawaka, IN 46544-4639	4. Expiration date February 28, 1997
	5. Docket or Reference No 030-32564

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Molybdenum-99	A. Any Molybdenum-99/ technetium-99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. 35 curies
B. Any byproduct material listed in paragraph 31.11(a) of 10 CFR Part 31	B. Prepackaged in vitro diagnostic test kits	B. 50 millicuries total possession limit
C. Any byproduct material authorized under paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987)	C. Any sealed source listed in paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	C. 50 millicuries total for all sources authorized under Subitem 6.C.

mk
3P
DH 2

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-26367-01MD
Docket or Reference number: 030-32564

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
D. Xenon-133	D. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	D. 800 millicuries
E. Iodine-131	E. Any form listed in Groups I through V of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200, 35.300 of 10 CFR Part 35 (effective April 1, 1987)	E. 500 millicuries
F. Technetium-99m	F. Any form listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 and 35.200 of 10 CFR Part 35 (effective April 1, 1987)	F. 35 curies
G. Any byproduct material, except iodine-131 and technetium-99m, listed in group I of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 of 10 CFR Part 35 (effective April 1, 1987)	G. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 of 10 CFR Part 35 (effective April 1, 1987)	G. 50 millicuries total possession limit

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-26367-01MD
Docket or Reference number: 030-32564

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
H. Any byproduct material, except iodine-131 and technetium-99m, listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.200 of 10 CFR Part 35 (effective April 1, 1987)	H. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.200 of 10 CFR Part 35 (effective April 1, 1987)	H. 400 millicuries total possession limit
I. Any byproduct material, except iodine-131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.300 of 10 CFR Part 35 (effective April 1, 1987)	I. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.300 of 10 CFR Part 35 (effective April 1, 1987)	I. 100 millicuries total possession limit
J. Uranium (depleted in the isotope Uranium 235)	J. Metal encased in stainless steel	J. 110 kilograms
K. Cesium-137	K. Sealed source (Technical operations Model 77302)	K. One source not to exceed 165 millicuries

9. Authorized Use:

A. Production of technetium-99m pertechnetate. Redistribution of unused generators to authorized recipients in accordance with statements, representations and procedures contained in application dated November 4, 1991 and letter dated January 21, 1992.

B. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in application dated November 4, 1991 and letter dated January 21, 1992.

C. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Section 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) or under equivalent licenses of Agreement States.

D. Distribution to authorized recipients.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-26367-01MD
Docket or Reference number: 030-32564

E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Compounding of iodine-131 capsules and distribution of these capsules to authorized recipients in accordance with statements, representations and procedures contained in application dated November 4, 1991 and letter dated January 21, 1992.

F. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

G. through I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

J. Shielding for Mo99/Tc99m generators.

K. For use in Technical operation Model 773 calibration device for instrument calibration.

Pursuant to Sections 32.72, 32.73 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200 and 35.300 of 10 CFR Part 35 (effective April 1, 1987), or under equivalent licenses of Agreement States, for the Groups or Sections indicated below:

A. Unused molybdenum-99/technetium-99m generators may be redistributed to persons licensed pursuant to Group III or Section 10 CFR 35.200.

D. Gas or gas in saline may be distributed to person licensed pursuant to 10 CFR 35.200 (effective April 1, 1987).

E. through I. Any form listed in each group, Groups I, II, IV and V of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or authorized by Sections 35.100, 35.200 and 35.300 (effective April 1, 1987), may be distributed to persons licensed pursuant to that Group or Section.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1301 Milburn Boulevard, Mishawaka, Indiana.

11. A. Licensed material listed in Item 6. above, except for Subitem 6.K., shall be used by, or under the supervision of:

David S. Andrews	Quent Besing	Brian C. Blaum
Curtis Blaum	Scott C. Brower	Mark E. Brown
Dale Bultmeier	E. Dean Dome'	Kurt F. Dunphy
Albert Easley	Gregory Edquist	Gregory Green
Ned Gregorio	Paul Gotti	Gregory S. Hiatt
Danny L. Hinel	George H. Hinkle	Louis Juliano

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-26367-01MD
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11. A. (Continued)

Donald Kapolnek	Keith Koontz	James W. Korb
William McHugh	Stanley R. Miller	David Newbaker
Stephen Piepenbrink	Timothy M. Quinton	Paul D. Sale
John D. Scheu	Jay R. Simon	David Small
Cynthia Anne Smith	William Thompson	Scott E. Van Heesbeke
Dawn K. Whitney	Benson Yang	

B. Licensed material listed in Subitem 6.K. shall be used by Gregory S. Hiatt, Robert Anger, Andrea Brown or John D. Scheu.

12. At least one individual named in Condition 11.A. shall be physically present at the authorized place of use whenever licensed material is being used.

13. The Radiation Protection Officer for the activities authorized by this license is Gregory S. Hiatt.

14. A. (1) The source(s) specified in Item(s) 7.C. and K. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

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

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

MATERIALS LICENSE
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Docket or Reference number: 030-32564

15. Sealed sources containing licensed material shall not be opened.

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

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

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

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

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

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

(i) In accordance with the directions provided by the sponsor of the IND, and

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

19. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

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

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

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-26367-01MD
Docket or Reference number: 030-32564

20. (Continued)

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

21. Any proposed changes in packaging, shielding or labelling shall be submitted for review to the U.S. Nuclear Regulatory Commission, Region III, Nuclear Material Licensing Section, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137.

22. Reagent kits may be redistributed to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35, or under equivalent licenses of Agreement States, for Group III.

23. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in application dated November 4, 1991.

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

25. The licensee may use the Lineator device for doing linearity tests of its dose calibrator provided it follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1963.

26. The licensee shall have quarterly audits of their radiation safety program, performed in accordance with statements contained in application dated November 4, 1991 and letter dated January 21, 1992.

27. The licensee shall maintain records of information important to safe and effective decommissioning at the address specified in Condition 10. per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

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

A. Application dated November 4, 1991; and

B. Letters dated January 21, 1992 and February 1, 1992.

For the U.S. Nuclear Regulatory Commission

Date: 2/3/92

By: John R. Madera
Materials Licensing Section, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

NOV 3

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE:
STATUS CODE: 3
FEE CATEGORY: 3C 2B
EXP. DATE: 0
FFE COMMENTS:
DECOM FIN ASSUR REQD:

LICENSE FEE TRANSMITTAL

A. REGION III

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: GREGORY S. HIATT
RECEIVED DATE: 911105
DOCKET NO: 3032564
CONTROL NO.: 392519
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: 1100.00
CHECK NO.: 1324

3. COMMENTS

SIGNED Rose V. Rogers
DATE 11-6-91

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

1. FEE CATEGORY AND AMOUNT: 3D $1100

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

3. OTHER

SIGNED Rita Jacques
DATE 11/8/91

RECEIVED
NOV 12 1991
REGION III

NRC FORM 313
(9-88)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 4-30-90

APPLICATION FOR MATERIAL LICENSE

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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

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

[X] A. NEW LICENSE

[ ] B. AMENDMENT TO LICENSE NUMBER _____

[ ] C. RENEWAL OF LICENSE NUMBER _____

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

Gregory S. Hiatt
17460 Farmington Square Rd.
Granger, Indiana 46530

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

Spectrum Pharmacy
1301 Milburn Blvd.
Mishawaka, Indiana 46544

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

Gregory S. Hiatt | (219) 271-7183

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

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

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

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

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

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 3.D. | AMOUNT ENCLOSED $ 1,100.00

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

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

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

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Gregory S. Hiatt	Gregory S. Hiatt	Proprietor	11/4/91

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS
APP	Nov 3 III	3C 2B	

AMOUNT RECEIVED	CHECK NUMBER
$1,100+$24.00	124/1837

CONTROL NO. 92519

APPROVED BY	DATE
Rita Jacques	11/8/91

NRC FORM 313 (9-88)

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 7.5 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE RECORDS AND REPORTS MANAGEMENT BRANCH (P-530), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

SPECTRUM

U.S. Nuclear Regulatory Commission, Region III
Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, IL 60137

Gregory S. Hiatt Gregory S Hiatt
Spectrum Pharmacy
17460 Farmington Square Road
Granger, IN 46530

To Whom It May Concern:

Enclosed I have included an application for a material license for a radiopharmacy. I have also included a check for $1100.00 for a schedule 3.D. license.

I would like to be able to open my pharmacy as soon as possible so I will make myself readily available to you if you have any questions. My home phone number is: 219/ 271-7183.

Thank you in advance for your assistance.

CONTROL NO. 92519

RECEIVED
NOV 05 1991
REGION III

License Fee Information
on Next Page

NOV 5 1991

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OCT 26 1992

Spectrum Pharmacy, Inc.
ATTN: Gregory S. Hiatt
President
17460 Farmington Square Road
Granger, IN 46530

Gentlemen:

This refers to Materials License 13-26367-01MD which was issued February 3, 1992. The license was issued in accordance with your application dated November 4, 1991.

Through an oversight, the license was issued without the required fee being collected. At the time your application was filed, it appeared that your request would be subject to fee Category 3D of §170.31 of the enclosed 10 CFR 170, and the fee of $1,100 was paid.

However, since the license was issued to authorize the processing of byproduct material and the use of depleted uranium for shielding, a fee of $3,510 is required as specified in fee Categories 3C ($3,400) and 2B ($110) of §170.31. Accordingly, an additional fee of $2,410 is required. Payment should be made to the U.S. Nuclear Regulatory Commission and mailed to the following address:

Cheryl
Is this the correct amount for 1991?

U.S. Nuclear Regulatory Commission
Attn: Cheryl Phillips
License Fee and Debt Collection Branch, OC/DAF
Mail Stop MNBB 4503
Washington, DC 20555

We apologize for the delay in notifying you of the additional fee due and for any inconvenience this matter may cause you.

Sincerely,

Doug Weiss

Attn:

Doug Weiss, Chief
Materials License Fee Section
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

Enclosure:
10 CFR 170

SPECTRUM
PHARMACY, Inc.

January 21, 1992

ATTN: Mr. Loren J. Hueter
Nuclear Regulatory Commission
Region III
Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Hueter:

The following information has been written in response to your letter dated January 10, 1992 that requested clarification on certain issues. I will follow the order of items in your letter.

"1". Name and Mailing Address of Applicant (Item 2)

Spectrum Pharmacy, Inc.
1301 Milburn Blvd.
Mishawaka, Indiana 46544-4639

I would like my correspondence with the NRC to come to my home until I have received my license. My home address is:

Gregory S. Hiatt
17460 Farmington Square Rd.
Granger, Indiana 46530

Telephone number (Item 4)

(219) 255-5072

Title of Certifying Officer

President

RECEIVED
JAN 24 1992
REGION III

1301 Milburn Blvd
Mishawaka, IN 46544
(219) 255-5072

CN 92519

JAN 24 1992

"2". Needed Additions to Items 5. and 6. of Application

Please add the following:

ITEM 5

Radioactive Material

Element and Mass Number	Chemical and/or Physical Form	Maximum Amount Which Will be Possessed at any One Time
K. Depleted Uranium Uranium-235	K. Metal encased in stainless steel	K. 110 Kilogram
L. Cesium-137	L. Sealed Source	L. 170 millicuries

The number of sources being requested for calibration services is one (1) at this time.

1. Redistribution of Reagent Kits

Reagent kits will be redistributed in the original manufacturer's kit sleeve and as smaller units as requested by a physician or a physician's representative. The smaller units will require the original manufacturer's sleeve to be broken down and the desired quantities removed. At no time will the individual kit package be opened prior to dispensing.

All reagent kits will be redistributed accompanied by a copy of the manufacturer's package insert or brochure, leaflet or other document that describes the procedures to be followed and the equipment and shielding to be used in processing radioactive material with the reagent kit.

2. REDISTRIBUTION OF SEALED SOURCES--CALIBRATION AND REFERENCE SOURCES

a. These sources will be redistributed to customers licensed under the provisions of 35.14 of 10 CFR, or to customers specifically licensed to receive calibration sources for medical equipment calibration.

b. The calibration or reference sources to be redistributed will have been from a manufacturer authorized to distribute

the sources in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent regulations of an Agreement state.

c. The manufacturer's labeling and packaging will not be altered and redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure or other document tht provides radiation safety instructions for handling and storing the sources.

3. Redistribution of In-Vitro Kits

A. For redistribution of In-Vitro Kits to **General** licenses;

1. The prepackaged in vitro kits to be redistributed will have been obtained from a manufacturer authorized to distribute the in vitro kits in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State.

2. The manufacturer's packaging and labeling of the in vitro kits will not be altered in any way.

3. Each redistributed in vitro kit will be accompanied by a copy of the manufacturer supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

B. For redistribution of In-Vitro kits to **Specific** licenses;

1. Spectrum Pharmacy, Inc. will obtain prepackaged in vitro kits (as described in 10 CFR 31.11 (a)) for redistribution to specific licensees.

2. Spectrum Pharmacy, Inc. will ensure that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed in vitro kits do **NOT** reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11).

3. Spectrum Pharmacy, Inc. will ensure that labeling on redistributed in vitro kits conforms to the requirements of 10 CFR 20.203.

4. Redistribution of Unused Generators

a. All unused generators to be redistributed will have been obtained from a manufacturer authorized to distribute the generators in accordance with a specific license issued pursuant to 10 CFR 32.73 or under equivalent regulations of

an Agreement State.

b. All unused generators will be redistributed without opening or altering the manufacturer's packaging.

NOTE: It is not the intent of Spectrum Pharmacy, Inc. to actively solicit business by selling unused generators. Spectrum Pharmacy, Inc. does want the option to provide unused generators in order to meet specific customer's needs.

"Under the redistribution of unused generators a description of the facilities generator waste storage and the ultimate disposition of the generators was requested."

A. Generator waste storage

The generator/waste room has approximately 184 Sq. Ft. of floor space and I have allocated approximately 75 Sq. Ft. of that space for radioactive waste storage. The spent generators will be stored behind 1/8 inches of lead. The wall separating the waste room and the dispensing room as well as the exterior wall in the waste room are a minimum of 8 inches of concrete block.

Used Generators will be returned to the original Manufacturer or stored until decayed.

1. Generators returned to the original manufacturer (most manufacturers are requiring return of their generators)

   a. Return the Mo-99, Tc-99m generator to the original shipping container while wearing disposable gloves.

   b. Perform wipe test on surface of container

   c. Obtain radiation levels at surface and one (1) meter

   d. Complete appropriate labeling and prepare shipping certificate.

2. Generators stored for decay

   a. Returned Mo-99, Tc-99m generator's surface will be wipe tested while wearing disposable gloves.

   b. Mo-99, Tc-99m generator will be dated with the current date and place in the appropriate shielded area.

   c. The spent generators will be decayed a minimum of ten (10) half-lifes (about one month). The cores will

be removed and further decayed to background and the lead core as well as the container will be wipe tested for any removable contamination. Once all items have decayed to background and show no removable contamination they will be disposed of.

Item 6

Purposes for Which Licensed Material Will be Used

Material reference Letter from Item 5	**Purposes for which Material Will be Used**
K.	Shielding of Mo-99, Tc-99m Generators
L.	Technical operation of Model 77302 Tech Ops calibration device

"3". Item 7 of Application

"Clarify spelling of last name of pharmacist Brian c. Blaum."

The correct spelling is: Brian Craig Blaum and he is listed on license number 34-16654-01MD Syncor Corporation, Toledo Ohio. I am using amendment number 62 dated November 30, 1988.

Please add the following names to my list of Individuals Responsible for Radiation Safety etc.

Scott ~~Vanhosebeck~~ VanHeusbeke R.Ph
Listed as authorized user on N.R.C. license #34-16654-01MD, Syncor Corp., Toledo, Ohio

Albert Easley R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD, Syncor Corp., Toledo, Ohio

Keith Koontz R.Ph.
Listed as authorized user on N.R.C. License #34-16654-01MD,

William Thompson R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

David Small R.Ph.

Listed as authorized user on N.R.C. license #34-16654-01MD

Paul D. Sale R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Benson Yang R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Stanley R. Miller R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Danny L. Hinel R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Gregory E. Green R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Donald Kapolnek R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Stephen Piepenbrink R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

George H. Hinkle R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Louis Juliano R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

James W. Korb R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Kurt F. Dunphy R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Jay R. Simon R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

David S. Andrews R.Ph.

Listed as authorized user on N.R.C. license #34-16654-01MD

Scott C. Brower R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Gregory Edquist R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

William McHugh R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

Quent Besing R.Ph.
Listed as authorized user on N.R.C. license #34-16654-01MD

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3. Item 7 of Application cont'd

"Please clarify the working status/relationship that John D. Scheu, Ph.D., R.Ph., will have with Spectrum Pharmacy."

I would like to replace John D Scheu, as my quarterly auditor, with Robert T. Anger. GSN

Please find attached the qualifications of Robert T. Anger, Jr. Mr. Anger is currently working with Medical Physics Consultants, Inc. thus affording a wider range of services and coverage to Spectrum Pharmacy, Inc.

I would also like to request that John D. Scheu, Ph.D. remain on my license as an authorized user.

4. Facility Description

The delivery vestibule, used for drop-off of radioactive shipments, will be heated to prevent freezing of delivered packages in cold weather.

FUME HOOD AND GLOVE BOX DESCRIPTION

All work involving the handling of open containers of millicurie quantities of liquid radioiodine will be performed within the glove box. (see diagram 5a)

The fume hood will have a minimum flow rate of 400 CFM and will be used mainly for the storage of all volatile materials as well as xenon-133 and Iodine-131. The fume hood will be running 24 hours each day and will be exhausted through the roof of the building. Air monitoring of the unrestricted space will take place in the stack above the

point where the glove box's exhaust is connected. The air monitoring of the restricted space will take place in the breathing zone somewhere in the iodine work room. The filter for the unrestricted space will be an in-line charcoal filter and the filter for the restricted space will be an open faced charcoal filter.

The glove box's effluent charcoal filters will be approximately 1 inch thick in a 12 inch square frame. The theoretical trapping efficiency for each inch is 82%. Therefore, two one (1) inch filters should have a trapping efficiency greater than 98%. The annual concentration of radioiodine in effluents released to the environment should be less than 1 x 10 e-10 uCi/ml for the unrestricted space and less than 9 x 10 e-9 uCi/ml for the restricted space.

The above estimates of the concentration of radioiodine in effluents released to the environment should be very conservative based upon previous experience with a radiopharmacy in a market the size of the market for Spectrum Pharmacy, Inc. Routine sampling of both the restricted and unrestricted areas should substantiate the validity of the above estimates.

Prior to use, at installation, of the glove box the linear flow across each arm port of the hood will be determined with an anemometer under conditions of normal operation with both charcoal filters in place and with the standard laboratory fume hood on. The linear flow test across each arm port as indicated above will be repeated at least quarterly to insure that the unit continues to operate at this base line level. If the air flow drops below 75% of the initial flow (baseline) then the filters will be changed to insure proper operation.

In the case of a mechanical failure of the fume hood the emergency procedure will be to essentially halt any manipulation of Iodine-131 until the equipment is functioning properly again. If the glove box has a mechanical failure the sash of the fume hood will be closed off thus maximizing the negative pull through the glove box by the fume hoods blower.

"Confirm that disposable gloves will be worn when surveying and changing the charcoal filters."

Spectrum Pharmacy, Inc. confirms that the use of disposable gloves will be required when any employee is involved in handling the changing of the charcoal filters.

"Describe special shielding that will be available and used

during iodine-131 therapy capsule preparation, in addition to the previously described lead block with two holes (e.g. 1 block shield and lead glass or other type of window in glove box)."

The glove box is constructed of a plexi-glas type of material and there will be a L shield constructed of one (1) inch of lead inside the glove box. The L shield will have a lead glass window.

"State the storage location of stock Xenon-133, stock Iodine -131 and waste Iodine-131 as well as the location where Iodine -131 will be handled in millicurie quantities of liquid."

Xenon-133 and stock Iodine-131 will be stored in the fume hood as indicated in diagram 5a. Waste Iodine-131 will be placed in a zip-lock type of plastic bag and then that plastic bag will be placed inside another plastic bag and then the outer bag will also be sealed. Waste items included will be syringes, vials, charcoal filters, absorbent materials, returned waste from customers.

Liquid iodine-131 will be handled in the glove box where there will be charcoal filters in-line with the effluent air flow Sealed tins containing therapy solution or diagnostic capsules of Iodine-131 will only be opened in this charcoal filtered glove box. Vial septums, syringes, pipettes, etc., which may be contaminated with iodine-131, will be rinsed or decontaminated before removal from the glove box. In the case an item is difficult to decontaminate the item in question will be treated as waste and double bagged.

The integrity of the safety procedures for handling Iodine-131 will be substantiated by the routine sampling of both the restricted and unrestricted air space. The sampling system will run continuously for both the restricted and unrestricted areas and each area will have an air flow gauge in line with the vacuum line running from the pump to the appropriate filter. The restricted area sample will be collected in the breathing zone of workers processing Iodine-131 (e.g. outside the glove box above the area where an individual would be working).

The samples will be collected and analyzed to evaluate air concentration in both restricted and unrestricted areas at the end of each work day that liquid iodine is opened and dispensed in millicurie quantities and at not greater than

weekly intervals regardless of work activity with iodine-131.

"5" Thyroid Monitoring

The iodine bioassay program specified in Regulatory Guide 8.20, "applications of Bioassay for I-125 and I-131", will be implemented. Iodine-125 will not be handled in an open form so a bioassay for Iodine-125 will not be performed.

The equipment that will be used for the bioassay determination is a Tennelec/Nucleus MCA (PCA-P) with 2048 channels. This MCA utilizes a windowing technique with pulldown menus. The probe is a two (2) inch NaI crystal that will be housed in a lead shield. This configuration has been marketed for thyroid uptake systems and well counting systems. As in all uptake systems this system will also have a collimator when being used as an uptake system. The extra shielding provided by the larger well shielding increases sensitivity by reducing the amount of background noise.

"6" Health Physics Procedures

"What additional health physics procedures will be employed because your personnel will be using I-131 of a higher specific activity and higher concentration than they are accustomed to using?"

When handling I-131 employees will be instructed to wear two sets of vinyl or latex disposable gloves. All personnel will also be instructed to utilize tongs to increase the distance from the hands to the source material and all personnel will be reminded to keep the "time" variable in mind (time, distance and shielding). Additionally, all waste will be placed in a plastic bag that can be sealed and then that plastic bag will be placed inside another plastic bag that can be sealed. When venting a new vial of Iodine-131 Spectrum Pharmacy, Inc. personnel will be instructed to utilize a syringe with activated charcoal inside. The charcoal is to absorb the volatilized iodine. This syringe will then be "double bagged" and put in a leaded waste container specific for iodine.

Because of the nature of iodine-131, Spectrum Pharmacy, Inc. has set aside a special room just for the handling of this material. Very few other radiopharmaceuticals will be stored in this room. Additionally, Spectrum Pharmacy, Inc. has gone to the expense of installing a glove box with a charcoal filtering system along with a normal fume hood. Continuous monitoring of the air in both the restricted and unrestricted space has also been established.

"7" ALARA

"What steps will you take to ensure that personnel exposures and effluent releases of I-131 are kept ALARA during preparation of therapy capsules?"

All personnel that will be handling Iodine-131 will be trained in the proper procedures for preparing therapy capsules and only the pharmacist handling the prescription will be in the iodine room at the time. Initially, the pharmacists will be instructed using normal saline instead of radioactive iodine. The pharmacists will be instructed in the placement of the capsule in the lead holder and on the quick handling of the iodine (using lo-dose insulin syringes). A dose calibrator has been purchased for the iodine room just for the purpose of reducing handling time.

NOTE: Lo-dose insuling syringes deliver all of the contents leaving little to no residue. When preparing capsules the amount of activity assayed will be very close to the amount the capsule is made from.

"7" ALARA CONT'D

All personnel will be instructed in decontamination procedures and the need to do so quickly.

The iodine-131 in the effluent air will be kept ALARA by venting new containers with charcoal filled syringes, only opening containers in the charcoal filtered glove box, only preparing capsules in the glove box, double bagging all waste and cleaning up the work area immediately.

"8" Preparation and Assay of Capsules of Prescribed Activity

The special correction factor that is needed for the dose calibrator when preparing capsules is called a K factor. Spectrum Pharmacy, Inc. will determine the K factor for its calibrators by acquiring an NBS traceable capsule. The Cs-137 rod source will be used to determine the K factor.

$$K = \frac{A \times B}{C} \quad \text{where}$$

A = Certified activity of I-131 standard corrected to the time of measurement.

B = Dose calibrator reading for Cs-137 reference source at time of measurement.

C = Dose calibrator reading for I-131 standard at time of measurement.

The Cs-137 source would need to be corrected for decay thereafter.

As stated above, capsule compounding will first be practiced using normal saline by all pharmacists prior to actual use of I-131 solution.

"9" Survey Meter Calibration

Please amend page P4, item E of my application to read: Survey meter calibration procedures will be in accordance with Appendix B of NRC Regulatory Guide 10.8.

"10" Transportation

Spectrum Pharmacy, Inc. confirms that any use of a common carrier for transport of material will involve only delivery of packages which are already packaged and labeled in accordance with DOT regulations.

Please amend paragraph 1 of page 22 of Spectrum Pharmacy, Inc.'s application to read:

A copy of written instructions will be kept conspicuously available (ie. dashboard or window) in each delivery vehicle for driver, police or civil authorities in case of traffic accidents, etc.

Please amend item #1, page 22 of Spectrum Pharmacy, Inc.'s application Pharmacy Phone # to the following:

Pharmacy Phone # (219) 255-5072

"11" See attachments

"12" Labels

It is my understanding that the label submitted is being used by some other independent pharmacies and a large national chain pharmacy. Based upon this information I am understanding that NRC Region III will approve my use of this label.

"13" see enclosed license (will be sent when received)

14. Please amend Spectrum Pharmacy, Inc.'s application as follows:

A. Page 18, paragraph two should read Canberra series 35 multichannel analyzer or equivalent.

B. page 10; phone number needs changed to (219) 255-5072

C. Page 21; Phone number needs changed from (219)255-0572 to (219) 255-5072

D. Page 22; phone number needs changed to (219) 255-5072

E. Appendix F bottom; phone number needs changed to (219) 255-5072

F. Appendix I-2; Office Phone needs changed to (219) 255-5072

G. Item 5, B, Please increase the maximum amount for possession from 15 millicuries (mCi) to 50 millicuries (mCi)

MEDICAL PHYSICS CONSULTANTS, INC.

5230 N. WASHINGTON BLVD.
P.O. BOX 30269
INDIANAPOLIS, IN 46230
1-800-321-2207

2309 SHELBY
ANN ARBOR, MI 48103
1-313-662-3197

Medical Physics Consultants, Inc. (MPC) has been a "group" for over 11 years and has maintained an excellent reputation with regulatory agencies. We have six full-time physicists, a full-time physicist assistant, 1.5 FTE secretaries, and three senior physics consultants (including myself in Indianapolis) who support MPC in their special areas of expertise. We are the only group in Michigan and Indiana with full-time physicists certified by the American Board of Radiology in both Medical Nuclear Physics (3, plus one in progress) and Diagnostic X-Ray Physics (2). We have over 70 cumulative years of experience in Nuclear Medicine and 30 years in Diagnostic Radiology, and currently service over 150 institutions in Michigan and Indiana. One of our full-time medical physicists has now relocated to the northside of Indianapolis, thus clearly establishing our long-term commitment to the Indiana medical community.

At the Ann Arbor location, we have a survey meter calibration and repair facility. One employee is dedicated to performing survey meter calibrations (at no additional charge to Nuclear Medicine accounts). We have one senior consultant physicist who is dedicated to forms/software development, and one contracted physicist for other software development (e.g., SPECT acceptance testing software). All of our inspection forms and the associated software are original to MPC and are continually upgraded to reflect regulatory changes.

ROBERT T. ANGER, JR.
Medical Physicist/Radiation Safety Officer
Methodist Hospital of Indiana, Inc.
1701 North Senate Blvd.
Indianapolis, IN 46202

B.S. in Zoology from University of Michigan (1965)
M.S. in Radiological Health from University of Michigan (1966)
M.P.H. in Radiological Health from University of Michigan (1967)

Certified in Medical Nuclear Physics by the American Board of Radiology (1975)

Twenty-two (22) years experience as a Medical Physicist and Radiation Safety Officer, with the last 20 years in Indiana

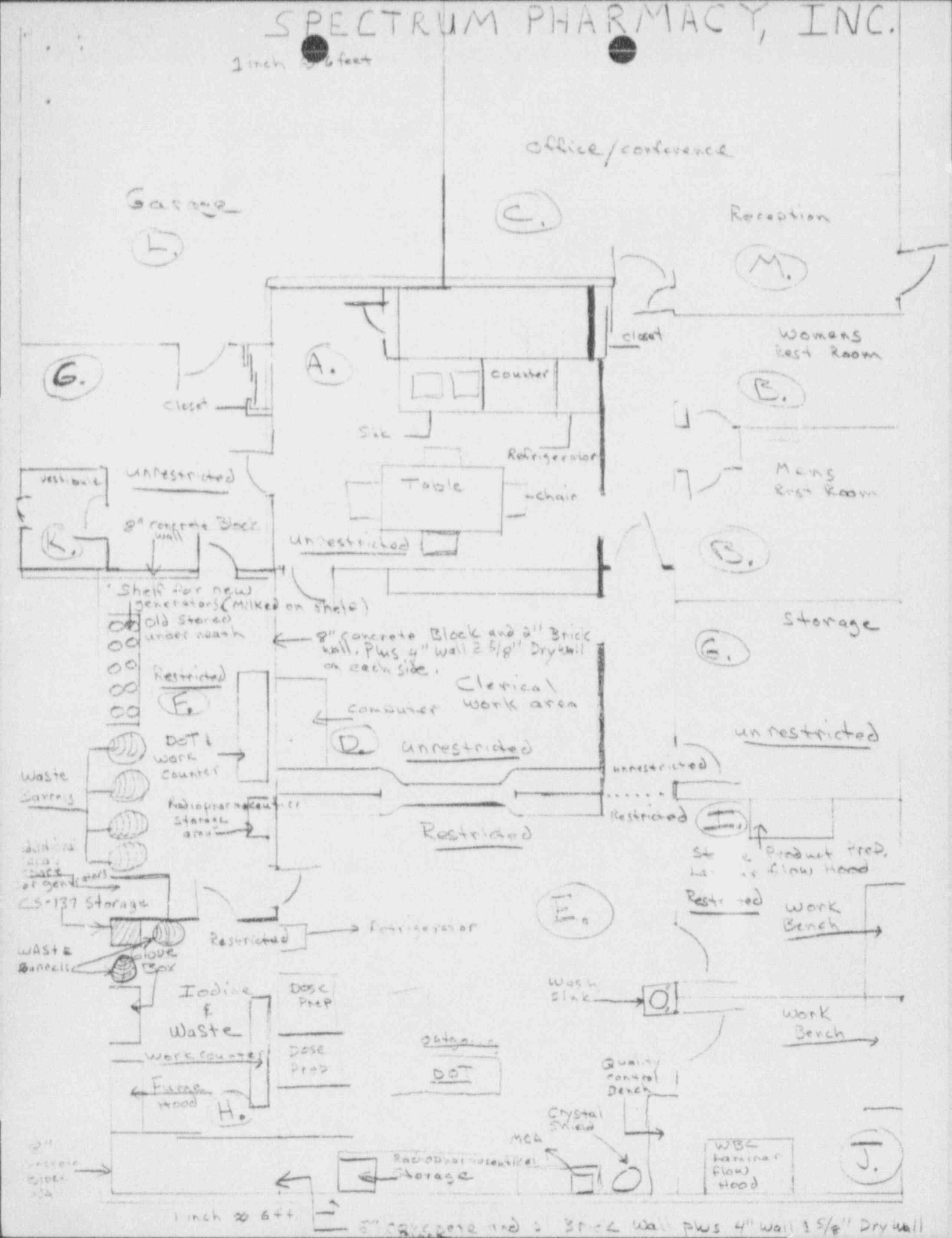
1971-76	Indiana University Medical Center, Indianapolis, IN
1976-Present	Methodist Hospital, Indianapolis, IN
1971-Present	Consulting Medical Physicist for a number of hospitals/clinics in Indiana. Since 1988, have been affiliated with Medical Physics Consultants, Inc. (MPC), a group of M.S. level medical physicists based in Ann Arbor Michigan. MPC now covers over 25 hospitals in Indiana along with over 130 hospitals/clinics in Michigan.

Adjunct Professor of Physiology and Health Science, Ball State University, Muncie, IN, September 1985 to present
Adjunct Assistant Professor, Radiology Department, Indiana University Medical Center, Indianapolis, IN, September 1976 to present

Member, Society of Nuclear Medicine (since 1969) - elected member of Board of Trustees (1978-86), Past President of Instrumentation Council (1984-85)
Member, American Association of Physicists in Medicine (since 1973), Past President of Ohio River Valley Chapter (1978-79)
Charter member of Hoosier Chapter of the Health Physics Society (1976) - Past President (1987-88)

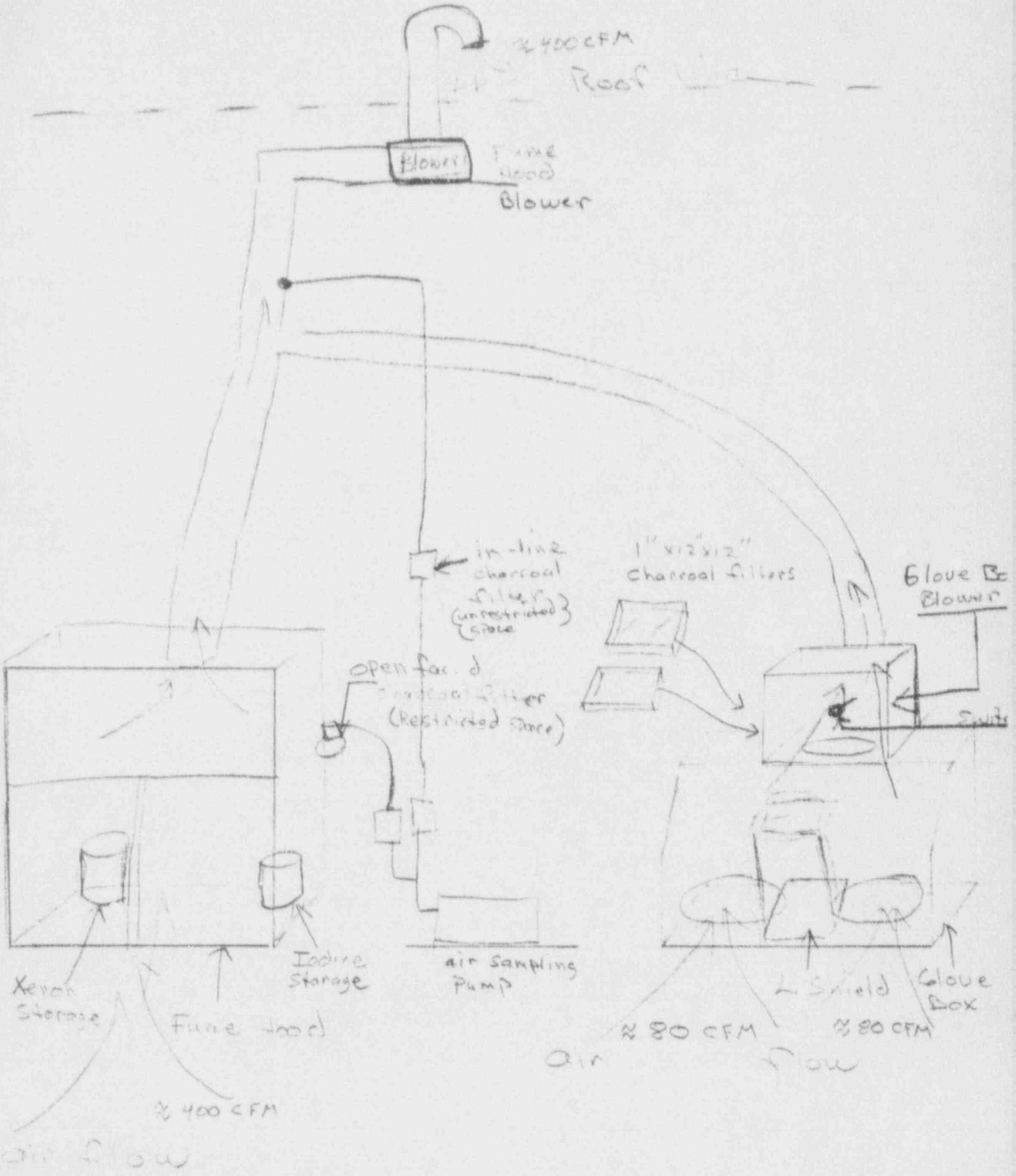
Approved by Indiana State Board of Health as a "Radiation and Health Physicist" and as an "X-Ray Machine Physicist"

SPECTRUM PHARMACY, INC.



SPECTRUM PHARMACY, INC.

Diagram 5 of 6SM



10.14 Product Shielding

Maximum Activity for Each Type of Container (e.g., vial, syringe)

Radionuclide	Max mCi Vial	Max mCi Syringe
Tc-99m	1000	200
I-131	250	0.5
Xe-133	40	N/A
I-125	2	2
Cr-51	1	0.25
P-32	20	10

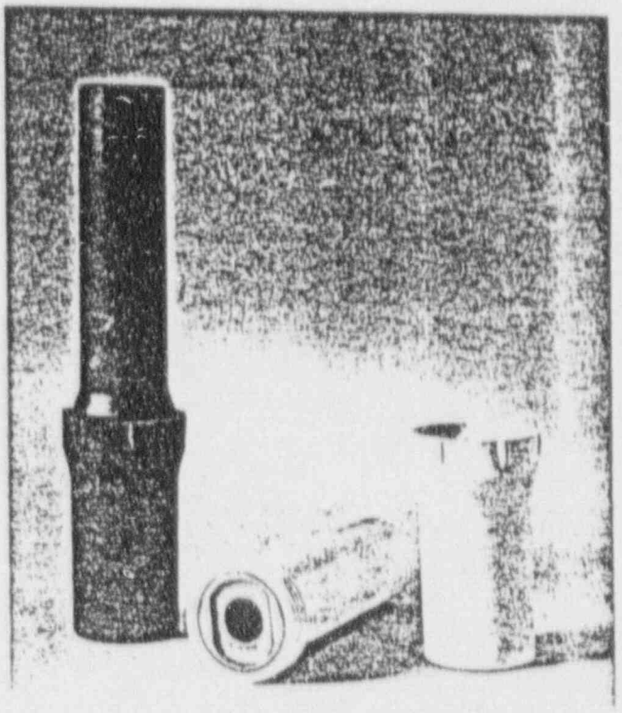
Most radiopharmaceuticals are shipped in enough shielding to reduce the exposure rate at 0.5 meter to 0.25 mR/hr or less. The following table shows the shielding required to meet this criteria.

Radionuclide	Max. Quantity in mCi	Lead, mm	Expected Surface Reading mR/hr
Tc-99m unit dose	60	2.0	0.1
Tc-99m multi dose	1000	2.6	0.2
Cr-51	2	0	0.03
Ga-67 multi dose	100	7.0	11.5
Xe-133 unit dose	40	1.0	0.5
In-111 unit dose	5	3.2	2.0
I-123 multidose	5	1.0	1.0
I-125	10	1.0	0.1
I-131 diagnostic	1	6.0	1.0
I-131 therapeutic	200	50.0	20.0

Normal shielding for unit dose syringes is a lead lined, screw top closure, leak proof plastic syringe carrier. Vial of radioactive material distributed by the pharmacy will be shielded in vial shields that the manufacturers utilize. the average lead thickness of the shielded syringe carriers is no less than 5mm. The lead thickness of manufacturer supplied vial shields used for pharmacy distribution is no less than 4mm.

The maximum radiation level to be expected at the surface of each type of shielded container when filled with the maximum activity is less than 50mR/hr.

ISOTOPE SYRINGE SHIPPING CONTAINERS



- Ideal for handling syringes within the hospital or radiopharmacy, as well as for shipping.

MODEL IC-004

- Features a 1/4" lead wall encased in a durable plastic housing with threaded closure.
- Compatible with all medical radioisotopes and limits gamma ray radiation to acceptable levels for 150 n 67-Ga; 250 mCi of I-123 and 1.2 mCi of I-131, according to independent test reports.

