# MATERIALS LICENSE

Amendment No. 18

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. Syncor International Corporation<br>Medical Services Group<br><br>2. 7446 Derry Street<br>Harrisburg, Pennsylvania 17111 | In accordance with application dated September 27, 1991,<br>3. License number 37-19586-01MD is amended in its entirety to read as follows:<br><br>4. Expiration date December 31, 1997<br><br>5. Docket or Reference No 030-18920 |

| 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. 80 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 |

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
37-19586-01MD

Docket or Reference number
030-18920

Amendment No. 18

(Items 6., 7., and 8. continued)

| 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 |
|---|---|---|
| C. Any byproduct material authorized under paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) | C. Any sealed source listed in paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or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. |
| D. Xenon 133 | D. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA | D. 1.5 curie |
| 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. 990 millicuries |

MATERIALS LICENSE
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License number
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030-18920
Amendment No. 18

(Items 6., 7., and 8. continued)

| 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 |
|---|---|---|
| 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 Sections 35.100 and 35.200 of 10 CFR Part 35 (effective April 1, 1987) | F. 50 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. 100 millicuries total |
| 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. 200 millicuries total |
| 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 |

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030-18920

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(Items 6., 7., and 8. continued)

| 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 |
|---|---|---|
| J. Iodine 131 | J. Any iodide listed in Groups IV and V 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) | J. 500 millicuries |
| K. Uranium (depleted in the isotope Uranium 235) | K. Metal encased in stainless steel | K. 100 kilograms |
| L. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Sections 35.400 and 35.500 of CFR Part 35 (effective April 1, 1987) | L. Any sealed source 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 | L. 2500 millicuries |
| M. Cesium 137 | M. Sealed source (Technical Operations Model 773) | M. 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 September 27, 1991.

B. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in application dated September 27, 1991.

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.

E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

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

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

MATERIALS LICENSE
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(9. continued)

J. Redistribution of sealed sources as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions to authorized recipients for use and storage.

K. Shielding for Mo99/Tc99m generators.

Pursuant to Sections 32.72, 32.73, 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, 35.300, 35.400 and 35.500 of 10 CFR Part 35 (effective April 1, 1987), or under equivalent licenses of Agreement State, 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 J. 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.

L. and M. Sealed sources may be redistributed to persons licensed pursuant to Group VI or Sections 35.400 and 35.500.

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CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 7446 Derry Street, Harrisburg, Pennsylvania.

11. A. Licensed material shall be used by, or under the supervision of, individuals who are specifically named as users in Condition 11.A. of License Number 34-16654-01MD. The licensee shall verify that each individual selected as a user is specifically named in Condition 11.A. of License Number 34-16654-01MD and, for this purpose, shall maintain for inspection by the Commission copies of License Number 34-16654-01MD.

B. 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.

C. The Radiation Safety Officer for this license is Robert Grobinski, R.Ph.

12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

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License number
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(12. continued) CONDITIONS

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

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

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

(i) they contain only hydrogen 3; or

(ii) they contain only a gas; or

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

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

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

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.

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

MATERIALS LICENSE
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030-18920

Amendment No. 18

(Continued) CONDITIONS

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

14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.

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

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

(i) Repackaged from prepared radiopharmaceuticals that are the subject of 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 pharmaceuticals 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.

C. 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.

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

18. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.14 and 10 CFR 35.100 (superseded) for Group III or pursuant to 10 CFR 35.200 (effective April 1, 1987) or under equivalent licenses of Agreement States.

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(Continued) CONDITIONS

19. 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 September 27, 1991.

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.

    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, labelling, shielding, or instructions for use and storage shall be submitted for review to the Nuclear Materials Safety Branch, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406 and approval of the changes shall be received by the licensee prior to implementing the changes.

22. 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 September 27, 1991
    B. Letter dated November 23, 1992

For the U.S. Nuclear Regulatory Commission

Date DEC 03 1992

By Original Signed By:
Thomas K. Thompson
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

DEC 03 1992

License No. 37-19586-01MD
Docket No. 030-18920
Control No. 115573

Syncor Corporation
ATTN: Frank M. Comer
7446 Derry Street
Harrisburg, Pennsylvania 17111

Dear Mr. Comer:

Please find enclosed the renewal of your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Thomas K. Thompson

Thomas K. Thompson
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 18
2. Requirements for Materials Licensees

DRSS:RI
Mann/cmm
12/2/92

DRSS:RI
Thompson
12/3/92

syncor

November 23, 1992

Jenny M. Johansen, Chief
Medical Licensing Section
Division of Radiation Safety and Safegaurds
U. S. Nuclear Regulatory Commission
Regiion 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

RE: Mail control number 115573, License Number 37-19586-01MD. Harrisburg, Pennsylvania.

Dear Ms. Johansen:

The following information is submitted for continued review of the above referenced licnese.

1. Xenon-133 not marketed to customers will be held for decay for 10 half lives and will be disposed of in the normal trash when monitoring with a low level survey meter in a low background area demonstrates that the vials are at background levels.

2. We confirm that the Iodine-131 glove box type fume hood will be dicontaminated until the removable contamination is less than 2200 dpm/100 $cm^2$.

3. Syncor's program for exchanging and processing extremity badges is as follows:

All dispensers (dose drawers) have their badges exchanged weekly and these individuals are issued a dosimeter for each hand. Individuals who handle radioactive materials in shielded containers or unopened containers are issued a single ring badge which is worn on the hand which would be expected to receive the most exposure. The exchange frequency for these individuals is monthly.

The RSO at the Syncor location disignates an individual to retrieve the badges at their location and send them to the dosimeter supplier. Each location receives a dosimetry report from the supplier and in addition a copy of each dosimetry report for all locations is received at the corporate office. Syncor's policy is that all individuals at the location initial the dosimetry report indicating that they have read their exposure for the badge period being reported.

At the corporate office all reports are reviewed. We have established two levels of exposures which trigger a report from the supplier to the corporate office. In addition we can also electronically "browse" the reports for real time evaluation of exposures for those individuals who have exceeded either of the two trigger levels established for supplier reporting.

All ordering and transferring of badges is done by computer at the corporate office.

4. We confirm that all the instruments referred to in Item 10.2 will be calibrated every 12 months.

5. Item 10.9 A.2.b page 10 will be corrected to delete the "or" and add "and".

6. The minimum qualifications for our independent auditors are as follows.

A bachelors degree in health physics, physic, pharmacy or a related field with three to five years experience. A masters in health physics and one year of experience. At the present time we do not have any one on our staff with less than 4 years experience who perform audits. We have two individuals doing audits with masters degrees, one with a Ph.D. and two with bachelors degrees. These last two have over 40 years between them as occupational radiation workers.

7. We confirm that our decay in storage records will be the same as those requirements indicated in 10 CFR 35.92(b).

If additional information is needed do not hesitate to contact me.

Sincerely,

Frank M. Comer

Frank M. Comer
Program Director, Regulatory Support

cc: Robert Grobinski, R.Ph., Manager
License File

NOV 19 1992

License No 37-19586-01MD
Docket No. 030-18920
Control No. 115573

Syncor Corporation
ATTN: Frank M. Comer
7446 Derry Street
Harrisburg, Pennsylvania 17111

Dear Mr. Comer:

This is in reference to your application dated September 27, 1991 to renew License No. 37-19586-01MD. In order to continue our review, we need the following additional information:

1. Please describe the disposal method used for $^{133}Xe$ that is not marketed from item 9.3.F.1.

2. In item 9.4, the note following item #12 in your Procedure for Contaminated Sources (pg. 35) indicates that the sources will be decontaminated to 2200 dpm/100 cm. Please confirm that you intend to decontaminate to 2200 dpm/100 $cm^2$ and revise your procedure accordingly.

3. Regarding item 10.1, please describe your exchange program for extremity monitoring devices and the review process for the results. Do the individuals exchange the badge for themselves and receive and review the results for compliance with the regulations; or is the exchange process centralized with the RSO receiving and reviewing the results for compliance with the regulations. Please include the appropriate time frames in your response to this question.

4. Regarding item 10.3, please confirm that your instruments will be calibrated at intervals not to exceed 12 months.

5. Regarding item 10.9, your Radioactive Waste Handling and Disposal procedure item A.2.b. states "container emptying rotation cycle is established to ensure that all material has been stored for a minimum of ten (10) half-lives or until it has reached background levels." Please revise this statement to delete the "or until it has reached background levels" and substitute "and until it has reached background levels".

6. Regarding item 10.16, please provide the minimum qualifications that your independent auditors will have prior to performing audits for the corporate RSO.

7. Regarding item 11, please confirm that your decay-in-storage records will be the same as those requirements indicated in 10 CFR 35.92(b).