MODEL IC-008

- Features a 1/8" lead wall encased in a durable plastic housing with threaded closure.
- Designed for use with technetium and eliminates measurable gamma ray radiation from Tc99m (assumi container is filled with 100 mCi), according to independent test reports.
- Both models available in white or red, with quantity discount pricing.

Cat. No.	Description	Price
11-11-004	1/4" Lead Wall	$12.45
11-11-008	1/8" Lead Wall	10.95

Evaluation of Shielded Syringe Carriers for Transporting Radioactive Doses

Norman B. Levit and Mary Ogiela-Bazner

University of New Mexico Radiopharmacy, College of Pharmacy, Albuquerque, New Mexico

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.

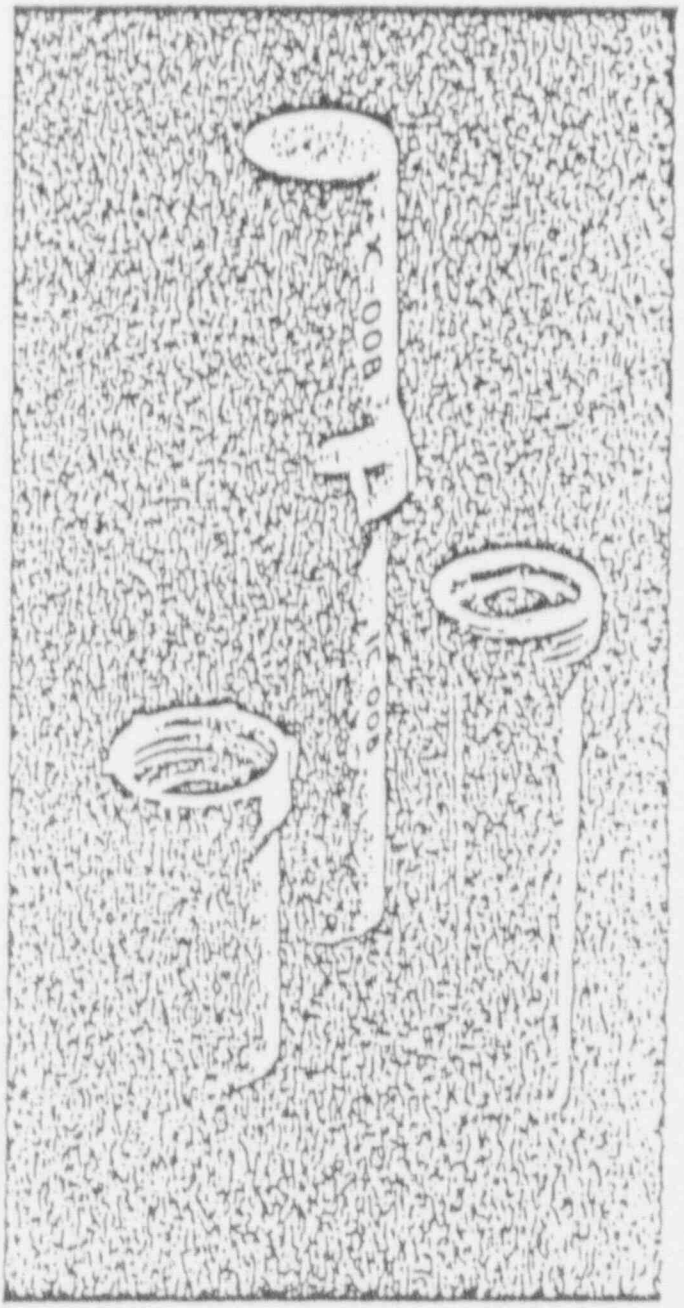


FIG. 1. Syringe carrier shield, 1 C-008 with screw-on top and continuous plastic coating.

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

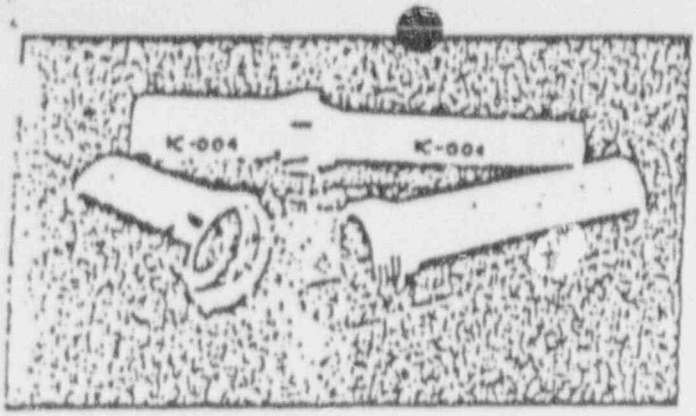


FIG. 2. Syringe carrier shield, 1 C-004 with screw-on top, continuous plastic coating.

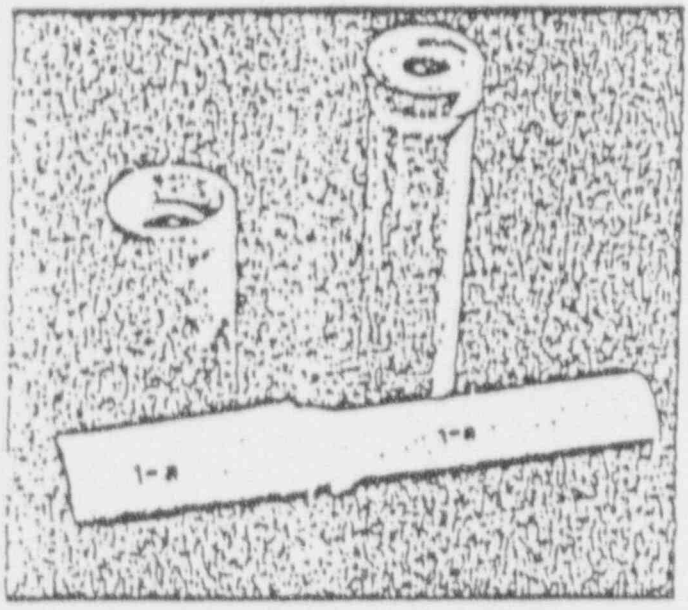


FIG. 3. Syringe carrier shield, 1a with slip-on top, plastic coating.

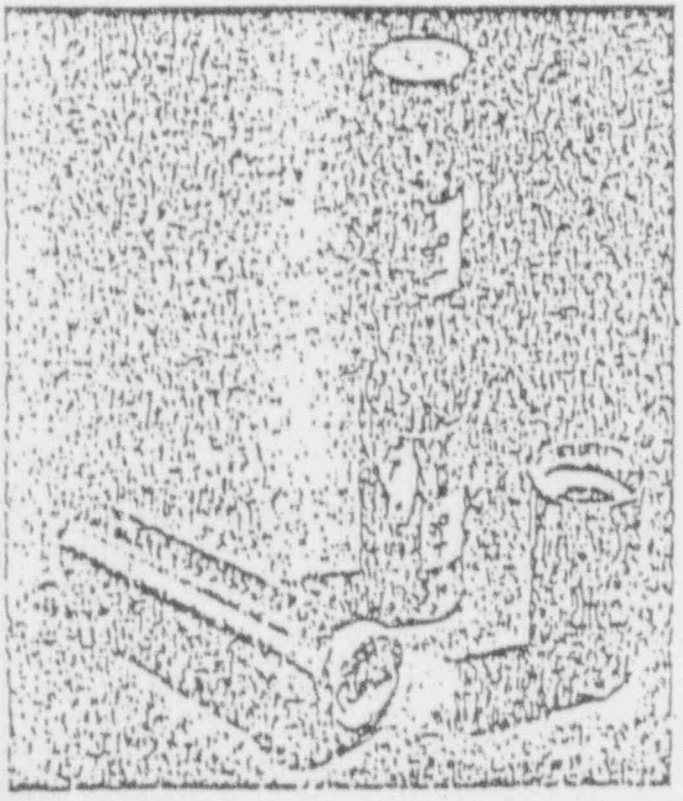


FIG. 4. Syringe carrier shield, 1b with slip-on top, steel covering.

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 regulations.

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	0.63	0.38	1.11
I C-004	1536	0.63	1.11	0.85	0.63	1.27
Ia	1364	0.79	0.71	0.79	0.63	0.63
Ib	1516	0.71	0.79	0.85	0.63	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 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.

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 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	8.0	0.65	0.05
Ib	0.30	2.0	8.0	0.45	0.10

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	11.5	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

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	0.70	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 for all of the radionuclides tested. The I C-008 carrier attenuated technetium as well as 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

Item 10
Date: 5/26/86

Facsimile letter - Nu Medico Associates

NU MEDICO

Associates

Radiological Consultants

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2 November 1974

Quality Assurance
Teaching
Diagnostic Radiology
Health Physics
Instrumentation
Medical Physics
Nuclear Medicine
Radiation Dosimetry
Radiation Physics
Radiation Therapy
Radiologic Calibration

General Design/Development
4526 Brookwood, N. E.
Albuquerque, New Mexico 87109

RE: ATTENUATION TESTING OF MODEL 1C-004 SYRINGE SHIPPING CONTAINER

Method of Testing

The attenuation of 131-I and 51-Cr gamma rays by the sample syringe container was measured in a low level scintillation counter. The effective thickness and the dose rates/mCi were calculated using standard techniques. Both film and active dosimetry were employed to measure the dose-rates at 6", 1' and one meter from the holder loaded with 5 mCi of 131-Iodine.

Results

1. The average effective thickness of the sample was 0.92 cm. of lead. Less than 3% variation was noted in rotation through 90, 180, and 270 degrees.

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2. The permissible levels for such items, in most Agreement States are:

a. 2 mrem in any one hour
b. 100 mrem in any seven days, or
c. 0.5 rem in any one year.

Since it appears unlikely that these items would remain in any uncontrolled area for more than one (1) hour during routine transit, loading calculations were based upon the 2 mrem/hr. The results for three common isotopes are as follows:

SAFE LOADING IN MILLICURIES*

(2 mrem/hr at ____ distance)

ISOTOPE	6 INCHES	1 FOOT	1 METER
131-I	1.2	5	50
123-I	250**	____	____
67-Ga	150	____	____

* Total loading -- whether 1 unit or several

** Presence of high-energy contaminants are not considered.

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By-Product Material	Chemical/Physical Form	Max. mCi per vial/ syringe	Shield to be used for Dispensing	Maximum Radiation Level on the Syringe Shield or Vial in mR/hr		
Group I				IC-008	IC-004	Heavier than IC-004
Iodine-131	Sodium Iodide Soln/cap	3.0 mCi	X *			
Iodine-125	Human Serum Albumin Soln	2.0 mCi	IC-008 or IC-004 or X	.03	.03	.03
Iodine-131	Rose bengal Soln	4.0 mCi	X			
Iodine-131	O-Iodohippurate Soln	3.0 mCi	X			
Chromium 51	Sodium Chromate Soln	2.0 mCi	IC-008 or IC-004 or X	.03	.03	.03
Tc-9 **	Sodium Pertechnetate Soln	500.0 mCi	IC-008 or IC-004 or X	2.2	.1	.05
Iodine-131	O-Iodonippurate Soln	300.0 µCi	IC-004		6.0	
Group II						
Iodine-131	Sodium-Iodide Soln/cap	5.0 mCi	X			
Iodine-131	Human Serum Albumin Soln	1.0 mCi	X			
Iodine-131	Macroaggregated Albumium Suspension	2.0 mCi	X			
Iodine-131	Rose Bengal Soln	3.0 mCi	X			
Chromium 51	Sodium Chromate Soln	1.0 mCi	See Group I			
Tc-99m	Sodium Pertechnetate Soln	500.0 mCi	IC-008 or IC-004 or X	2.2	0.1	.05
Tc-99m	Sulfur Colloid	50.0 mCi	IC-008 or IC-004 or X	0.3	.05	.05
Tc-99m	Macroaggregated Albumium Suspension	50.0 mCi	IC-008 or IC-004 or X	0.3	.05	.05
Tc-99m	Polyphosphate, Stannous Soln	200.0 mCi	IC-008 or IC-004 or X	0.5	.07	.05
Tc-99m	Diphosphonate, Stannous Soln	200.0 mCi	IC-008 or IC-004 or X	0.5	.07	.05
Tc-99m	Pyrophosphate	200.0 mCi	IC-008 or IC-004 or X	0.5	.07	.05
Tc-99m	Iron-Ascorbate Diethylenetriamine	100.0 mCi	IC-008 or IC-004 or X	0.4	.06	.05
Tc-99m	DTPA	200.0 mCi	IC-008 or IC-004 or X	.05	.07	.05

* X has more shielding thar IC-004 (Manufacturer's Shield)

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By-Product Material	Chemical/Physical Form	Max. mCi per vial/ syringe	Shield to be used for Dispensing	Maximum Radiation Level on the Syringe Shield or Vial in mR/hr		
Group II				IC-008	IC-004	Heavier than
Tc-99m	Human Serum Albumin Microspheres	50.0 mCi	IC-008 or IC-004 or X	0.3	.05	.05
Tc-99m	Human Serum Albumin Soln	100.0 mCi	IC-008 or IC-004 or X	0.4	.07	.05
Tc-99m	Methylene Diphos-phonate Soln	200.0 mCi	IC-008 or IC-004 or X	0.5	.07	.05
Tc-99m	Gluceptate, Stannous Soln	200.0 mCi	IC-008 or IC-004 or X	0.5	.07	.05

Maximum Surface Radiation for IC-004 Screw Top Unit Dose Shield:

99m-Tc

500 mCi 0.05 mR/hr

* Maximum Surface Radiation for IC-008 Screw Top Dose Shield:

99m-Tc

500 mCi 2.2 mR/hr

These values were obtained with a Victoreen 491 low level survey meter.

**Curie quantities of 99m-Technetium are shipped in cylindrical lead shields (manufacturer's shield) containing a minimum of 5/16" of lead shielding on all sides.

Maximum Surface Radiation for this shield:

99m-Tc

10.0 curies 5.0 mR/hr

SPECTRUM PHARMACY, INC.

IODINE-131 HANDLING PROCEDURES

DOCUMENTATION CHANGE FROM FUME HOOD TO GLOVE BOX

9.3 Adequacy of Facility for Handling Xenon-133

Xenon-133 gas will be purchased as unit-dose vials and dispensed as such. There will be no manipulations of the contents of the vials between receipt and dispensing. The estimated fraction of xenon-133 lost during storage is 0.5% per day from its unit-dose vial.

Xenon-133 will be stored in its lead shipping containers within a fume hood with airflow of 400 cubic feet per minute (6.796E8 ml/hr). The airflow rate will be determined by actual measurement with a volumeter or similar device at least every six months.

The estimation of the concentration of xenon-133 in the effluent to unrestricted areas is:

Possession limit of xenon-133: 800mCi

$C = \frac{A}{V} \leq$ 3.0E-7 uCi/ml of xenon-133 released to unrestricted areas.

A= estimated maximum uCi xenon-133 released per week
= 800,000uCi X 0.5%/day X 7 days/week = 28,000uCi/week

V= 6.796E8 ml/hr X 168 hr/week = 1.142E11 ml/week

C= $\frac{28{,}000 \text{ uCi/week}}{1.142E11 \text{ ml/week}}$ = 2.0E-7 uCi/ml

9.4 **Special Equipment for Handling Millicurie Quantities of Liquid Iodine**

The facility will be equipped to maintain releases of radioactive iodine at ALARA levels in accordance with paragraph 20.1 (c) of 10 CFR Part 20. All work involving the handling open containers of millicurie quantities of liquid radioiodine will be performed within the glove box.

In order to maintain releases of radioiodine to the environment at ALARA levels, the glove box will be equipped with a charcoal filtration system consisting of two charcoal filters that are 1' X 1' X 1". It is expected that 98% of radioiodine will be removed from the effluent by this system. Air sampling will be performed in the restricted area (iodine room) and the unrestricted area (air vented through stack). This air sampling system will be running continuously and a diagram of this system and the fume hood relationship can be seen in diagram #5.

Procedures for I-131 Air Monitoring

1. Air monitoring is to be performed weekly
2. Use a vacuum pump with either a known rated air flow or a pump with an air flow gauge.
3. Use two filter holders (unrestricted and restricted area)
4. Use charcoal impregnated filter paper
5. Wearing clean disposable gloves, remove charcoal filter paper from the air sampling apparatus and replace with a new piece of impregnated charcoal filter paper.
6. Place the removed filter in a clean counting tube
7. Count the filter in the scintillation counter for one minute. Make sure that the analyzer window is set for I-131 and that an efficiency factor (Fe I-131 in dpm/cpm) for this analyzer setting has been calculated.
8. Count an empty counting tube for a one minute background
9. Note the sampling pump air flow in ml/minute from measured flow of vacuum pump.
10. Determine pump on duration in minutes from last air monitoring
11. Calculate the concentration of volatile I-131 in uCi/ml in the unrestricted area using the following equations.
    a. $\text{uCi I-131 in filter} = \frac{\text{filter cpm X Fe I-131}}{2.22 \text{ X } 10E6 \text{ dpm/uCi}}$
    b. ml air flow = sampling pump air flow X pump on duration
    c. uCi/ml I-131 = (a)/(b)
12. Assure concentration calculated in step 11.c above is less than 1 X 10E-10 uCi/ml. Notify R.S.O. immediately if concentration exceeds 1 X 10E-10 uCi/ml

Glove Box Charcoal Filter Monitoring and Exchange Procedure

1. Charcoal filters are to be monitored weekly and exchanged or replaced if necessary
2. Both charcoal filters will be surveyed on both sides with a survey meter and pancake probe.
3. Remove the second filter in line of air flow (top filter), and measure the radiation exposure on each side of the filter.
4. Remove the first filter in line of air flow (bottom filter), and measure the radiation exposure on each side of the filter
5. Calculate the ratio of the top filter reading to the bottom filter reading. Assure the top filter reading is less than 10% of the bottom filter reading, and that the top filter reading is less than 2mR/hr.
6. If the top filter reading equals or exceeds 10% of the bottom filter reading, remove the bottom filter, place in plastic bag and hold for decay behind appropriate lead shielding. Replace the bottom filter with the top filter, and replace the top filter with a new charcoal filter.
7. If the top filter reading is equal to or greater than 2mR/hr, seal both the top and bottom filters in a plastic bag and hold for decay behind appropriate lead shielding.

RADIONUCLIDE			MAXIMUM RETURNABLE QUANTITY (mCi)
Cobalt-57	(Co-57)		9
Cobalt-58	(Co-58)		2
Chromium-51	(Cr-51)		60
Gallium-67	(Ga-67)		10
Iodine-123	(I-123)		5
Iodine-125	(I-125)		7
Iodine-131	(I-131)		1
Indium-111	(In-111)		2.5
Molybdenum-99	(Mo-99)		2
Phosphorus-32	(P-32)		3
Selenium-75	(Se-75)		4
Technetium-99m	(Tc-99m)		10
Thallium-201	(Tl-201)		20
Xenon-133	(Xe-133)	uncompressed	1000

When returning a package containing more than one of the above radionuclides, the maximum returnable quantity is determined by the lowest mCi quantity assigned for the items shipped. For example, if Tc-99m and I-131 are being shipped in the same package, only 1 mCi of total activity may be contained in the package.

3. If radioactive quantities are greater than those specified on the attached table, retain the material behind appropriate shielding until it has decayed to an acceptable quantity.

4. Using your low-level survey meter, measure all points on all surfaces of the package to be returned to insure that at no point on the surface the exposure exceeds 0.5mR/hr.

10.10 Precautionary Measures for Handling Millicurie Quantities of Liquid Radioiodine

Opening and dispensing from vials containing millicurie quantities of liquid radioiodine will be perfcrmed in the glove box behind lead shielding. Protective gloves will be worn, and remote handling tools (tongs) will be used by persons handling liquid radioiodine.

Therapy capsules and therapy solution will be dispensed in the original manufacturer's shipping container. (see appendix M for capsule compounding procedures)

An iodine bioassay program equivalent to that specified in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131" will be implemented. Iodine-125 will not be handled in an open form. Therefore, bioassay will not be performed for I-125.

Iodine-131 CAPSULE PR PARATION PROCEDURE USING MICROPIPETING DEVICE

Materials

-No. 0 gelatin capsule
-No 1 gelatin capsule
-Dibasic sodium phosphate anhydrous powder (U.S.P.)
J.T. Baker catalog #3828-1 or Mallinckrodt catalog #7917-1

The sodium phosphate must be indicated for human use. Do not use any that states to the contrary such as "for laboratory use". The sodium phosphate should be stored tightly sealed to assure freshness. Capsules prepared in advance may be stored inside a capped 20 dram plastic prescription vial placed inside a 40 dram; this may be placed in the refrigerator freezer. By starting with a very cold sodium phosphate capsule, you reduce the chance of melting the gelatin capsule upon injection of liquid sodium iodide. If the sodium phosphate is left open to room air, it will become hydrated.

-I-131 sodium iodide solution
-Micropipetter with disposable pipets
-Plastic capsule container (e.g. I-123 inner container or falcon tube
-Dispensing container
-Capsule holder made out of a lead block with two 1/4 inch hole, 1/2 inch deep. Plastic wrap is placed on the block to avoid radiocontamination of the block.
-3cc syringe in 1/2" lead unit dose container
-Drawing station in fume hood
-Shoulder length plastic gloves; lab safety supply order #3217
-Tweezers, tongs
-Absorbent material
-Gloves: it is a good technique to double glove while working inside the fume hood. When leaving, take off the outer gloves and place into a zip lock bag. Re-glove, with second pair, upon entering the fume hood.
-Survey meter

Procedure

1. Organize materials in the ~~fume hood~~ Glove box.
2. Place a portion of dibasic sodium phosphate powder on part of a sheet of clean white paper. Fold paper over powder. Fill bottom portion of size 1 capsule 3/4 full. Fill the the top portion of the capsule.
3. Place fitted bottom portion of size 1 capsule within capsule holding device behind L block shield.
4. Vent the iodine-131 solution through a charcoal syringe.

5. Draw necessary I-131 solution with micropipette. As air displacement units, there is a calibrated plunger inside the handle which, when depressed, displaces a precise volume of air. This moving air pushes measured amounts of liquid out of a plastic conical pipet tip. Laboratory procedures are kept contamination-free by disposing and replacing the tips. Be aware that roughly one-day's decay should also be considered if the dose is for the next day. The volume of the solution needed should be based on its current assay. The maximum concentration of I-131 stock solution to be used will be 100 mCi/ml. Should the volume exceed 0.2 to 0.25cc, the capsule's estimated holding capacity, the activity should be divided between two or more capsules. Each capsule would contain approximately 25mCi of I-131. The maximum activity of I-131 that would be handled at any one time during preparation would be 200 mCi. This would require at least 8 capsules to be made, assuming the maximum concentration of therapy solution to be used in compounding.
6. Add the I-131 solution onto the dibasic sodium phosphate which is inside the capsule. Begin injecting with a smooth, slow injection. The injection can not be too slow or the powder will harden in the pipet tip and clog it; if too fast, the capsule's capacity may be exceeded. It is important to watch the capsule closely, in case the volume exceeds the capacity of the capsule. This dibasic sodium will harden as liquid is added; therefore, if the top of the powder hardens before completion, stop your capsule compounding immediately.
7. Once the injection is complete, remove the pipet from the capsule and place a lead cover over the capsule in the holding apparatus. Place empty pipettes in leaded waste containers. Monitor the pipetting device with a survey meter. If it is contaminated, place it in a shielded holding tank for decay.
8. Using forceps, pick up the other filled end of size 1 capsule and place over open end of bottom cap. Tap it down firmly in place.
9. Using long forceps, place the entire cap inside an empty size 0 gelatin capsule. This step is an extra precaution against leakage.
10. Grasp capsule with forceps and place in a 3 cc syringe,which is shielded by a unit dose container.
11. Remove the I-131 capsule from the glove box and place the unshielded capsule in a dose calibrator. The final activity is calculated by multiplying current activity by the appropriate decay factor. The final activity should not vary by more than +/- 10% from the activity ordered. If the final assay is outside of the dispensing range of +/- 10%, the capsule will be placed in a well shielded storage container and maintained in storage until decayed to background.
12. Replace stock I-131 solution into storage. Be sure the container is recapped or resealed.
13. Check the glove box area for contamination with the survey meter. All radiocontaminated materials should be st ed in sealed containers and promptly disposed of to prevent possible volatile iodine contamination.

Notes

1. Since the binding of I-131 solution to the anhydrous powder undergoes an exothermic reaction, heat is released. For this reason, the capsule should be refrigerated until such dispensing time.

2. Thyroid bioassay will be conducted before 24 hours have elaspsed since capsule preparation. See thyroid bioassay procedure for a description of this procedure.

3. Evaluate the effluent monitoring equipment for the fume hood before staring preparing the capsule.

4. Perform an area survey of the ~~fume hood~~ Glove box before and after capsule preparation. If the area is not radiocontamination-free, decontaminate before starting.

Iodine-131 CAPSULE PR PARATION PROCEDUR :
USING TUB RCULIN SYRINGE

Materials

-No. 0 gelatin capsule
-No 1 gelatin capsule
-Dibasic sodium phosphate anhydrous powder (U.S.P.)
J.T. Baker catalog #3828-1 or Mallinckrodt catalog #7917-1

The sodium phosphate must be indicated for human use. Do not use any that states to the contrary such as "for laboratory use". The sodium phosphate should be stored tightly sealed to assure freshness. Capsules prepared in advance may be stored inside a capped 20 dram plastic prescription vial placed inside a 40 dram; this may be placed in the refrigerator freezer. By starting with a very cold sodium phosphate capsule, you reduce the chance of melting the gelatin capsule upon injection of liquid sodium iodide. If the sodium phosphate is left open to room air, it will become hydrated.
-I-131 sodium iodide solution
-Tb syringes
-Plastic capsule container (e.g. I-123 inner container or falcon tube
-Capsule holder made out of a lead block with two 1/4 inch hole, 1/2 inch deep. Plastic wrap is placed on the block to avoid radiocontamination of the block.
-3cc syringe in 1/2" lead unit dose container
-Drawing station in ~~fume hood~~ Glove box
-Shoulder length plastic gloves; lab safety supply order #3217
-Tweezers, tongs
-Absorbent material
-Gloves: it is a good technique to double glove while working inside the fume hood. When leaving, take off the outer gloves and place into a zip lock bag. Re-glove, with second pair, upon entering the fume hood.
-Survey meter

Procedure

1. Organize materials in the glove box.
2. Place a portion of dibasic sodium phosphate powder on part of a sheet of clean white paper. Fold paper over powder. Fill bottom portion of size 1 capsule 3/4 full. Fill the top portion of the capsule, and place short side of filled capsule into long end of size 0 capsule.
3. Place fitted bottom portion of size 0 capsule within capsule holding device behind L block shield.
4. Vent the iodine-131 solution through a charcoal filled syringe
5. With draw the necessary iodine-131 solution using a shielded tuberculin syringe. The necessary activity drawn into the syringe should include 5% excess which allows for residual left inside the syringe, hub and needle. Be aware that roughly one-day's decay should also be considered if the dose is for the next day. The volume of the solution needed should be based on its current assay. The maximum concentration of I-131 stock solution to be used will be 100 mCi/ml. Should the volume exceed 0.2 to 0.25 cc, the capsule's estimated holding capacity, the activity should be divided between two or more capsules. Each capsule would contain approximately 25 mCi of 1-131. The maximum activity of I-131 that would be handled at any one time during preparation would be 200 mCi. This would require at least 8 capsules to be made, assuming the maximum concentration of therapy solution to be used in compounding.
6. Add the I-131 solution onto the dibasic sodium phosphate which is inside the capsule. This is done by puncturing the center of exposed portion of the filled #1 capsule, sticking the needle portion all the way into it. Begin injecting with a smooth push. The injection can not be too slow or the powder will harden in the needle and clog it; if too fast, the capsule's capacity may be exceeded. It is important to watch the capsule closely, in case the volume exceeds the capacity of the capsule. If this occurs, draw back slightly on the syringe plunger to remove the excess liquid. This dibasic sodium will harden as liquid is added therefore, if the top of the powder hardens before completion, stop your capsule compounding immediately.
7. Once the injection is complete, remove the needle from the capsule and place a lead cover over the capsule in the holding apparatus. Place empty syringes in sealed plastic bags and put complete unit in leaded waste for I-131.
8. Using long forceps, place the size 0 capsule top over the size 1 exposed section. This step is an extra precaution against leakage.
9. Grasp capsule with forceps and place in a 3 cc syringe, which is being shielded using a unit dose container.
10. Remove the I-131 capsule from the glove box and place the unshielded capsule in a dose calibrator. The final activity is calculated by multiplying current activity by the appropriate decay factor. The final activity should not vary by more than +/- 10% from the activity ordered. If the final assay is outside of the dispensing range of +/- 10%, the capsule will be placed in a well shielded storage container and maintained in storage until decayed to background.

11. Replace stock I-131 solution into storage. Be sure the container is recapped or resealed.
12. Check the ~~fume hood~~ glove box area for contamination with the survey meter. All radiocontaminated materials should be stored in sealed containers and promptly disposed of to prevent possible volatile iodine contamination.

Notes

1. Since the binding of I-131 solution to the anhydrous powder undergoes an exothermic reaction, heat is released. For this reason, the capsule should be refrigerated until such dispensing time.

2. Thyroid bioassay will be conducted before 24 hours have elaspsed since capsule preparation. See thyroid bioassay procedure for a description of this procedure.

3. Evaluate the effluent monitoring equipment for the fume hood before staring preparing the capsule.

4. Perform an area survey of the ~~fume hood~~ glove box before and after capsule preparation. If the area is not radiocontamination-free, decontaminate before starting.

STATE OF INDIANA

EVAN BAYH, Governor

HEALTH PROFESSIONS BUREAU

402 West Washington Street Room 041
Indianapolis, Indiana 46204
Telephone: (317) 232-2960
Fax: (317) 233-4236

January 21, 1992

Gregory S. Hiatt
1301 Milburn Blvd.
Mishawaka, IN 46530

Re: Spectrum Pharmacy

Dear Mr. Hiatt:

Your application for a pharmacy permit has been considered by the members of the Indiana Board of Pharmacy. Tentative approval has been given pending inspection by a representative of our board. The following numbers have been issued to enable you to obtain a registration from the Drug Enforcement Administration (DEA):

Pharmacy identification number 60004137
Controlled Substances Registration

In order for a new pharmacy to be inspected, the following items must be installed in the new premises:

Sink (hot and cold water)
Refrigeration
Dispensing equipment (as listed on application)

You must also have in your possession:
Reference books
Exempt Narcotic Register

Please notify this office at least one week prior to the date you are requesting an inspection. No sales may be transacted until after the inspection has been completed for final approval of your pharmacy permit number.

Sincerely yours,

Pat Calhoun

Pat Calhoun
License Issuance

NEW OPENING

INDIANA BOARD OF PHARMACY INSPECTION REPORT

State Form 35890 (R3 / 6-87)

Name of Pharmacy	SPECTRUM PHARMACY
Street Address	1301 MILBURN BLVD. SUITE 100
City and ZIP Code	MISHAWAKA 46544

oday's Date and Time	County		Telephone Number	DEA Number	
1-28-92 130 PM	ST. JOSEPH		219-255-5072	NA	
SR Number	I.D. Number	Type	Total Weekly Hours	Gen. Appearance	Open for Bus.
NA	4137	V	80	EXCELLENT	2-10-92

	NAMES OF PHARMACISTS EMPLOYED	LICENSE NO.	PRESENT	ABSENT	WEEKLY HOURS	LICENSE CURRENT
MANAGER	GREGORY S. HIATT	14314	✓			YES
OTHERS						

	YES	NO
. Are all certificates properly displayed, current and correct?	✓	
. Is the pharmacy equipped as required by law?	✓	
. Are Rx files properly kept?	✓	
Including Name and Address of patient filed numerically and chronologically?	✓	
Retai..ed a period of 5 years?	✓	
Red "C" on Sch Drug Rxs? NA		
. Are refills of Rx properly recorded? NA		✓
. Where?		
. Are Rxs being refilled beyond Date of Validity?		
. Are refills being made without authorization on the face of the Rx?		
. If Sch II Emer. Rxs filled, are proper records kept?		
. Are medications being returned to stock after dispensed?		✓
. Is proper Rx format used (i.e. generic law)?	✓	
0. Date of last Biennial Inventory:		
1. Are federal DEA order forms properly kept? NA		
2. Any practitioner purchasing an excessive amount of controlled drugs for office use?		✓
3. Schedule V Register kept? NA		✓
Entries for the last 3 months: NA		
4. Are Schedule V Sales controlled by the pharmacist? NA		
5. Are current Reference Books and laws available?	✓	
6. If a 14-hour sign is used is sign posted and record kept?		✓
Hours per day: Week: NA		
7. Are Biologicals in date and stored as required? NA		✓
8. Previous violations been corrected since last inspection?		
9. Is computer in use? Type: IN HOUSE	✓	
0. Are computer records properly kept?		
Including on line retrieval of Rx status?		
Printout of Rx order and Refill Data for each day's dispensing?		
1. Are all Rx's verified by pharmacist?		
2. Are Rx transfers properly performed?		

ote irregularities in number or type of Rx's on file and other comments:

OPENING INSPECTION ON 1-28-92. TARGET OPENING DATE IS 2-10-92. THIS IS A NUCLEAR DIAGNOSTIC PHARMACY. THE PHYSICAL LAY OUT, SUPPLIES & EQUIPMENT, MEETS STATE REQUIREMENTS. THE PHARMACY, NEWLY CONSTRUCTED, IS MODERN & SECURE. THE BUILDING IS ALARMED TO LOCAL AGENCY.

PHARMACY MEETS ALL REQUIRMENTS. EXCELLENT.

wner, Pharmacist or Employee: Gregory S. Hiatt

Inspector: Donald P. Smith

JAN 1 0 1992

Spectrum Pharmacy
ATTN: Gregory S. Hiatt
Proprietor
17460 Farmington Square Road
Granger, IN 46530

Dear Mr. Hiatt:

We have reviewed your application dated November 4, 1991 requesting a new nuclear pharmacy license and find that we will need additional information as follows:

1. Name and Mailing Address

Please clarify the Name and Mailing address in your application. The name of applicant should be the pharmacy rather than the proprietor. Also the mailing address should be the pharmacy rather than your personal address. If you need mail sent to your personal residence until the pharmacy is established, please so state.

2. Needed Additions to Items 5. and 6. of Application

Since you have requested authorization for Mo99/Te99 generators, you need to request authorization for uranium (depleted in the isotope Uranium-235) for the use of shielding in these generators. The physical form is metal encased in stainless steel and the possession limit is 110 kilograms in a typical nuclear pharmacy license.

The Technical operations model 773 calibration device for instrument calibration described in Appendix P of your application needs to be requested for authorized possession in Items 5. and 6. of your application. For your information the sealed source is a Technical Operations Model 77302 with a maximum source strength of 165 millicuries. Specify the number of sources you want to possess.

Regarding redistribution of reagent kits, state whether or not kit packages will be redistributed as received from the manufacturer in the "kit sleeve". If not, and you intend to break down a multiple kit package, please so state and confirm that individual kit packages will not be opened. Further, confirm that copies will be made and provided with each individual redistributed kit of all of the following items: manufacturer-supplied package insert, leaflet, brochure, or other documents that describes the procedures to be followed and the equipment and shielding to be used in processing radioactive material with the reagent kit.

Regarding redistribution of In-Vitro kits, you submitted information indicating your wish to redistribute to both general licensees and to specific licensees. However your submittal does not address these two requests in the manner prescribed in Draft Regulatory Guide FC 410-4, dated August 1985. Please address each of the three items for both general and specific licensees as described on pages 45 and 46 of the guide.

Please clarify the request in your application regarding redistribution of unused generators. In Item 6.A on Page 5 of your application you request authorization to redistribute generators to authorized recipients. However, your application did not address Items 1. and 2., as required, at the top of page 43 of the draft guide regarding procedures for this activity. If you so choose to redistribute unused generators, describe the adequacy of your facilities to store the waste generators and ultimate disposition of the generators.

3. Item 7 of Application

Clarify spelling of last name of pharmacist Brian C. Blaum. The referenced license indicates it should be spelled Blum.

Please note that we can not give blanket authorization for you to use radiopharmacists named on another NRC license. You must provide the names of each radiopharmacist you wish named on your license as an approved user.

Please clarify the working status/relationship that John D. Scheu, Ph.D. R. Ph., will have with Spectrum Pharmacy. You appear to be requesting that he be listed on the license as an authorized user involved in your day to day nuclear pharmacy operations as well as an independent consultant to conduct quarterly audits to ensure compliance with all regulatory requirements, including the terms and conditions of the requested NRC license. As noted on page 36 of the Draft Guide, the individual or group conducting the audit should not be connected with your day to day operations. Accordingly, please request deletion of Dr. Scheu as an authorized user in Item 7. of your application or alternatively provide the name and qualifications of an independent individual to conduct the audits.

4. Facility Description

Please confirm that the delivery vestibule, used for drop-off of radioactive shipments when your facility is not staffed, will be heated to prevent freezing of delivered packages in cold weather.

Provide a larger more detailed drawing of your restricted area and include storage location of new generators, used generators and location(s) where generators are "milked."

Described in more detail (including diagrams) your fume hood. Include the glove box addition you mentioned in a recent telecon. Show location of dampers, fan(s) and their capacities, effluent filters, including sizes and locations, location of effluent sampling port (e.g. glove box effluent or combined hood and glove box) and an estimate of the concentration of radioiodine in effluents released to the environment.

Note that if compounding of iodine will take place in the "glove box" appendix M of your application will have to be modified regarding many references to the "fume hood". Submit the modified appendix M.

Confirm that prior to use, at installation, the linear flow across each arm port of the hood will be determined with an anemometer under conditions of normal operation i.e., negative air flow speed adjusted to maximum with both charcoal filters in place, and the standard laboratory fume hood on. Confirm that Quarterly measurements will be obtained to insure that the unit continues to operate at this base line level determination with respect to negative linear flow. Confirm that if flow decreases below a specified level (i.e., 80 percent) of the baseline values, the filter(s) will be changed to insure proper operation.

Confirm that disposable gloves will be worn when surveying and changing the charcoal filters.

Describe special shielding that will be available and used during iodine-131 therapy capsule preparation, in addition to the previously described lead block with two holes (e.g. L block shield and lead glass or other type of window in glove box).

State the storage location of stock Xenon-133, stock iodine-133 and waste iodine-131 as well as the location where iodine-131 will be handled in millicurie quantities of liquid.

Confirm that sealed tins containing therapy solutions or diagnostic capsuls of iodine will only be opened in your charcoal filtered glove box.

Confirm that items such as vial septums, syringes, pipettes, etc., which may be contaminated with iodine-131, will be rinsed or decontaminated before removal from the glove box.

Confirm that the air sampling system runs continuously for both the restricted area (room where iodine is stored and processed) and the unrestricted area (air vented through stack).

Confirm that an air flow gauge will be used to measure air flow for both types of samples.

Confirm that the restricted area sample is collected in the breathing zone of workers processing iodine-131 (e.g. outside the glove box above the area where an individual would be working).

Confirm that samples will be collected and analyzed to evaluate air concentration in both restricted and unrestricted areas at the end of each work day that liquid iodine is opened and dispensed in millicurie quantities and at not greater than weekly intervals regardless of work activity with iodine-131.

5. Thyroid Monitoring

Confirm that you will implement the iodine bioassay program specified in Regulatory Guide 8.20, "applications of Bioassay for I-125 and I-131", or provide complete details of your bioassay program so we can evaluate its equivalency to the guide.

Describe, including make and model number, the equipment you will use for thyroid counting. If it is not a standard type of tyroid counter, describe its characteristics and show how it can provide equivalent evaluations including reproducible geometry and sensitivity levels sufficient to demonstrate compliance with the levels of exposure in Regulatory Guide 8.20.

6. Health Physics Procedures

What additional health physics procedures will be employed because your personnel will be using I-131 of a higher specific activity and higher concentration than they are accustomed to using?

7. ALARA

What steps will you take to ensure that personnel exposures (especially extremity exposures) and effluent releases of I-131 are kept ALARA during preparation of therapy capsules?

8. Preparation and Assay of Capsules of Prescribed Activity

What special correction factors are needed for a dose calibrator when capsules (rather than liquid in vials or syringes) are assayed? How are these correction factors determined? If you believe that such correction factors are not needed, explain the basis for your belief.

Confirm that this technique for compounding capsules will be practiced using saline by all pharmacist prior to actual use of I-131 solution.

9. Survey Meter Calibration

On page P4 of your application, in Item E, correct the reference from "Appendix D" to "Appendix B" of NRC Regulatory Guide 10.8.

10. Transportation

Confirm that any use of a common carrier for transport of material will involve only delivery of packages which are already packaged and labeled in accordance with DOT regulations. Note that keeping instructions in a glove box does not constitute conspicuous availability, contrary to your example at the top of page 22. Therefore, please modify the parenthetical insert, in the third line in page 22 of your application, from "glove box" to "dashboard" or "window".

11. Maximum Radiation Levels at Surface of Shielded Containers

Your response is not definitive to Item 10.14.3.3 of the nuclear pharmacy guide. The guide asks that you provide the expected maximum radiation level at the surface of each type of shielded container when filled with the maximum activity. A separate value should be provided for each item you listed in response to Item 10.14.3.2, with the maximum shielding you will use for each quantity of isotope. For example, frequently used materials for diagnostic purposes such as Tc99m should not have a radiation level of more than 2 or 3 milliroentgen per hour at the surface of the shielded container you will use for distribution.

12. Labels

Please submit a modified licensing statement (label) to be placed on the outside of the container shield (as shown at top of page K2 of Appendix K of your application). It should be modified to reference "10 CFR 35.14 and 35.100 Group ____ of 10 CFR Part 35 (superseded) or Section's _____ of 10 CFR Part 35 (effective April 1, 1987)".

13. State Pharmacy License

Please submit a copy of your pharmacy license issued by the State of Indiana. It is necessary that we have a copy of your state license before we can issue your requested nuclear pharmacy license.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 15 days, and refer to Control Number 92519.

Sincerely,

Original Signed By
Loren J. Hueter
Materials Licensing Section

Hueter/ms
01/10/92

TABLE OF CONTENTS

ITEM 5

Radioactive Material

Element and Mass Number	Chemical and/or Physical Form	Maximum Amount Which Will be Possessed at any One Time
A. Molybdenum-99	A. Any molybdenum-99/ Technetium-99m generator manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Sec 32.73 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations.	A. 35 curies (Ci)
B. Any byproduct material authorized under paragraph 35.14 (d) (4) of 10 CFR Part 35 or paragraph 35.57 (a) of 10 CFR Part 10 (effective April 1, 1987)	B. Any sealed source listed in paragraph 35.14 (d) (4) 10 CFR Part 35 or paragraph 35.57 (a) of 10 CFR Part 35 (effective April 1, 1987) that has been manufactured labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an agreement state pursuant to equivalent state regulations.	B. 15millicurie (mCi) total for all sources under Subitem 6.C.
C. Xenon-133	C. Unit dose containers of gas or gas in solution that is the subject of an active "New Drug Application" (NDA) approved by the FDA or an active "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA.	C. 800 mCi

Radioactive Material		
Element and Mass Number	Chemical and/or Physical Form	Maximum Amount Which Will be Possessed at any One Time
D. Iodine-131	D. Any form listed in Groups I through V of Schedule A, Sec. 35.100 of 10 CFR Part 35 or Sections 35.100, 35.200 35.300 of 10 CFR Part 35 effective April 1, 1987.	D. 500 mCi
E. Technetium-99m	E. Any form listed in Groups I and II of Schedule A, Sec. 35.100, 35.200 of 10 CFR Part 35 (effective April 1, 1987)	E. 35 Curies (Ci)
F. Any byproduct material, except iodine-131 and technetium-99m, listed in Group I of schedule A, Sec. 35.100, of 10 CFR Part 35 Human Uses of Byproduct Material	F. Any form listed in Group I of Schedule A, Sec. 35.100, of 10 CFR Part 35 Human Uses of Byproduct Material	F. 50 mCi total possession limit
G. Any byproduct material, except iodine-131 and technetium-99m, listed in group II of Schedule A, Sec 35.100, of 10 CFR Part 35 Human Uses of Byproduct Material	G. Any form listed in Group II of Schedule A, Sec 35.100, of 10 CFR Part 35 or Sec 35.200 of 10 CFR Part 35 (effective April 1987)	G. 400 mCi total possession limit
H. Any byproduct material, except iodine-131, listed in Group IV of Schedule A, Sec 35.100, of 10 CFR Part 35 or Sec 35.300	H. Any form listed in Group IV of Schedule A, Sec 35.100, of 10 CFR Part 35 or section 35.300 of 10 CFR Part 35 (effective April 1, 1987)	H. 100 mCi total possession limit

of 10 CFR Part 35
(effective April 1, 1987)

Radioactive Material

Element and Mass Number	Chemical and/or Physical Form	Maximum Amount Which Will be Possessed at any One Time
I. Any byproduct material, except iodine-131, listed in Group V of Schedule A, Sec 35.100 of 10 CFR Part 35 Human Uses of Byproduct Material	I. Any form listed in Group V of Schedule A, Sec 35.100, of 10 CFR Part 35 Human Uses of Byproduct Material	I. 100mCi total possession limit
J. Any byproduct material listed in Sec 31.11 (a) of 10 CFR Part 31	J. Prepackaged <u>in vitro</u> diagnostic test kits	J. 50 mCi total possession limit

<u>Request for Authorization to Redistribute Various Items</u>

1. Redistribution of Reagent Kits

Reagent kits to be redistributed will have been obtained from a manufacturer authorized to distribute reagent kits in accordance with a specific approval issued pursuant to Sec 32.73 of 10 CFR Part 32 or under equivalent regulations of an Agreement State. Reagent kits will be redistributed accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that describes the procedures to be followed and the equipment and shielding to be used in processing radioactive material with the reagent kit.

2. Redistribution of Sealed Sources Calibration and Reference Sources

Sealed sources will be redistributed to group medical licensees and other licensees specifically authorized to receive the sources. The calibration and reference sources to be redistributed will have been obtained from a manufacturer authorized to distribute the sources in accordance with a specific license issued pursuant to Sec 32.74 of 10 CFR Part 32 or under equivalent regulations of an Agreement State. The manufacturers labeling and packaging will not be altered and the redistributed sources will be accompanied by the manufacturer supplied calibration

David Newbaker, R.Ph.
Listed as authorized user of N.R.C. License # 34-16654-01MD, Syncor International Corp., Toledo, Ohio

All authorized users
Listed as authorized users under condition 12A of N.R.C. License # 34-16654-01MD, Syncor International Corp., Toledo, Ohio

Ned Gregorio, R.Ph.
Listed as authorized user of N.R.C. License # 11-27398-01MD, Nuclear Pharmacy of Idaho, Inc., Boise, Idaho

John D. Scheu, Ph.D., R.Ph.
Listed as authorized user of N.R.C. License # 13-02650-02, St. Joseph Medical Center, South Bend, Indiana

Cynthia Anne Smith, M.S., R.Ph.
Listed as authorized user of N.R.C. Licenses #21-17189 01MD Syncor Corp., Ferndale, Michigan and # 13-02812 04 Purdue University, West Lafayette, Indiana

II. The proposed Radiation Safety Officer (RSO) is Gregory s. Hiatt, P.D.. The RSO will assume the typical duties and responsibilities of a RSO in a nuclear pharmacy as outlined in Appendix B of Draft Regulatory Guide FC 410-4, dated August 1985. In the absence of the RSO, one of the other authorized users listed above will assume the RSO's duties.

Gregory S. Hiatt, P.D., will also have responsibilities in other areas including serving as general manager, preparing and dispensing radiopharmaceuticals, calling on accounts, etc. The RSO will be able to devote approximately 25% of his time to the radiation safety program.

Item 8
Training for Individuals Working in
or Frequenting Restricted Areas

I. Individuals who work in or frequent restricted areas will be instructed in the items specified n 10 CFR section 19.12 at the time of their initial employment and at least annually thereafter.

II. A radiation safety manual containing radiation safety policies, procedures, and forms for use in documenting compl'ance with 10 CFR, state regulations, and license conditioons has been developed. Individuals who work in or frequent restricted areas will be instructed about the contents of the radiation safety manual at the time of their initial employment and annually thereafter.

III. Other individuals whose duties may require them to work inthe immediate vicinity of licensed material will be irformed about radiation safety hazards and appropriate precautions at the time of their initial employment and at least annually thereafter.

IV. Records documenting initial and refresher training, and indentifying the individual who conducted the training, the individuals who were trained, the date of the training, and the topics covered will be maintained until NRC terminates this nuclear pharmacy license.

V. We, the Spectrum Pharmacy, have established and agree to follow the procedures for the training program as described in Appendix C of Draft Regulatory Guide FC 410-4, dated August 1985.

Item 9

Facilities and Equipment

9.1 Site Description

The pharmacy is located within 3,500 square feet of a single level cement block and brick building utilizing wood ceiling and floor joists. There is a basement underneath part of this building that will not be utilized by the other tenant in this building. This other tenant, a bank, is using their space for storage and light carpentry repair work for the Bank's various branches. This other tenant is currently not planning on having any employees assigned to this space on more than a periodic basis. See diagram #1

The zoning for this area is light industrial and commercial with some residential areas on the fringes. The nearest residential area borders on the edge of the facility's parking lot on the south and west sides and are between fifty and two hundred feet away. Fencing is used to separate the residential areas from the facility's parking lot and there are not any openings or gates in this fencing. The properties to the east and north are light industrial and commercial. see diagram #2

There are three entrances into the facility. The main entrance is located at the front office area (unrestricted) and the other two entrances are located at the back of the pharmacy and enter into the restricted space. The double door entering into the building will be locked with a dead-bolt lock during non-working hours. The door leading into the front office area is a solid wood door with glass side windows. The back doors are made of metal with metal frames and the garage doors are insulated aluminum doors with electric openers. All entrances to the outside and basement will be locked at all times to prevent unauthorized access. When the pharmacy is not open all doors will be secured with a dead-bolt lock. Additionally, an intrusion alarm system will be utilized to deter and detect any unwelcome attempts to gain access to this pharmacy. See diagram #1

The fume hood stack will be located at least 25 feet from any intake air system or window. The stack outlet is located at least two feet above roof level.

Operation of a nuclear pharmacy on the site does not conflict with local codes and zoning laws.

The following letter will be sent to the fire department annually.

DATE

ADDRESS

Attention: (Chief of Fire Department)

We are required by the Nuclear Regulatory Commission to notify you that we are utilizing radioactive materials under an NRC license at:

Spectrum Pharmacy
1301 Milburn Blvd.
Mishawaka, Indiana 46544
Phone Number: (219) 255-0572

This notification is for your information in case of a fire or disaster which might involve this office.

The material with which we work is for use by physicians for medical purposes and, therefore, is comprised of short-lived radioisotopes. Very little danger would exist in case of a fire or disaster; however, precaution should be exercised by fire fighting personnel should it be necessary to enter the room in which radioactive material is stored. In the case of a fire, the material would remain confined to this room due to the nature of this building's construction.

Should it become necessary to enter the pharmacy area, survey instruments are readily available in this area. Also, personnel trained in the use of survey instruments and familiar with hazardous radiation levels would be available to assist your personnel. If the pharmacy is closed, you may contact someone for assistance by calling the above phone number.

If you have any questions concerning this notification, or if you would like to visit our facility to familiarize yourself with our location, do not hesitate to contact us.

9.2 General Description of Facility (See diagram #3)

Every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as reasonably achievable (ALARA).

The pharmacy is divided into two general areas: restricted (rear, dispensing/generator/iodine/WBC/ and clean) and unrestricted (front, office/reception/break room/ restrooms/ computer room/ both storage areas and the garage). The restricted area is approximately 24' X 41' in the main area plus a 9' X 12' section for a total of approximately 1092 square feet. The unrestricted space is approximately 49' X 32' (1568 SQ. FT.) in the main area plus an additional 848 square feet in the garage and storage section for a total of 2416 square feet of unrestricted space.

Within the pharmacy, all radioactive materials will be stored and handled in areas along outside and interior walls on the south side of the restricted area. Radioactive materials will not be stored nor handled next to the wall common with the building's vacant space. Sources of greatest activity will not be stored directly against outside walls.

Mo-99/Tc-99m generators will be located in the generator room in their factory supplied auxiliary shielding. Additional lead shielding will be used when necessary to assure all six sides of each generator is shielded.

Non-refrigerated radiopharmaceuticals will also be stored in the generator room when not in use in the main laboratory. These will be kept in their factory supplied shields and/or behind additional lead shielding. Refrigerated radiopharmaceuticals will be stored in the refrigerator located in the dispensing room. These radiopharmaceuticals will also be stored in their factory supplied lead shields at all times. Additionally, at least 1/8" lead sheet or lead bricks may be used. No food or drinks will be stored in this refrigerator at any time.

Radioactive waste, including expired Mo-99/Tc-99m generators, will be held within the decay room behind at least 1/8" lead shielding. Tc-99m waste generated at the drawing station may be stored in leaded containers at least 1/8" thick at the drawing station. Multiple shielded containers will be used for the long-term storage of radioactive waste to allow for segregation of wastes with different half-lives. Waste containers will have shielded

covers to maintain occupational exposure at ALARA levels.

9.2 **General Description of Facility**

The generator/waste room is 20.5' X 9' (184 SQ.FT.) and approximately 75 SQ. FT. will be used for radioactive waste storage. This is a sufficient space to house all waste generated in-house as well as that retrieved from customers.

The preparation and dispensing of kit radiopharmaceuticals will be performed behind a lead/lead-glass L-block at the drawing station.

During hours when the facility is not staffed, shipments containing radioactive materials will be delivered to the delivery vestibule located on the south side of the facility. This vestibule is in a non-restricted area as is the space on the other side of the vestibule's interior door. This interior door will remain locked and alarmed to prevent delivery personnel from entering into the pharmacy.

Radioactive material will not be received, stored, nor used frequently near the common wall. A film badge will be attached in the center of the common wall in the restricted area to monitor exposure incident on the common wall. The monitor will be exchanged monthly to assure radiation levels below that specified in 10 CFR 20.105. The south and east walls of the building will be surveyed daily with a GM meter to assure radiation levels are below 2 mR/hr.

Air from the pharmacy is not circulated to other areas of the building because the pharmacy has two dedicated HVAC systems. One system will be dedicated to the front half of the pharmacy (unrestricted) and the other unit will be dedicated to the rear half of the pharmacy (restricted). The common wall extends to the wood joists directly attached to the roof of the building and this common wall is constructed to be a fire wall. Airflow begins in the basement and flows through ducts to outlet vents in each of the other rooms except the garage. There are not any cold air returns located in the iodine or WBC rooms. Airflow begins in an unrestricted area and flows to the other unrestricted areas or the restricted areas before it is recirculated or exhausted by the fume hood in the iodine room. see diagram #4

9.3 **Adequacy of Facility for Handling Xenon-133**

Xenon-133 gas will be purchased as unit-dose vials and dispensed as such. There will be no manipulations of the contents of the vials between receipt and dispensing. The estimated fraction of xenon-133 lost during storage is 0.5% per day from its unit-dose vial.

Xenon-133 will be stored in its lead shipping containers within a fume hood with airflow of 400 cubic feet per minute (6.796E8 ml/hr). The airflow rate will be determined by actual measurement with a volumeter or similar device at least every six months.

The estimation of the concentration of xenon-133 in the effluent to unrestricted areas is:

Possession limit of xenon-133: 800mCi

$C = \frac{A}{V} \leq 3.0E\text{-}7$ uCi/ml of xenon-133 released to unrestricted areas.

A= estimated maximum uCi xenon-133 released per week
= 800,000uCi X 0.5%/day X 7 days/week = 28,000uCi/week

V= 6.796E8 ml/hr X 168 hr/week = 1.142E11 ml/week

C= $\frac{28,000 \text{ uCi/week}}{1.142E11 \text{ ml/week}}$ = 2.0E-7 uCi/ml

9.4 **Special Equipment for Handling Millicurie Quantities of Liquid Iodine**

The facility will be equipped to maintain releases of radioactive iodine at ALARA levels in accordance with paragraph 20.1 (c) of 10 CFR Part 20. All work involving the handling open containers of millicurie quantities of liquid radioiodine will be performed within the fume hood.

In order to maintain releases of radioiodine to the environment at ALARA levels, the fume hood will be equipped with a charcoal filtration system consisting of two charcoal filters that are 1' X 1' X 1". It is expected that 98% of radioiodine will be removed from the effluent by this system. Air sampling will be performed in the restricted area (iodine room) and the unrestricted area (air vented through stack). This air sampling system will be running continuously and a diagram of this system and the fume hood relationship can be seen in diagram #5.

Procedures for I-131 Air Monitoring

1. Air monitoring is to be performed weekly
2. Use a vacuum pump with either a known rated air flow or a pump with an air flow gauge.
3. Use two filter holders (unrestricted and restricted area)
4. Use charcoal impregnated filter paper
5. Wearing clean disposable gloves, remove charcoal filter paper from the air sampling apparatus and replace with a new piece of impregnated charcoal filter paper.
6. Place the removed filter in a clean counting tube
7. Count the filter in the scintillation counter for one minute. Make sure that the analyzer window is set for I-131 and that an efficiency factor (Fe I-131 in dpm/cpm) for this analyzer setting has been calculated.
8. Count an empty counting tube for a one minute background
9. Note the sampling pump air flow in ml/minute from measured flow of vacuum pump.
10. Determine pump on duration in minutes from last air monitoring
11. Calculate the concentration of volatile I-131 in uCi/ml in the unrestricted area using the following equations.
    a. $\text{uCi I-131 in filter} = \frac{\text{filter cpm X Fe I-131}}{2.22 \text{ X } 10E6 \text{ dpm/uCi}}$
    b. ml air flow = sampling pump air flow X pump on duration
    c. uCi/ml I-131 = (a)/(b)
12. Assure concentration calculated in step 11.c above is less than 1 X 10E-10 uCi/ml. Notify R.S.O. immediately if concentration exceeds 1 X 10E-10 uCi/ml

Fume Hood Charcoal Filter Monitoring and Exchange Procedure

1. Charcoal filters are to be monitored weekly and exchanged or replaced if necessary
2. Both charcoal filters will be surveyed on both sides with a survey meter and pancake probe.
3. Remove the second filter in line of air flow (top filter), and measure the radiation exposure on each side of the filter.
4. Remove the first filter in line of air flow (bottom filter), and measure the radiation exposure on each side of the filter
5. Calculate the ratio of the top filter reading to the bottom filter reading. Assure the top filter reading is less than 10% of the bottom filter reading, and that the top filter reading is less than 2mR/hr.
6. If the top filter reading equals or exceeds 10% of the bottom filter reading, remove the bottom filter, place in plastic bag and hold for decay behind appropriate lead shielding. Replace the bottom filter with the top filter, and replace the top filter with a new charcoal filter.
7. If the top filter reading is equal to or greater than

2mR/hr, seal both the top and bottom filters in a plastic bag and hold for decay behind appropriate lead shielding.

Thyroid Bioassay

Thyroid bioassay will be performed on all individuals who handle open forms of liquid radioiodine. A description of the bioassay program is described as part of Spectrum Pharmacy's radiation safety program.

Item 10
Radiation Safety Program

10.1 Personnel Monitoring Program
Written personnel monitoring procedures that include as requirements the criteria in Item 10.1.2 of Draft Regulatory Guide FC 410-4, dated August 1985 have been established and will be followed.

10.2 Instruments
Instruments specified in Item 10.2.2 of Draft Regulatory guide FC 410-4 (dated August 1985) will be in the possession of the nuclear pharmacy and available for use when operation begins.

10.3 Calibration of Survey Instruments
Survey instruments will be returned to the manufacturer for calibration, or they will be calibrated by an organization that is licensed by NRC or an Agreement State to perform calibrations for others.

Additionally, survey instruments will be calibrated at the facility in accordance with written procedures that include as requirements the criteria described in Item 10.3.4 of Draft Regulatory Guide FC 410-4, dated August 1985. (See Appendix's O and P)

Calibration of survey instruments in the facility will be done in the manner described in Appendix D of Draft Regulatory Guide FC 410-4, dated August 1985.

Survey instruments will be calibrated at 1 year intervals and after repair.

Records of each calibration will be maintained for at least 2 years after the calibration. These records will show the date and results of the calibration and the name of the organization that provided the service.

10.4 Calibration of Dose Calibrators
The dose calibrator calibration program described in Appendix E of Draft Regulatory Guide FC 410-4, dated August

1985 will be used. Additionally, approval is requested to use a Lineator (Atomic Products #086-56 or similar) for performing linearity of dose calibrators. (see appendix N)

10.5 Procedures for Receiving Shipments Containing Radioactive Material

Procedures described in Appendix F of Draft Regulatory Guide FC 410-4, dated August 1985, for ordering and receiving radioactive material will be used.

10.6 Procedures for Safely Opening Packages Containing Radioactive Material

Procedures for opening packages described in Appendix G of Draft Regulatory Guide FC 410-4, dated August 1985 will be used.

10.7 General Procedures for Safe Use of Radioactive Material
General rules for safe use of radioactive material described in Appendix H of Draft Regulatory Guide FC 410-4, dated August 1985 will be followed.

10.8 Emergency Procedures
Emergency procedures described in Appendix I of Draft Regulatory Guide FC 410-4, dated August 1985 will be used.

10.9 Procedures for Retrieving Radioactive Waste from Customers
Only those items that contain or are contaminated with radioactive materials that were supplied by the nuclear pharmacy will be retrieved.
Detailed instructions to customers that will package radioactive waste for return to the nuclear pharmacy will be provided to all customers (see below).

INSTRUCTIONS TO CUSTOMERS RETURNING RADIOACTIVE WASTE TO THE NUCLEAR PHARMACY

Only items containing or contaminated with radioactive materials that were supplied by Spectrum Pharmacy may be returned for disposal.

the following procedures should be utilized when returning radioactive waste:

1. After use, return the dose container (ie., syringe or vial) to the shield in which the dose was delivered.

2. Insure that radioactive quantities returned are equal to or less than those specified below for radionuclides contained in the most commonly used radiopharmaceuticals:

RADIONUCLIDE			MAXIMUM RETURNABLE QUANTITY (mCi)
Cobalt-57	(Co-57)		9
Cobalt-58	(Co-58)		2
Chromium-51	(Cr-51)		60
Gallium-67	(Ga-67)		10
Iodine-123	(I-123)		5
Iodine-125	(I-125)		7
Iodine-131	(I-131)		1
Indium-111	(In-111)		2.5
Molybdenum-99	(Mo-99)		2
Phosphorus-32	(P-32)		3
Selenium-75	(Se-75)		4
Technetium-99m	(Tc-99m)		10
Thallium-201	(Tl-201)		20
Xenon-133	(Xe-133)	uncompressed	1000

When returning a package containing more than one of the above radionuclides, the maximum returnable quantity is determined by the lowest mCi quantity assigned for the items shipped. For example, if Tc-99m and I-131 are being shipped in the same package, only 1 mCi of total activity may be contained in the package.

3. If radioactive quantities are greater than those specified on the attached table, retain the material behind appropriate shielding until it has decayed to an acceptable quantity.

4. Using your low-level survey meter, measure all points on all surfaces of the package to be returned to insure that at no point on the surface the exposure exceeds 0.5mR/hr.

10.10 Precautionary Measures for Handling Millicurie Quantities of Liquid Radioiodine

Opening and dispensing from vials containing millicurie quantities of liquid radioiodine will be performed in the fume hood behind lead shielding. Protective gloves will be worn, and remote handling tools (tongs) will be used by persons handling liquid radioiodine.

Therapy capsules and therapy solution will be dispensed in the original manufacturer's shipping container. (see appendix M for capsule compounding procedures)

An iodine bioassay program equivalent to that specified in

Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131" will be implemented. Iodine-125 will not be handled in an open form. Therefore, bioassay will not be performed for I-125.
Bioassay frequency, action levels, and actions taken will be those specified in Regulatory guide 8.20. Specifically, authorized-users who handle and dispense radioiodine will be required to have a thyroid bioassay performed weekly or within 24 hours after handling liquid iodine, whichever comes first.

Thyroid I-131 activity will be measured with a 2" or larger NaI (Tl) detector and a Canberra series 35 multichannel analyzer.

The bioassay procedure is as follows:
1. With I-131 source, peak the analyzer on 364 KEV
2. Set the region of interest from 100 to 500 KEV
3. Obtain background counts for one minute
4. Place < 10uCi I-131 (standard) in thyroid neck phantom, position detector on phantom, and acquire for one minute.
5. Obtain counts with detector positioned over thyroid
6. Calculate thyroid activity in uCi:

$$\frac{\text{(Net thyroid cpm) (uci Standard)}}{\text{Net standard dpm}} = \text{uCi in thyroid}$$

The action level from NRC Regulatory Guide 8.20 is 0.14 uCi of iodine-131. The investigation level is 0.04 uCi.

10.11 Area Survey Procedures
The area survey procedures described in Appendix J of Draft Regulatory Guide FC 410-4, dated August 1985 will be used.

10.12 Operations
Licensing of Spectrum Pharmacy by the Indiana State Board of Pharmacy is pending as of this date.

The activities of the nuclear pharmacy will be limited to the preparation of radiopharmaceuticals for delivery prescription to physicians within a 90 mile radius of South Bend, Indiana.

The activities of the nuclear pharmacy will be limited to repackaging IND/NDA radiopharmaceuticals or preparing radiopharmaceuticals by tagging IND/NDA reagent kits with a radionuclide eluted from an IND/NDA generator.

10.13 Product Labels

The actual prescription label is seen in appendix K. The label will be placed on the outside of the unit-dose syringe

container shield. The specific group (I,II, IV, or V) of 35.100 of 10 CFR Part 35 that applies to the individual radiopharmaceutical will be placed on the container shield.

10.14 Product Shielding

Maximum Activity for Each Type of Container (e.g., vial, syringe)

Radionuclide	Max mCi Vial	Max mCi Syringe
Tc-99m	1000	200
I-131	250	0.5
Xe-133	40	N/A
I-125	2	2
Cr-51	1	0.25
P-32	20	10

Most radiopharmaceuticals are shipped in enough shielding to reduce the exposure rate at 0.5 meter to 0.25 mR/hr or less. The following table shows the shielding required to meet this criteria.

Radionuclide	Max. Quantity in mCi	Lead, mm
Tc-99m unit dose	60	2.0
Tc-99m multi dose	1000	2.6
Cr-51	2	0
Ga-67 multi dose	100	7.0
Xe-133 unit dose	40	1.0
In-111 unit dose	5	3.2
I-123 multidose	5	1.0
I-125	10	1.0
I-131 diagnostic	1	6.0
I-131 therapeutic	200	50.0

Normal shielding for unit dose syringes is a lead lined, screw top closure, leak proof plastic syringe carrier. Vial of radioactive material distributed by the pharmacy will be shielded in vial shields that the manufacturers utilize. the average lead thickness of the shielded syringe carriers is no less than 5mm. The lead thickness of manufacturer supplied vial shields used for pharmacy distribution is no less than 4mm.

The maximum radiation level to be expected at the surface of each type of shielded container when filled with the maximum activity is less than 50mR/hr.

10.15 Procedures for Packaging and Transporting Radiopharmaceuticals

The nuclear pharmacy will comply with applicable regulations for packaging and transporting radioactive material as specified in 10 CFR Part 71, 49 CFR Parts 170-189, and 14 CFR Part 173.443.

Packaging and Transport of Radioactive Materials:
1. Radioactive material is placed into appropriate shielding with required labeling and absorbent material.
2. A wipe test is performed on the immediate container. Containers with removable contamination wipe test results greater than 220 dpm will not be dispensed.
3. Shielded containers are placed in specifically designed transport containers and sealed. These transport containers will be certified as USA DOT-7A type A containers. The test results for two of the containers can be found under appendix L. The third type of container's testing results can be found in a Mallinckrodt NRC license #24-04206-01 as their delivery container. This third containers test results will be acquired and kept on file prior to using this container (see also appendix L).

4. The delivery container is wipe tested, surveyed with a GM meter, and labeled according to DOT and NRC requirements. Containers with removable contamination wipe test results greater than 220 dpm will not be dispensed.

5. Radioactive packages are transported either by Spectrum Pharmacy personnel or common carrier.

6. Deliveries are made to specified locations only within customers facilities.

7. All carriers are instructed to keep their vehicles locked when left unattended.

Written instructions will be provided to drivers about radiation safety and delivery procedures that includes directions to lock the vehicle whenever it is left unattended, and to leave deliveries only in secured places that have been previously designated by the customers.

RADIATION SAFETY AND DELIVERY PROCEDURES

1. Place delivery cases in the rear of the vehicle. Do not carry cases in the passenger compartment of the vehicle. Be sure delivery cases are blocked and braced so that they will not change position during normal transportation conditions.
2. In case of an accident, consult the emergency procedures.
3. Never break the seal or open delivery cases.
4. When carrying radioactive materials, drive the delivery vehicle directly to your destination. Make no unauthorized stops or detours.
5. Lock vehicle whenever it is left unattended.
6. Leave deliveries only in secured places that have been previously designated. Never leave a radioactive package unattended.
7. No unauthorized passengers are allowed in the vehicle.

EMERGENCY PROCEDURES FOR VEHICLES INVOLVED IN TRAFFIC ACCIDENTS

Visible Instructions

A copy of written instructions will be kept conspicuously posted (ie. on the dashboard or window) in each delivery vehicle for drivers, police, or civil authorities in case of traffic accidents. This information is:

CAUTION: This vehicle may contain radioactive material (UN 2982)

In case of accident immediately notify:

Greg Hiatt, R.S.O.
(219) 255-0572
(219) 271-7183
Police 911
Fire 911

In the interim:

1. Keep persons away from vehicle
2. Do not attempt to remove materials from vehicle until appropriate help has arrived.

Written Instructions for Spectrum Personnel

A copy of written instructions will be kept conspicuously available (ie. glove box) in each delivery vehicle for driver, police or civil authorities in case of traffic accidents, etc.

1. Immediately notify the RSO or acting RSO. He in turn will notify the appropriate authorities. Maintain security over the vehicle and radioactive material and keep bystanders away while calls are being made.

Pharmacy Phone #: (219) 255-0572

2. All traffic should be detoured around the scene of the accident. If this is not possible, vehicles should be moved the shortest distance necessary to clear the right-of-way.

3. The area of the accident should be restricted. The public should be kept as far from the scene as is practical. Local authorities should make only necessary entries and investigations into the accident area. Do not attempt to open the radioactive container, or clean up debris or material involved in the accident prior to the arrival of experienced help.

4. Any persons who have had possible contact with the radioactive material should be segregated and confined until they can be examined further.

5. Injured persons who have had possible contact with the radioactive material should be removed from the area if possible. Except in extreme emergencies, patients should not be moved to a local hospital or doctor's office before a radiological survey has been made.

6. If the accident involves fire, attempts to extinguish it should be made from as great a distance as possible. The fire should be treated as one involving toxic chemicals. Clothing and tools used at the fire should be segregated until they can be checked by the monitoring team.

7. Eating, drinking, or smoking in the area of the accident should be prohibited.

8. Careful attention and considerations should be given in matters of public relations to:

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

b. Tactful handling of volunteers and crowds of

curious onlookers.

10.16 Independent Audit Program

Compliance Audits will be conducted on a quarterly basis by an independent consultant to ensure compliance with all regulatory requirements, including the terms and conditions of the approved NRC license (see the attached audit form in Appendix Q). The person assuming primary responsibility for performing these audits is John D. Scheu Ph.D. health physicist (see attached training and experience in Appendix A). Dr. Scheu will have the authority to mandate changes as necessary for NRC compliance and good radiation health physics practice, and will be compensated to assume this authority.

Item 11

Waste Management

We, Spectrum Pharmacy, have established and agree to follow the procedures for disposal of radioactive waste as described in Item 11.2.2 of the Draft Regulatory Guide FC 410-4, dated August 1985. We will dispose of radioactive waste in accordance with the requirements in 10 CFR Part 20, Sections 20.301 and 20.303, but also request authorization pursuant to Section 20.302 of 10 CFR Part 20 to dispose of radioactive waste by decay storage.

DIAGRAM 1

SITE SCHEMATIC

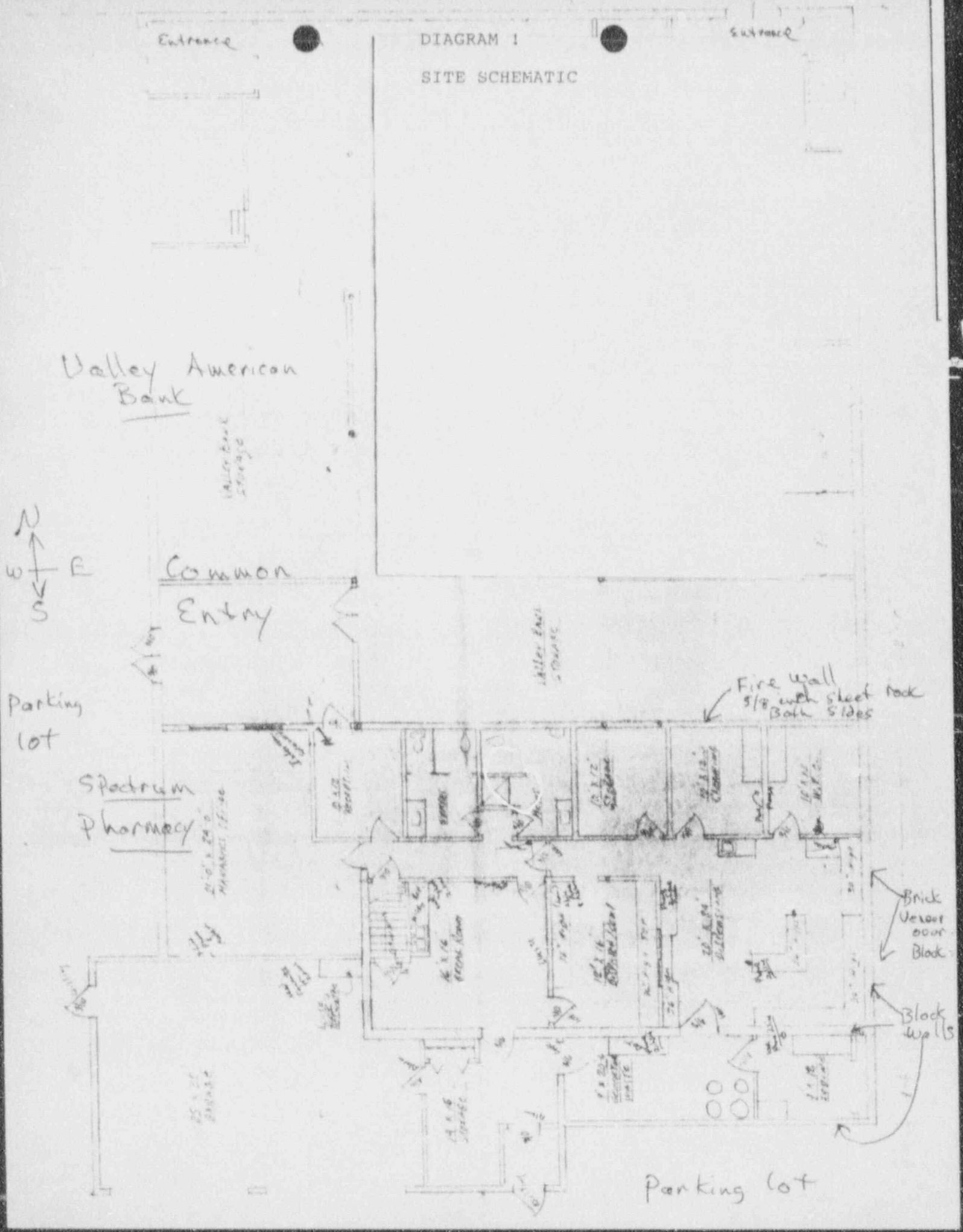
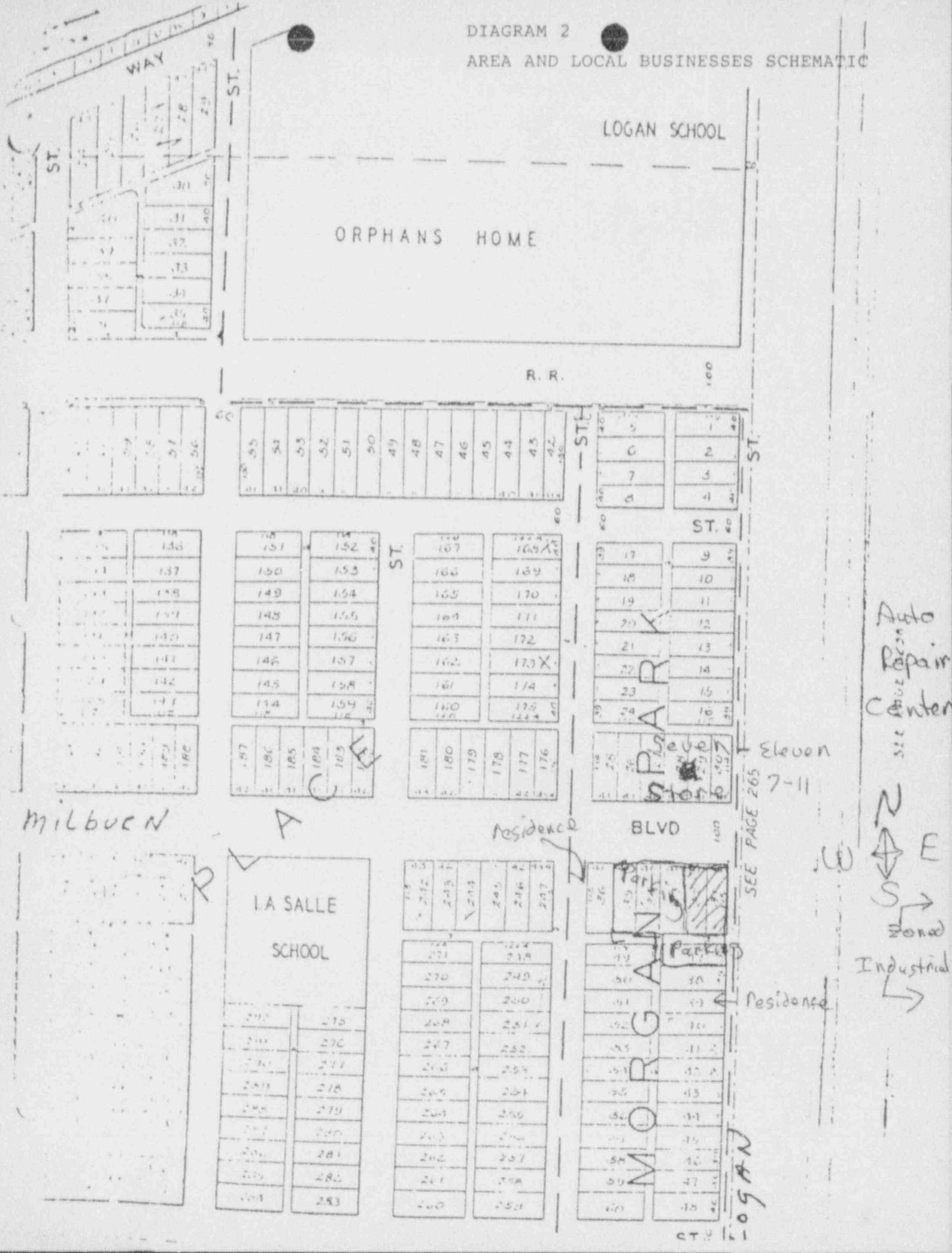


DIAGRAM 2

AREA AND LOCAL BUSINESSES SCHEMATIC



certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

3. Redistribution of In-Vitro Kits

In-Vitro kits will be redistributed to group medical licensees and other licensees specifically authorized to receive in-vitro kits. The in-vitro kits to be redistributed will have been obtained from a manufacturer authorized to distribute the in-vitro kits in accordance with a general license issued pursuant to 10 CFR 32.71 or in accordance with a specific license pursuant to Section 31.11 of 10 CFR Part 31 or under equivalent licenses of an Agreement State. In-Vitro kits will be redistributed accompanied by the manufacturer supplied package insert, leaflet, brochure, or other document that describes the procedures to be followed and the equipment, and radiation safety instructions. In-Vitro kits redistributed to specific licenses will not receive documentation referencing general licenses, exempt quantities or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11).