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 115573. The reviewer for this licensing action is David Mann. If you have any technical questions regarding this deficiency letter please call the reviewer at (215) 337-5237.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original Signed By:
Thomas K. Thompson

Jenny M. Johansen, Chief
Medical Licensing Section
Division of Radiation Safety
and Safeguards

Enclosures:
1. 10 CFR Part 35
2. Regulatory Guide FC 410-4
3. Form NRC 313, 3

DRSS:RI
Mann/David:cmm
11/19/92

DRSS:RI
Johansen
11/20/92

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OCT 24 1991

Docket No. 030-18920
License No. 37-19586-01MD
Control No. 115573

Syncor Corporation
ATTN: Frank M. Comer
7446 Derry Street
Harrisburg, Pennsylvania 17111

Dear Mr. Comer:

SUBJECT: LICENSE RENEWAL APPLICATION

This is to acknowledge receipt of your application for renewal of material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified above.

Sincerely,

Original Signed By:
Sheryl Villar

Sheryl Villar, Chief
Licensing Assistant Section
Division of Radiation Safety
and Safeguards

10/24/91 SV 10/25/91
Rgt

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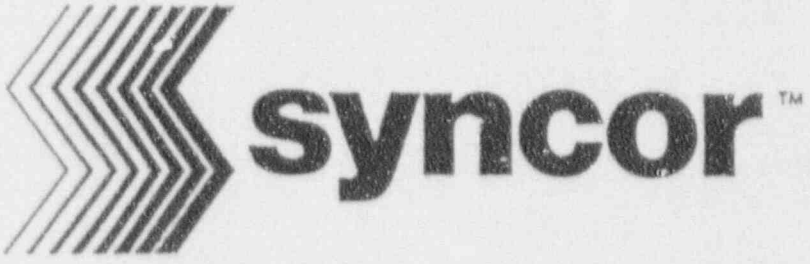
10/08/91

ML 10

030-18920

SYNCOR INTERNATIONAL CORPORATION




Harrisburg, PA Lic #37-19586-01MD

115573

ML 10

OFFICIAL RECORD COPY

SEP 2 6 1991

syncor®

03D-18920 X

September 27, 1991

U.S. Nuclear Regulatory Commission
Material Licensing Section
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406

*Re: Renewal Application of NRC License # 37-19586-01MD*

To whom it may concern,

I have enclosed the application for renewal of the Harrisburg, Pennsylvania facility. Thanks for your consideration of this matter.

Sincerely,

Michael Mosley, R.Ph.
Program Manager, Licensing

cc: Location 73
License file

OFFICIAL RECORD COPY ML 10

115573

*Innovators in high-tech pharmacy services.*

Syncor International Corporation • 20001 Prairie Street • Chatsworth, California 91311
(818) 886-7400 • FAX 886-6028 • Telex MCI 67-18642 Syncor CHATS

SEP 26 1991

RADIOACTIVE MATERIALS

APPLICATION FOR LICENSE RENEWAL

SEPTEMBER 27, 1991

SYNCOR INTERNATIONAL CORPORATION
MEDICAL SERVICES GROUP
HARRISBURG, PENNSYLVANIA

37-19586-01MD

NRC FORM 313
(9 90)
10 CFR 30, 32, 33,
34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

# APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB NO 3150-0120
EXPIRES 5/31/93

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 3.75 HRS FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714) U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON DC 20555 AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120) OFFICE OF MANAGEMENT AND BUDGET WASHINGTON DC 20503

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
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)

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER
- [X] C. RENEWAL OF LICENSE NUMBER 37-19586-01MD

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

Syncor International Corporation
20001 Prairie Street
Chatsworth, California 91311

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

Syncor International Corporation
Medical Services Group
7446 Derry Street
Harrisburg, Pennsylvania 17111

per telecon with Syncor 12/2/92 DM

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Michael S. Mosley

TELEPHONE NUMBER: 818/886-7400, (X537)

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

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

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY: 3C
AMOUNT ENCLOSED: $ 1400.00

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 |
|---|---|---|---|
| Michael S. Mosley | Michael S. Mosley | Program Manager, Licensing | 9/27/91 |

FOR NRC USE ONLY

| TYPE OF FEE | FEE LOG | FEE CATEGORY | COMMENTS |
|---|---|---|---|
| Ren | Oct 15 I | 3C | |
| AMOUNT RECEIVED | CHECK NUMBER | | |
| $1400 | 275571 | | |

APPROVED BY: Rita Jacques DATE: 10/17/91

NRC FORM 313 (9 90)

TABLE OF CONTENTS

*ITEM 5 - NRC 313*

## RADIOACTIVE MATERIAL

| BYPRODUCT, SOURCE, AND/OR SPECIAL NUCLEAR MATERIAL | CHEMICAL AND/OR PHYSICAL FORM | MAXIMUM AMOUNT THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE |
|---|---|---|
| A. Molybdenum-99 | A. Any molybdenum-99/ technetium-99 generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations | A. 80 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 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 a manufacturer by an Agreement State pursuant to equivalent State regulations | C. 50 millicuries total possession limit |
| 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 terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA | D. 1.5 curies |
| 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. 990 millicuries |

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Date: 09/27/91

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| BYPRODUCT, SOURCE, AND/OR SPECIAL NUCLEAR MATERIAL | CHEMICAL AND/OR PHYSICAL FORM | MAXIMUM AMOUNT THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE |
|---|---|---|
| F. Technetium-99m | F. Any form listed in Groups I and II of Schedule A, Sections 35.100 and 35.200 of 10 CFR Part 35 (superseded) or Sections 35.100 and 35.200 of 10 CFR Part 35 (effective April 1, 1987) | F. 50 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. 100 millicuries total possession limit |
| 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. 200 millicuries total possession limit |
| I. Any byproduct material, except iodine-131 and technetium-99m, 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. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Sections 35.400 and 35.500 of 10 CFR Part 35 (effective April 1, 1987) | J. Any sealed source 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 a manufacturer by an Agreement State pursuant to equivalent State regulations | J. 2.5 curies |
| K. Uranium (depleted in the isotope Uranium-235) | K. Depleted encased in steel | K. 100 kilograms |
| L. Cesium-137 | L. Sealed source (Technical Operations Model 773) | L. 165 millicuries |

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*ITEM 6 - NRC-313*

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

A. Byproduct material under (A) will be used to produce 99m Technetium Pertechnetate. Byproduct material under (A) (99 Molybdenum Generators) unused will be redistributed to our customers from manufacturers licensed or approved to distribute them in accordance with Section 32.73 of 10 CFR, Part 32.

1. Redistribution of Reagent Kits

   a. 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 10 CFR 32.73 or under equivalent regulations of an Agreement State;

   b. Reagent Kits will be redistributed as received from the manufacturer in the "kit sleeve" (i.e., cardboard enclosure holding a styrofoam container with 5 reaction units) and 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, or distributed as individual vials by prescription.

2. Redistribution of Generators

   a. All 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. "Unused" generators will be redistributed without opening or altering the manufacturer's packaging;

B. Byproduct material listed under (B) will be distributed in accordance with the following:

1. Redistribution of In-Vitro Kits

   a. For redistribution of In Vitro Kits to GENERAL licensees;

      1. repackaged 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 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 is accompanied by 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 licensees;

1. Syncor will obtain prepackaged in vitro kits (as described in 10 CFR 31.11(a)) for redistribution to specific licensees;

2. Syncor will ensure that the labels, package insert, leaflets, 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. Syncor will ensure that labeling on redistributed in vitro kits conforms to the requirements of 10 CFR 20.203.

C. Instrument calibrati . Redistribution of sources to specifically authorized recipients.

1. Redistribution of Sealed Sources - Calibration and Reference Sources

a. These sources will be redistributed to customers licensed under the provisions of 35.57 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 obtained 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 opened or altered, and redistributed sources will be accompanied by the manufacturer's calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

D. For byproduct material listed under " ", see 133-Xenon information under Item 9.3.

E. Byproduct material under (E) will be used for processing or compounding, to include compounding Iodine-131 therapy capsules, and distribution of prepared radiopharmaceuticals to authorized recipients.

F-I. Byproduct material under (F), (G), (H), and (I), will be used for

processing, mixing or compounding, and distribution of prepared radiopharmaceuticals to authorized recipients.

J. Byproduct material listed under (J) and (L) will be redistributed in accordance with the following:

1. Redistribution of Sealed Sources

a. Sealed sources to be redistributed will have been obtained from a manufacturer authorized to distribute these sources in accordance with a specific license issued pursuant to paragraph 32.74 of 10 CFR Part 32 or under equivalent regulations of an Agreement State.

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

K. Shielding for the Mo-99/Tc-99m generator.

ITEM 7 NRC - 313

Item 7. Individuals(s) Responsible for Radiation Safety Program and Their Training and Experience.

1. We request authorized user status for all authorized users listed under Condition 11A of our NRC master license No. 34-16654-01MD, Toledo, Ohio.