ITEM 6

Purposes for Which Licensed Material Will be Used

Material Reference Letter from Item 5	Purposes for Which Material Will be Used
A.	Production of technetium-99m pertechnetate. Redistribution to authorized recipients.
B.	Instrument calibration. Redistribution of sources to specifically authorized recipients.
C.	Distribution to authorized recipients
D.	Dispensing and/or distributing prepared radiopnarmaceuticals to authorized recipients. Prepare I-131 capsules using I-131 NaI. (see appendix M)
E.	Dispensing and/or distributing prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

F. through I. Dispensing and/or distributing prepared radiopharmaceuticals to authorized recipients.

J. Distribution to authorized recipients

ITEM 7

Individuals Responsible for Radiation Safety Program and Their Training and Experience

I. The following individuals will use or directly supervise the use of radioactive material. At least one of these individuals will be physically present at the facility whenever licensed material is being used.

Gregory S. Hiatt, P.D.
Listed as authorized user on N.R.C. License # 13-19229-01MD, Syncor Corp., Indianapolis, Indiana

Timothy M. Quinton, Pharm. D., M.S.
Listed as authorized user on N.R.C. License # 12-26246-01MD, Radiopharmacy, Inc., Evansville, Indiana

E. Dean Dome' R.Ph.
Listed as authorized user on N.R.C. License # 12-26246-01MD, Radiopharmacy, Inc., Evansville, Indiana

Paul Gotti, R.Ph.
Listed as authorized user on License # NM-NPI-RP-08 issued by the state of New Mexico

Curtis Blaum, R.Ph.
Listed as authorized user on N.R.C. License #34-16654-01MD, Syncor International Corp., Toledo, Ohio

Brian C. Blaum, R.Ph.
Listed as authorized user on N.R.C. License # 34-16654-01MD, Syncor International Corp., Toledo, Ohio

Dale Bultmeier, R.Ph.
Listed as authorized user on N.R.C. License # 13-19229-01MD, Syncor Corp., Indianapolis, Indiana

Dawn K. Whitney, R.Ph.
Listed as authorized user on N.R.C. License # 13-19229-01MD, Syncor Corp., Indianapolis, Indiana

Mark E. Brown, D.Ph.
Listed as authorized user of N.R.C. License # 34-16654-01MD, Syncor International Corp., Toledo, Ohio

DIAGRAM 2

AREA SCHEMATIC

INDIANA MORTGAGE REPORT

SURVEY ORDERED BY: ST. JOSEPH TITLE CORPORATION
SURVEY DATED: October 2, 1991
PROJECT NO. 912794

ADDRESS:

LEGAL DESCRIPTION

Lots #31, 32, 33, 34, 35 & 37 together with the vacated alley in the recorded plat of **MORGAN PARK ADDITION** as recorded in the records of St. Joseph County, Indiana.

NOTE: This Lot or Parcel DOES NOT fall within the FLOOD HAZARD AREA as defined by H.U.D.

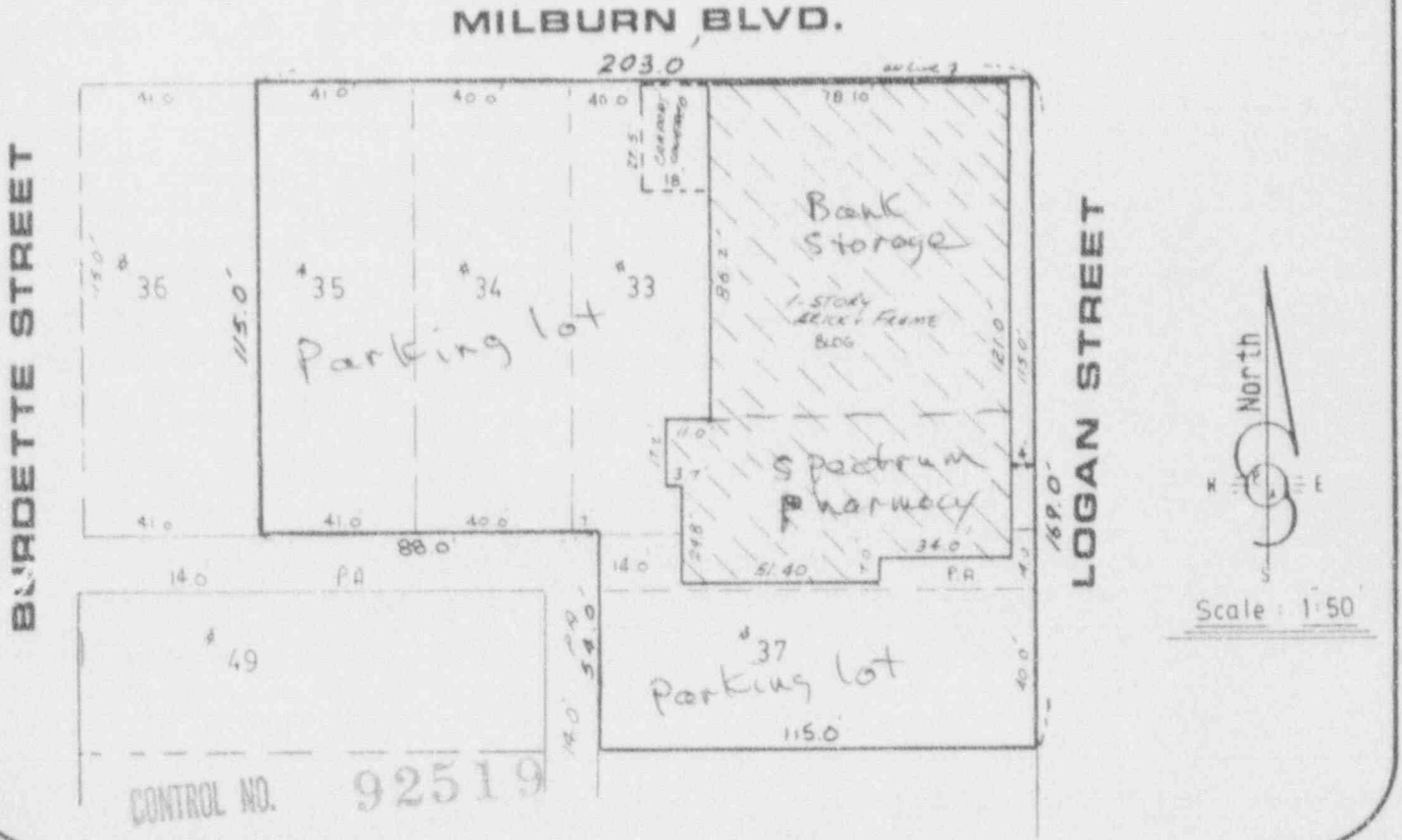
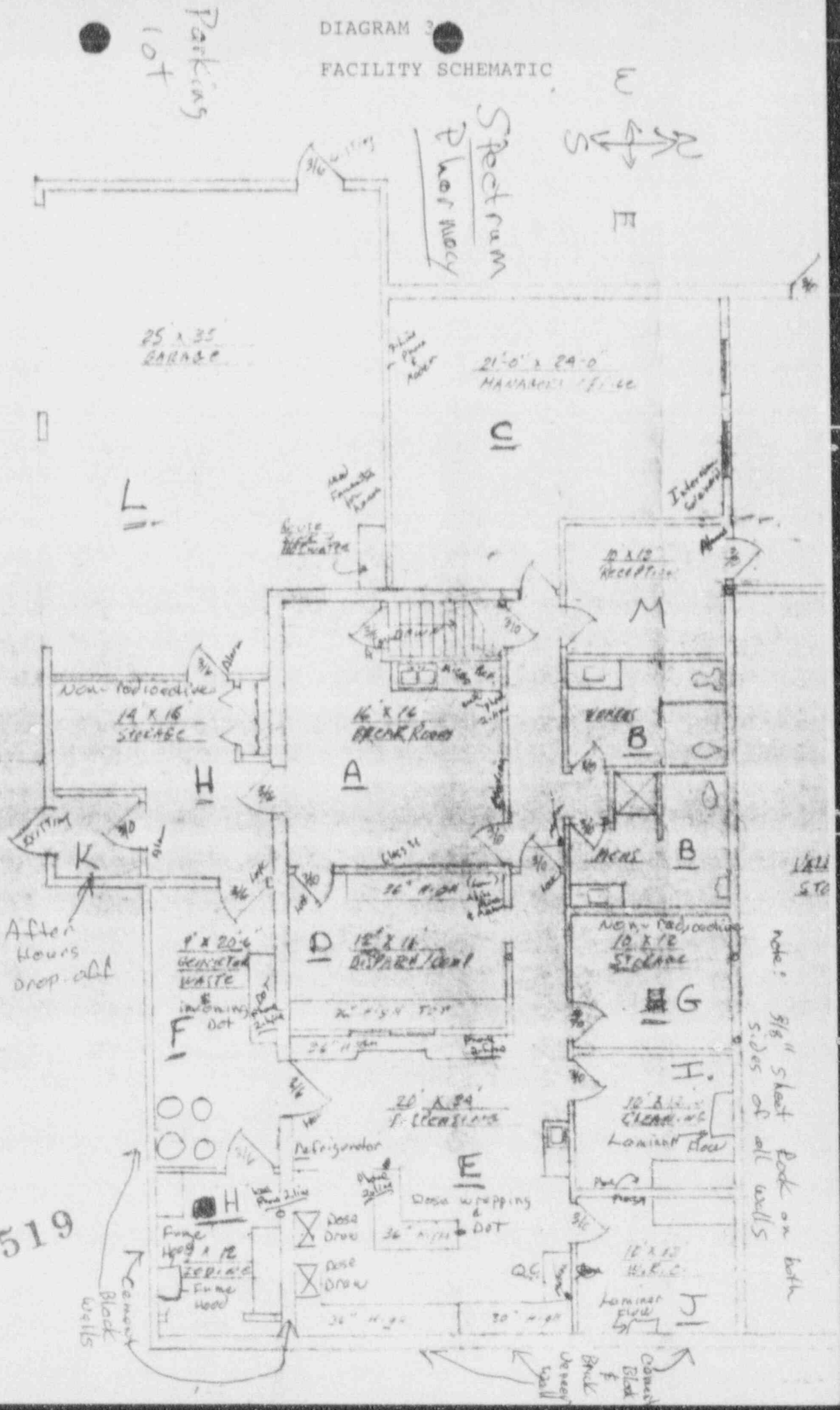


DIAGRAM 3

FACILITY SCHEMATIC



CONTROL NO. 92519

DIAGRAM 4

AIR FLOW SCHEMATIC

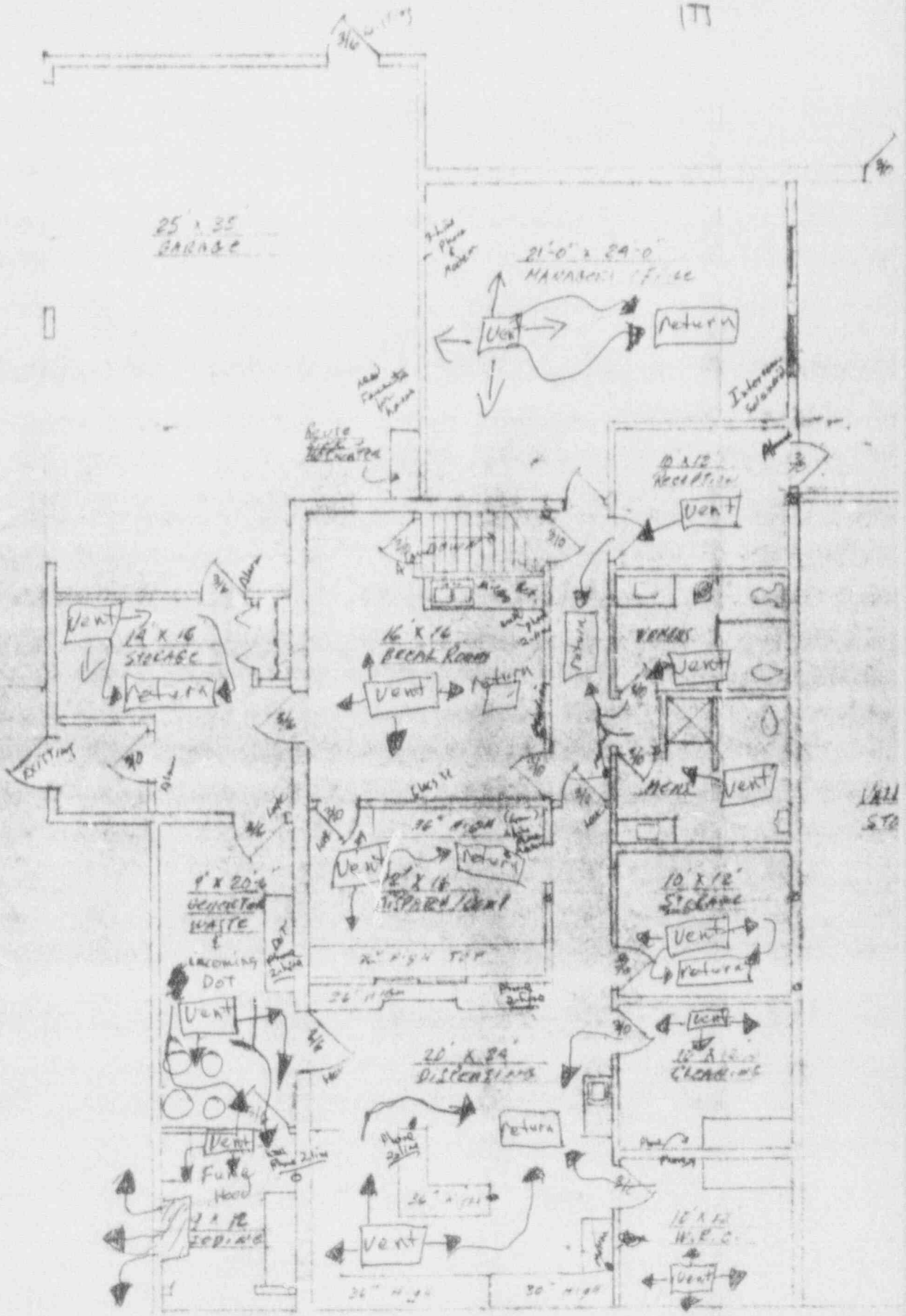
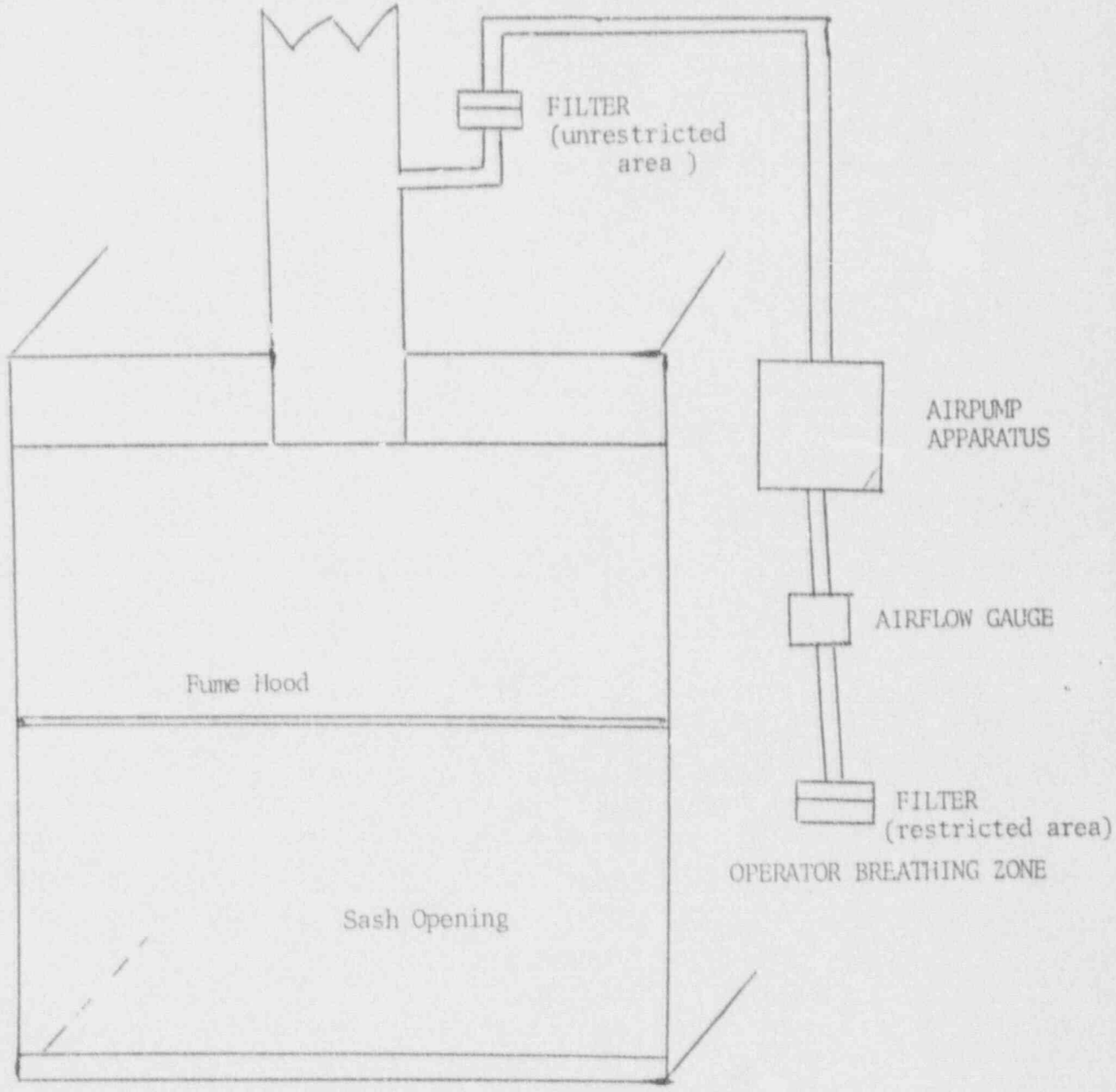


DIAGRAM # 5

FUMR HOOD



Fume Hood and Filter Design

ENVIRONMENTAL PRODUCTS

DIAGRAM 6

AIR MONITORING FILTERS

FILTER HOLDERS

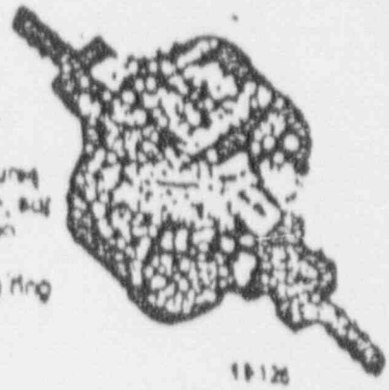
OPEN TYPE
ALUMINUM, 47 mm
• open form for 47 mm filters • effective filtration diameter 36 mm • body made of anodized aluminum, seals without pressure and is opened by ¼ turn • filter support screen is stainless steel • plastic cap provided to protect collected samples

1-124 $90.00

1-124

IN LINE TYPE
ALUMINUM
47 mm
• for closed system sampling or line filtration of gases or liquids at pressures of 200 psi • contains filter, support screen and perforated support disc of stainless steel • teflon compressing ring and O-ring seal of Viton

1-126 $90.00



1-126

AIR SAMPLER
CLOSED TYPE
• constructed of polycarbonate • designed for sampling from ducts or other flowing gases • accommodates 47 mm filters • effective filter area

1-224 $23.75

1-225

AIR SAMPLER
OPEN TYPE
• constructed of polycarbonate • for all monitoring or personal sampling • accommodates 47 mm filters • effective filter area

1-224 1-1224

1-226

AIR ANALYSIS FILTER PAPERS

GLASS FIBER FILTERS
• recommended for air sampling and liquid filtration • thickness 0.294 inches • maximum operating temperature 540° • sold in boxes of 100 circles

Glass Fiber Filter, 13 mm diameter	1-145	$3.85
Glass Fiber Filter, 25 mm diameter	1-146	4.75
Glass Fiber Filter, 47 mm diameter	1-147	8.40

NITROCELLULOSE FILTERS
• suitable for most applications — biological studies, aerosol sampling, DNA/RNA hybridization studies, filtration of aqueous solutions, etc. • available in two pore sizes • sold in boxes of 100 circles

Nitrocellulose Filters, 13 mm-.8 um	1-139	$26.75
Nitrocellulose Filters, 25 mm-.8 um	1-140	28.40
Nitrocellulose Filters, 47 mm-.8 um	1-141	42.50
Nitrocellulose Filters, 13 mm-.8 um	1-142	26.75
Nitrocellulose Filters, 25 mm-.8 um	1-143	28.40
Nitrocellulose Filters, 47 mm-.8 um	1-144	42.50

CHARCOAL IMPREGNATED FILTER PAPER
• ideal for use in sampling for iodine • effective in removing better than 75% of iodine vapors sold in boxes of 100 circles

Charcoal Impregnated Filter Paper 25 mm	1-171	$13.00
Charcoal Impregnated Filter Paper 47 mm	1-172	13.00

CELLULOSE
• pure cellulose ashless filter with small particle retention • ideal for monitoring metallic aerosols • high flow rate

Cellulose Filters 25 mm box of 1000	1-206	$32.00
Cellulose Filters, 37 mm box of 1000	1-207	32.00
Cellulose Filters, 47 mm box of 100	1-208	4.00
Cellulose Filters, 8" x 10" box of 100	1-209	32.00
Cellulose Filters, 8" x 10" box of 100	1-210	28.00

APPENDIX A

RESUME

JOHN D. SCHEU, Ph.D.

HOME ADDRESS	21200 Clover Hill Drive South Bend, Indiana 46614
BUSINESS ADDRESS	808 East Jefferson Blvd. South Bend, Indiana 46617
BIRTH	June 23, 1943 in South Bend, Indiana
MARITAL STATUS	Married to Kathleen C. Szalay, August 1968; 2 Children: John Paul and Nicholas David
EDUCATION	Ph.D., 1973, Purdue University Major: Bionucleonics/Health Physics Thesis Problem: The use of synthetic polymers in developing a microencapsulated controlled release parenteral dosage form and the use of radionuclides in the evaluation of such a system. M.S., 1969, Purdue University Major: Clinical Pharmacy B.S., 1967, Purdue University Major: Pharmacy 1961-1963, Indiana State University Major: Business/Pre-pharmacy
SCHOLARSHIPS, FELLOWSHIPS, AND AWARDS	Indiana State Scholarship (4 years), American Foundation of Pharmaceutical Education Fellowship, Rho Chi Honorary Society.
ADDITIONAL TRAINING	Two weeks at the Indiana University Radiation Therapy Department, Indianapolis, Indiana, 1971. Worked with a nuclear reactor for purposes of neutron activation, 1972. Attended the First International Symposium on Radiopharmaceutical held in Atlanta, Georgia, 1974. Attended the Second International Symposium on Radiopharmaceuticals held in Seattle, Washington, 1979. Attended a Hazardous Chemical Safety School and Workshop, presented by J.T.Baker Chemical Company in Columbus, Ohio, January 1980.

RESUME JOHN D. SCHEU, PH.D.

BOARDS — American Board of Science in Nuclear Medicine

AFFILIATIONS, LICENSURE, RECOGNITION AND COMMITTEE — Society of Nuclear Medicine, Health Physics Society, Licensed Pharmacist, recognized radiation expert and x-ray machine physicists, member of the northen Indiana Radiation Emergency Response Committee.

POSITIONS

Retail pharmacist, (1967-1969)

Assistant Professor, Ohio State University, School of Pharmacy (1973-1980).

Director, Radionuclide Laboratory, Ohio State University, (1973-1980).

Diagnostic Imaging Consultant, Clinical Application Specialist, Radiation Safety Officer, and Medical Radiation and Nuclear Physicist at:

Saint Joseph's Medical Center
South Bend, Indiana (1980-).

Saint Joseph Hospital Mishiwaka
Mishawaka, Indiana (1980-).

Holy Cross Parkview Hospital
Plymouth, Indiana (1980-).

Elkhart General Hosptial
Elkhart, Indiana (1980-).

Health Physics Consultant
Howment Turbine Components Corp.
LaPorte, Indiana (1985-).

Guest Professional Faculty Specialist
University of Notre Dame
Notre Dame, Indiana (1985-).

TEACHING EXPERIENCE

Teaching Assistant (1968-1972)
Purduce University
Courses:"Pharmaceutical Calculation", "Pharmaceutical Formulations" and "Cosmetics".

Assistant Professor (1973-1980)
Ohio State University
Courses:"Radioisotope Tracer Techniques", "Principles and Applications of Radiopharmaceuticals", Medical Applications of Radionuclides and Other Forms of Radiation.

RESUME JOHN D. SCHEU, Ph.D.

PRESENTATIONS

"A Comparative Guide of Veterinary and Human Pharmaceuticals", presented to the Joint Committee of the American Pharmaceutical Association and the American Veterinarian Association, North Chicago, Illinois, November, 1972. J.D. Scheu and Dan Hansel.

"Nuclear Medicine", Purdue University, School of Pharmacy, November, 1974.

"Future Directions in Nuclear Medicine and Radiopharmaceuticals", Presented to the Diagnostic Division of Abbott Laboratories, December, 1974.

Participated in the 17th Annual Educational Meeting of the Ohio Society of Radiologic Technologists on Nuclear Medicine. Columbus, Ohio, April, 1975.

"The Efficacy of IV Perchlorate in Choroid Plexus Blocking", Presented to the Society of Nuclear Medicine 23rd Annual Meeting, Dallas, Texas, June, 1976.
Scheu, J.D., Tetalman,M.R., Araujo, O. and Sheriff, R.A.

"A Comparison of I-123 and I-131 for thyroid Up-take Measurement", Presented at Ohio State Radiologic Society meeting, Cincinnati, Ohio, May, 1976.
Filiatraut, A.Z., Tetalman, M.R., Dare, J., Scheu, J.D., Gray, B., and Gerdes, S.

"The Optimal Pharmaceutical for Brain Imaging", Presented at the Association of University Radiologists 26th annual meeting at the University of Texas Health Science Center, San Antonio, Texas, April 30 to May 4, 1978. Tetalman, M., Deutchman, A., Scheu., Olsen, J., and Chiles,J.

"The Optimal Pharmaceutical for Brain Imaging", Presented at the 25th annual meeting of the Society of Nuclear Medicine, at Anaheim, California, June 26 - 30, 1978. Tetalman, M., Deutchman, A., Scheu, J., Olsen, J., and Chiles, J.

"Comparative Usefulness of Exercise Thallium-201 Imaging and Resting Intracoronary Particle distribution", Presented at the 25th Annual Meeting of the Society of Nuclear Medicine, At Anaheim, California, June 26-30, 1978. Kolibash, A., Call, T., Bush, C., Tetalman, M., Olsen, J., and Scheu, J.

RESUME JOHN D. SCHEU, Ph.D.

PRESENTATIONS

"Indium-111 Labeling of MAA Particles for Use in Perfusion Studies", Presented at the Radiological Society of North America Annual Meeting, Atlanta, Georgia, November 26, 1979. Scheu, J.D., Tetalman, M.R., Kolibash, A.J., and Olsen, J.O.

"Radiopharmaceuticals for Nuclear Cardiology", Presented to the Central Chapter of the Society of Nuclear Medicine, Columbus, Ohio, June 2, 1979.

"Radiation Risks For the Patient and the Technologist", Presented to Indiana State Radiological Tecnologist, Section II, South Bend, Indiana, October 10, 1982.

"Indium-111 Labeled White Blood Cells In Abdominal Imaging", Bronson Hospital, Kalamazoo, Michigan, May 17, 1983.

"Radiation Exposure Policies And The Medical Radiographer", Region VI Educaltional Conference of the American Society of Radiologic Technologists, South Bend, Indiana, April 12, 1984.

RESUME JOHN D. SCHEU, Ph.D.

PUBLICATIONS

Hansell, D. N. and Scheu, J.D.: Comparative Guide of Veterinary and Human Pharmaceuticals, APhA Academy of General Practice and Pharmacy, Washington, D.C., 1973.

Scheu, J.D., Ph.D.: An Investigation into the Possibilities of Using a Microcapsule as a Time-release Parenteral Dosage Form and as a Radiopharmaceutical Organ Imaging Agent, Thesis, Purdue University, West Lafayette, Indiana, 1973.

Khullar, S.C., Fulmer, L.R., Scheu, J.D., Riccobono, X.J. and Leighton, R.F.: "Myocardial Perfusion Scintography After Intra-coronary Injection of Radioactive Labeled Macroaggregated Albumin (MAA)", Clin. Res. 22 281A, 1974.

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RESUME JOHN D. SCHEU, Ph.D.

EXHIBITS

THE USEFULNESS OF INTRACORONARY PARTICULATE MYOCARDIAL PERFUSION SCANS IN EVALUATING CORONARY ARTERY DISEASE: John Olsen, M.D., Marc Tetalman, M.D., Albert Kolibash, M.D., and John D. Scheu, Ph.D.. Ohio State University Hospitals, Columbus, Ohio. Exhibited at the Radiological Society of North America Meeting, November, 1978.

INDIUM-111 LABELING OF MAA PARTICLES FOR USE IN PERFUSION STUDIES. J.D. Scheu, Ph.D., M.R. Tetalman, M.D., A.J. Kolibash, M.D. and J.O. Olsen, M.D.. The Ohio State University Hospitals, Columbus, Ohio. The Second Internation Symposium of Radiopharmaceuticals, Seattle, Washington, March 19-23, 1979.

THE USE OF INDIUM-111 LABELED WHITE BLOOD CELLS IN LOCATING SITES OF ABSCESS AND INFLAMMATION: John D. Scheu, Ph.D., Dean L. Cook, M.D. and Richard Slabaugh, NMRT. Saint Joseph's Medical Center, South Bend, Indiana. Indiana State meeting of Radiological Technologists, South Bend, Indiana, September, 1982.

RESUME JOHN D. SCHEU, Ph.D.

RESEARCH AND PROFESSIONAL ACTIVITIES

Formulated a sodium perchlorate injection to be used as a choroid plexus blocking agent in brain imaging.

Developed a method of tagging Indium-113m and Indium-111 to MAA particles for use in dual nuclide myocardial imaging.

Developed the methodology to label C-parvum bacteria with technetium-99m.

Consulted with a number of radiopharmaceutical companies on the development of imaging agents.

Developed a regional nuclear pharmacy program.

Member of the Nuclear Medicine Technology Advisory Committee, Ohio State University Hospitals, 1978-1980.

Advisor to the Ohio State Board of Pharmacy on radiopharmaceuticals.

Prepared research protocols for submission to Human Research Committee, Radioisotope Committee and FDA (IND Applications).

Supervisor of graduate study on, "The Availability of Insulin from Continuous Insulin Infusion Administration".

Member of the Medical Radionuclide Committee, Ohio State University Hospitals (1978-1980).

Manuscript Reviewer for American Journal of Hospital Pharmacy on Radiopharmaceuticals.

Member of the Joint Radioactive Waste Disposal Study Subcommittee, Ohio State University (1979-1980).

Have labeled proteins, such as antibodies, fragments of antibodies, and toxoids with Iodine isotopes for use in animal studies and clinical evaluation.

Have labeled bleomycin with Cobalt-57 for use in animal studies and as a clinical diagnostic imaging agent.

Have labeled leukocytes and platelets with Indium-111 for use in clinical studies to locate sites of abscess and inflammation or thrombus formation.

Member of the Northern Indiana Radiation Emergency Response Committee.

Recognized by the Indiana State Board of Health as a Qualified Radiation Expert.

Recognized by the Indiana State Board of Health as a Board-Approved X-Ray Machine Physicists.

SUPPLEMENT A

SUPPLEMENT — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
John D. Scheu, Ph.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Science in Nuclear Medicine	Radiopharmaceutical and Radiochemistry	June 23, 1979

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	Purdue University Lafayette, Indiana	40	30
b. RADIATION PROTECTION	"	36	12
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	35	-
d. RADIATION BIOLOGY	"	30	-
e. RADIOPHARMACEUTICAL CHEMISTRY	"	24	10

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

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Au-198	100uCi	Purduce University	2 yrs.	Experimental
C-14	100uCi	" "	1 yr	"
Mo-99	5 Ci	Ohio State University	7 yrs	Rx
Tc-99m	5 Ci	" " "	"	Rx
P-32	10mCi	" " "	"	Dx
I-131	300mCi	" " "	"	Rx, Dx
I-123	2mCi	" " "	"	Rx
Xe-133	400mCi	" " "	"	Rx

Continued

5. EXPERIENCE WITH RADIATION (Continued)

Tl-201	25mCi	Ohio State University	Rx
Ga-67	20mCi	" " "	Rx
In-111	10mCi	" " "	Rx,Experimental
In-113m	40mCi	" " "	Rx, Experimental
Cr-51	5mCi	" " "	Rx, Experimental
Se-75	2mCi	" " "	Rx
Co-57	1mCi	" " "	Rx, Experimental
I-125	100uCi	Notre Dame University	Experimental

THE AMERICAN BOARD OF SCIENCE IN NUCLEAR MEDICINE

Incorporated September 9, 1976

organized through the cooperation of
the American College of Nuclear Medicine,
the American College of Nuclear Physicians,
and The Society of Nuclear Medicine

hereby certifies that

John D. Scheu, Ph.D.

has met established standards and qualifications,
and has passed the examinations conducted under the authority of
The American Board of Science in Nuclear Medicine
on the 23rd day of June, 1979,
thereby demonstrating to the satisfaction of the Board
the ability to practice Nuclear Medicine Science
in all its branches, with special competence in
Radiopharmaceutical and Radiochemistry Science

CONTROL NO. 92519

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APPENDIX A PAGE ( )

President

Vice President

Secretary

Treasurer

APPENDIX B

TYPICAL DUTIES AND RESPONSIBILITIES OF A
DAY-TO-DAY RADIATION SAFETY OFFICER
FOR A NUCLEAR PHARMACY

In a nuclear pharmacy, the day-to-day Radiation Safety Officer's (RSO's) duties and responsibilities usually include:

1. General surveillance over all activities involving radioactive material, including routine monitoring and special surveys.
2. Ensuring compliance with NRC rules and regulations as well as conditions of the NRC license.
3. Monitoring the performance of fume hoods that are associated with isotope work.
4. Serving as the primary source of radiation protection information for personnel at all levels of responsibility.
5. Supervising and coordinating the receipt, opening, and delivery of all shipments of radioactive material arriving at the nuclear pharmacy.
6. Supervising and coordinating the preparation of all shipments of radioactive material leaving the nuclear pharmacy.
7. Supervising the distribution and processing of personnel monitoring equipment.
8. Conducting training programs in proper procedures for the use of radioactive material.
9. Supervising and coordinating the radioactive waste disposal program.
10. Supervising the safe storage of all radioactive materials not in current use.
11. Ensuring that sealed sources are leak-tested at proper intervals.
12. Maintaining an inventory of all radioactive materials and limiting the quantity of radionuclides at the facility to the amounts authorized by the license.

NOTE: In the absence of the RSO (e.g., in the early morning when only one authorized user is present, when the RSO is sick or on vacation), authorized users must assume the duties of the RSO and ensure compliance with NRC's regulations and the terms and conditions of the NRC license.

APPENDIX C

PERSONNEL TRAINING PROGRAM

1. Schedule for Training

Training will be provided:

a. Before an employee assumes duties with or in the immediate vicinity of radioactive materials,
b. Annually as refresher training for all employees,
c. Whenever a significant change occurs in duties, regulations, or the terms of the NRC license.

2. Description of the Training Program

Training will be sufficient to ensure that:

a. Individuals who work in or frequent restricted areas are instructed in the items specified in § 19.12 of 10 CFR Part 19,
b. Individuals whose duties may require work in the immediate vicinity of radioactive materials are informed about radiation hazards and appropriate precautions.

3. Content of the Training Program

The training program will include the following topics:

a. Pertinent terms and conditions of the NRC license, including written procedures developed as a prerequisite for obtaining the license and commitments that have been incorporated into the license,
b. Areas where radioactive material is used or stored,
c. Potential hazards associated with radioactive material,
d. Radiological safety procedures appropriate to the duties of the employee,
e. Pertinent NRC regulations,

f. The employee's obligation to report unsafe conditions to the RSO,

g. The appropriate response to emergencies or unsafe conditions,

h. The right to be informed of personal radiation exposure and bioassay results,

i. The locations where the firm has posted or made available notices, copies of regulations, and copies of licenses and license conditions (including applications and applicable correspondence) as required by 10 CFR Part 19.

4. Records That Document Training

Records of initial and refresher training will be maintained until NRC terminates the nuclear pharmacy license and will include:

a. The name of the individual who conducted the training,

b. The names of the individuals who received the training,

c. The date of the training session, and

d. A list of the topics covered.

APPENDIX D

PROCEDURES FOR CALIBRATION OF SURVEY INSTRUMENTS

1. Calibration of survey meters will be performed with radionuclide sources.

   a. The sources will be approximate point sources.

   b. The source used will be one of those listed in Table D-1.

Table D-1

SOURCES USED FOR SURVEY INSTRUMENT CALIBRATION

Radionuclide	Minimum Activity (To give at least 700 milliroentgens per hour at 20 cm)
Cesium-137	85 millicuries
Cobalt-60	21 millicuries
Radium-226	34 millicuries

   c. The source activities or exposure rates at given distances will be traceable by documented measurements to a standard source certified within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibration sources.

   d. Calibration will be performed at intervals not to exceed 12 months and after servicing.

   e. Instruments will be calibrated on every scale or range of the instrument, up to 1 roentgen per hour.

   f. The exposure rate measured by the instrument will differ from the true exposure rate by less than ±10% at the calibration points (read the appropriate section of the instrument manual to determine how to make necessary adjustments to bring the instrument into calibration). Readings within ±20% will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings.

2. A reference source (check source) that has a long half-life, e.g., cesium-137 or radium D and E, will also be read at the time of the calibration or as soon as the instrument is received from a calibration laboratory. The readings will be taken with the reference source placed in specific geometry relative to the detector. A reading of this reference source should be taken:

   a. Before each use and after each survey to ensure that the instrument was operational during the survey,
   b. After each maintenance or battery change, and
   c. At intervals not to exceed 3 months.

   If any reading with the same geometry is not within ±20% of the reading measured immediately after calibration, the instrument will be recalibrated.

3. Records of Items 1, 2.b, and 2.c above will be maintained for at least 2 years after each calibration or check.
4. The use of the small check source that is in some survey meters is not appropriate or acceptable for calibration purposes.
5. The inverse square law and radioactive decay law may be used for calibration.

   a. A calibrated source will have a calibration certificate giving its output at a given distance or its activity measured on a specified date by the manufacturer.

      (1) The inverse square law may be used with any point source to calculate the exposure rate at other distances.
      (2) The radioactive decay law may be used to calculate the output at any time.

   b. Inverse Square Law

      If R_a is the exposure rate at a distance D_a from a point source and R_b is the exposure rate at a distance D_b from the same point source, then

$$R_a D_a^2 = R_b D_b^2$$

NOTE: R_a and R_b must be in the same units of exposure rate (e.g., milliroentgens per hour, roentgens per hour) and D_a and D_b must be in same units of distance (e.g., centimeters, meters).

If R_a, D_a, and D_b are known, R_b can be calculated from

$$R_b = \frac{D_a^2}{D_b^2} \times R_a$$

c. Radioactive Decay Law

The exposure rate of a standard source at a time t after a specified calibration date is given by

$$R_t = R_0 \times e^{-(0.693 \times \frac{t}{T_{\frac{1}{2}}})}$$

$$= R_0 \times (\tfrac{1}{2})^n$$

where

R_t is the exposure rate at a time t after the source calibration date

R_0 is the exposure rate on the day the standard source was calibrated

t is the time elapsed since the calibration date

$T_{\frac{1}{2}}$ is the radionuclide half-life

n is the number of half-lives through which the radioactive source has decayed and is equivalent to the quantity of $t/T_{\frac{1}{2}}$

NOTE: R_t and R_0 must be in the same units of exposure rate (e.g., milliroentgens per hour, roentgens per hour), and t and $T_{\frac{1}{2}}$ must be in the same units of time (e.g., second, days, years).

APPENDIX E

PROCEDURES FOR CALIBRATION OF DOSE CALIBRATORS*

1. Test for the following:

   a. Instrument constancy (each day of use)
   b. Instrument accuracy (at installation and 1-year intervals thereafter)
   c. Instrument linearity (at installation and 3-month intervals thereafter)
   d. Geometrical variation (at installation)

2. Maintain a record of the results of each test for NRC inspection for 2 years after each test.

3. After repair or adjustment of the dose calibrator, repeat all the appropriate tests depending on the nature of the repairs.