In support of this request, we confirm that at least one individual named in Condition 11A shall be physically present at the authorized place of use whenever licensed material is being used. We also confirm that a copy of the "master" (Toledo Radioactive Materials License and all current amendments will be obtained and maintained on file at our location.

2. The designated RSO will be: Robert Grobinski, RPh.

The day to day radiation safety officer will be present on a daily basis in order to implement and direct the corporate radiation safety program. Since the corporate program, when implemented, consists of an ongoing audit of personnel whole body and extremity exposures and ongoing audit of all documentation required to comply with the conditions of the license and NRC regulations, it is expected that the day to day RSO will have to spend a minimum of 10% of his time directing the radiation safety program.

Corporate management has provided a firm commitment to provide and maintain the staff, ancillary support and oversight necessary to assure that the day to day RSO will have the time available on continuing basis for radiation safety officer duties. The present staff is:

| Name | Previous Authorization |
|---|---|
| Robert Grobinski, RPh | 37-19586-01MD |
| Nhan Duong, RPh | 37-19586-01MD |
| Peggy Williamson, RPh | 37-19586-01MD |

The day-to-day duties of the RSO are as follows:

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.*

*ITEM 8 - NRC 313*

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 in 10 CFR 19.12 at the time of initial employment, before an employee assumes duties with or in the immediate vicinity of radioactive materials, and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.
b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.
d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. This information will be provided initially at pharmacy employee orientation sessions and annually thereafter at in-service meetings.

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.

*ITEM 9 - NRC 313*

FACILITIES AND EQUIPMENT

Item 9.1 Site Description

1. Syncor Corp has leased approximately 3000 of space in a single story building housing commercial interests. Common walls are shared with Control Data Corporation and Underwriters & Administrators. The walls are concrete block extending from floor to roof.

   Wall monitors have been placed in neighboring business offices, (adjacent to the drawing station and generator room), to ensure safety, and copies of exposure reports are sent to those businesses when we receive them.

2. After hours deliveries are placed in the room at the rear of the building in an area that is equidistant between the neighbors' office space. There are two entrances to the building (front and rear). Security is provided by closed circuit contacts on exterior doors plus interior infrared motion detectors, serviced by Sonitrol Security of Harrisburg.

3. The heating and cooling system is exclusive for this area with no air exchange with the adjacent tenants.

4. Please refer to attached sketches, maps, and diagrams.

5. We confirm that operation of a nuclear pharmacy does not conflict with any local codes or zoning laws.

6. See attached letter which is sent to the local police and fire department annually, unless the facility is inspected by the fire department on a yearly basis.

7. The fume hood stack extends 34 inches above the roof line. It is 24 feet away from one of our own air conditioners, and over 50 feet away from the nearest point of access to an adjacent building.

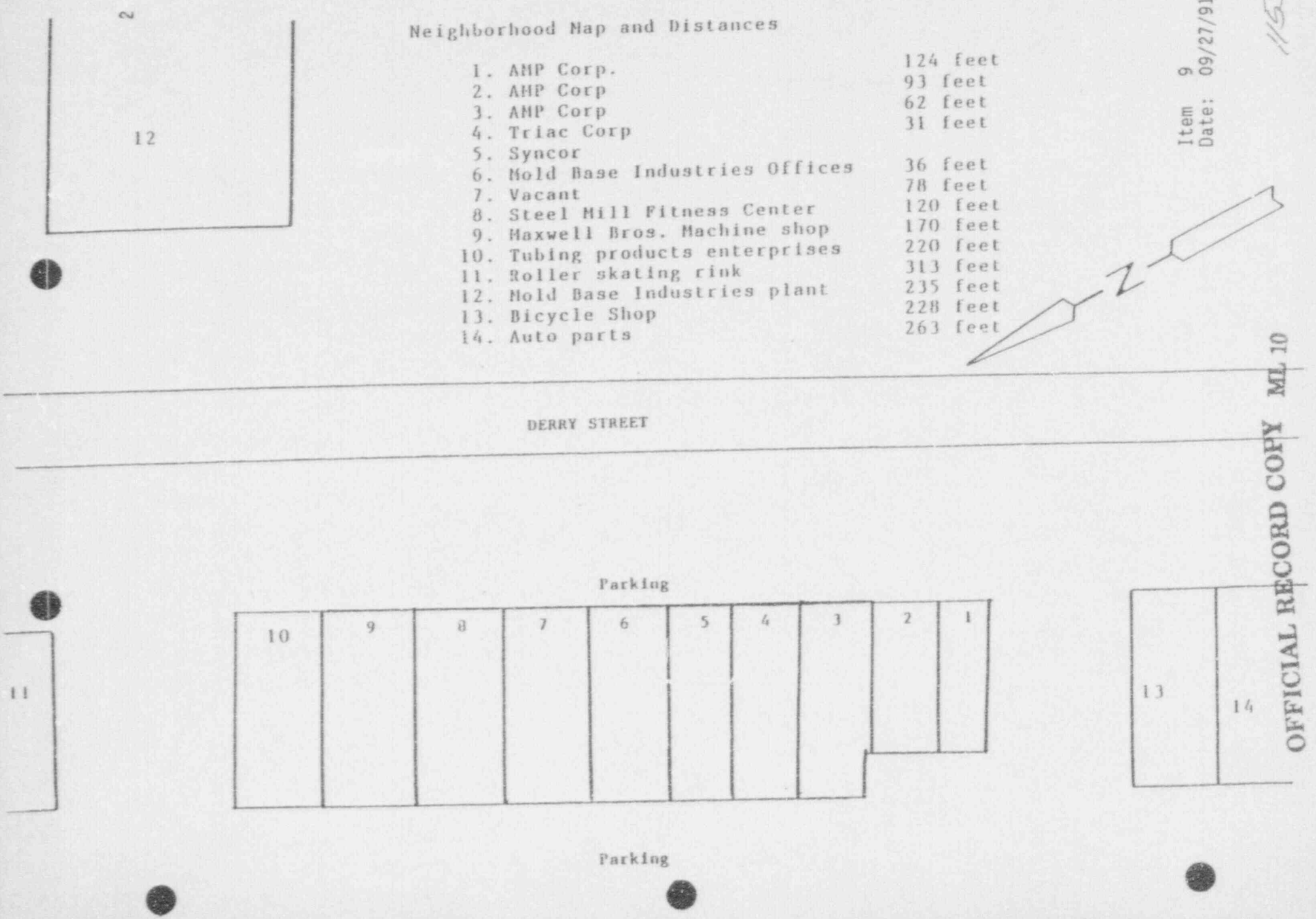
Item 9
Date: 09/27/91

11573

OFFICIAL RECORD COPY ML 10

## Neighborhood Map and Distances

| | | |
|---|---|---|
| 1. | AMP Corp. | 124 feet |
| 2. | AMP Corp | 93 feet |
| 3. | AMP Corp | 62 feet |
| 4. | Triac Corp | 31 feet |
| 5. | Syncor | |
| 6. | Mold Base Industries Offices | 36 feet |
| 7. | Vacant | 78 feet |
| 8. | Steel Mill Fitness Center | 120 feet |
| 9. | Maxwell Bros. Machine shop | 170 feet |
| 10. | Tubing products enterprises | 220 feet |
| 11. | Roller skating rink | 313 feet |
| 12. | Mold Base Industries plant | 235 feet |
| 13. | Bicycle Shop | 228 feet |
| 14. | Auto parts | 263 feet |



Date:

Address

Attention: (Chief of the Police Department)
(Chief of the Fire Department)

Gentlemen:

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

Syncor International Corporation
Medical Services Group
7446 Derry Street
Harrisburg, Pennsylvania 17111

This notification is for your information in the event that a fire or disaster might involve this building.

The material which we work with is for use by physicians for medical purposes and, therefore, is comprised of short-lived radiopharmaceuticals.

Very little danger would exist in the event of a fire or disaster; however, caution should be exercised by police or fire fighting personnel should it be necessary and possible to enter the area in which radioactive materials are stored. In the event of a fire, radioactive material would remain confined to this area, due to the nature of the building's construction.

Should it become necessary and possible to enter the nuclear pharmacy area, survey instruments are readily available, located in rooms adjacent to the primary radioactive materials storage area. Also, personnel trained in the use of survey instruments and familiar with hazardous radiation levels would be readily available to assist your personnel.

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

Item 9.2 General Description of Facility

Syncor has leased approximately 3000 square feet for use as a Pharmacy Service Center in a single story building. This building is in a commercially zoned area, (see attached area description), and is located at 7446 Derry Street, Harrisburg Pennsylvania 17111. This building is constructed of concrete block and steel, and a fire wall extends to the roof on all walls shared with adjacent tenants.

The area designated as the receiving area (U-6) will be used for receipt of after-hours radioactive material shipments. Sketches of the floor plan and equipment placement are attached to this written description.