4. Test for Instrument Constancy.

   Instrument constancy means there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Before using the instrument each day, assay at least one of the reference sources listed in Table E-1 using reproducible geometry. Preferably, at least two reference sources (for example, 1 millicurie of cobalt-57 and 100 microcuries of cesium-137) should be alternated to test the instrument's performance over a range of photon energies and source activities.

   a. Assay each reference source using the appropriate instrument setting (i.e., cesium-137 setting for cesium-137).
   b. Measure the background level at the same instrument setting or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

*See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides." Copies may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

c. Calculate the net activity of each source after subtracting the background level.

d. Indicate the predicted activity of each source based on decay calculations and ±5% limits.

e. For each source, list the net activity versus the predicted activity.

f. Repeat the procedure using the same source on all commonly used radionuclide settings.

g. If variations greater than ±5% are noted, either adjust the instrument or use an arithmetic correction factor to correct the dosage assays obtained at that instrument setting. If variations greater than ±10% are noted and the instrument cannot be properly adjusted, it must be taken out of service immediately and repaired or replaced.

h. Investigate higher-than-normal background levels to determine their origin and to eliminate them, if possible, by decontamination, relocation, etc.

5. Test for Instrument Linearity.

The linearity of a dose calibrator must be ascertained over its entire range of activities. This test must use a vial of technetium-99m that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator).

a. Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

b. Assay the technetium-99m vial in the dose calibrator and subtract background to obtain net activity in millicuries.

c. Repeat step a at time intervals of 6, 24, 30, and 48 hours after the initial assay.

d. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time* (hours)	Correction Factor
0	31.633
6	15.853
24	1.995
30	1
48	0.126

*Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The half-life of $T_{\frac{1}{2}}$ = 6.02 hours has been used in calculating these correction factors.

Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

e. On semilog coordinate paper, plot the measured net activity and the calculated activity versus time.

f. On the graph, the measured net activity plotted should be within ±5% of the calculated activity if the instrument is linear and functioning properly. If variations greater than ±5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

g. If instrument linearity cannot be corrected, for routine assays it will be necessary to use either an aliquot of the eluate that can be accurately measured or the graph constructed in step e to relate measured activities to calculated activities.

6. Test for Geometrical Variation.

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors should be computed if variations are significant, i.e., greater than ±2%. When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with a volume of liquid, a 30-cc vial containing 2 millicuries of cobalt-57 or other appropriate radionuclide in a volume of 1 ml can be used.

a. Assay the vial at the appropriate instrument setting and subtract background to obtain net activity.

b. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake the vial to mix the contents and assay as in step a. (Be sure to follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

c. Select one volume as a standard (such as the volume of the reference standard used in performing the test for instrument accuracy) and calculate the ratio of measured activity for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes, and 10 ml is the reference volume selected:

$$4 \text{ ml volume CF} = \frac{2.00}{2.04} = 0.98$$

d. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

e. The true activity of a sample is calculated as follows:

True activity = Measured activity x Correction factor

where the correction factor used is for the same volume and geometrical configuration as for the measured sample.

f. Similarly, the same activity of cobalt-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

7. Test for Instrument Accuracy.

Check the accuracy of the dose calibrator using each of the reference sources listed in Table E-1. The lower energy reference standard (cobalt-57) must be in a vial that has the same thickness of glass as the actual samples to be measured for best accuracy.

a. Assay each reference standard in the dose calibrator at the appropriate setting and subtract the background to obtain the net activity.
b. Repeat step a three times and average the three results.
c. The average activity determined in step b should agree with the certified activity of the reference source within ±5% after decay correction.
d. If variations greater than ±5% are noted, either adjust the instrument or have it repaired as soon as possible. If variations greater than ±10% are noted and the instrument cannot be properly adjusted, it must be taken out of service immediately and repaired or replaced.

Table E-1

DOSE CALIBRATOR REFERENCE STANDARDS

Radionuclide	Activity	Calibration Accuracy
Cesium-137	100 microcuries or more	Within ±5%
Barium-133	100 microcuries or more	Within ±5%
Cobalt-57	1 millicurie or more	Within ±5%

APPENDIX F

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. An authorized user 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. The receiving area will be located so that the radiation levels in unrestricted areas do not exceed the limits specified in paragraphs 20.105(b)(1) and (2) of 10 CFR Part 20.

3. When the nuclear pharmacy is open, carriers will be instructed to deliver radioactive packages directly to the receiving area of the nuclear pharmacy.

4. When the nuclear pharmacy is closed, delivery firms will have written 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 who will then come 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 following letter will be posted in the receiving area and will be given to each carrier service.

TO: Any courier service delivering radioactive materials to (name of nuclear pharmacy)*

FROM: (name of radiation safety officer)*

RE: Delivery of packages containing radioactive material

Any packages containing radioactive material 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 *255-0572. Remain at the nuclear pharmacy until it can be determined that neither you nor the delivery vehicle is contaminated.

---

*This information will be filled in and updated as necessary.

APPENDIX G

PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

1. Determine the status of the shipment with respect to the requirements of paragraphs 20.205(b) and (c) of 10 CFR Part 20. Implement any special procedures for package receipt as required by these regulations. (A chart showing routinely expected shipments and their status with respect to these regulations may be prepared in advance to facilitate this step.)

2. The following procedures must be carried out for all packages containing radioactive material:

   a. Put on waterproof gloves to prevent hand contamination.
   b. Visually inspect the package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop and notify the Radiation Safety Officer (RSO).
   c. Measure the exposure rate at 3 feet (or 1 meter) from the package surface and record it. If >10 milliroentgens per hour, stop and notify the RSO.
   d. Measure the surface exposure rate and record it. If >200 milliroentgens per hour, stop and notify the RSO.
   e. Open the package with the following precautionary steps and record receipt of the radioactive material.

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove the packing slip.
      (2) Open the inner package and verify that the contents agree with those on the packing slip. Compare the requisition, packing slip, and label on the bottle.
      (3) Check the integrity of the final source container (i.e., inspect for broken seals or vials, loss of liquid, and discoloration of packaging material).
      (4) Check also that the shipment does not exceed possession limits.

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

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

(1) If contaminated, treat as radioactive waste.

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

3. Records of exposure rate and contamination surveys in items 2.c, 2.d, and 2.f will be maintained for at least 2 years. Records of receipt of by-product material will be maintained in accordance with the requirements of § 30.51 of 10 CFR Part 30.

4. Special procedures will be followed for receiving packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (e.g., more than 20 curies for molybdenum-99 and technetium-99m). These packages 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 that exceed 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 μCi per 100 cm^2 or if external radiation levels exceed 200 milliroentgens per hour at the package surface or 10 milliroentgens per hour at 3 feet (or 1 meter). Records of the results of monitoring required by paragraphs 20.205(b) and (c) will be maintained in accordance with the requirements in § 20.401.

APPENDIX H

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Always wear laboratory coats or other protective clothing in areas where radioactive materials are used.

2. Always wear disposable gloves when handling radioactive materials.

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

4. Always use syringe shields and vial shields for preparing and dispensing radiopharmaceuticals.

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

6. Do not store food, drink, or personal effects with radioactive material.

7. Assay each vial, syringe, and capsule containing more than 10 microcuries of a gamma-emitting radiopharmaceutical in the dose calibrator before distribution for use in humans.

8. For each elution of technetium-99m from a molybdenum-99/technetium-99m generator:

   a. Assay the eluate for technetium-99m in a dose calibrator; record the results and retain the record for 3 years after the assay.
   b. Test for total molybdenum-99 activity or test for molybdenum-99 concentration; record the results and retain the record for 3 years after the test (see paragraph 35.14(b)(4)(iii) of 10 CFR Part 35).

9. Do not distribute technetium-99m for human use if the technetium-99m contains more than 1 microcurie of molybdenum-99 per millicurie of technetium-99m or if it contains more than 5 microcuries of molybdenum-99 per dose of

technetium-99m at the expiration time and date shown on the package label. The expiration date and time shown on the label must be such that the limits specified above are not exceeded for any single patient dose.

10. Always wear personnel monitoring devices (film badge or TLD) in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in the designated low-background area.

11. Always wear TLD (or film) finger badges when eluting the generator and preparing, assaying, or dispensing millicurie quantities of radioactive material.

12. Never pipette by mouth.

13. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

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

15. Confine radioactive solutions in covered containers that are clearly identified and labeled with the name of the compound, radionuclide, date, and activity.

16. Always transport radioactive material in shielded containers.

APPENDIX I

EMERGENCY PROCEDURES

1. A copy of these procedures will be posted in each area where radioactive material is used or stored.

2. A decontamination kit is located *area E. The contents of this kit include disposable waterproof gloves, remote handling tongs, absorbent paper, disposable pads, and plastic bags.

3. Minor Spills

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

4. Major Spills

   a. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
   b. PREVENT THE SPREAD: Cover the spill with absorbent paper or pads, but do not attempt to clean it up. Confine the movement of all potentially contaminated personnel to prevent the spread.
   c. SHIELD THE SOURCE: It possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

*This information will be filled in and updated as necessary.

d. CLOSE THE ROOM: Leave the room and lock the doors to prevent entry.

e. CALL FOR HELP. Notify the RSO immediately.

f. PERSONNEL DECONTAMINATION: Remove contaminated clothing and store for further evaluation by the RSO. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: * Gregory S. Hiatt

OFFICE PHONE: * (219) 255-0572

HOME PHONE: * (219) 271-7183

NAMES AND TELEPHONE NUMBERS OF ALTERNATES DESIGNATED BY THE RSO:

*

*This information will be filled in and updated as necessary.

APPENDIX J

AREA SURVEY PROCEDURES

1. All elution, preparation, assay, and dispensing areas will be surveyed daily with a low-range survey meter and decontaminated if necessary.*

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 milliroentgen per hour.
   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 220 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other high-background areas will be removed to a low-background area for measurement.

5. Records of all survey results,* including negative results, will be kept for 1 year after each survey. The record will include:

   a. A drawing of the area surveyed identifying relevant features such as active storage areas, active waste areas, etc.
   b. Measured exposure rates (in units of milliroentgen per hour) keyed to locations on the drawing.
   c. Detected contamination levels (in units of dpm or microcuries) keyed to locations on the drawing.
   d. 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.

*For daily surveys in which no abnormal exposures are found, only the date, the name of the person performing the survey, and the survey results will be recorded.

6. The area will be either cleaned or posted and restricted from use if the contamination level exceeds 2,200 dpm per 100 cm^2.

7. The area will be covered, cleaned, or identified to all employees if the contamination level exceeds 220 dpm per 100 cm^2 but is less than 2,200 dpm per 100 cm^2.

APPENDIX K

LABELS

The following labels are actual forms that will be use at Spectrum Pharmacy.

Spectrum Pharmacy
1301 Milburn Blvd.
Mishawaka, IN 46544
Ph: 219/255-0572

Hospital St. Joseph Medical Center
Dr. Burns Rx00100
Radionuclide Technetium 99m
Pharmaceutical MDP (Mall.) (I.V.)
Procedure Bone imaging
Lot # 50001 Assay 40mCi/ml
Activity Desired 20 mCi as of 1000
Volume 0.5ml Activity
Mo99<.15uCi/mCi Tc99m
Patient Expires: 1400
Date 11/3/91 Price

Use as directed by Physician

CAUTION RADIOACTIVE MATERIAL

MDP Tc99m
Rx00100 11-3-91
20 mCi

← Vial shield or Unit dose container label

↑ Syringe label

Spectrum Pharmacy
1301 Milburn Blvd.
Mishawaka, IN 46544
Ph: 219/255-0572

Hospital Community Hospital
Dr. Jones Rx 00103
Radionuclide Gallium-67
Pharmaceutical Gallium Citrate
Procedure Abscess localization
Lot # Ga00011 Assay 2.0mCi/ml
Activity Desired 5mCi as of 1200
Volume 2.5ml Activity
Expires 11-5-91 @ 2400
Patient
Date 11-3-91 Price

Use as directed by Physician

CAUTION RADIOACTIVE MATERIAL

Gallium-67
Rx 00103 11-3-91
5 mCi

← Vial shield or Unit Dose container label

↑ Syringe label

APPENDIX K

LABELS

A. The licensing statement to be placed on the outside of the container shield should read:

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

Spectrum Pharmacy
1301 Milburn Blvd.
Mishawaka, IN 46544
Ph: 219/255-0572

Hospital Memorial Hospital
Dr. Smith Rx 00101
Radionuclide N/A
Pharmaceutical MDP vials (Mall.)
Procedure Preparation Of Tc-99m
Lot # K0100 Assay N/A
Activity Desired NA as of
Volume 2 vials Activity NA
Patient
Date 11-3-91 Price

Use as directed by Physician

MDP Vials
Rx 00101 11-3-91
2 vials

CONSOLIDATED BUSINESS FORMS, INC.

CONTROL NO. 92519

Professional Service Industries, Inc.
Albuquerque Testing Laboratory Division

June 4, 1987

The University of New Mexico
College of Pharmacy/Radiopharmacy
North Campus
Albuquerque, New Mexico 87131

Attention: Paul Gotti

PSI Lab No.: 534-70058

TYPE A PACKAGE TESTS

(49CFR Part 173.465)

Requested by: Paul Gotti

Tested by: Jerry Parker and Tracy Morrison, PSI Representatives

A. INTRODCUTION:

Part 173 of Title 49 of the Code of Federal Regulations contains the regulations governing the shipping and packaging of poisonous and radio-active materials. Paragraphs 173.463 through 174.466 contain the testing requirements for shielding and package integrity. The following tests were conducted in accorance with these regulations.

B. COMMON NAME OF CONTAINER:

A. DOD 50 caliber ammo box

B. Southwest Forest Industries, 10 3/4 in. by 6 in. by 6 in., single wall cardboard box having glued seam or equivalent.

C. AUTHORIZED CONTENTS:

Type A quantities of radiopharmaceuticals packaged in several types of internal packagings.

CONTROL NO. 92519

D. DESCRIPTION OF CONTAINERS AND INNER PACKAGINGS:

1. Two DOD 50 caliber ammo boxes, measuring 5 1/2 in. by 11 in. by 11 1/2 in., with lid hinged at one end and closed by clasp at the end oppposite the hinge and fitted with a rubber gasket in the lid to insure a water-tight seal, were tested.

   a. One box contained six plastic coated lead pipes with screw-on caps. Each pipe contained one plastic syringe fitted with needle and end cap. The box also contained two small lead pigs each containing a glass vial with a rubber/metal cap. The syringes and vials were filled with water.

   b. The other ammo box contained a large open-ended lead cylinder with a medium lead pig inside. The medium lead pig held a glass vial fitted with a screw-on plastic cap. The medium lead pig was fitted with a drop-on lead lid.

2. The Southwest Forest Industries container was a single wall cardboard box with a glued seam. It measured 6 1/8 in. by 4 1/2 in. by 9 1/4 in. The box contained the following "Box Manufacturer's Certificate".

Bursting Test	200 lb.
Min. Comb. Wt. Facings	84 lb. per M. sq.ft.
Size Limit	75 in.
Gross Wt. Limit	65 lbs.

   The container held three plastic coated lead pipes with screw on caps. Each pipe contained one plastic syringe fitted with needle and end cap. The container also held two small lead pigs with drop-on lead lids, each containing one glass vial with a rubber/metal cap. Both the syringes and the vials were filled with water.

3. The inner containers tested were as follows:

   a. A large open cylinder lead pig, 6 in. high by 5 1/2 in. outside diameter, containing a smaller lead pig, 5 1/2 in. by 2 3/4 in. outside diameter with a fitted drop-on lead lid was contained in a 50 caliber ammo box. The two pigs were separated by an open ended 5/8 in. thick foam plastic cylinder. The drop-on lid of the small pig was taped in place. The small pig contained one 10 cc glass vial with a plastic screw-on lid. The inner pig contained absorbent/cushioning material which separated it from the glass vial. The large lead pig was held in position in the ammo box by a fitted two-piece foam plastic insert.

b. Plastic coated lead pipes with screw-on plastic coated lead caps each containing one plastic syringe (1/2 to 2 cc) fitted with needle and needle end cap and filled with clean water to simulate a liquid radiopharmaceutical were contained in a 50 caliber ammo box. The lead pipe contained absorbent material which surrounded the end cap and cushioned the syringe. The lead pipes were held in position by and were separated from the metal ammo box by two fitted foam plastic inserts - one at each end of the pipes

c. A small lead pig 3 in. high by 1 3/4 in. outside diameter with a drop-on lid. Each pig contained a glass vial with a rubber/metal sealed cap to hold 10 cc of liquid raiopharmacueticals.

E. TESTS PERFORMED:

1. Water Spray

A 2 in. per hour water spray test was applied simultaneously to four sides of each box for a period of one hour. Immediately after the water spray test was completed the box was subjected to the following tests:

2. Free Drop Test

The free drop test consisted of a fall from a height of 30 ft to a flat horizontal surface of such mass and rigidity that any increase in its resistance to displacement or deformation upon impact by the specimen would not significantly increase the damage to the specimen.

3. Compression Test

The box was subjected to a compressive load of 265 lbs per sq. ft for 24 hours or five times the weight of the container.

4. Penetration Test

The box was placed on a flat rigid horizontal surface (concrete floor) while the test was performed. A 1.25 in. diameter steel bar with a hemispherical end, weighing 13.2 lbs. was dropped on to the center of the weakest part of the box, so that, if it penetrated far enough, it will hit the containment system. The drop height to the upper surface of the box was 5.5 ft.

F. RESULTS:

1. Two hour water spray.

a. The two metal ammo boxes passed.

b. The Southwest Forest Industries cardboard container passed.

2. Free drop from 30 ft.

a. The metal ammo boxes were dented but remained intact with the lids in place. The inner containers suffered damage as follows:

The large lead pig was somewhat fattened and one small lead pig was dented in the bottom, another was somewhat flattened. Three lead pipes holding the syringes were damaged; two had cracks in the female threads and one was dented. The inner packaging retained the syringes and/or vials. There was no loss of liquid contents.

b. The cardboard box was cracked/split but the inner packaging remained in the box. Two syringe holders were broken above the female threaded portion of the pipe. The other lead pipe and the two small lead pigs were undamaged. The syringes and vials were undamaged and there was no loss of the liquid contents.

3. Compression Test.

a. Ammo boxes were undamaged when subjected to the compression test. The boxes weighed 20.9 lbs. and 33.7 lbs. respectively. The dimensions were 11 in by 5.56 in. with a cross sectional area of 61.19 sq. in.

The criteria requires a load of 265 lbs. per sq. ft or 5 times the weight, which ever produces the greated loading.

61.19 sq. in.by 265 lbs/sq.in. = 112.6 lbs.
144 sq. in./sq.ft.

5x33.7 lbs. = 168.5 lbs./sq.ft.

The load was 168.5 lbs./sq.ft and therefore the authorized gross weight is 33.7 lbs.

b. The cardboard box was partially collapsed by the compression test, however the inner containment system and its contents were undamaged.

The criteria for loading when applied to the 9 1/4 in by 1/8 in. box resulted in a compresive load of 104.3 lb therefore the authorizsd gross weight is 9.8 lbs.

4. Penetration Test From 5.5 ft.

. The impact of ..emispherial end of the vertical steel cylinder 1 1/4 in. diameter, dropped from 5.5 ft. produced a large dent on the side of one ammo box and a small indentation on the other one. The large lead pig was slightly flattened. However, the inner containment system retained the syringes and vials with no loss of liquid.

b. The cardboard box was penetrated on the impacted side and a 1/2 in. diameter hole was punched in the opposite side. However, the inner containment system was intact and no liquid was lost from the syringes or vials.

G. Additional Requirements

a. The smallest overall external dimension of the package is not less than 10 centimeters (4 inches);

b. The outside of the packaging incorporates a feature, such as a seal, that is not readily breakable, and that, while intact, is evidence that the package has not been opened. In the case of packages shipped in exclusive use closed transport vehicles, the cargo compartment may be sealed instead of the individual packages;

c. As far as practicable, the external surfaces are free from protrusions and are designed and finished so that they can be easily decontaminated;

d. Containment and shielding would be maintained during transportation and storage in a temperature range of -40^{0} C (-40^{0} F) to 70^{0} C (158^{0} F) with account being taken of the possibility of brittle fracture;

e. It is able to withstand the effects of any acceleration, vibration, or vibration resonance that may arise during normal transportation, without any deterioration of the effectiveness of closing devices or of the integrity of the package as a whole and without loosening or unintentional release of nuts, bolts, or other securing devices even after repeated use;

f. It includes a containment system securely closed by a positive fastening device that cannot be opened unintentionally or by pressure that may arise within the package during normal transport. Special form, as demonstrated in accordance with 173.469 may be considered as a component of the containment system;

g. The materials of the packaging and any components or structures are physically and chemically compatible with each other and with the contents, taking into account the behavior of each under irradiation;

h. For each component of the containment system account is taken, where applicable, of radiolytic decomposition of materials and the generation of gas by chemical reaction and radiolysis;

i. The containment system will retain its radioactive contents under the reduction of ambient pressure to 0 .25 kilograms per square centimeter (3.5 pounds per square inch);

j. Each valve through which the radioactive contents could otherwise escape is protected against damage and unauthorized operation and, except for a pressure relief device, has an enclosure to retain any leakage;

k. Any radiation shield that encloses a component of the packaging specified as part of the containment system will prevent the unintentional escape of that component from the shield;

l. Failure of any tie down attachment on the packaging under excessive load will not impair the ability of the package to meet other requirments of this subpart;

m. When subjected to the tests specified in 173.465 or evaluated against these tests by any of the methods authorized by 173.641(a).

H Results

a. The smaller overall dimension exceeded 4 in.

b. The ammo boxes incorporated a lead/wire seal. The cardboard box was sealed with paper tape.

c. The exterior surfaces are reasonably free of protrusion and can probably be easily decontainmented.

d. Heat/cold tolerances of the packaging or sheilding were not tested.

e. Acceleration, vibration and resonance characterestics were not tested.

f. Inner containment-systems provided reasonable security from unintentional opening and since they are breathable containers, pressure build-up is unlikely.

g. There was no evidence of physical incompatibility of the various components.

h. Radioactive decomposition and the generation of gas by chemical reaction and radiolysis were not evaluated or tested.

i. The containment systems will retain its contents under reduced ambient pressure since the package breathes.

j. Pressure relief devices were not present.

k. Ability of radiation shields to prevent unintentional escape of components appeared to be satisfac ory

l. Failure of tie downs was not applicable.

m. When subjected to the tests specified in 49CFR section 173.465, the packaging prevented loss or dispersal of radioactive contents.

n. The packages contained liquids and had sufficient absorbent material to absorb twice the volume of the liquid contents.

o. The containers were not designed for compressed gasses, and contained none.

I. Conditions

1. Syringes and Carriers

a. Only plastic syringes are allowed and end caps must be in place.

b. Only plastic coated lead pipe with screw-on caps are permitted as syringe carriers.

c. Each syringe carrier must contain sufficient absorbent material to absorb twice the volume of liquid contained in the syringe.

2. Rubber/metal sealed glass vials and lead pig carrier with drop-on lids.

a. The drop-on lids of the lead pigs must be taped.

b. The vials must be cushioned with foam plastic or other suitable material to seperate them from the pigs.

c. Each pig must contain sufficient absorbent material to absorb twice the volume of contained liquid.

3. Glass vials with plastic screw-on caps and meduim sized lead pigs with slip-fit lids shielded by open ended lead ring.

a. Glass vials must be fitted with an appropriately designed holder or space maintenance device which prevents the vial from inpacting
the pigs.

b. The lead pig must contain sufficient absorbent material to absorb twice the volume of liquid held in the vial it contains.

c. The lead pig slip-fit lid must be taped.

d. The large lead pig must be seperated from the box and from the inner medium sized pig by appropriately fitted foam plastic material.

4. The ammo box lids must be sealed with a wire-lead seal to indicate tampering and to prevent the latch from opening accidently.

5. The cardboard box must be sealed with 3 in. wide fiber reinforced paper tape or 3 in. wide transparent plastic tape.

J. Shippers Reminder

1. The shipper is reminded that each time the container is offered for shipment, the shipper is certifying the package as meeting the DOD specification 7A requirements. Therefore, the shipper is reminded that the tests herein reported is based upon surrogate packagings, materials and inner containment systems and that substitution of packages, materials or containment systems which differ from the surrogates tested may produce different results.

K. Certification Statement

1. Based upon the results obtained during the tests reported herein, the boxes tested meet the DOD specification 7A requirements when packaged as described in this document.

Respectfully submitted,

Julian R. Franklin,
Project Engineer

J. Patrick Callahan, P.E.
Vice President

JOSEPH P. CALLAHAN NEW MEXICO No. 7130 REGISTERED PROFESSIONAL ENGINEER

JRF/JPC/peq
Enclosure

CONTROL NO. 92519

PHOTOGRAPHS

Packages as received.

Metal ammo box showing inner and outer lead pigs packing material.

Metal ammo box with lead syringe carrier and lead pig vial carrier.

Both metal ammo boxes showing packing and inner containment systems.

2 inch rain spray being applied to the cardboard box.

Metal ammo boxed during compression test.

Cardboard box during compression test after being subjected to the 2 in./hour rain spray test.

Metal boxes after compression test.

Cardboard box after compression test.

Cardboard box ready for 30 foot drop test.

Cardboard box after 30 foot drop test.

Metal ammo box containing syringes with carrier and vials with carrier.

Ammo box after 30 foot drop.

Ammo box containing lead pigs and glass vials.

Ammo box after 30 foot drop.

Penetration test of cardboard box.

Results of penetration test.

Results of penetration test.

Penetration test of ammo box containing syringes and carriers and vials and carriers.

Results of penetration test.

Results of penetration test.

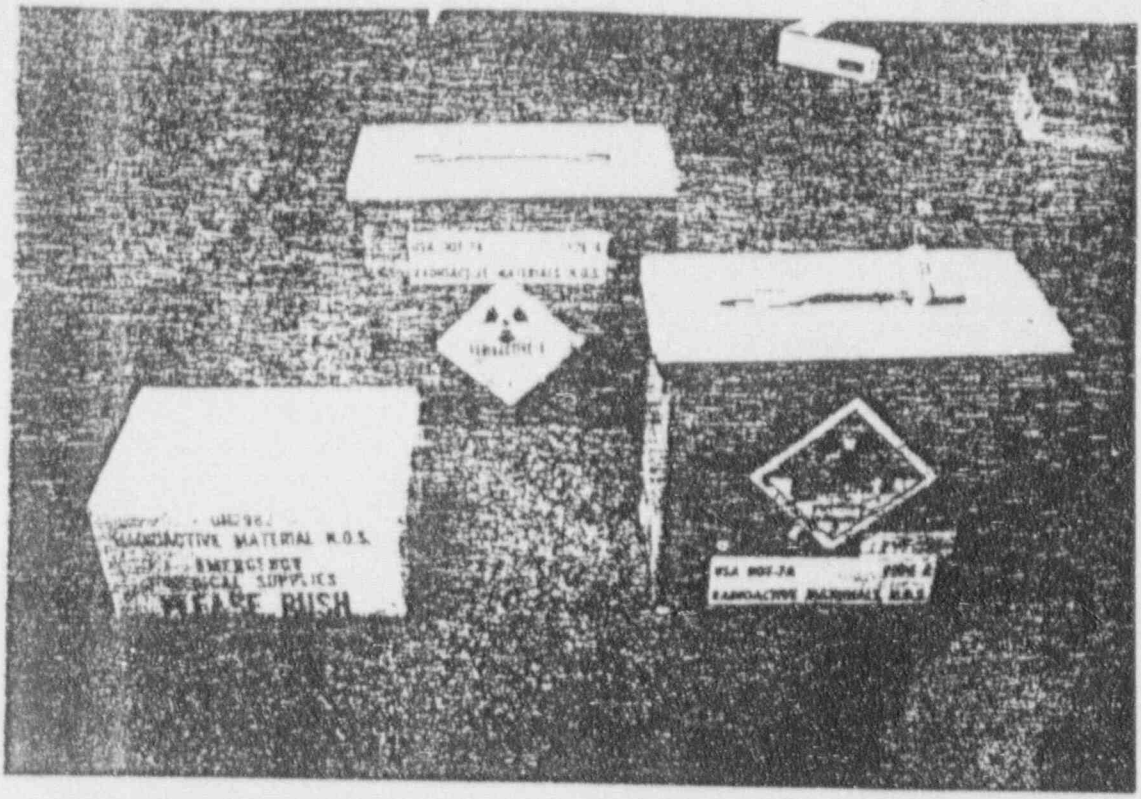
Pentration test of box contaning two lead pigs with vials.

Results of penetration test.

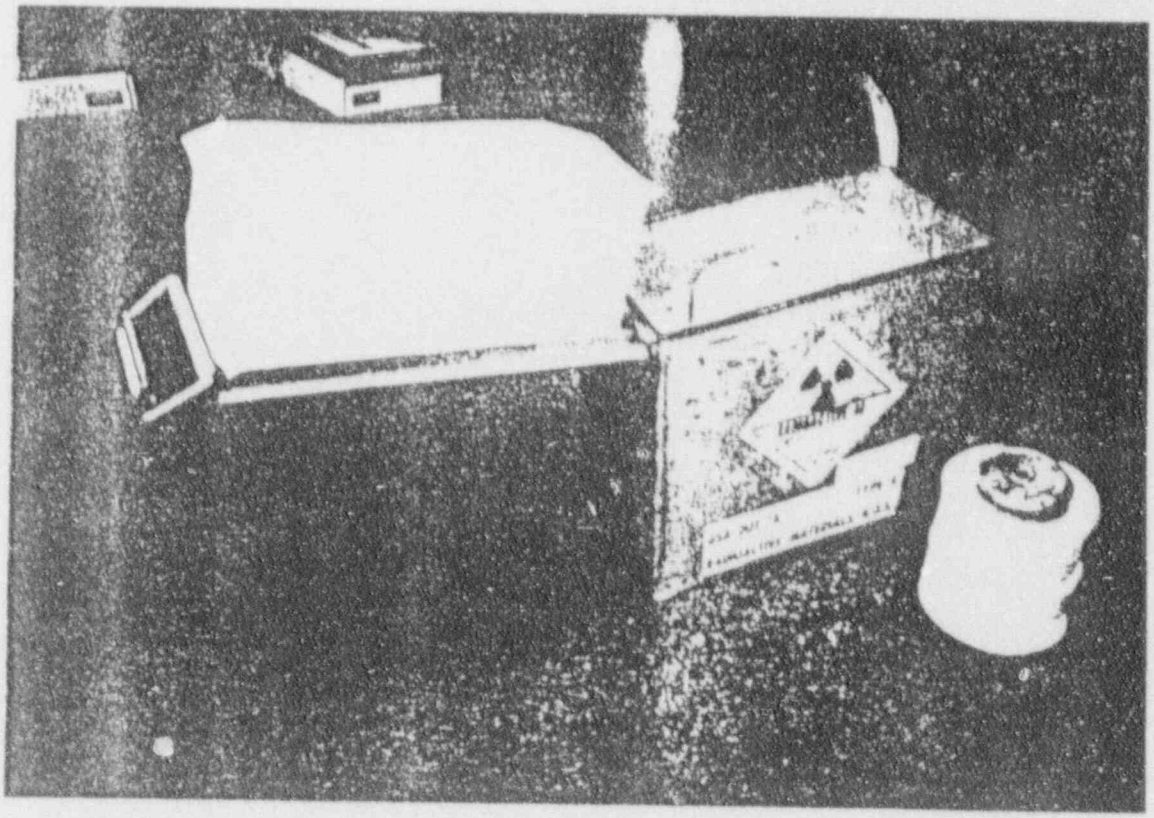
Condition of cardboard box and contents after 30 foot drop and penetration test.

Condition of ammo box and contents after 30 foot drop and penetration test.

Condition of ammo box and contents after 30 foot drop and penetration test.

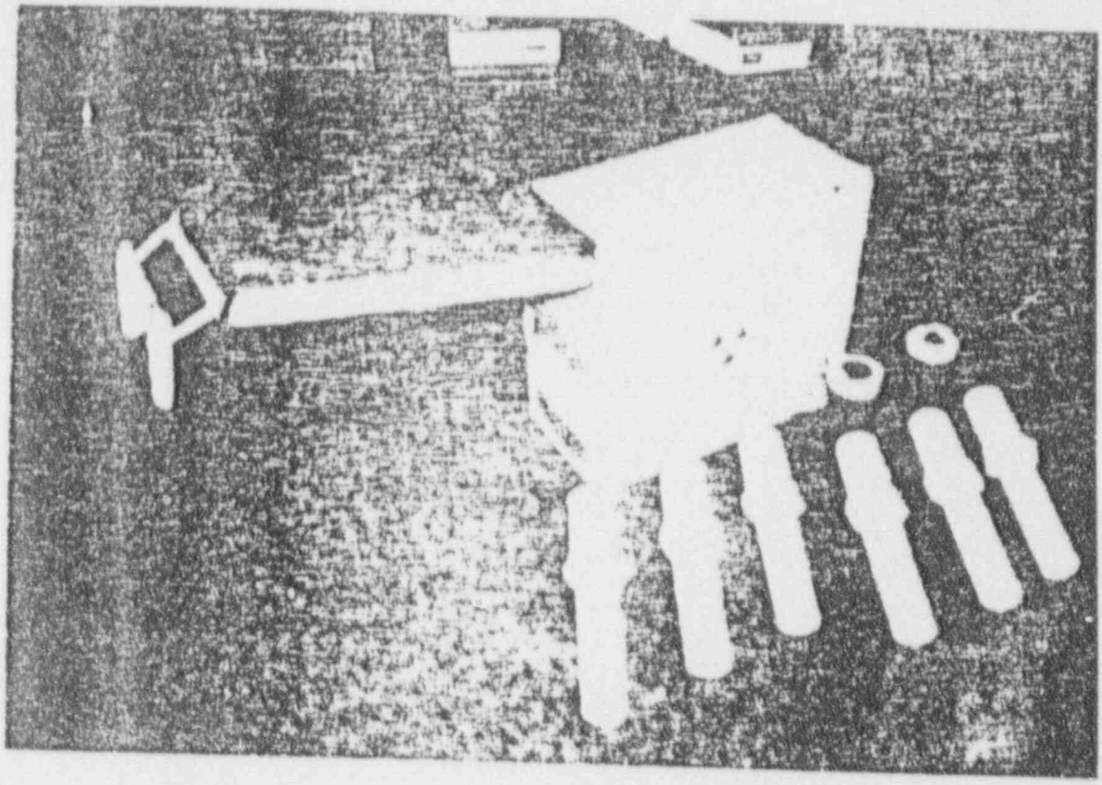


Photograph 1 - Packages as recieved

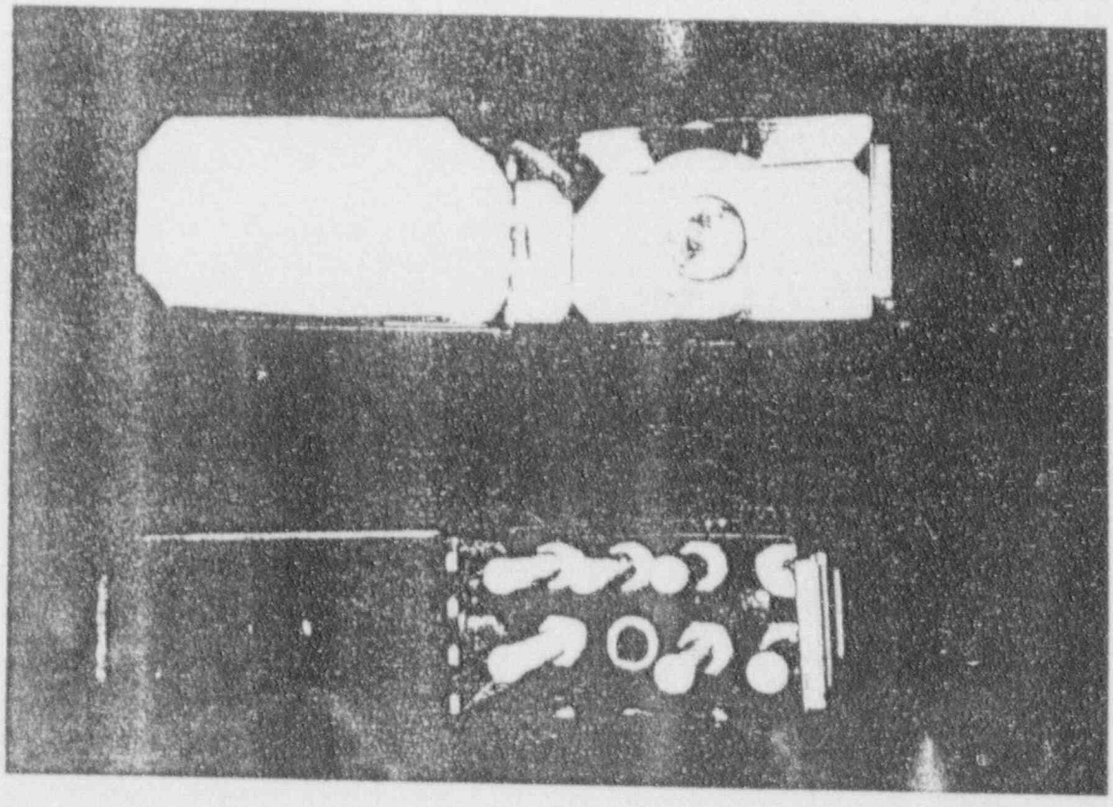


Photograph 2 - Metal Ammo box showing inner and outer lead pigs and packing material.

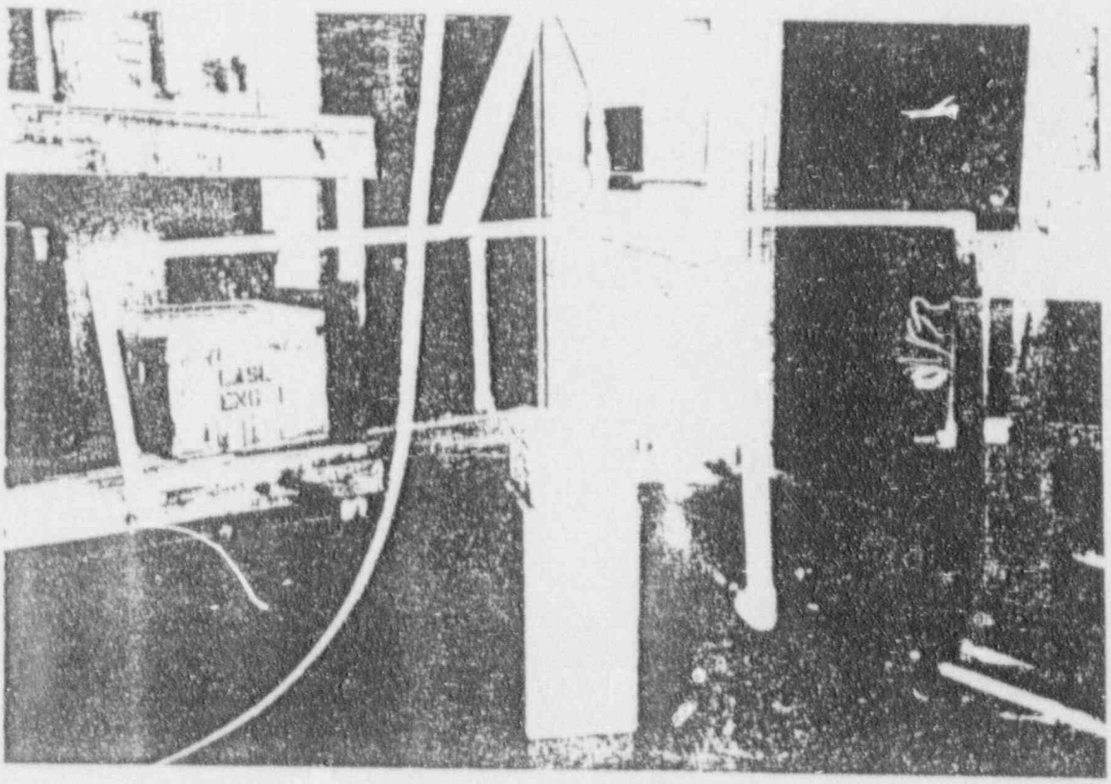
CONTROL NO. 92519

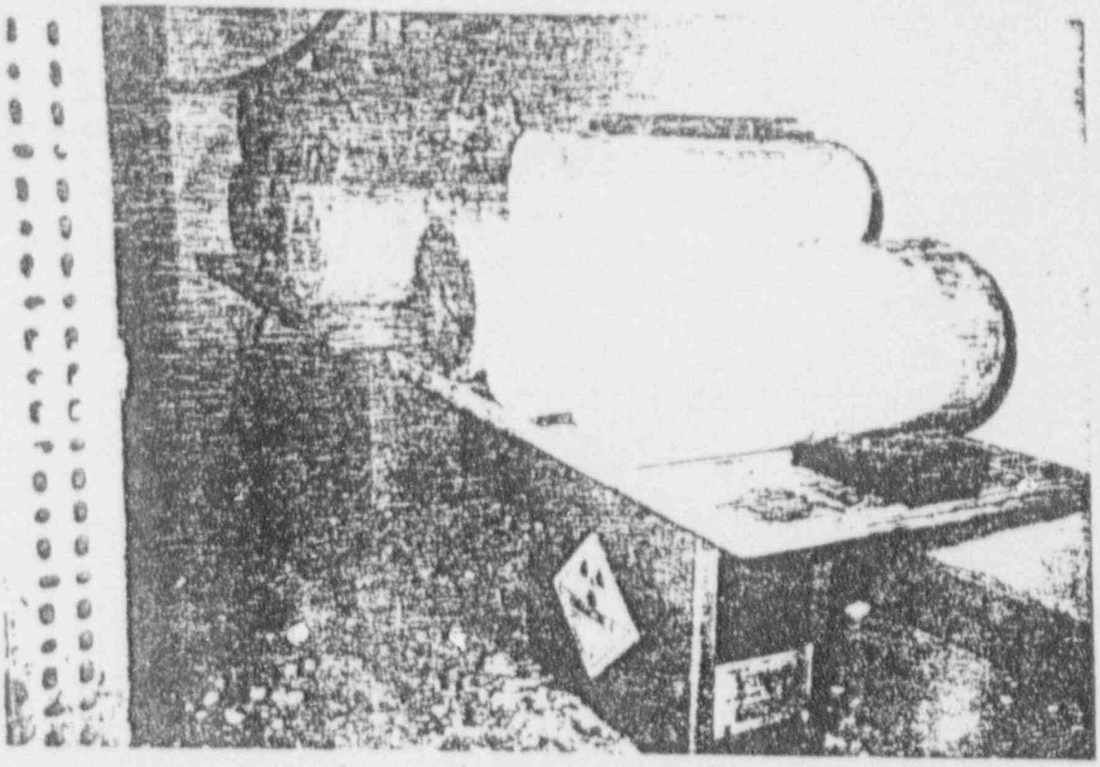


Photograph 3 - Metal ammo box with lead syringe carrier and lead pig vial carrier

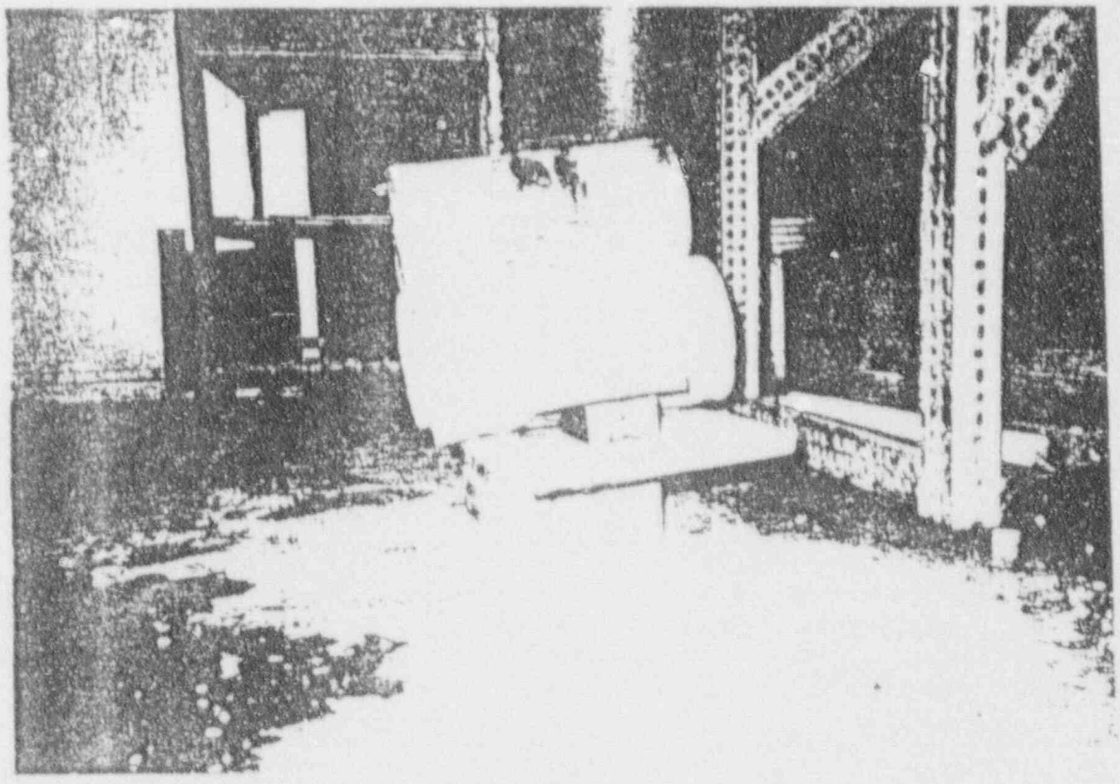


Photograph 4 - Both metal ammo boxes showing packing and inner containment systems.

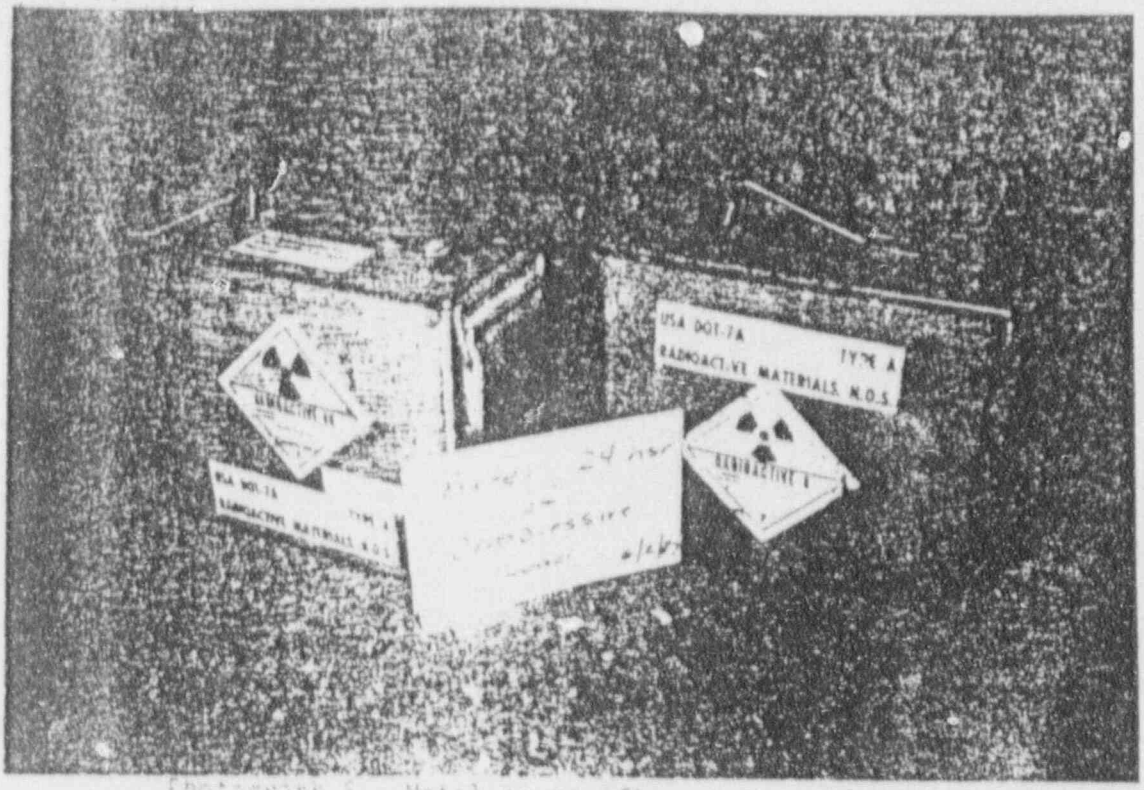

LASL
EXC 1



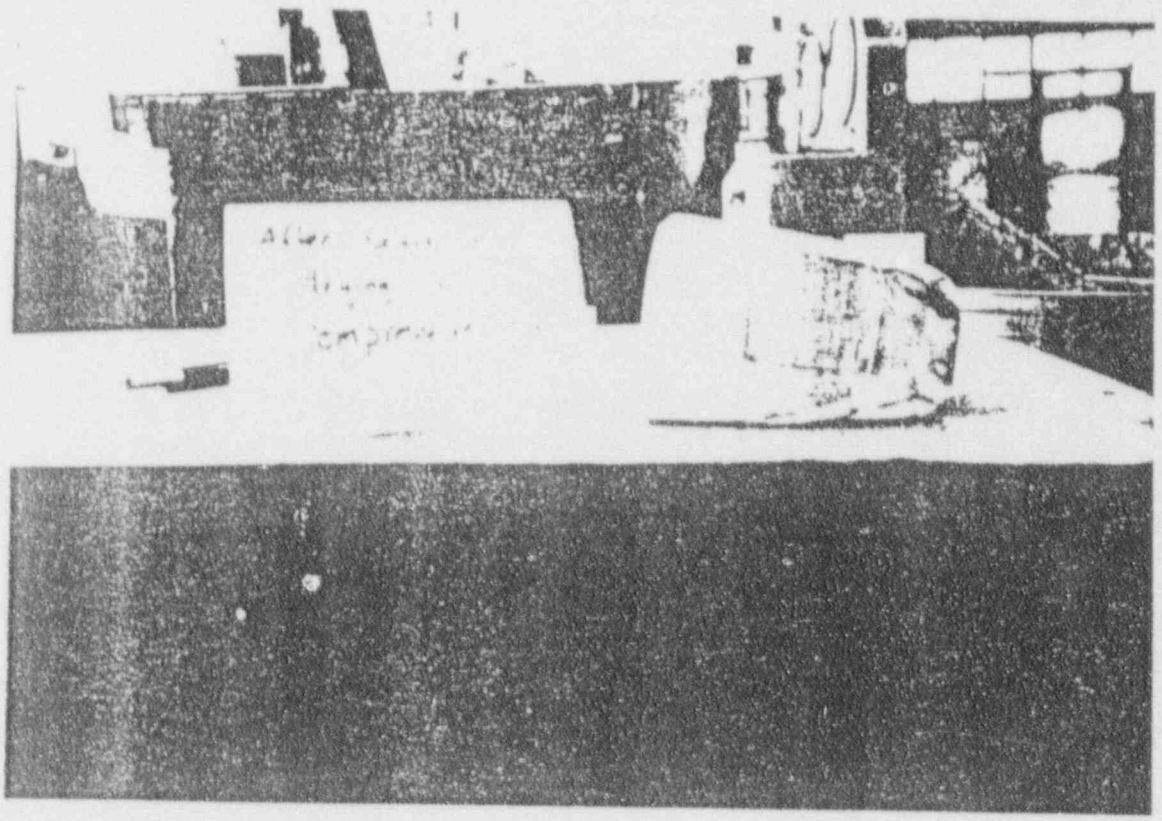
Photograph 5 - Metal arms bowed during
[illegible] test.



Photograph 6 - Cardboard box during compression
test after being subjected to the
2 in/hour rain spray test.

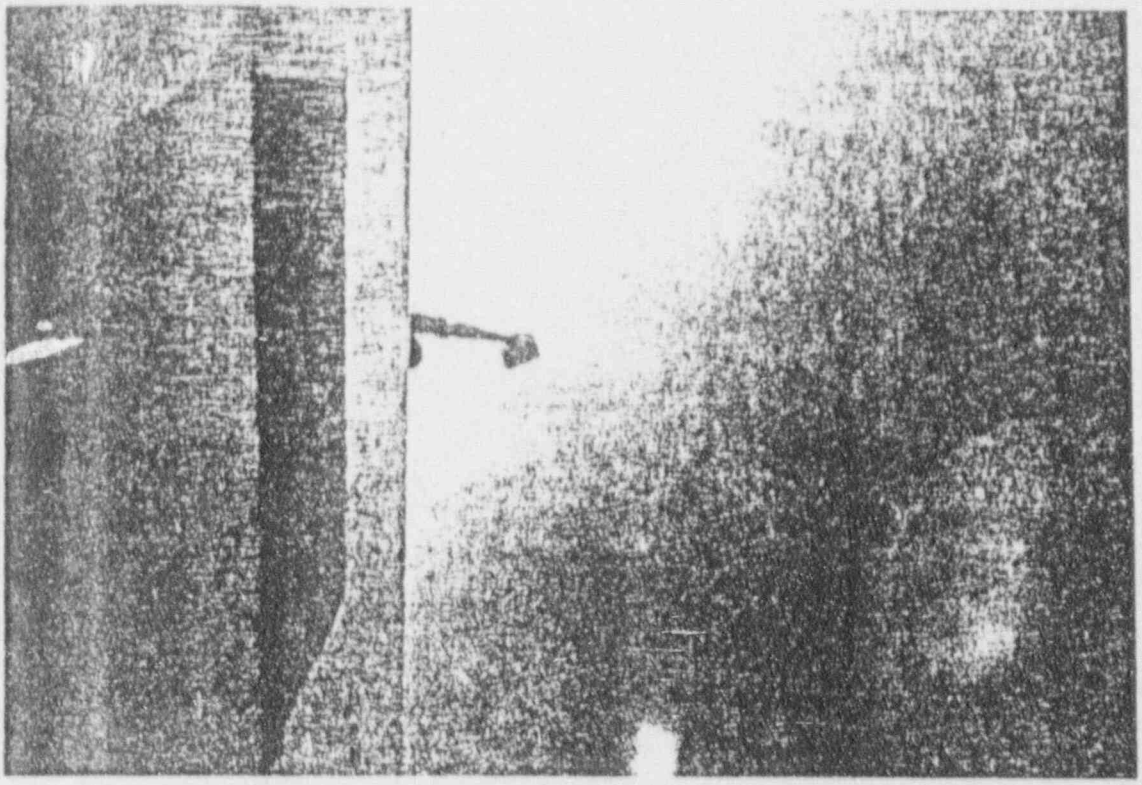


Photograph 2 - Metal boxes after compression test.

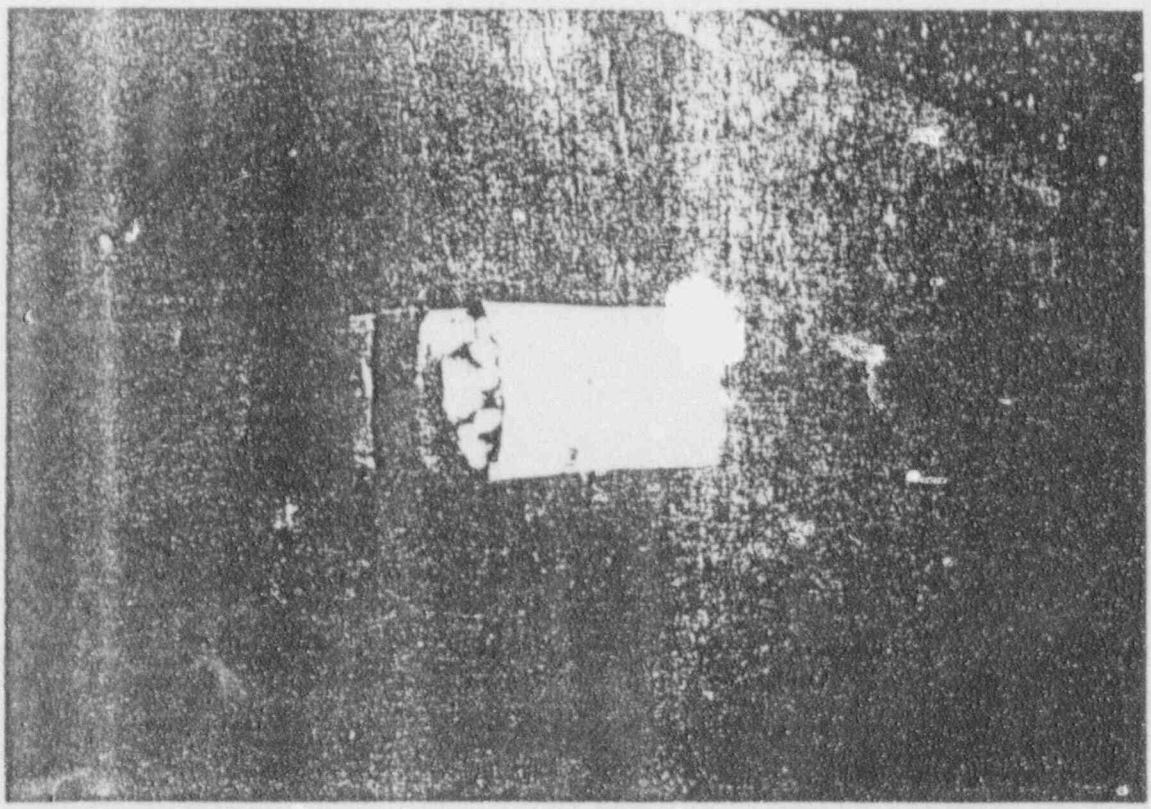


Photograph 3 - Cardboard box after compression test.

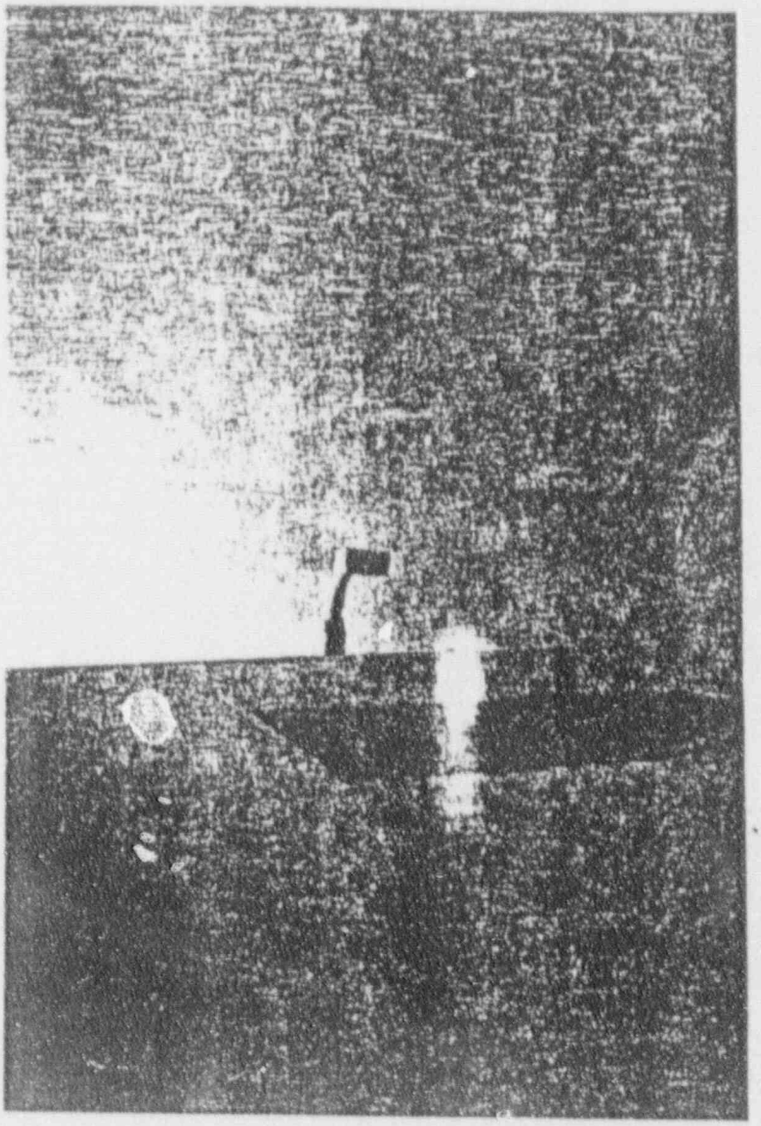
CONTROL NO. 92519



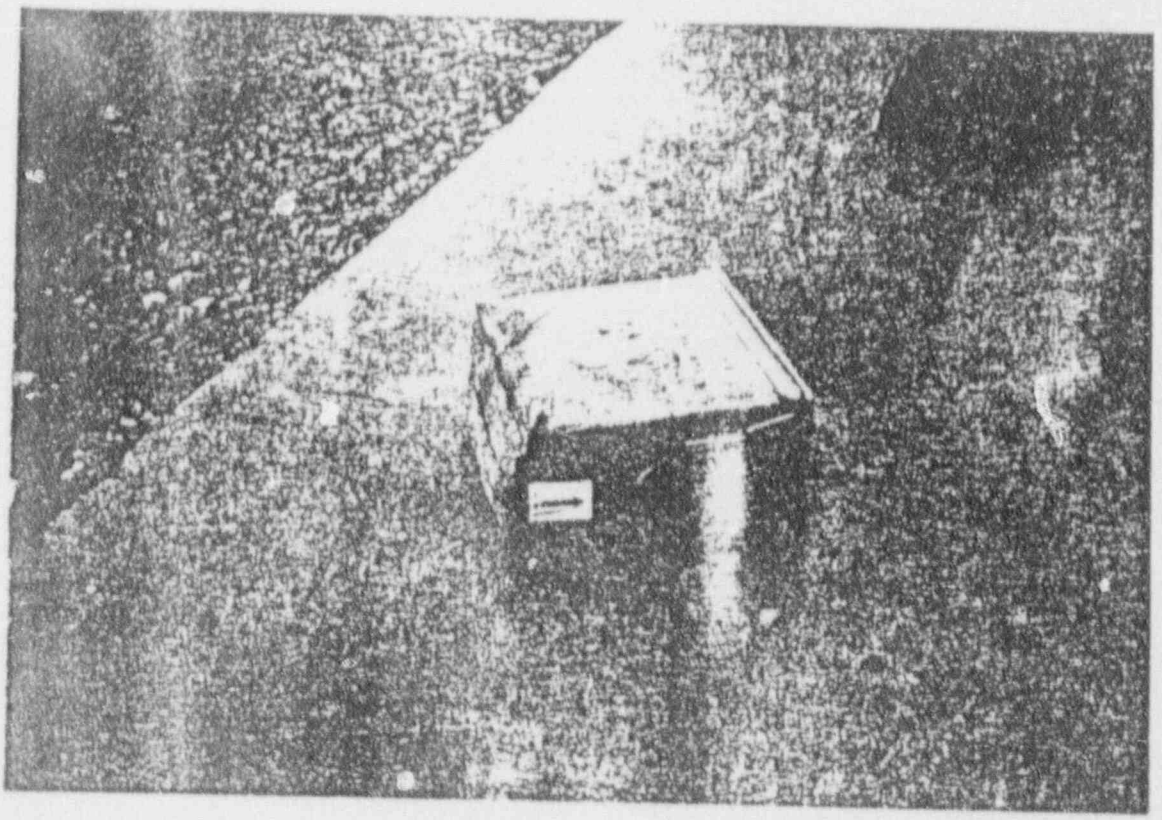
Photograph 13 - Cardboard box ready for 20 foot drop test.



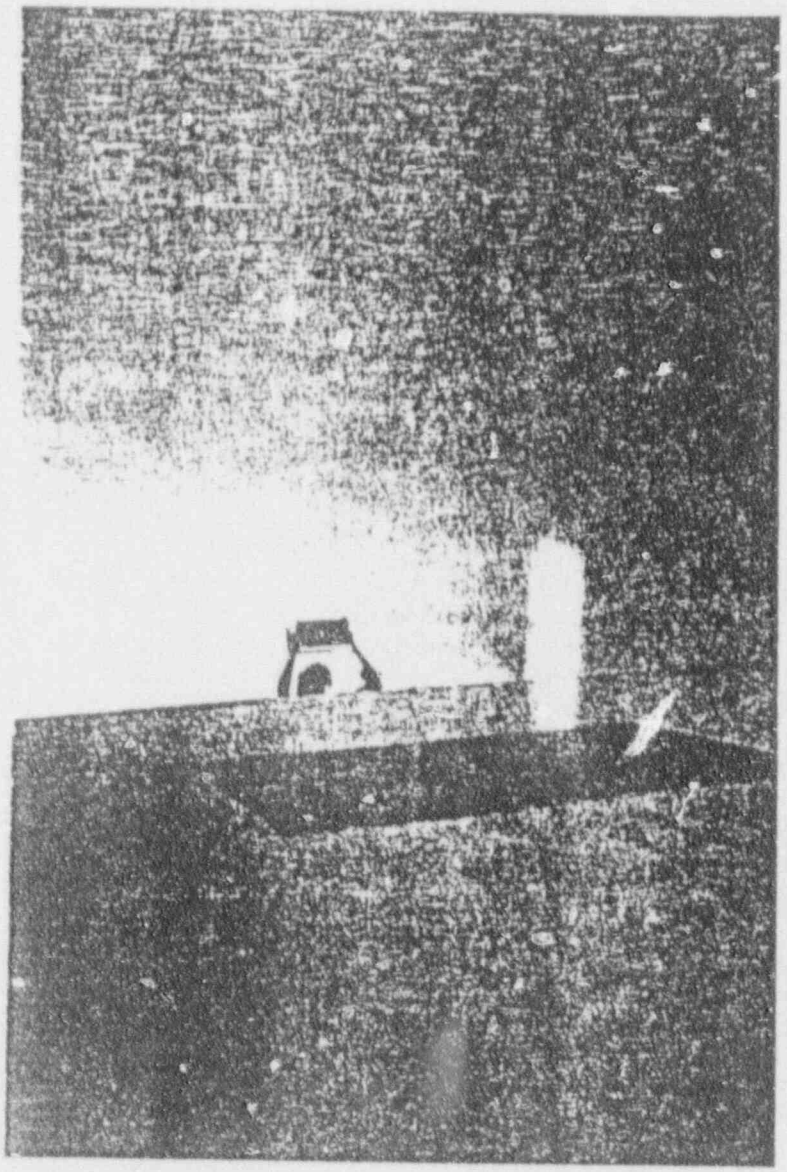
Photograph 14 - Cardboard box after 20 foot drop test.



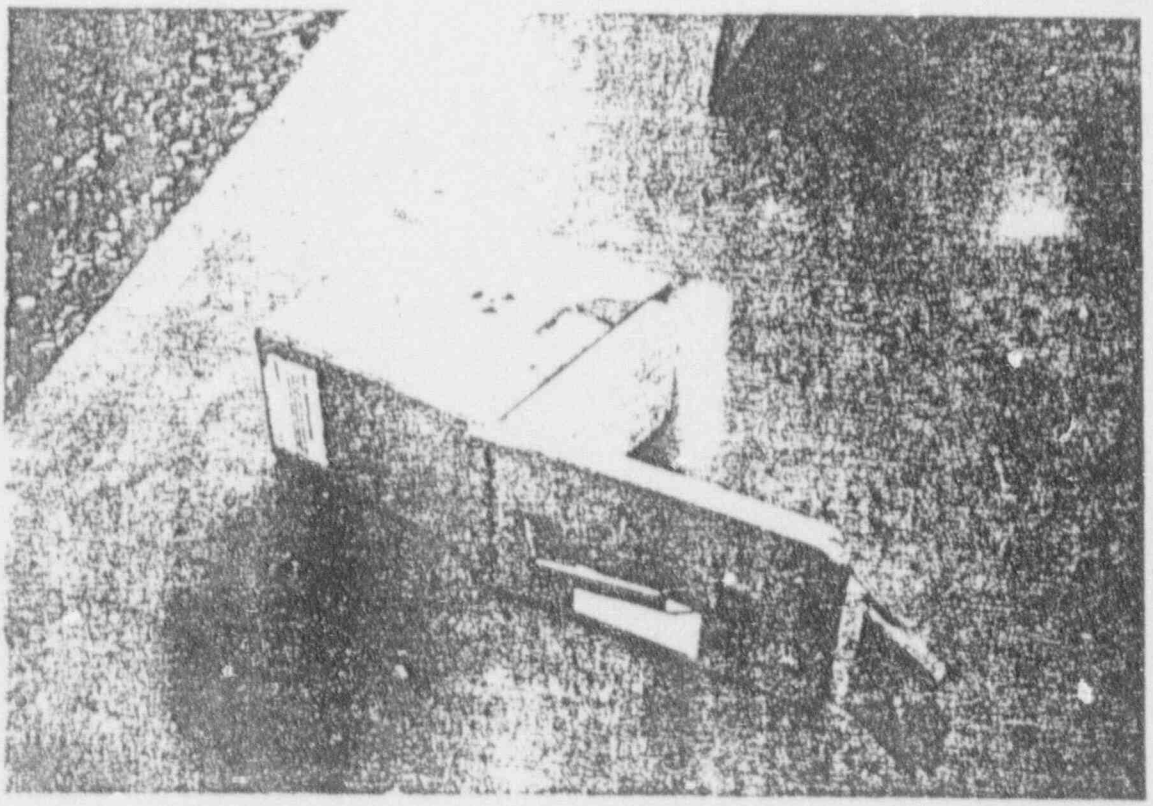
Photograph 12 - Metal ammo box containing syringes w carrier and vials w/ carrier.



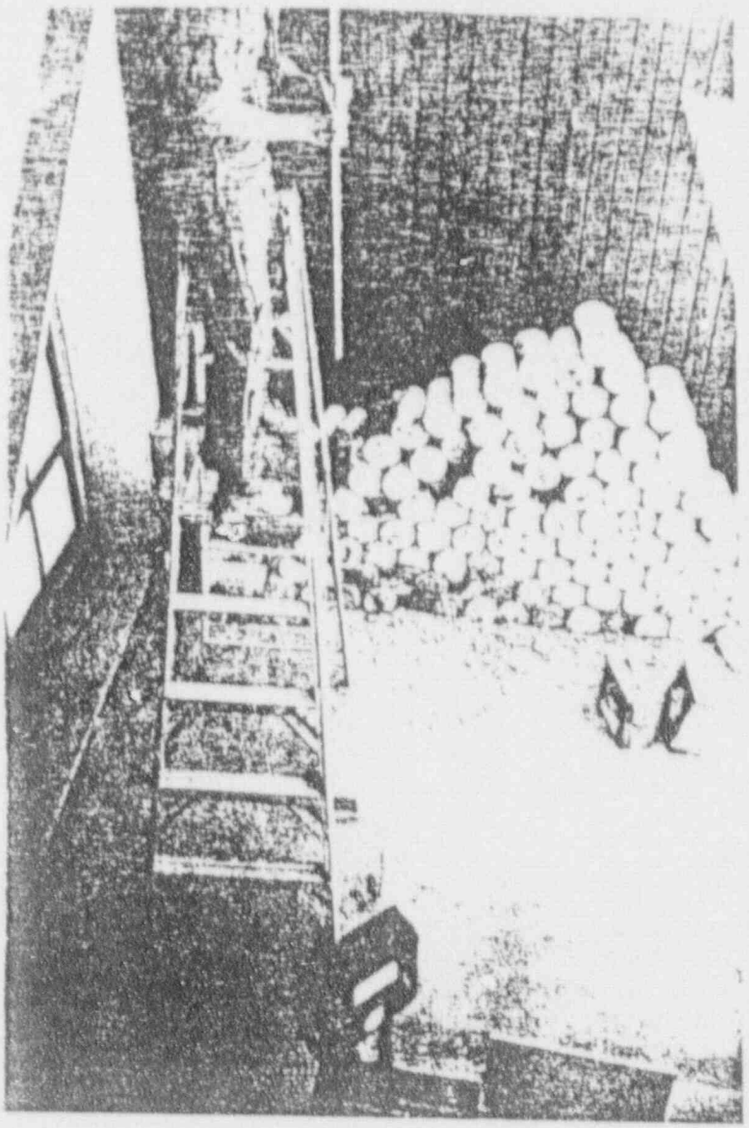
Photograph 13 - Ammo box after 30 foot drop.



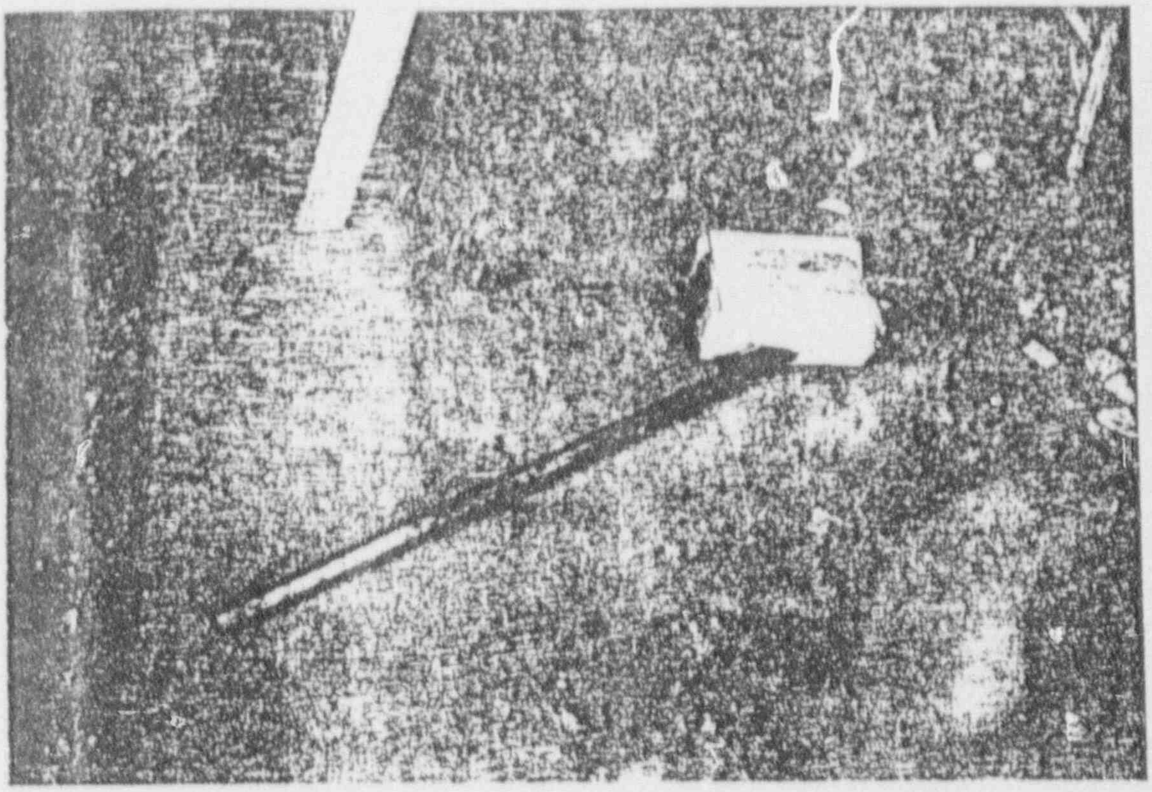
Photograph 24 - Army box containing lead rings and glass vials.



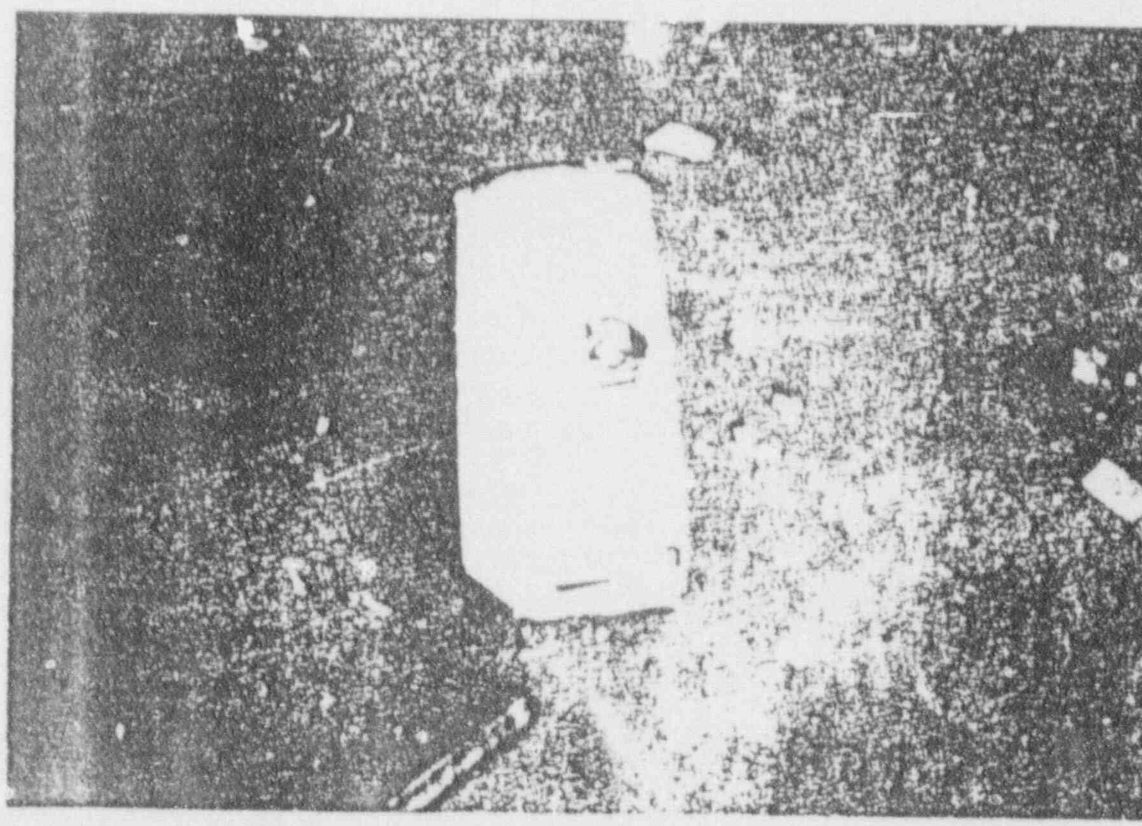
Photograph 15 - Army Jet after 30 foot drop.



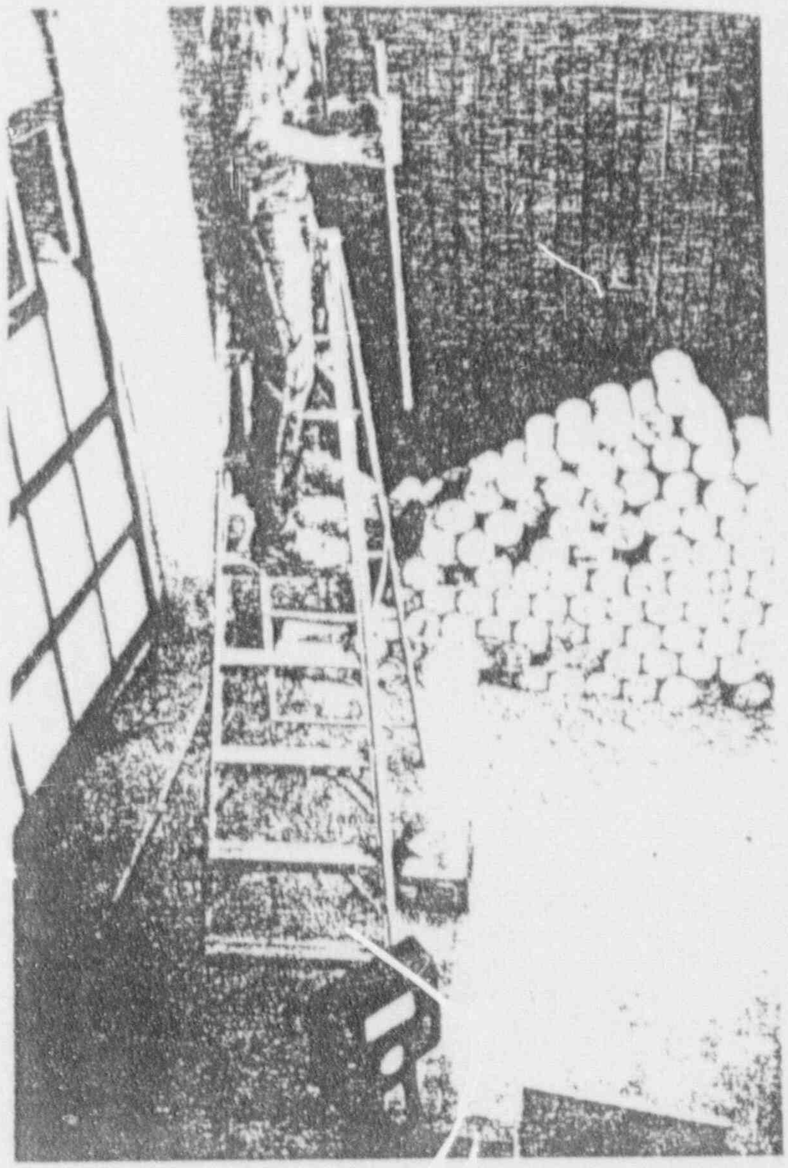
Photograph 16 - Penetration test of cardboard box.