UNRESTRICTED AREA

See attached sketch

RESTRICTED AREA

Radiopharmacy Dispensing Area (R1) - Approx. 500 feet$^2$

This area is used for preparation and dispensing of radiopharmaceuticals. One drawing station is located in this area, as shown on the attached sketch. The drawing station consists of a leaded glass L-block shield, a dose calibrator , and a lead bin for waste. The leaded glass shield is a minimum of ½" thick, and the L-block shield a minimum of ½" thick. Another drawing station is located in the fume hood on the opposite wall. The L-block shield at this station is 1" thick lead with a ½" thick leaded glass. The fume hood and Iodine (glove-box type) hood is located in this area, and all volatile substances will be stored and handled here.

Technetium and Tc-99m products will be eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers, all of which has a minimum of 1/4" thick lead. The refrigerator will be utilized for storage of both radiopharmaceuticals (in appropriate shielding) and cold kits needing refrigerated storage.

Non-Radioactive Storage (R2) - Approx. 190 feet$^2$

This area is used for storing non-radioactive supplies.

Generator Room (R3) - Approx. 170 feet$^2$

This area is used for storing Mo-99-Tc99m generators, and actively used radiopharmaceuticals, except Xenon-133 and Iodine-131. Generators are stored in original manufacturer shielding plus manufacturer secondary shields. These are placed in a bin constructed of ¾" plywood. The hollow-wall construction uses scrap lead as additional shielding. An attached lid carries ½" shielding. Prepared radiopharmaceuticals from manufacturers will be stored in shipping containers behind a minimum of ¾" lead shielding. The heating bath is housed in ½" lead shielding. The top has ½" leaded glass. Inside the bath, a ½" lead collar rests to shield radiopharmaceuticals during the heating process.

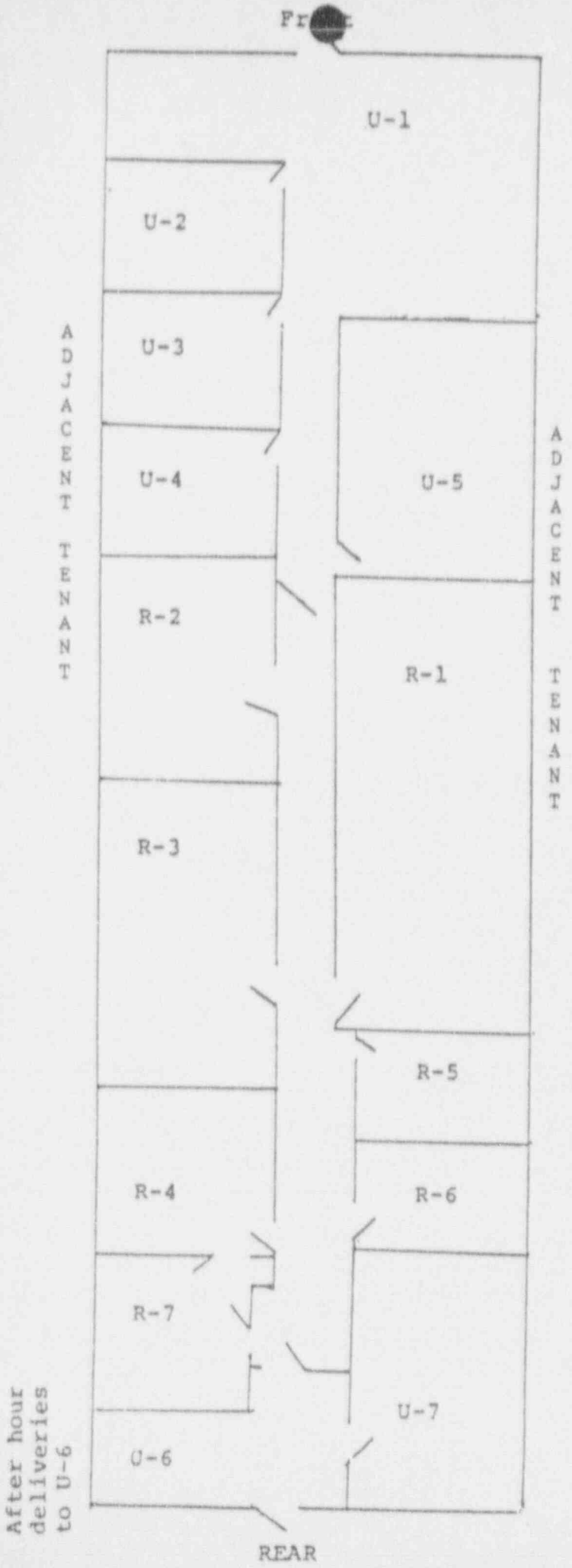
Radioactive Waste Storage Area (R4) - Approx. 144 feet$^2$

This area is used for storage of all radioactive material being held for decay. Waste is stored in a concrete block bin that is 38" tall, 48" deep and 12¾' wide. The walls are 12" thick and are filled with scrap lead. The top is ⅛" lead attached to wood. Additional lead is added to the top as required.

Rest Rooms (R6)

Package Receipt and Breakdown Room (R-7) - Approx. 96 feet$^2$

Packages are checked in this area and radioactive waste from customers is handled in this area. Returned radioactive waste is placed in ¼" thick generator collars that are 12" tall, surrounded by 2" thick lead bricks. Short-lived material is stored here and decayed about four days before being transferred to the waste bins. A probe for performing return wipes is housed in ¼" thick lead.




Scale 6

1cm= 4 feet

| | |
|---|---|
| U-1 | Entrance/Reception Area |
| U-2 | Office |
| U-3 | Office |
| U-4 | Break Room |
| U-5 | Computer Room |
| U-6 | Receiving Area |
| U-7 | Cold Waste Storage |
| R-1 | Dispensing Room |
| R-2 | Storage |
| R-3 | Generator Room |
| R-4 | Decay room |
| R-5 | Rest Room |
| R-6 | Rest Room |
| R-7 | Break Down Room |

Syncor Corp. Harrisburg, PA

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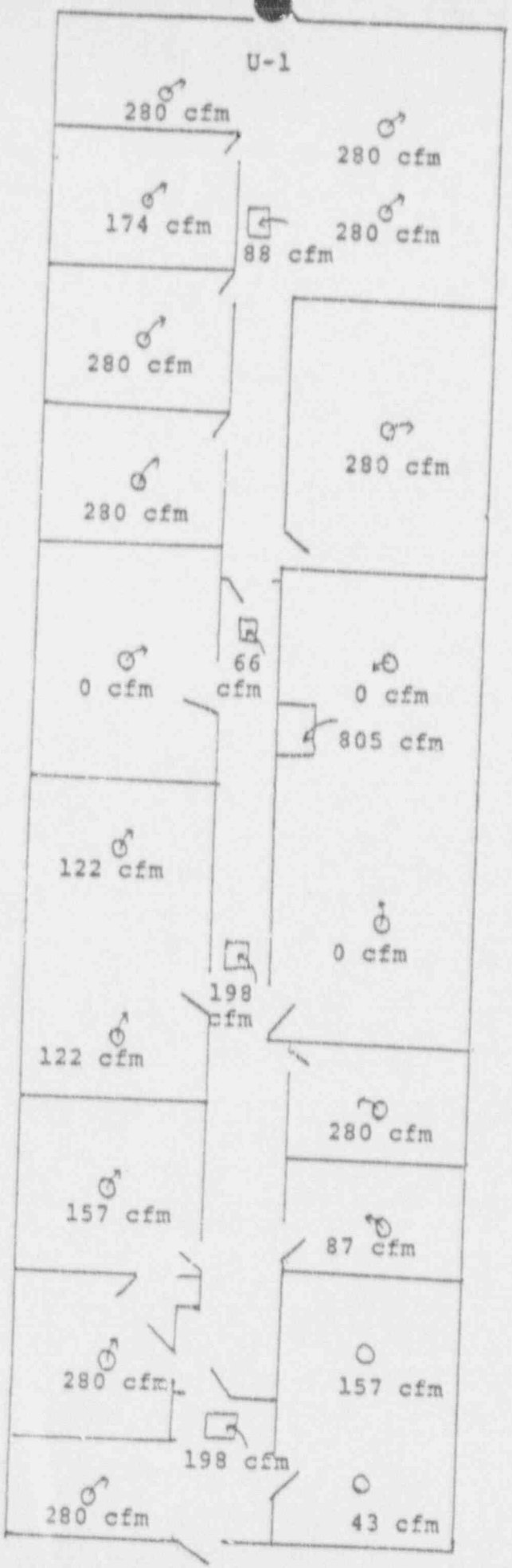
Syncor Corp. Harrisburg, PA