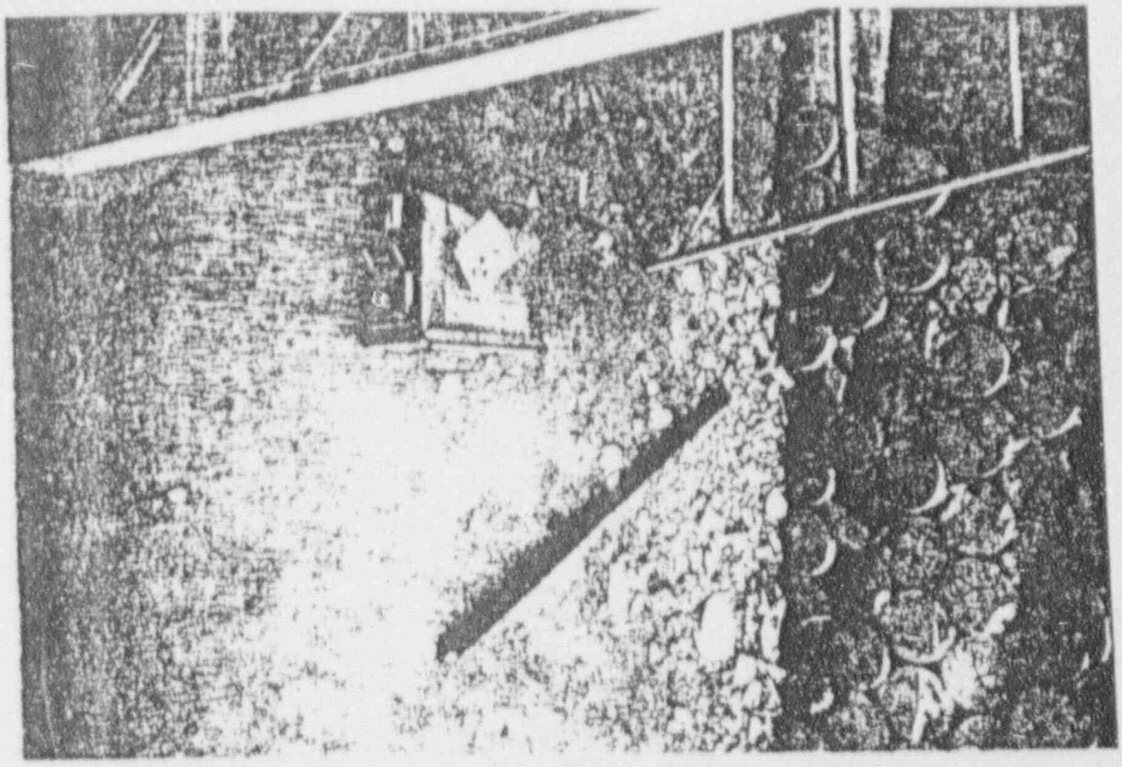
Photograph 17 - Results of penetration test.



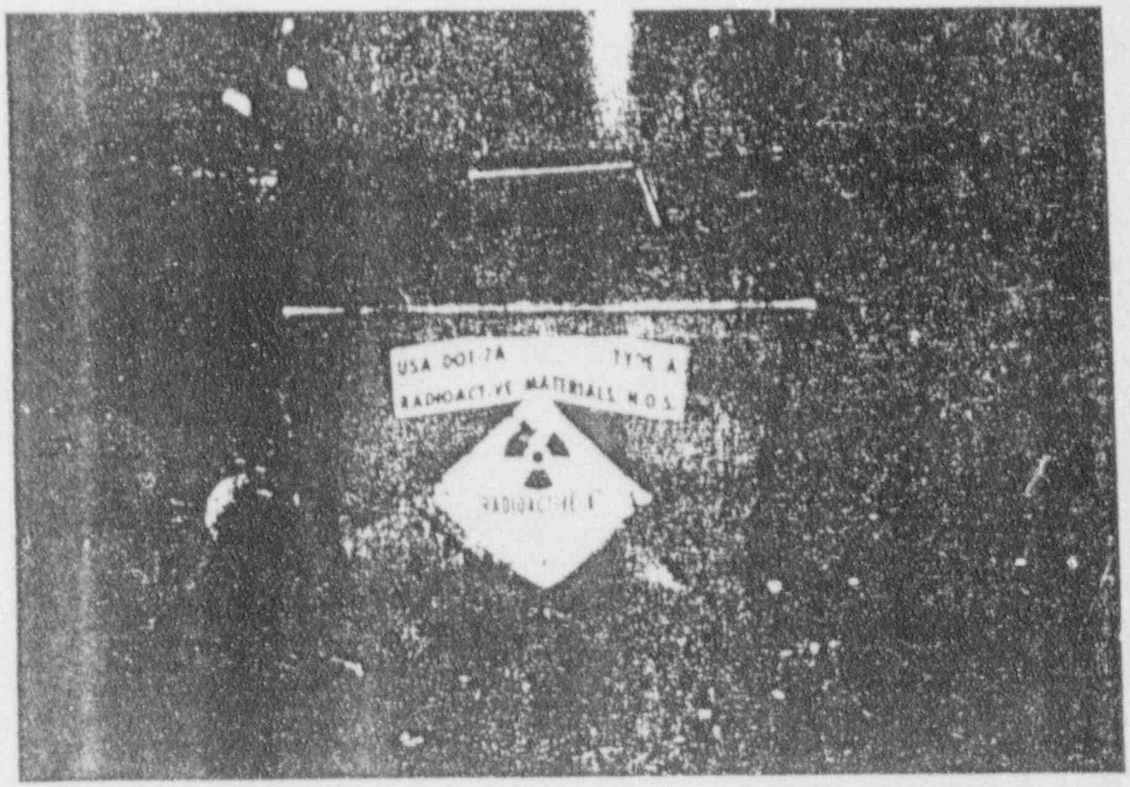
Photograph 18 - Results of penetration test.



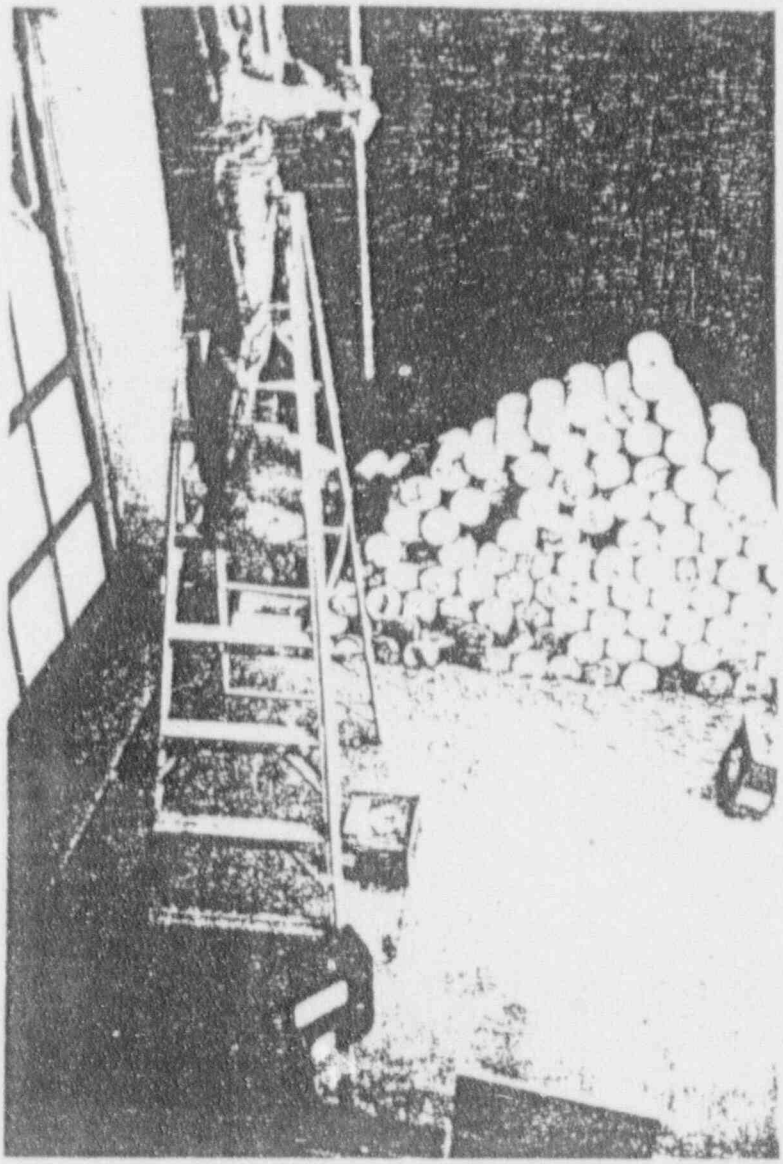
Photograph 13 - Penetration test of [illegible] box containing [illegible] and [illegible] vails and [illegible]ers.



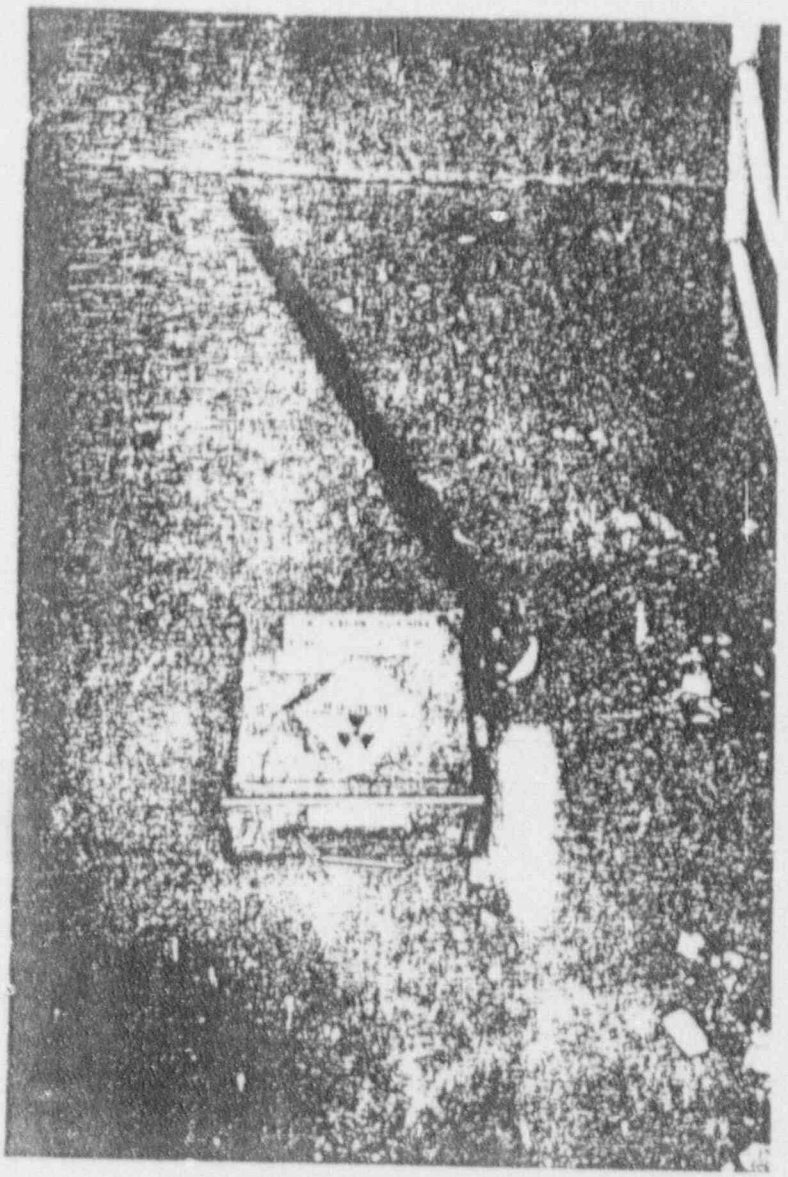
Photograph 20 - Results of penetration test.



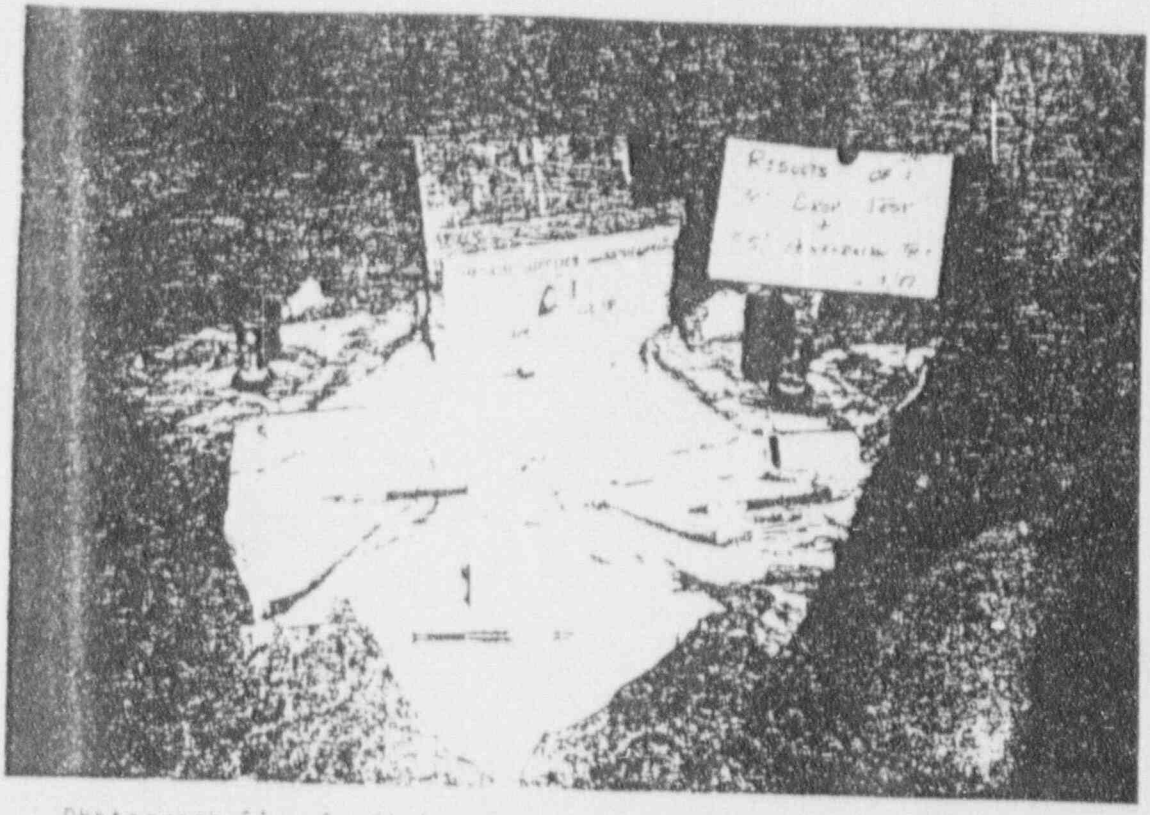
Photograph 21 - Results of penetration test.



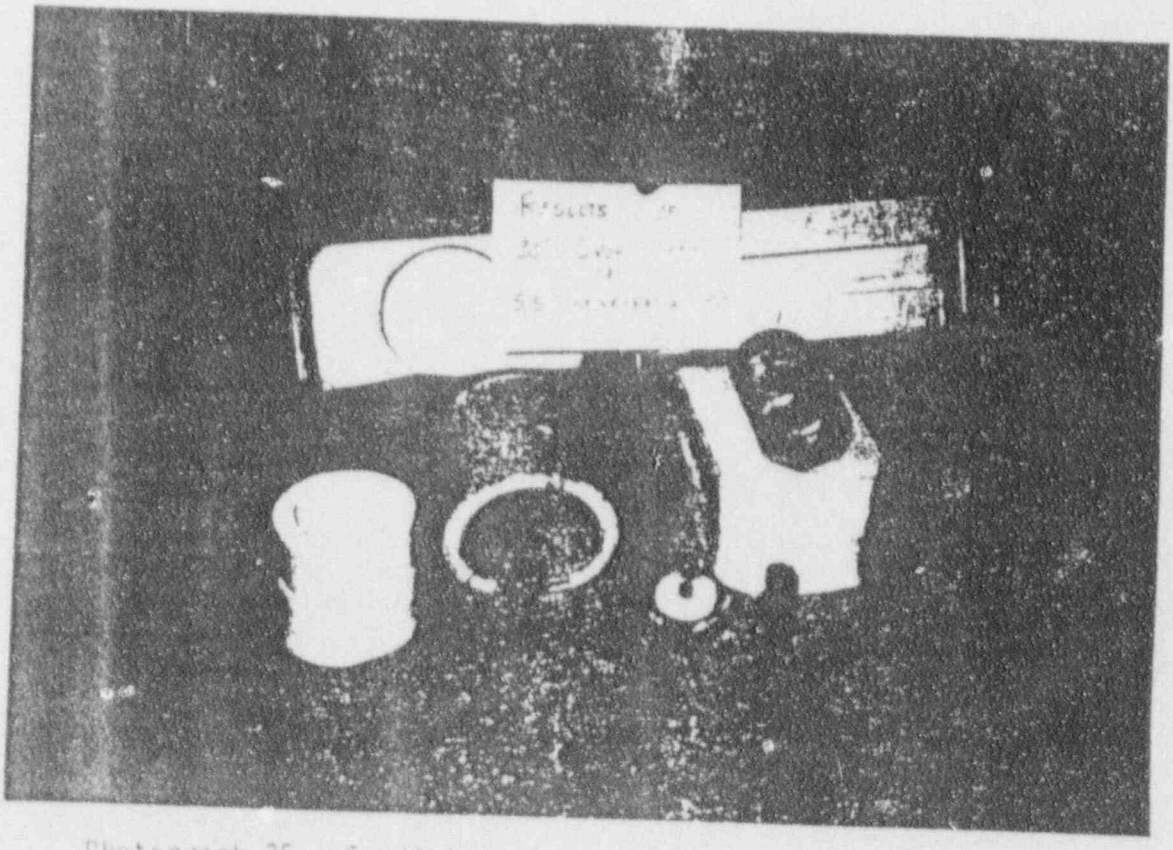
Photograph 22 - Penetration test of box containing two lead pigs with vials.



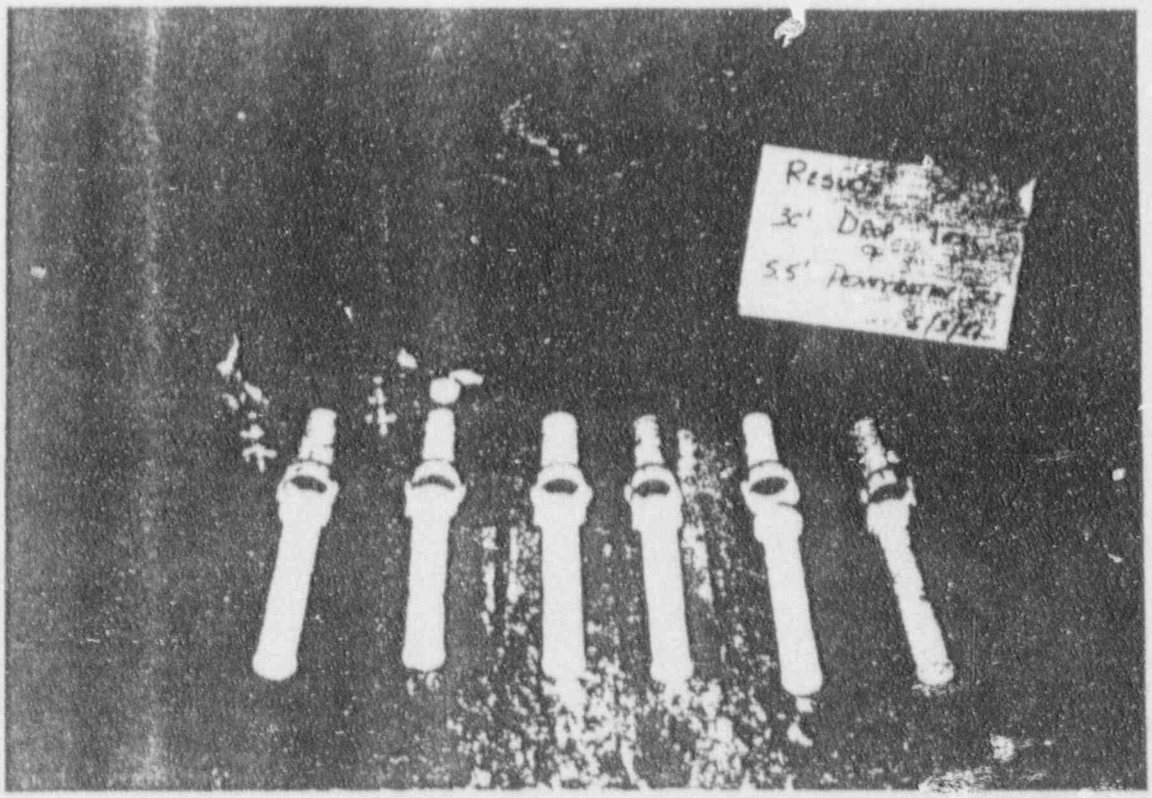
Photograph 23 - Results of penetration test.



Photograph 24 - Condition of cardboard box and contents after 30 foot drop and penetration test.



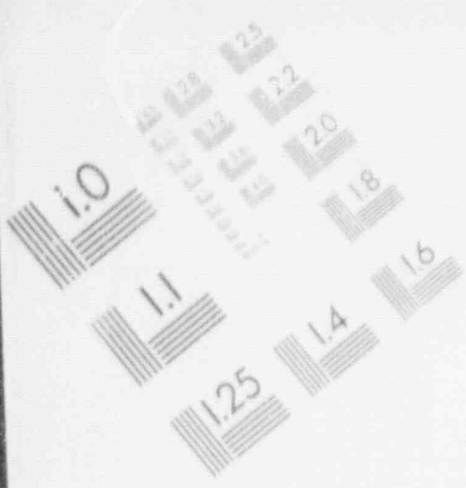
Photograph 25 - Condition of shipping box and contents after 30 foot drop and penetration test.

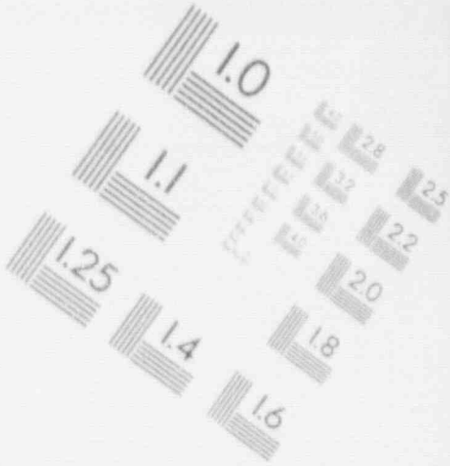


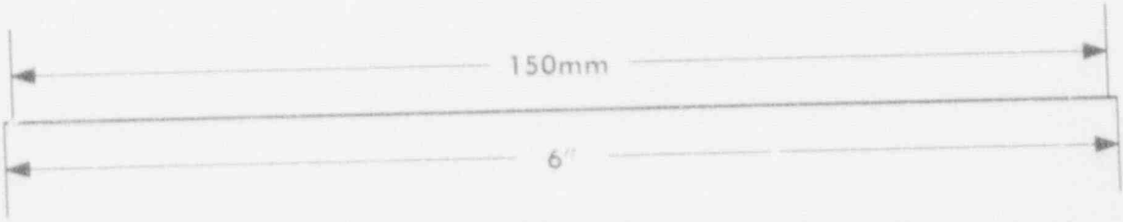
Photograph 26 - Condition of ammo box and contents after 30 foot drop and penetration test.

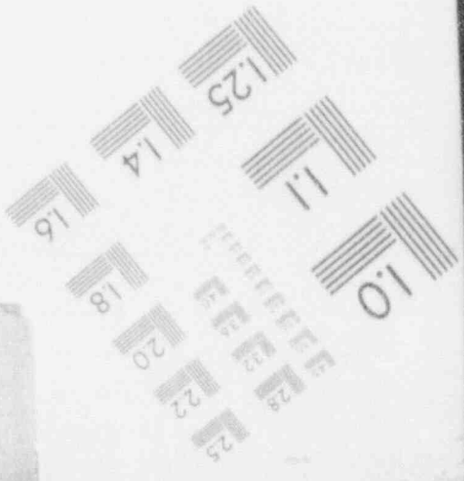
1

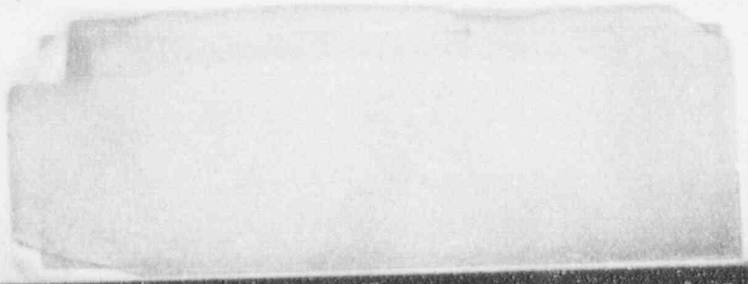
IMAGE EVALUATION
TEST TARGET (MT-3)





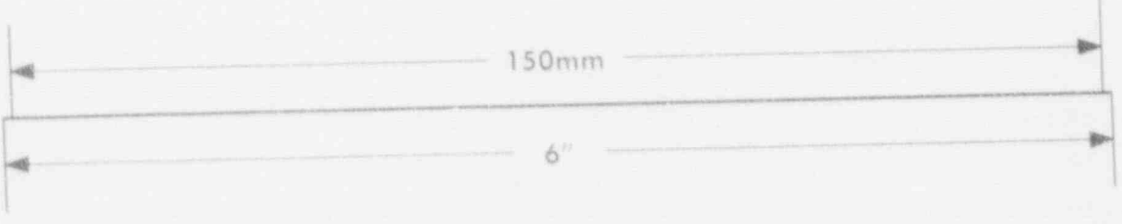






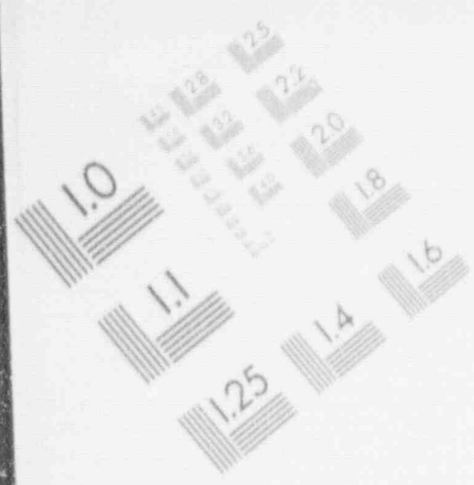
1

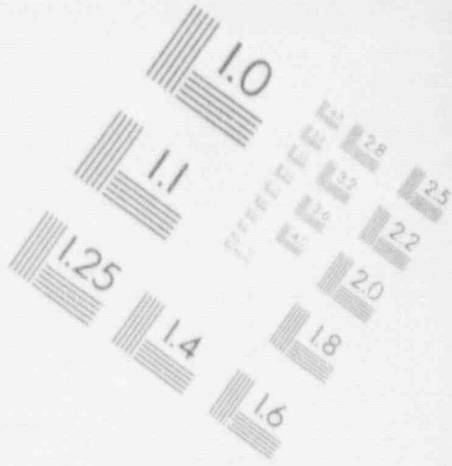
IMAGE EVALUATION TEST TARGET (MT-3)

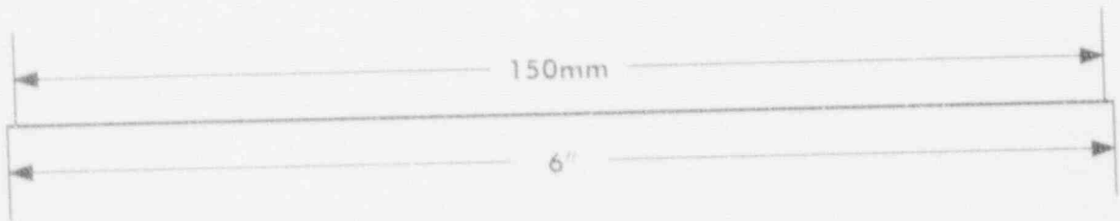


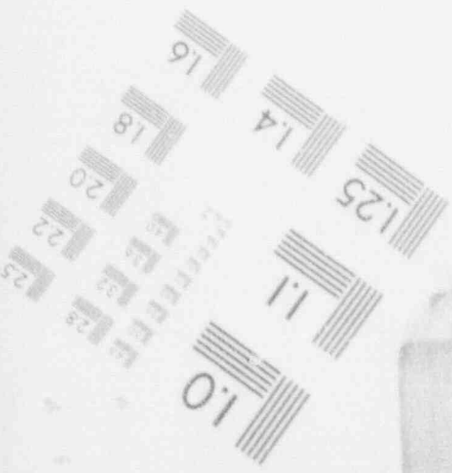
1

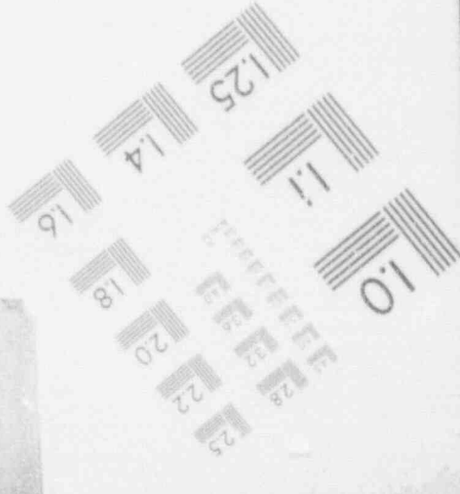
IMAGE EVALUATION TEST TARGET (MT-3)











MATERIALS LICENSE

Amendment No. 44

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

Licensee	
1. Mallinckrodt, Inc.	In accordance with application dated November 27, 1985 3. License number 24-04206-01 is amended in its entirety to read as follows:
2. 2703 Wagner Place Maryland Heights, MO 63043	4. Expiration date: January 31, 1992
	5. Docket or Reference No.: 030-00001

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with Atomic Nos. 1 through 83,	A. Any	A. Not to exceed 100 curies of each radionuclide, except as listed below: Strontium-90 25 curies Molybdenum-99 10,000 curies Technetium-99m 10,000 curies Iodine-131 500 curies Selenium-75 200 curies Xenon-133 200 curies
B. Cesium-137	B. Sealed Sources	B. Not to exceed 100 curies total

9. Authorized Use

A. For research and development of radiopharmaceuticals as defined in 30.4(q), 10 CFR Part 30, including animal studies. For use in manufacturing, processing and packaging of radiochemicals and radiopharmaceuticals.

B. For use in instruction calibration and irradiation of TLD materials.

CONDITIONS

10. Licensed material shall be used only at facilities of the licensee located at 2703 Wagner Place, Maryland Heights, Missouri.

11. A. Licensed material shall be used by or under the supervision of, individuals approved by the licensee's Radiation Safety Committee, Roy W. Brown, Chairman.

CONTROL NO. 92519

MALLINCKRODT DIAGNOSTICS
MALLINCKRODT, INC.

Certificate of Compliance For Radioactive Materials Packages
D.O.T. Specification 7A, Type A

1. Package Identification: K620-1 Common Name: UTK Generator Packaging

2. PREAMBLE

2a. This certificate is issued to satisfy sections 171.2, 171.12, 173.411, 173.412, 173.415, 173.431, 173.461 through 173.466 and Subpart K of Part 178 of the Department of Transportation Hazardous Materials Regulations (49 CFR), as amended.

2b. The packaging and contents described in item 4 below were found to meet the safety standards set forth in, and tested, according to the more stringent recommendations for general performance testing from:

Subpart C, 10 CFR 71.

ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air, 1985 Edition, Part 3, Chapter 9 (9.1, 9.3) and Part 7, Chapter 7 (7.1 through 7.4 and 7.9 through 7.11).

IATA Dangerous Goods Regulations, 26th Edition, Section 6 (6.3.1 through 6.3.19 and 6.4.1 through 6.4.27).

IAEA Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material 1985 Revised Edition, Section VI (614 through 625).

ANSI, American National Standard N14.7-1975.

Canadian TDG, Transportation of Dangerous Goods Regulations and Transport Packaging of Radioactive Materials Regulations.

49 CFR as listed in item 2a above.

2c. This certificate does not release the consignor from compliance with any requirement of the regulations of the U.S. Department of Transportation or other applicable regulatory agencies, including the government of any country through or into which the package will be transported.

3. This certificate is issued on the basis of a safety analysis report of the package design or application (Safety Analysis Data, File # K620-1).

Prepared By: A Borchardt

Title : Radiation Specialist

Date : 8-13-85

CONTROL NO. 92519

CC:L:(6)8/12/85 L31

4. Descriptions of Packaging and Authorized contents, Other Conditions, and References:

Authorized Contents:
Normal Form Radioactive Material in Type A quantities

Description of Outer Packaging and Components:
Box: 275# test, single wall, C flute, RSC, 15 11/16" X 15 11/16" X 16 5/16"
Foam: 1.5 # density expandable polystyrene shipping cube, SRC: K616

Description of Primary and Secondary Containment:
UIK: All plastic parts: Foster grant 840 high impact polystyrene (American Hoechst), light blue
Lead: Up to 33 lbs (96% lead purity)
Glass Column: Type 1 glass (Borsilicate)
Stoppers: red rubber (SRC: S87)
Brass insert: .328" long, 8/32 threaded
Bolts: Round phillips head, 8/32 thread, 3 1/4" long
Vial Support: 1.8# density, expandable polystyrene
Bottle Wrap: 1.8# density, expandable polystyrene
Eluant: 500 ml bottle, Type 1 glass (Borosilicate).
Stoppers: #1704 gray (SRC: S51)

Specifications and Restrictions:
None

Prototype Divergence from Spec. Box:
None

5. CERTIFICATION

This document is to certify that to the best of my knowledge, information and belief, the construction methods, the packaging design and the materials of construction for this specification package utilized by Mallinckrodt, Inc. comply with the standards described in items 2a., 2b., and 2c. herein.

Approved: Mark Doyle

Title : Supervisor, Health Physics

Date : 8-13-85

6. This Certificate of Compliance has been reviewed by the Packaging Committee and is approved for use as described in item 4, herein. Any deviation from these conditions must be safety tested and approved prior to use.

Approved: Roger Brown

Title : Chairman, Packaging Committee
Diagnostic Products Group

Date : 8/15/85

CC:L:(7)8/12/85

MALLINCKRODT, INC.

ST. LOUIS.

MALLINCKRODT DIAGNOSTICS
MALLINCKRODT, INC.

Certificate of Compliance For Radioactive Materials Packages
D.O.T. Specification 7A, Type A

1. Package Identification: J701 or J702 Common Name: Pharmacy Case

2. PREAMBLE

2a. This certificate is issued to satisfy sections 171.2, 171.12, 173.411, 173.412, 173.415, 173.431, 173.461 through 173.466 and Subpart K of Part 178 of the Department of Transportation Hazardous Materials Regulations (49 CFR), as amended.

2b. The packaging and contents described in item 4 below were found to meet the safety standards set forth in, and tested, according to the more stringent recommendations for general performance testing from:

Subpart C, 10 CFR 71.

ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air, 1989 Edition, Part 3, Chapter 9 (9.1, 9.3) and Part 7, Chapter 7 (7.1 through 7.4 and 7.9 through 7.11).

IATA Dangerous Goods Regulations, 30th Edition, Section 6 (6.3.1 through 6.3.19 and 6.4.1 through 6.4.27).

IAEA Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1985 Revised Edition, Section VI (614 through 625).

ANSI, American National Standard N14.7-1975.

Canadian TDG, Transportation of Dangerous Goods Regulations and Transport Packaging of Radioactive Materials Regulations.

49 CFR as listed in item 2a above.

2c. This certificate does not release the consignor from compliance with any requirement of the regulations of the U.S. Department of Transportation or other applicable regulatory agencies, including the government of any country through or into which the package will be transported.

3. This certificate is issued on the basis of a safety analysis report of the package design or application (Safety Analysis Data, File # J701).

Prepared By: D Drumm

Title : Supervisor, Health Physics Services

Date : 22 Feb 1989

Descriptions of Packaging and Authorized contents, Other Conditions, and References:

Authorized Contents: Normal form radioactive materials in Type "A" quantities.

Description:

CASE: Plywood with fiberglass laminate. 10 lbs., double latched with single handle. 4 1/2" X 19" X 12".

FOAM: 1.5# Density Ethafoam. With syringe cutouts (J702) or convoluted (J701).

Syringes: 3 cc B-D, plastic

Shields: Lead lined syringe shield (1/4" wall SRC: J946, 1/8" wall SRC: J947)

Restrictions: Tested and approved for a maximum of 8 syringes and shields

5. CERTIFICATION

This document is to certify that to the best of my knowledge, information and belief, the construction methods, the packaging design and the materials of construction for this specification package utilized by Mallinckrodt, Inc. comply with the standards described in items 2a., 2b., and 2c. herein.

Approved: _____

Title : Manager, Regulatory Compliance

Date : 2/23/89

6. This Certificate of Compliance has been reviewed by the Packaging Committee and is approved for use as described in item 4, herein. Any deviation from these conditions must be safety tested and approved prior to use.

Approved: _____

Title : Chairman, Packaging Committee
Diagnostic Products Group

Date : 22 Feb 89

Iodine-131 CAPSULE PR PARATION PROCEDURE USING MICROPIPETING DEVICE

Materials

-No. 0 gelatin capsule
-No 1 gelatin capsule
-Dibasic sodium phosphate anhydrous powder (U.S.P.)
J.T. Baker catalog #3828-1 or Mallinckrodt catalog #7917-1

The sodium phosphate must be indicated for human use. Do not use any that states to the contrary such as "for laboratory use". The sodium phosphate should be stored tightly sealed to assure freshness. Capsules prepared in advance may be stored inside a capped 20 dram plastic prescription vial placed inside a 40 dram; this may be placed in the refrigerator freezer. By starting with a very cold sodium phosphate capsule, you reduce the chance of melting the gelatin capsule upon injection of liquid sodium iodide. If the sodium phosphate is left open to room air, it will become hydrated.

-I-131 sodium iodide solution
-Micropipetter with disposable pipets
-Plastic capsule container (e.g. I-123 inner container or falcon tube
-Dispensing container
-Capsule holder made out of a lead block with two 1/4 inch hole, 1/2 inch deep. Plastic wrap is placed on the block to avoid radiocontamination of the block.
-3cc syringe in 1/2" lead unit dose container
-Drawing station in fume hood
-Shoulder length plastic gloves; lab safety supply order #3217
-Tweezers, tongs
-Absorbent material
-Gloves: it is a good technique to double glove while working inside the fume hood. When leaving, take off the outer gloves and place into a zip lock bag. Re-glove, with second pair, upon entering the fume hood.
-Survey meter

Procedure

1. Organize materials in the fume hood.
2. Place a portion of dibasic sodium phosphate powder on part of a sheet of clean white paper. Fold paper over powder. Fill bottom portion of size 1 capsule 3/4 full. Fill the the top portion of the capsule.
3. Place fitted bottom portion of size 1 capsule within capsule holding device behind L block shield.
4. Vent the iodine-131 solution through a charcoal syringe.