Ventilation Data

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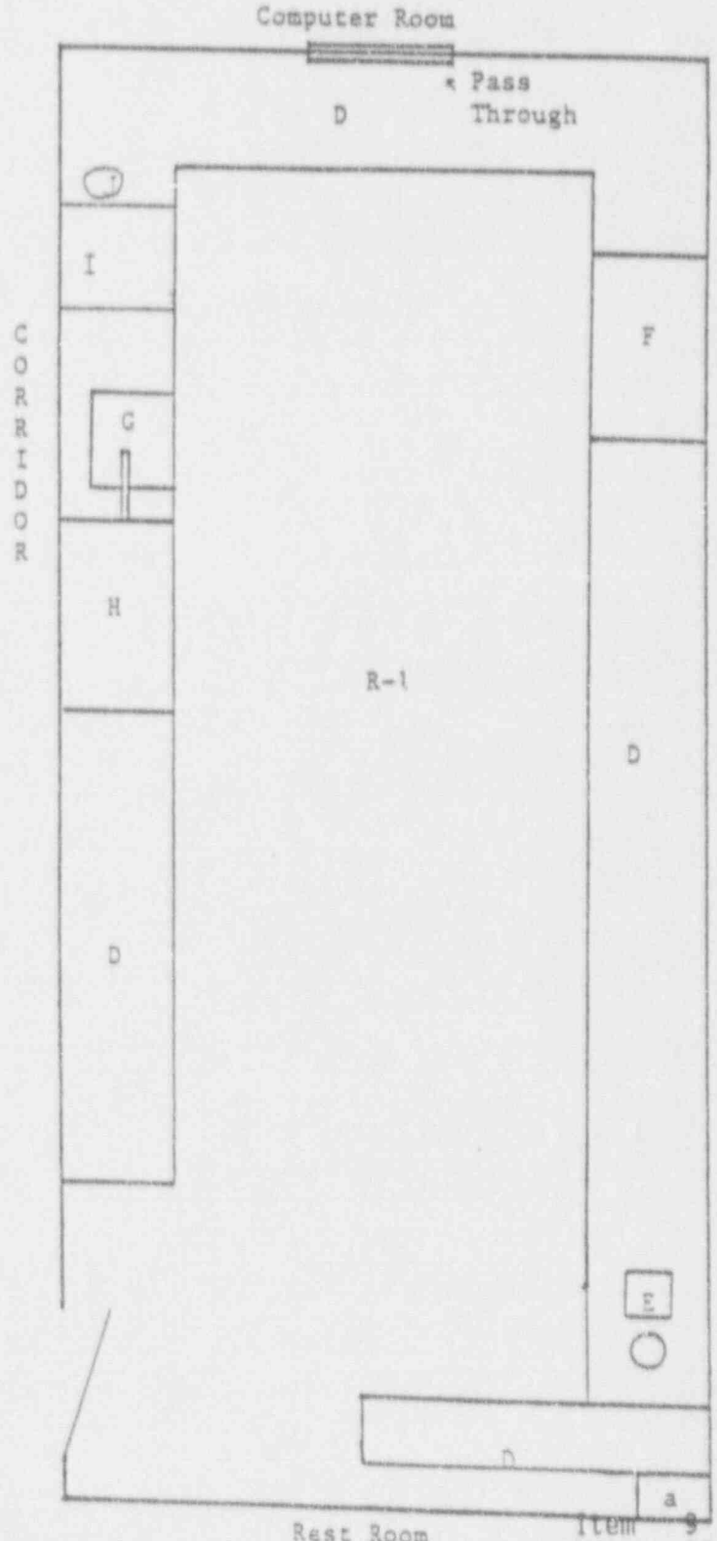
a. Sink

D. Counter
E. Well System
F. Drawing Station
G. I-131 Fume Hood
H. Lab Fume Hood
I. Dose Drawing Station
J. Isotope Storage




Scale 1/4" = 1'

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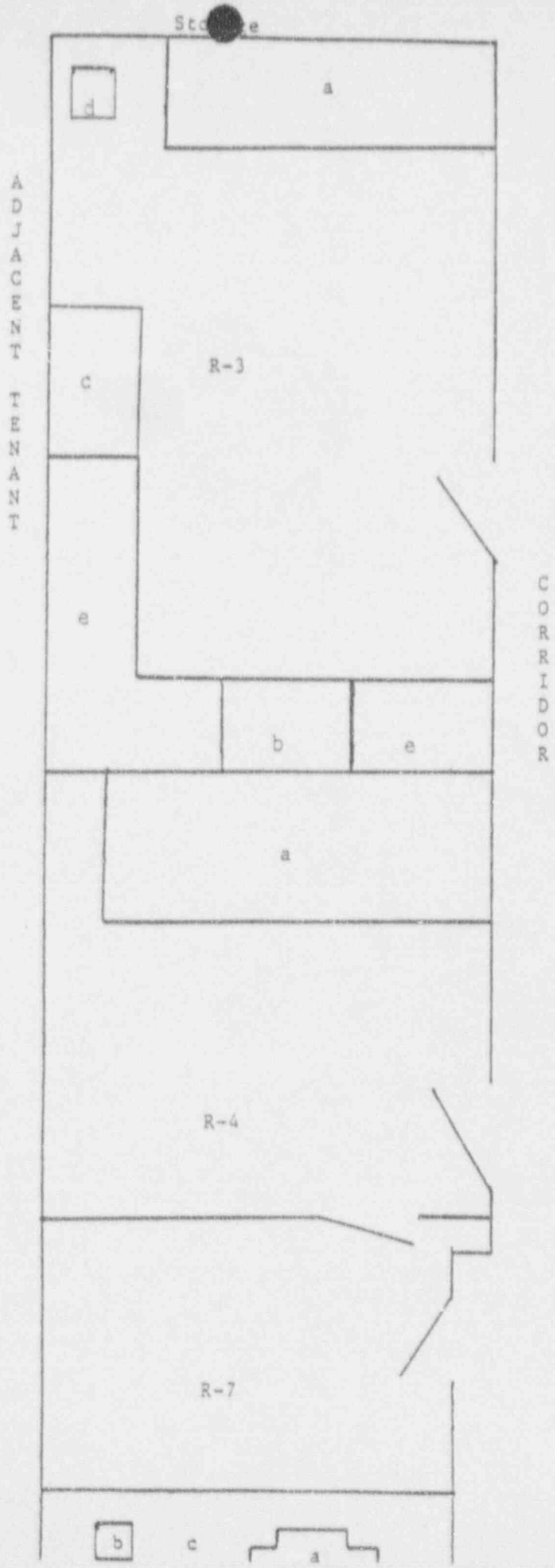


RESTRICTED AREA

R-3 Generator Room

a. Generator storage
b. Leucocyte labeling hood
c. Persantine hood
d. Refrigerator
e. Counter space

R-4 Waste Storage
   a. Waste Storage Bins

R-7 Package Receipt and Break Down Return Package Area
   a. 2" x 4" x 8" Lead Brick Bin
   b. Wipe Sample Equipment
   c. Counter

Item 9
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Scale 1/4" = 1'

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

DECONTAMINATION KIT

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

# SHIELDING

| | |
|---|---|
| G Generator Area: | Manufacturer's Shielding ¼" lead "Barn" around each generator. |
| R Refrigerator: | Manufacturer's shielding ¼"lead around isotope storage. |
| IS Isotope Storage: | Manufacturer's Shielding ¾" lead around isotope storage. |
| WS Waste Storage: | ¾" lead barrels 16" in diameter, 24" high mounted ¼" lead plates on casters. A ¼" lead plate (18 inch$^2$) is used as a lid. See description in 9.2 (room R-4). |

Note: Total radioactive waste storage volume available is approximately 150 cubic feet. Using rotation of materials based on half life this has been an adequate volume for our present needs.

Item 9.3 Adequacy of Facility for Handling Xenon-133

A. Quantities to be used

1. State the desired possession limit.

The desired possession limit is 1.5 Ci of Xenon-133 in gas form.The only forms of Xenon-133 we are requesting are sealed glass vials of the New England Nuclear and Medi-Physics type of glass vial containing gas. The rubber septums on these vials will not be punctured nor the contents of the vials altered in any way. These vials will be shipped from the nuclear pharmacy in the same containers and form in which they are shipped to the pharmacy, reducing the possibility of Xenon-133 leaks, spills, or contamination essentially to zero.

B. Use and Storage Areas

1. Describe the area in which you plan to use and store Xenon-133

When the pharmacy receives shipments of Xenon-133, the gas will be in sealed glass vials which will be shipped to authorized users without being opened or without the septum being punctured by anyone in the pharmacy. The sealed vials will be stored in a fume hood, nevertheless, and will remain inside the lead containers used by the manufacturer for shipment of Xenon-133. Please see attached floor plan diagram for the location of the fume hood. The nearest uncontrolled area is the exit from the restricted area which is 25 feet away.