5. Draw necessary I-131 solution with micropipette. As air displacement units, there is a calibrated plunger inside the handle which, when depressed, displaces a precise volume of air. This moving air pushes measured amounts of liquid out of a plastic conical pipet tip. Laboratory procedures are kept contamination-free by disposing and replacing the tips. Be aware that roughly one-day's decay should also be considered if the dose is for the next day. The volume of the so'.tion needed should be based on its current assay. The maximum concentration of I-131 stock solution to be used will be 100 mCi/ml. Should the volume exceed 0.2 to 0.25cc, the capsule's estimated holding capacity, the activity should be divided between two or more capsules. Each capsule would contain approximat . 25mCi of I-131. The maximum activity of I-131 that would be ndled at any one time during preparation would be 200 mCi. This would require at least 8 capsules to be made, assuming the maximum concentration of therapy solution to be used in compounding.
6. Add the I-131 solution onto the dibasic sodium phosphate which is inside the capsule. Begin injecting with a smooth, slow injection. The injection can not be too slow or the powder will harden in the pipet tip and clog it; if too fast, the capsule's capacity may be exceeded. It is important to watch the capsule closely, in case the volume exceeds the capacity of the capsule. This dibasic sodium will harden as liquid is added; therefore, if the top of the powder hardens before completion, stop your capsule compounding immediately.
7. Once the injection is complete, remove the pipet from the capsule and place a lead cover over the capsule in the holding apparatus. Place empty pipettes in leaded waste containers. Monitor the pipetting device with a survey meter. If it is contaminated, place it in a shielded holding tank for decay.
8. Using forceps, pick up the other filled end of size 1 capsule and place over open end of bottom cap. Tap it down firmly in place.
9. Using long forceps, place the entire cap inside an empty size 0 gelatin capsule. This step is an extra precaution against leakage.
10. Grasp capsule with forceps and place in a 3 cc syringe,which is shielded by a unit dose container.
11. Remove the I-131 capsule from the fume hood and place the unshielded capsule in a dose calibrator. The final activity is calculated by multiplying current activity by the appropriate decay factor. The final activity should not vary by more than +/- 10% from the activity ordered. If the final assay is outside of the dispensing range of +/- 10%, the capsule will be placed in a well shielded storage container and maintained in storage until decayed to background.
12. Replace stock I-131 solution into storage. Be sure the container is recapped or resealed.
13. Check the fume hood area for contamination with the survey meter. All radiocontaminated materials should be stored in sealed containers and promptly disposed of to prevent possible volatile iodine contamination.

Notes

1. Since the binding of I-131 solution to the anhydrous powder undergoes an exothermic reaction, heat is released. For this reason, the capsule should be refrigerated until such dispensing time.

2. Thyroid bioassay will be conducted before 24 hours have elaspsed since capsule preparation. See thyroid bioassay procedure for a description of this procedure.

3. Evaluate the effluent monitoring equipment for the fume hood before staring preparing the capsule.

4. Perform an area survey of the fume hood before and after capsule preparation. If the area is not radiocontamination-free, decontaminate before starting.

Iodine-131 CAPSULE PREPARATION PROCEDURE USING TUBERCULIN SYRINGE

Materials

-No. 0 gelatin capsule
-No 1 gelatin capsule
-Dibasic sodium phosphate anhydrous powder (U.S.P.)
J.T. Baker catalog #3828-1 or Mallinckrodt catalog #7917-1

The sodium phosphate must be indicated for human use. Do not use any that states to the contrary such as "for laboratory use". The sodium phosphate should be stored tightly sealed to assure freshness. Capsules prepared in advance may be stored inside a capped 20 dram plastic prescription vial placed inside a 40 dram; this may be placed in the refrigerator freezer. By starting with a very cold sodium phosphate capsule, you reduce the chance of melting the gelatin capsule upon injection of liquid sodium iodide. If the sodium phosphate is left open to room air, it will become hydrated.
-I-131 sodium iodide solution
-Tb syringes
-Plastic capsule container (e.g. I-123 inner container or falcon tube
-Capsule holder made out of a lead block with two 1/4 inch hole, 1/2 inch deep. Plastic wrap is placed on the block to avoid radiocontamination of the block.
-3cc syringe in 1/2" lead unit dose container
-Drawing station in fume hood
-Shoulder length plastic gloves; lab safety supply order #3217
-Tweezers, tongs
-Absorbent material
-Gloves: it is a good technique to double glove while working inside the fume hood. When leaving, take off the outer gloves and place into a zip lock bag. Re-glove, with second pair, upon entering the fume hood.
-Survey meter

Procedure

1. Organize materials in the fume hood.
2. Place a portion of dibasic sodium phosphate powder on part of a sheet of clean white paper. Fold paper over powder. Fill bottom portion of size 1 capsule 3/4 full. Fill the top portion of the capsule, and place short side of filled capsule into long end of size 0 capsule.
3. Place fitted bottom portion of size 0 capsule within capsule holding device behind L block shield.
4. Vent the iodine-131 solution through a charcoal filled syringe
5. With draw the necessary iodine-131 solution using a shielded tuberculin syringe. The necessary activity drawn into the syringe should include 5% excess which allows for residual left inside the syringe, hub and needle. Be aware that roughly one-day's decay should also be considered if the dose is for the next day. The volume of the solution needed should be based on its current assay. The maximum concentration of I-131 stock solution to be used will be 100 mCi/ml. Should the volume exceed 0.2 to 0.25 cc, the capsule's estimated holding capacity, the activity should be divided between two or more capsules. Each capsule would contain approximately 25 mCi of I-131. The maximum activity of I-131 that would be handled at any one time during preparation would be 200 mCi. This would require at least 8 capsules to be made, assuming the maximum concentration of therapy solution to be used in compounding.
6. Add the I-131 solution onto the dibasic sodium phosphate which is inside the capsule. This is done by puncturing the center of exposed portion of the filled #1 capsule, sticking the needle portion all the way into it. Begin injecting with a smooth push. The injection can not be too slow or the powder will harden in the needle and clog it; if too fast, the capsule's capacity may be exceeded. It is important to watch the capsule closely, in case the volume exceeds the capacity of the capsule. If this occurs, draw back slightly on the syringe plunger to remove the excess liquid. This dibasic sodium will harden as liquid is added therefore, if the top of the powder hardens before completion, stop your capsule compounding immediately.
7. Once the injection is complete, remove the needle from the capsule and place a lead cover over the capsule in the holding apparatus. Place empty syringes in sealed plastic bags and put complete unit in leaded waste for I-131.
8. Using long forceps, place the size 0 capsule top over the size 1 exposed section. This step is an extra precaution against leakage.
9. Grasp capsule with forceps and place in a 3 cc syringe, which is being shielded using a unit dose container.
10. Remove the I-131 capsule from the fume hood and place the unshielded capsule in a dose calibrator. The final activity is calculated by multiplying current activity by the appropriate decay factor. The final activity should not vary by more than +/- 10% from the activity ordered. If the final assay is outside of the dispensing range of +/- 10%, the capsule will be placed in a well shielded storage container and maintained in storage until decayed to background.

11. Replace stock I-131 solution into storage. Be sure the container is recapped or resealed.
12. Check the fume hood area for contamination with the survey meter. All radiocontaminated materials should be stored in sealed containers and promptly disposed of to prevent possible volatile iodine contamination.

Notes

1. Since the binding of I-131 solution to the anhydrous powder undergoes an exothermic reaction, heat is released. For this reason, the capsule should be refrigerated until such dispensing time.

2. Thyroid bioassay will be conducted before 24 hours have elaspsed since capsule preparation. See thyroid bioassay procedure for a description of this procedure.

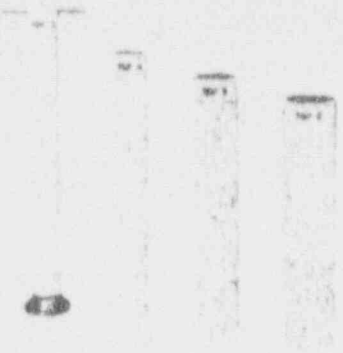
3. Evaluate the effluent monitoring equipment for the fume hood before staring preparing the capsule.

4. Perform an area survey of the fume hood before and after capsule preparation. If the area is not radiocontamination-free, decontaminate before starting.

The Lineator*

Tests Linearity of Dose Calibrators Over a Wide Dymanic Range

- Simple
- Effective
- Economical



The Lineator is a simple device for testing linearity and dynamic range of isotope calibrator instruments. It simplifies compliance with the Nuclear Regulatory Commission regulatory guide 10.8 and various state requirements.

The Lineator consists of four tubes, three are lead-lined and can be arranged concentrically. The smallest diameter tube is labeled O and is used to contain and position a source of Technetium 99m of the maximum activity to be measured in the dose calibrator in normal service. The lead lined tubes, labeled A, B, and C, slide over the central tube, and are used singly, or in combination. Each of these outer tubes absorbs some of the radiation from the source and reduces the effective source activity seen by the dose calibrator. Use of the Lineator allows the operator to simulate a total of eight different source strengths with only one source. The effective reduction increases from tubes A to B to C, and is affected slightly by the shape of the source used, and by the characteristics of the isotope calibrator.

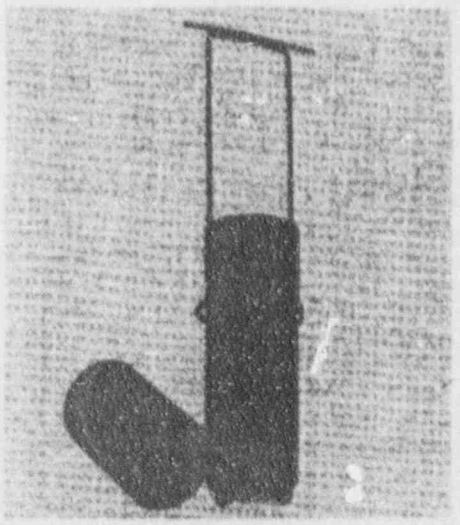
The principal of operation of the Lineator is reproducible over a wide dynamic range, rather than absolute calibration. Initially the linearity of the dose calibrator must be established by conventional means, such as dilution or decay of a technetium source. The initial calibration using the Lineator then establishes the effective reductions in activity (ratios of activity with lead tube(s) inserted relative to source in central tubes alone). All subsequent use of the Lineator will show the same effective ratios unless the dose calibrator becomes defective, at which time it must be repaired.

SPECIFICATIONS:
Weight: 6 lbs. (3 kgs.)

086-507 Lineator **$380.00**
**The Lineator #086-507 is used with any dose calibrator with a 2 1/2" chamber diameter.*

Lineator Shown with Atomlab 200 Dose Calibrator, #086-970 and Syringe Moly Assay Shield, #086-435

Syringe Moly Assay Shield



NOTE: Check your unit dose moly count.

Can be used with 1, 3, 5 and 10 cc syringes. Consists of shield top, bottom, holder and two plastic inserts.

Size: 9 1/8" H x 2 1/8" W (23.2 x 5.4 cm)

086-435 Syringe Moly Assay Shield **$250.00**

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES AND REGULATIONS
CFR 10 Ch. 1 (1-1-88 edition)

§35.50 Possession, use, calibration and check of dose calibrators.

...(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries; ...

— See pages 28-29 for calibrated and uncalibrated sources —

f. If the worst deviation is more than ±0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through g above.

f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.

i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

* The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

e. Continue for all sleeves.

f. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

g. Plot the data using the equivalent decay time associated with each sleeve.

h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/A-line = deviation.

i. If the worst deviation is more than ± 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be

necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

j. Put a sticker on the dose calibrator that says when the next linearity test is due.

6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (see Exhibit 9).

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for [illegible]

Appendix O

Information for authorization to
Perform Survey Meter Calibration

	Previous Authorization
Gregory S. Hiatt P.D.	13-19229-01 MD
Robert Anger, M.S. Medical Physicist	13-02063-01 Methodist Hospital, Indianapolis
Andrea Browne, PhD Medical Physicist	13-06009-01 MD Community Hospital, Indianapolis
John D. Scheu, Ph.D. Medical Physicist	13-02812-04 St. Joseph Medical Center, South Bend, Indiana

APPENDIX P

CALIBRATION CRITERIA

A. Following is information describing the areas if use and storage and the placement of shielding material to reduce radiation exposure to personnel and to individuals in unrestricted areas. In addition, calculations are submitted to show that the shielding used is sufficient to reduce radiation exposures in accordance with Section 20.1 (C), 20.101, 20.104 and 20.105 of Title 10 CFR Part 20.

1. Enclosed is the diagram showing both the area of use and storage. The unit is a self-contained unit which when stored has less than 200 mR/hr at its surface. See enclosed Victoreen Technical Information sheet for complete specification. This device is registered with the NRC under Tech Ops Number 773. Tecn Ops produces this source for the Victoreen Instrument Company.

   While not being used, this device will be stored in the Isotope Storage Room in storage unit H. This unit has 3/16" of lead shielding across the front and on each side. The device will be stored in a lead castle made of 2" x 4" x 8" lead bricks which will represent 5 cm of lead, plus the 3/16" or .476 cm additional lead in unit H.

   The level of radiation at the surface of the lead castle will be the following.

   Calculations: HVL 137- Cs = 0.65 cm*

$$\frac{5.08 \text{ cm lead} + .476 \text{ cm lead}}{0.65 \text{ cm lead}} = \frac{5.56 \text{ cm}}{0.65 \text{ cm}} = 8.5 \text{ HVL}$$

   This represents an antenuation of the radiation intensity of:

   Calculations

$$I_x = I_o e^{\frac{-0.693\ x}{X1/2}}$$

$$I_x = 200 \text{ mR/hr } e^{\frac{-0.693}{0.65}(5.56)}$$

$$I_x = 200 \text{ mR/hr } (.00266) = 0.53 \text{ mR/hr}$$

The source will be stored in the front portion of unit H. The closest point to an unrestricted area would be four feet to the parking lot. There is an 8" cement block wall on the outside wall of the building which will also act as shielding. If the radiation intensity is 0.53 mR/hr at 1 cm from the surface of the lead castle then the intensity in the unrestricted area will be

$$0.53 \text{ mR/hr} \times \frac{1}{(100 \text{ cm})^2} = 5.3 \times 10^{-5} \text{ mR/hr}$$

Laterally the closest point to an unrestricted area is 6 feet, and vertically the cement slab over grade and roof, represent unoccupied areas.

The source will be used for calibration purposes in the room designated E (dispensing area) on the enclosed sketch. Calibration procedures will be performed during non-business hours of a normal business day (after 5:00 P.M. and before 8:00 A.M.). It will be transferred to this room by hand and placed in the center of the room at the position shown on the sketch. The primary beam will be directed toward the outside wall only.

Four areas of concern enter the picture here.

a. Lateral Radiation from Calibrator

From specification sheet: <200 mR/hr at surface.
Closest point to unrestricted area laterally, 6 feet.

$$6 \text{ ft} = 72" \times 2.54 \frac{\text{cm}}{\text{inch}} = 183 \text{ cm}$$

$$\frac{I_1}{I_2} = \frac{D_2^2}{D_1^2} = 200 \text{ mR/hr} \frac{(1)^2 \text{cm}}{(183)^2 \text{cm}} = 0.006 \text{ mR/hr}$$

The level of activity is well below 0.2 mR/hr for an unrestricted area.

b. Primary beam of radiation from calibrator directed to outside wall. (unrestricted area, parking lot) Using the specific gamma ray constant for 137-Cs as

$$\frac{0.25 \text{ mR/hr } **}{\text{mCi @ 1 yard}}$$

one can calculate the radiation levels to the nearest unrestricted area which is the parking lot located 9 yards from the source.

Calculation:

$$0.25 \frac{\text{mR/hr}}{\text{mCi}} \times 165 \text{ mCi} = 41.25 \text{ mR/hr @ 1 yard}$$

$$41.25 \text{ mR/hr} \times \frac{(1)^2}{(9)^2} = 0.51 \text{ mR/hr}$$

If we assign a use factor of 1/4*** to the parking lot, the above value can be reduced to 0.51 mR/hr x 0.25 = 0.13 mR/hr. Further attenuation of the primary beam will occur in passing through two walls, one being an 8" concrete block wall.

c. Scattered radiation from the primary beam striking the wall. Estimated WUT in R/week at 1 meter:

41.25 mR/hr at 1 yard

$41.25 \times \frac{(1)^2}{(1.09)^2} = 34.7$ mR/hr at 1 meter

34.7 mR/hr at 1 meter for 4 hours/weeks =

0.139 R/week at 1 meter

This amount of radiation due to scatter is negligible for the scattered radiation and need not be considered. See Table 22 or 23, NCRP Report No. 34, Pages 77 and 78.

d. Exposure to an individual's hand carrying the calibrator from storage to area of use is 1.7 mR

<200 mR/hr at surface from specification sheet.

Time to carry source from storage to area of use: 30 seconds (overestimate).

$\frac{200 \text{ mR/hr}}{60 \text{ min/hr}} \times 0.5 \text{ min} = 1.67 \text{ mR}$

* NCRP Report No. 34, Table 26, Page 81.

** Radiological Health Handbook, U.S. HEW, Page 139

*** NCRP Report NO. 34, Table 4, Page 60

B. Security Procedures to Prevent Unauthorized Use and Accidental Exposures.

1.When use, the calibrator will never be left unattended. When in storage, no one will be allowed to check it out without signing a deposition sheet showing the time checkout and the time that the source was returned from use. During non-working hours, the Isotope Storage area and the Pharmacy area doors are locked with dead bolt locks and entire pharmacy and office space area are locked. Only the radiopharmacists have keys to the dead bolt locks. This source will be used at this address only, therefore only authorized personnel will have access to it. The key for unlocking the source will be kept in a locked file cabinet in office C and will be issued by the radiopharmacist at time of use.

C. Training and Experience

Training and experience requirements will be in accordance with Appendix A, #2 of NRC Guide 10.8. In addition, individuals on the radiopharmacy staff will be specifically instructed in the use and handling of the small instrument calibrator.

D. See attached safety instructions to be followed by radiopharmacy staff while using the 137-Cs gamma survey instrument calibrator.

E. Survey meter calibration procedures will be in accordance with Appendix D of NRC Regulatory Guide 10.8.

Safety instructions to be followed when using the Model 773 Gamma Survey Instrument Calibrator:

Note: All personnel authorized to perform calibration procedures must be familiar with the manufacturer's instructions for the proper operation of this device.

General Safety Instructions

1. Never place your hands or any portions of your body in the primary beam from the calibration device.

2. The source should be placed in the exposed position only when necessary to obtain an instrument reading.

3. Maintain as much distance between yourself and the source beam as practicable to obtain instrument reading.

4. Make sure the calibration device is placed in the lead castle provided before beginning calibration procedure, with the exit port directed to the outside wall.

5. Make sure you have on, your film badge and TLD ring badge before performing instrument calibration procedures.

6. The rear door from the parking lot to the isotope storage area must be locked from the inside to prevent access to this area at all times where survey meters are being calibrated using the Gamma Survey Instrument Calibrator. In the calibrator checkout log, enter the time the door is locked and the time the door is unlocked. Be sure that this door is unlocked at the completion of the calibration procedure so that pharmacists may enter this door to begin the early shift.

Instrument Calibration Procedure

1. All instruments being calibrated must be placed at the appropriate distance from the calibration source exit port, with the source in the stored position.

2. Place the source in the exposed position, obtain instrument reading and return source to the stored position. Record instrument reading.

3. Determine the degree of error from readings obtained relative to actual exposure expected.

   a. If readings agree within manufacturer's specifications, calibration of instrument is complete. Return calibration device to storage in Isotope Storge area.

b. If further adjustment must be done to calibrate instrument, proceed as follows:

(1.) Determine method for adjustment of meter scales from manufacturer's specifications. This is usually a screw driver adjustment. Go through a dry run to determine the correct method for adjusting the meter scale in the proper direction.

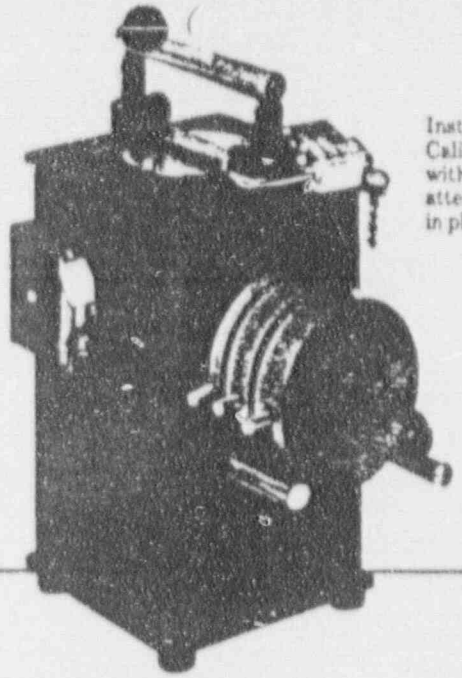
(2.) Repeat step 1 with the screw driver in place, ready to adjust.

(3.) Place the source in the exposed position. Make adjustment and return source to the stored position.

4. Calibration will be performed at two points on each scale up to 1 R/hr with the points located at approximately 1/3 and 2/3 of each scale.

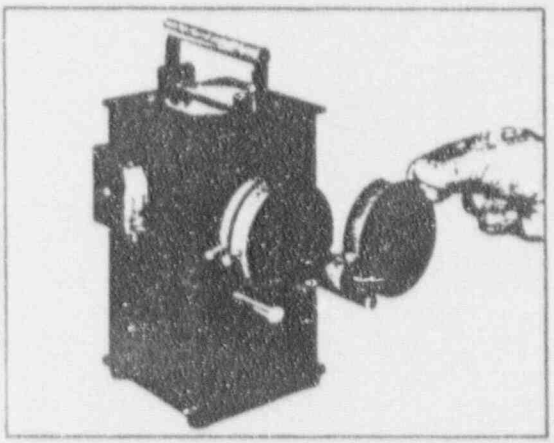
5. Calibration will be performed to within plus or minus 10 percent of the true value (plus or minus 20 percent of true value if a calibration chart or graph is prepared and attached to the instrument).

Gamma Survey Instrument Calibrator



Instrument Calibrator with three attenuators in place.

- Self-contained ^{137}Cs source.
- Calibrates instruments with ranges up to 2000 mR/hr.
- Calibration traceable to NBS.
- Attenuators eliminate repositioning for different scale measurements.
- Can be padlocked in closed position for safety.



Instrument Calibrator with one attenuator removed from radiation path.

This sturdy, easy-to-use device permits the safe, accurate calibration of instruments used for surveying gamma radiation. It enables users of dosage-measuring equipment to perform routine checks at will or as necessary to meet the regulations of the N.R.C. and Agreement States. This simple, fool-proof system eliminates the expense, inconvenience and work-time lost when sending such instruments to an outside calibration service.

The heavy-duty lead container holds 165 mCi of cesium-137 encapsulated at one end of a control rod. Since ^{137}Cs has a long half-life (30 yrs.), there is no need to calculate a correction factor for at least 1 or 2 years after the instrument is shipped.

The source is kept in either of 2 positions: stored or exposed. In the fully-shielded "stored" position, radiation at the container's surface is less than 200 mR/hr; at 1 meter away it is less than 10 mR/hr. In the "exposed" position, the source faces a 36° (horizontal) x 20° (vertical) port at the shield's side. The radiation field can be varied by means of three built-in attenuators (transmission factors 0.25, 0.10 and 0.10). These permit calibration of three meter scales, each at 20% and 80% of full scale, using only one source-to-meter distance measurement. The source is moved from "stored" to "exposed" merely by raising the control rod. For safety, the ^{137}Cs source cannot be removed from its shield except by the manufacturer.

A built-in tape measure helps determine the distance from the ^{137}Cs source to the instrument being calibrated. A padlock (not included) prevents unauthorized use of the equipment. Convenient carrying handle. Measures 5" square x 8¼" high. Weighs 52 lbs.

64-773 Instrument Calibrator $1830.00*

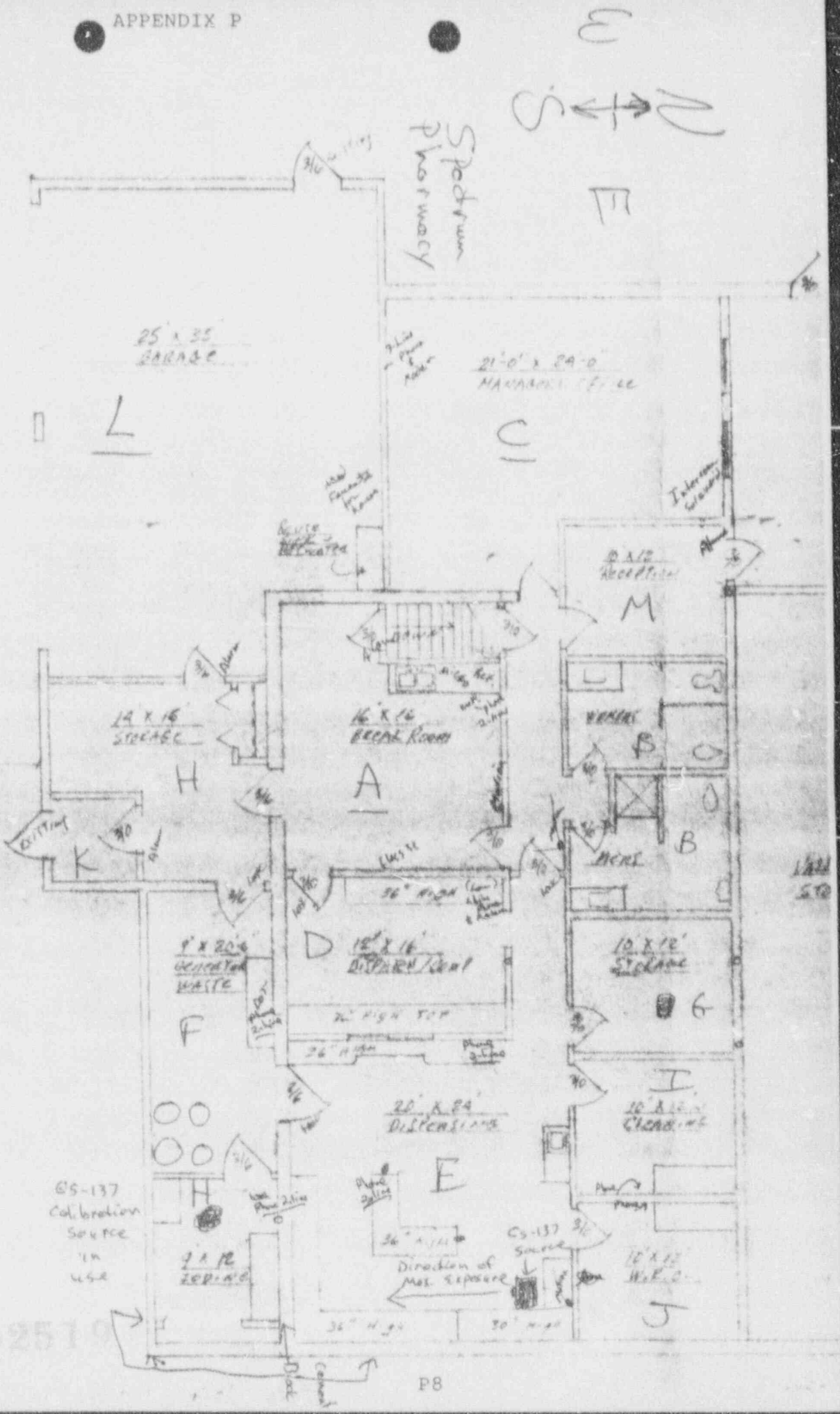
*An N.R.C. or Agreement State license is required. When applying, please designate the source as Technical Operations model 773. A copy of your license must accompany order.

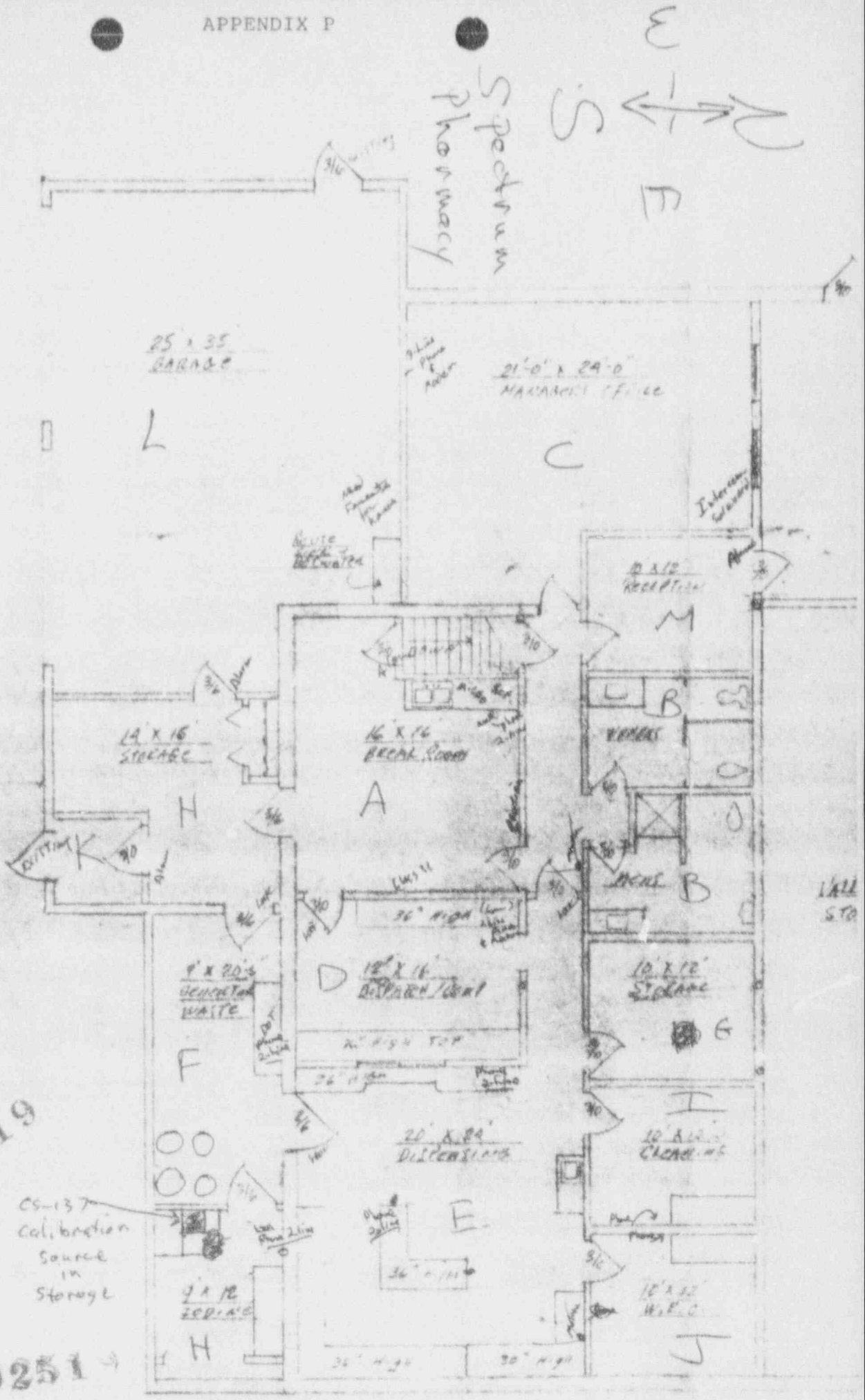
VICTOREEN
NUCLEAR ASSOCIATES

VICTOREEN

100 Voice Road
Carle Place, N.Y. 11514
(516) 741-6360
A Sheller-Globe Corporation Subsidiary SG

2-582 827


Stadrum Pharmacy
25 x 35 GARAGE
21'-0" x 24'-0"
16' X 16' RECAL Room
14' X 16' STORAGE
9' X 20'-6" GENERATOR WASTE
12' X 16' DISPENSING
10' X 12' STORAGE
20' X 24' DISPENSING
10' X 12' CLEANING
12' X 12' W.R.C.
Cs-137 Calibration Source in use
Cs-137 Source
Direction of Max Exposure
36" HIGH TOP
36" HIGH



CONTROL NO. 92519

CONTROL NO. 9251

MODEL RADIOPHARMACEUTICAL INSPECTION FORM

	YES	NO
1. Are adequate storage and security arrangements maintained?		
2. Any outdated or deteriorated drugs?		
3. Are radiopharmaceutical orders signed by a qualified physician?		
4. Are parenteral radiopharmaceuticals prepared and dispensed?		
a) Is there adequate space and equipment for aseptic preparation, dispensing, handling, and storage?		
b) Are personnel adequately trained in aseptic technique?		
5. Are all radiopharmaceuticals labeled adequately?		
a) Radiopharmaceutical identified by radionuclide and chemical form?		
b) Radiation symbol and caution statement?		
c) Amount of radioactivity with calibration date/time?		
d) Expiration date and time?		
e) Identification number?		
6. Are investigational drugs used?		
a) Adequate documentation maintained?		
b) Consent forms signed?		
7. Is there inventory control documentation?		
a) Is product history readily retrievable?		
b) Receiving records maintained?		
c) Patient name and number, dosage, date/time recorded?		
d) Disposition records maintained?		

FEB 03 1992

Spectrum Pharmacy, Inc.
ATTN: Gregory S. Hiatt
President
17460 Farmington Square Road
Granger, IN 46530

Dear Mr. Hiatt:

Enclosed is your NRC License Number 13-26367-01MD in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Possess radioactive material only in the quantity and form indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address.

5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

12519

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions or require clarification of any of the above stated information, contact us at (708) 790-5625.

Sincerely,

Original Signed By
Loren J. Hueter
Materials Licensing Section

Enclosure: License No. 13-26367-01
New License Package

RIII
Hueter/ps
02/3/92

SPECTRUM
PHARMACY, Inc.

IN REFERENCE TO CONTROL # 92519 for Spectrum Pharmacy, Inc.

Attn: Mr. Loren J. Hueter
Nuclear Regulatory Commission
Region III
Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, Ill 60137

Dear Mr. Hueter:

Please find the following information:

A. Replacement Air Flow Schematic (Diagram 4) from Spectrum Pharmacy application dated Nov. 4, 1991. See attachment

B. Additional information under item 9.2 (page 20 of application) re-describing Air Ventilation System.

The previous air ventilation system description is being revised in part due to the fact that the glove box/fume hood system have their own independent exhaust. The fume hood will have a dampered cold air supply vent that will be located approximately ten (10) feet from the fume hood's exhaust.

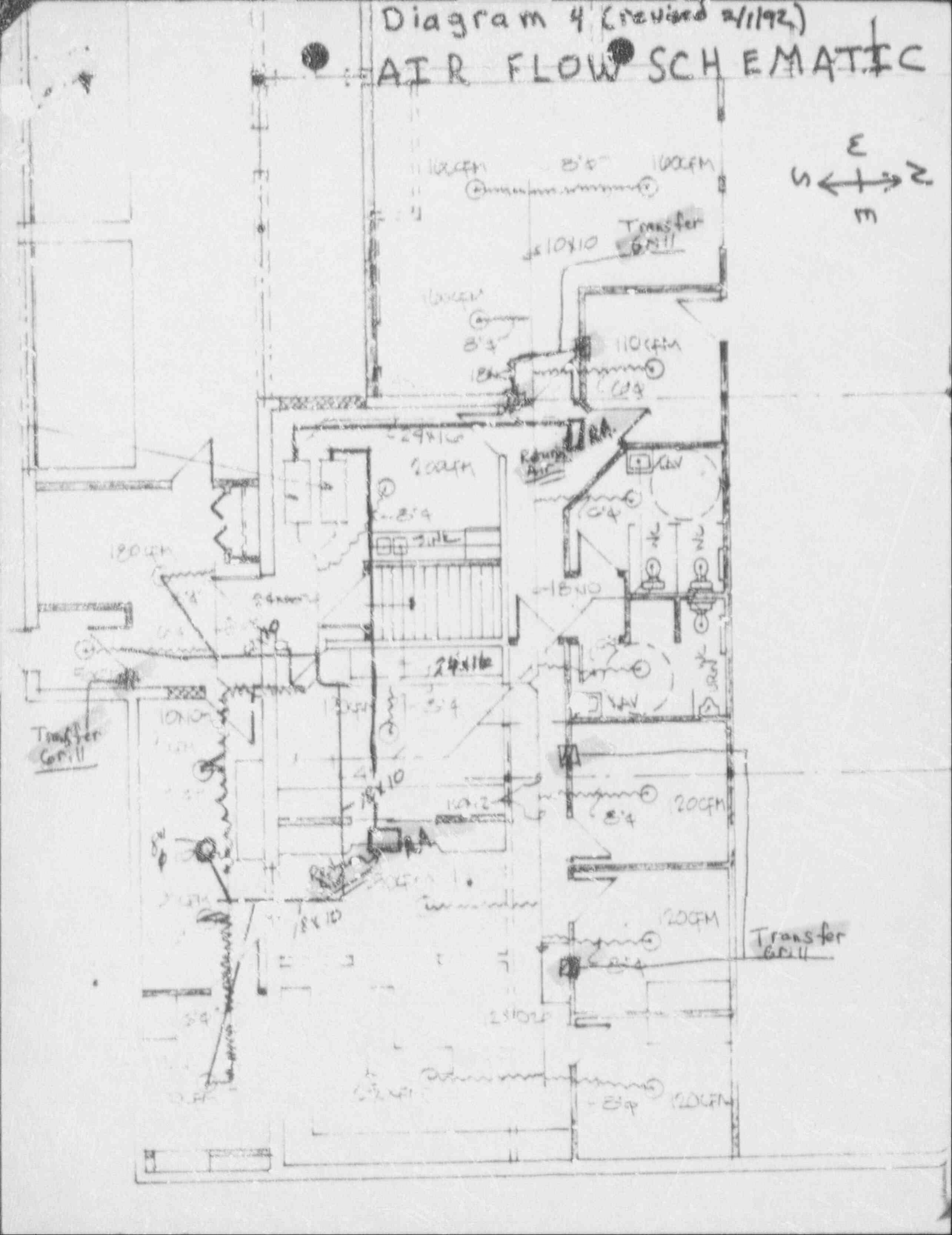
9.2 General Description of Facility

Air from the pharmacy is not circulated to other areas of the building because the pharmacy has two dedicated HVAC systems. These systems will be mounted in tandem and will have two main cold air return vents. One cold air return vent is located in the dispensing room and the other vent is located in the hallway in the unrestricted space. The common wall extends to the wood joists directly attached to the roof of the building and this common wall is constructed to be a fire wall. Airflow begins with the HVAC systems suspended above the ceiling in the break room and flows through ducts to outlet vents in each of the other rooms except the garage. There are not any passive cold air returns located in the iodine or WBC rooms but reception area, front office, and storage room will have passive air vents installed.

1301 Milburn Blvd
Mishawaka, IN 46544
(219) 255-5072

Diagram 4 (revised 2/1/92)

AIR FLOW SCHEMATIC



OCT 26 1992

Spectrum Pharmacy, Inc.
ATTN: Gregory S. Hiatt
President
17460 Farmington Square Road
Granger, IN 46530

Gentlemen:

This refers to Materials License 13-26367-01MD which was issued February 3, 1992. The license was issued in accordance with your application dated November 4, 1991.

Through an oversight, the license was issued without the required fee being collected. At the time your application was filed, it appeared that your request would be subject to fee Category 3D of §170.31 of the enclosed 10 CFR 170, and the fee of $1,100 was paid.

However, since the license was issued to authorize the processing of byproduct material and the use of depleted uranium for shielding, a fee of $3,510 is required as specified in fee Categories 3C ($3,400) and 2B ($110) of §170.31. Accordingly, an additional fee of $2,410 is required. Payment should be made to the U.S. Nuclear Regulatory Commission and mailed to the following address:

U.S. Nuclear Regulatory Commission
Attn: Cheryl Phillips
License Fee and Debt Collection Branch, OC/DAF
Mail Stop MNBB 4503
Washington, DC 20555

We apologize for the delay in notifying you of the additional fee due and for any inconvenience this matter may cause you.

Sincerely,

Doug Weiss, Chief
Materials License Fee Section
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

Enclosure:
10 CFR 170

DISTRIBUTION:
Pending Fee File OC/DAF R/F LFDCB R/F (2)

OFFICE:	LFDCB	LFDCB	LFDAF	
NAME:	RJacques:ht	MMessier	DWeiss	A:\Spectrum
DATE:	10/23/92	10/23/92	10/26/92	

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10/26/92