2. Describe the ventilation in all areas where Xenon 133 is stored and dispensed.

See attached sketch. There are no supply vents. The measured exhaust from the fume hood is >800 CFM, with no return air vents located in this area. The fume hood room remains under constant negative pressure.

Xenon is not to be used in the pharmacy; it will be stored and dispensed in the fume hood only. The exhaust fan from the fume hood is used to maintain a high flow rate through the hood. Measured fume hood flow is ≥800 CFM.

Total supply = zero
Return = zero
Exhaust = minimum 800 CFM

3. The fume hood will be checked every six months with a velometer to determine if the fume hood is operating adequately to satisfy the requirements of Section 21.106 of 10 CFR.

C. Procedures for routine use

1. Describe the procedures to be followed for routine use of Xenon-133 giving particular attention to radiological safety factors.

No patient procedures will be performed in the nuclear pharmacy. The Xenon-133 gas being order will be sealed in glass vials with rubber septums by the manufacturer. The septum will not be punctured nor the sealed vial opened in any way. The vials will be stored in the original shipping containers composed of lead, and they will be stored in the fume hood at all times. When an authorized user orders a quantity of Xenon-133 gas, the vials will be dispensed in their original containers to the physician.

D. Emergency Procedures in Case of Xenon-133 Release

1. Describe the emergency procedures to be used in case of accidental release of Xenon-133. This should include such considerations as temporary evacuation of the area of increasing the ventilation of the area.

Procedure

This pharmacy has an exclusive heating and cooling system with a fire wall between this facility and the adjacent tenant. In the case of an accidental spill, no Xe-133 could circulate to any other tenant areas.

1. Immediately evacuate all personnel in the area of the spill.

2. Notify all personnel, close all doors, and evacuate the room for 18 minutes. Be sure to take a GM survey meter to survey upon re-entry.

3. Upon re-entry, survey all areas, especially the area of the spill, to make sure no areas of high exposure exist. If high readings are obtained, evacuate for another 18 minutes or until normal background levels are measured in the facility.

4. Notify the Health Physics Group and document the incident.

These calculations demonstrate that 18 minutes evacuating time is adequate for Xenon concentration to return to the maximum permissible concentration (MPC) of 1 x $10^{-5}$ uCi/ml (10 uCi/$m^3$), if a unit dose is broken:

$$t = \frac{-V}{Q} \times \ln \left(C \times \frac{V}{A}\right)$$

where;

t = time in minutes
V = Room volume in milliliters
Q = Total room exhaust in ml/min
A = Activity of gas possible to spill in microcuries
C = Permissible air concentration for volatile substance in uCi/ml

Example:

What is the evacuation time for the volatile substance handling room if a 40 millicurie vial of Xenon-133 was dropped and broken?

$V = (4060)\ ft^3 \times 2.83 \times 10^4\ ml/ft^3 = 1.15 \times 10^8$ ml

$Q = 800\ ft^3/min \times 2.83 \times 10^4\ ml/ft^3 = 2.26 \times 10^7$ ml/min

$C = 1.0 \times 10^{-5}$ uCi/ml for restricted area

A = 40,000 uCi

$$t = \frac{-1.15 \times 10^8}{2.26 \times 10^7} \times \ln \frac{(1 \times 10^{-5} \times 1.15 \times 10^8)}{4 \times 10^4}$$

$t = -1.015 \times \ln (1 \times 10^{-5} \times 1.149 \times 10^8)$

t = 18 minutes

After 18 minutes, the concentration of Xenon-133 in this area would have returned to permissible level in uCi/ml.

E. Air concentrations of Xenon-133 for unrestricted areas

1. All Xenon-133 gas will be stored in the fume hood.

   a. Estimate the maximum amount of activity to be used per week (A).

   b. Estimate the fraction of Xenon-133 that is lost during use and storage (F).

   c. Determine the ventilation rate in the area of interest and calculate the volume of air available per week for dilution of Xenon-133 (V).

2. The maximum amount of activity on hand at any one time per week is 1500 mCi. This will be the maximum amount stored in the fume hood.

3. We recently completed a study which indicates that the leakage from Xenon-133 vial is more realistically 0.05% per vial per day, rather than 0.5% submitted by Dupont at an earlier date. Based on our findings, the following calculations are submitted.

   If we have a leakage of 0.05% per day and we assume that we will continually have 1500 mCi on hand seven days a week (both assumptions are excessive), then:

   $F = 0.05\%/day \times 7\ days \qquad F = 3.5 \times \frac{10^{-3}}{week}$

4. Assuming a minimum fume hood exhaust of 800 CFM, calculating (V) in metric terms:

   $$V = \frac{800\ ft^3}{min} \times \frac{60\ min}{hr} \times \frac{24\ hr}{day} \times \frac{7\ days}{week} \times 2.83 \times 10^4\ \frac{ml}{ft^3}$$

   $$V = 800\ ft^3 \times (1.008 \times 10^4) \times (2.83 \times 10^4)\ \frac{ml}{wk}$$

   $$V = 2.28 \times 10^{11}\ \frac{ml}{wk}$$

5. For unrestricted areas, Section 20.106 of 10 CFR, Part 20 requires that the maximum allowed concentration is:

   $$\frac{A \times F}{V} = 3 \times 10^{-7}\ \frac{uCi}{ml}$$

   In our case:

   $$\frac{1.5 \times 10^6\ uCi \times 3.5\ 10^{-3}}{2.28 \times 10^{11}} = 2.30 \times 10^{-8}\ \frac{uCi}{ml}$$

   If 0.5 % leakage $2.3 \times 10^{-7}$ would be result. This remains the fact

F. Methods for Xenon-133 disposal

1. Xenon vials not marketed to hospitals will be held for decay and will be disposed of in the normal trash when monitoring with a low level survey meter shows the vials to be at background radiation levels.

G. Please note that Xenon-133 will not be used in the radiopharmacy. It will repackaged in appropriate shielding and distributed to authorized recipients.

H. The exhaust stack from the fume hood is exclusive for this fume hood, and is located at least 24 feet from the nearest intake vent. The fume hood stack at this location exhaust is at least 34 inches above the roof line.

Item 9.4 Special Equipment for Handling Millicurie Quantities of Liquid Radioiodine

A radioiodine glove box type fume hood will be utilized for dispensing liquid I-131 Sodium Iodide and compounding Iodine-131 therapy capsules. The effluent from this fume hood will be connected directly into the standard laboratory fume hood.

Two charcoal filters will be used in the Iodine-131 fume hood. Each filter is one foot square and one inch thick. One filter will be stacked on top of the other so that the Iodine 131 will be exhausted through two inches of charcoal. This ensures a trapping efficiency of 98%. Measurements with an anemometer of air flow at the arm ports for this Iodine 131 fume hood show a linear air flow of 50 to 70 feet/min.

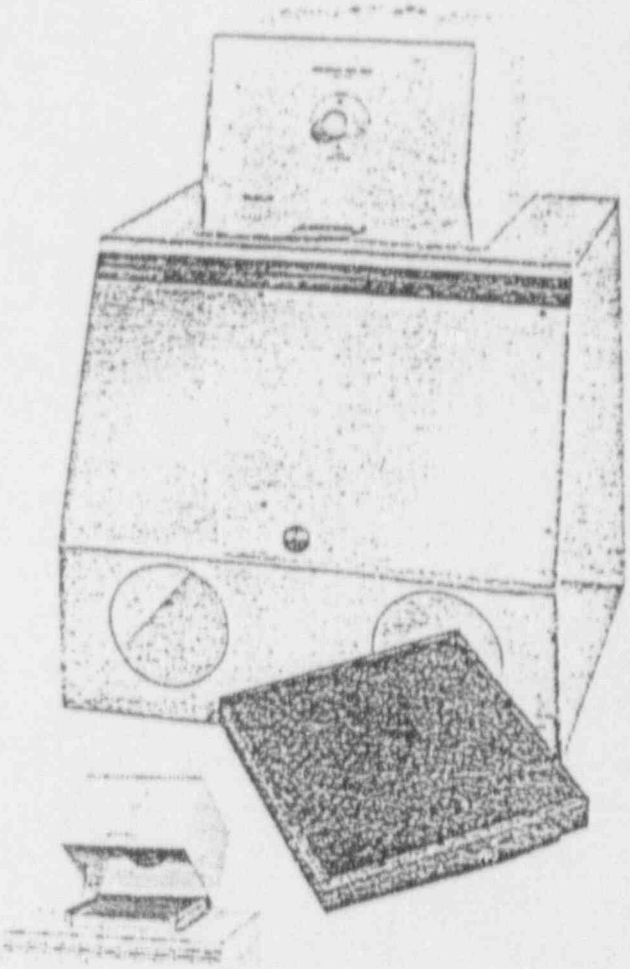
The efficiency of this trapping system is checked weekly. The filters are removed and the radiation level at their surfaces is measured with a pancake probe type survey meter or more sensitive device. When the measured level of the top filter is equal to or greater than 10% of the measured level of the bottom filter, the bottom filter will be replaced.

Air sampling for volatile I-131 will be performed in conjunction with the use of the radioiodine fume hood. See following air sampling procedure.

A flow meter device will be placed at all locations for evaluating linear flow through the arm ports of the glove box. A base line linear flow will be measured, which shall be consistent with the value used to calculate standard cubic feet per minute semi-annually. This linear flow measurement will be obtained at the same position to ensure consistency, and will be obtained daily or prior to use of the hood system for handling Iodine-131.

Whatever corrective actions are necessary to return exhaust flow to the required level will be taken in the event that linear flow falls below that quantity necessary for compliance with the commitments stated in the license application. Example of corrective actions: Replacement of clogged or saturated charcoal filter; replacement of inoperable or fatigued fan motor; repair of crimped or defective duct work, etc.

# Radioiodine Fume Hood



Constructed of 3/8" clear plexiglass, this rugged Radioiodine Fume Hood is designed to meet the problems associated with iodination procedures. The large internal work area and spacious arm ports allow maximum uninhibted manipulation of material within the unit. A 24" x 13" swing-away front door permits easy placement and retrieval of items. An air baffle assures an even flow speed of air out of the box. Negative air flow speed can be adjusted from 0 to a maximum of 80 CFM. The motor is a UL approved induction type. The disposable charcoal filter traps 98% of the radioiodine produced. Each unit can accommodate up to two filters. One filter is supplied with the system.

SPECIFICATIONS:

**Motor:** 1/45 H.P. 61 Watts, 3/4 Amps, 110 V.A.C. 50/60 Hz.

**Glove Box:** 24" x 20" base, 36" height

190-210 Radioiodine Fume Hood . . . . . $1475.00
112-036 Replacement Charcoal Filter . . . 95.00

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Procedures for Completion of 131-I Air Monitoring

The following pages give detailed instructions for performing I-131 air monitoring including operating procedures for air filters. This is followed by installation instructions.

Procedures for 131-Iodine Air Monitoring

a. Discussion

1. The handling of certain volatile radioactive materials may require that air sampling be performed to document that maximum permissible concentrations (MPC) are not exceeded in either restricted or unrestricted areas.

2. Acceptable methods include: (1) air sampling data and/or (2) calculations, if those calculations can demonstrate that the MPC for a particular substance is not exceeded. A good example of the use of calculations for this purpose is the 133-Xenon. If calculations are submitted, it is necessary to document those specifications and measurements (such as fume hood flow in cfm, etc.) are checked periodically to insure that the conclusions made from the calculations have not changed.

3. For volatile 131-Iodine, the approach of using calculations may be taken to document that the MPC is not exceeded. However, since many facilities are required to use air sampling data by the conditions of their license or license application, the following procedure is provided and is to be used with Form RS-55, or an equivalent form.

b. Equipment

1. Vacuum pump with known rated air flow or preferably an air flow gauge.

   Because we will operate our air sampling equipment continually, evaluation of the effluent concentration should be done in 24 hour increments or multiples of 24 hour increments. The activity in the filters must be measured each day that liquid Iodine-131 is handled or routinely every 24 hours.

2. Appropriate tubing.

3. Filter holder

4. Charcoal impregnated filter paper.

5. Scintillation well counter assembly and appropriate counting vials.

c. Operating Procedure for Air Filters

1. Mount the air sampling apparatus in a manner which will insure that effluents being released to both restricted and unrestricted areas will be sampled. See FIGURE 8.55-2 for an example of where the sampling filters may be located for sampling effluents being released to an unrestricted area. Sampling may be done in the exhaust vent pipe on the down stream side of any additional air filtering system. Be sure that the standard laboratory fume hood sash opening is closed as far as possible so that the face velocity across the fume hood opening is increased. This minimizes the escape of volatile I-131 Iodine into the restricted area.

2. The activity in the filter must be measured within 24 hours after handling the last 131-Iodine Solution.

3. To measure the activity in the filter from each holder:

   (a) Fold or roll up the filter, if applicable, using clean disposable gloves;

   (b) Place the filter in a counting vial or in the same geometrical configuration as the standard source; and,

   (c) Count it in or on the gamma well. Make sure that the analyzer window is set for 131-Iodine and that an efficiency factor ($F_e$ 131-Iodine) for this analyzer setting has been calculated.

4. Record the well counter background and net 131-Iodine count on Form RS-55.

5. Record the sampling pump air flow in ml from measured flow of vacuum pump.

d. Procedure for Calculating Concentration of Volatile Iodine

1. The following calculations may be used to determine the concentration of volatile iodine in uCi/ml in the restricted and unrestricted areas. (See worksheet given in Figure 8.55-3.)

   (a) Calculate "pump on duration" from pump on and off times.

   (b) Determine uCi of 131-Iodine present on filter using:

$$131\text{-Iodine uCi} = \frac{\text{Net cpm (filter)}}{2.2 \times 10^6 \text{ dpm/uCi} \times F_e \text{ 131-I}}$$

   (c) Determine ml of air flow through sampling pump from:

      1. Direct pump flow data x time

2. Pump flow data converted to ml/min x time

(d) Calculate uCi/ml of 131-Iodine concentration using the formula below.

$$\frac{\text{uCi 131 - I}}{\text{ml of flow through pump}}$$

(e) The maximum permissible concentrations are:

(i) For unrestricted area MPC = $1 \times 10^{-10}$ uci/ml
(ii) For restricted area MPC = $9 \times 10^{-9}$ uCi/ml

2. Useful Conversion Factors are:

(a) 1 $ft^3$ = $2.832 \times 10^{-2}$ $M^3$ = $2.832 \times 10^4$ ml
(b) 1 $ft^3$/min = $2.832 \times 10^4$ ml/min
(c) 1 $ft^3$/min = 28.3 liters/min
(d) 1 uCi = $10^{-3}$ mCi
(e) inches of Hg (see graph)
(f) ratio of Photon yield $\frac{\text{I-131}}{\text{Ba-133}} = R_p$

8.55.3.2 Procedures for Installation

a. Filter Holder #1 should be mounted on the OUTSIDE of the 131-Iodine hood above the area where an individual would be working. This filter monitors the air in a RESTRICTED area at the level of the operators breathing zone.

b. Filter Holder #2 should be an in-line filter with the sampling tube mounted in the vent stack. This filter monitors the air to the UNRESTRICTED area, i.e., the air being vented to the environment.

c. See FIGURE 8.55-2.

* If a Barium-133 standard is used, $F_e$ or CF may be corrected for photon yield, however, the actual correction factor is dependent on the equipment used to obtain your data.

SKETCH OF METHOD FOR MOUNTING
AIR SAMPLING APPARATUS



STANDARD LABORATORY FUME HOOD

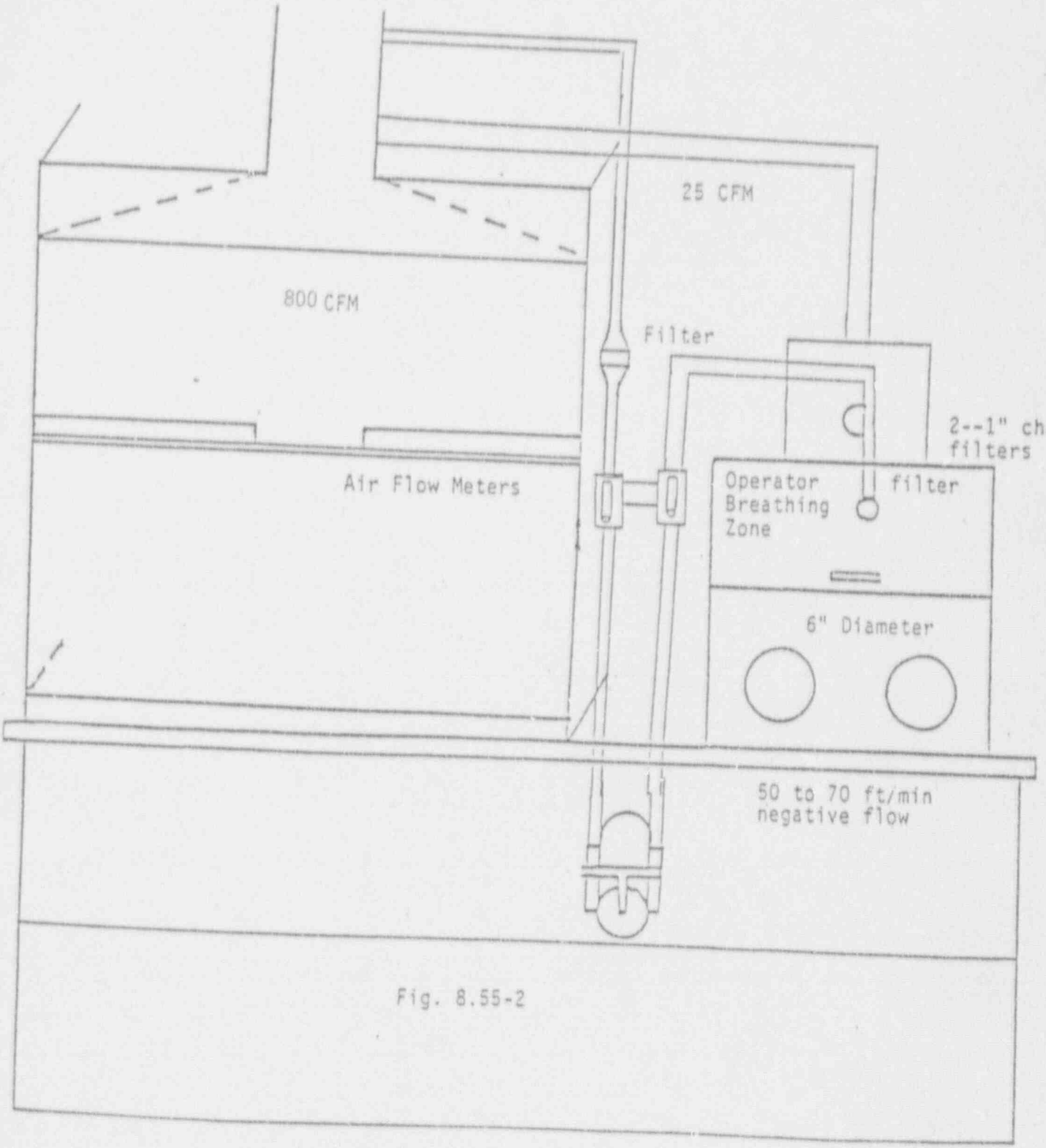


Fig. 8.55-2

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115573

# 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 gasket and is opened by ¼ turn • filter support screen is stainless steel • plastic cap provided to protect collected samples

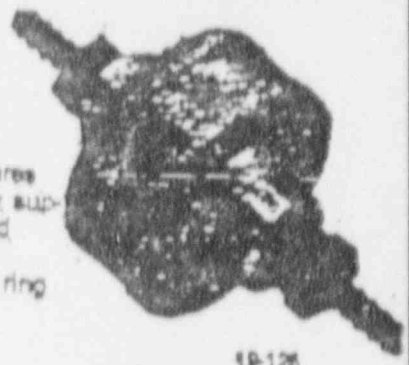
19-124 $90.00

19-124

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

19-126 $90.00



19-126

AIR SAMPLER,
CLOSED TYPE

• constructed of polycarbonate • designed for sampling from air ducts or other closed systems • accommodates 47 mm filters • effective filter area 14.5 sq. in.

19-225 $23.75

19-225

AIR SAMPLER,
OPEN TYPE

• constructed of polycarbonate • for air monitoring or aerosol sampling • accommodates 47 mm filter • effective filter area 10.6 sq. in.

19-226 $19.75

19-226

# 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 | 19-145 | $3.65 |
| Glass Fiber Filter, 25 mm diameter | 19-146 | 4.75 |
| Glass Fiber Filter, 47 mm diameter | 19-147 | 5.40 |

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-5 um | 19-139 | $26.75 |
| Nitrocellulose Filters, 25 mm-5 um | 19-140 | 28.40 |
| Nitrocellulose Filters, 47 mm-5 um | 19-141 | 42.50 |
| Nitrocellulose Filters, 13 mm-0.8 um | 19-142 | 26.75 |
| Nitrocellulose Filters, 25 mm-0.8 um | 19-143 | 28.40 |
| Nitrocellulose Filters, 47 mm-0.8 um | 19-144 | 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 | 19-171 | $13.00 |
| Charcoal Impregnated Filter Paper, 47 mm | 19-172 | 13.00 |

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LA(3.31(02/03/86)

Syncor Int'l Corporation # 010

Date 09/19/91

131-I RELEASED (YTD)



, Id : 010 Indianapolis, IN

Year: 1991

| Sampling Date/Time | | I131 Collected | Air Flow Sampled | Avg I131 Concentration | Fume Hood Flow Rate |
|---|---|---|---|---|---|
| 09/04/91 | 08:40 | 0.0001273090 uCi<br>1.274E-04 uCi | 14540000 ml<br>1.450E+07 ml | 0.0000000000088 uCi/ml<br>8.800E-12 uCi/ml | 823 cfm |
| 09/09/91 | 08:40 | 0.0000653094 uCi<br>6.531E-05 uCi | 43200000 ml<br>4.320E+07 ml | 0.0000000000015 uCi/ml<br>1.500E-12 uCi/ml | 823 cfm |
| 09/10/91 | 09:06 | 0.0000865559 uCi<br>8.656E-05 uCi | 14660000 ml<br>1.470E+07 ml | 0.0000000000059 uCi/ml<br>5.900E-12 uCi/ml | 823 cfm |
| 09/11/91 | 08:44 | 0.0000442630 uCi<br>4.426E-05 uCi | 14180000 ml<br>1.420E+07 ml | 0.0000000000031 uCi/ml<br>3.100E-12 uCi/ml | 823 cfm |
| 09/12/91 | 09:00 | 0.0000973271 uCi<br>9.733E-05 uCi | 14560000 ml<br>1.460E+07 ml | 0.0000000000067 uCi/ml<br>6.700E-12 uCi/ml | 823 cfm |
| 09/13/91 | 08:35 | 0.0000533010 uCi<br>5.330E-05 uCi | 14150000 ml<br>1.420E+07 ml | 0.0000000000038 uCi/ml<br>3.800E-12 uCi/ml | 823 cfm |
| ,16/91 | 08:36 | 0.0000691285 uCi<br>6.913E-05 uCi | 43210000 ml<br>4.320E+07 ml | 0.0000000000016 uCi/ml<br>1.600E-12 uCi/ml | 823 cfm |
| 09/17/91 | 09:00 | 0.0000737655 uCi<br>7.377E-05 uCi | 14640000 ml<br>1.460E+07 ml | 0.0000000000050 uCi/ml<br>5.000E-12 uCi/ml | 823 cfm |
| 09/18/91 | 08:42 | 0.0000612120 uCi<br>6.121E-05 uCi | 14220000 ml<br>1.420E+07 ml | 0.0000000000043 uCi/ml<br>4.300E-12 uCi/ml | 823 cfm |
| 09/19/91 | 11:22 | 0.0000295110 uCi<br>2.951E-05 uCi | 16000000 ml<br>1.600E+07 ml | 0.0000000000018 uCi/ml<br>1.800E-12 uCi/ml | 823 cfm |
| Totals: | | 0.0245474755 uCi<br>2.455E-02 uCi | 3759760000 ml<br>3.760E+09 ml | | |

| | | | |
|---|---|---|---|
| Avg I131 Concentration (YTD) | : | 0.0000000000 uCi/ml | 6.500E-12 |
| Avg Fume Hood Flow (YTD) | : | 818 cfm | 8.180E+02 |
| Total ml Of Fume Hood Flow (YTD) | : | 873894921600.00 ml | 8.740E+12 |
| Total I131 Released To Environment (YTD) | : | 56.80 uCi | 5.680E+01 |

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RSSS (1.0) Syncor Corp # 033 12/21/89

I-131 Air Monitoring Worksheet

---

Location Id: Sample Date: Samp): Time:

WC Serial #: Make: Model:

Desc:

Well Counter Bkg : cpm

Unrestr Filter Count: cpm Net Unrestr Filter Count: cpm

Restr Filter Count: cpm Net Restr Filter Count : cpm

I131 Cap Count: cpm Ba133 Src Count: cpm

Net Count: cpm Net Count: cpm

I131 Cap Lot : Ba133 Src Lot# :

I131 Cap Actv : uCi Ba133 Src Actv : uCi

Meas Pump Flow: ml/min Pump Flow : ml

Pump 'ON' Time: min Fume Hood Flow Rate : cf/min

(unrestricted area) (restricted area)

Total uCi of I131 : uCi uCi

'Air Conc' of I131: uCi/ml uCi/ml

MPC % : % %

Test Performed By :

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## SODIUM PHOSPHATE CAPSULE PREPARATION

### * * * MATERIALS NEEDED * * *

(1) SODIUM PHOSPHATE DI-BASIC ANHYDROUS, POWDER

Two Commercially available products:

| | | | |
|---|---|---|---|
| 1. | J.T. BAKER | 500 MG | CAT. # 3828-1 |
| 2. | MALLINCKRODT | 500 MG | CAT. # 7917-1 |

(SPECIAL NOTE) THE SODIUM PHOSPHATE MUST BE ACS REAGENT GRADE, ACCORDING TO THE USP MONOGRAPH.

THE SODIUM PHOSPHATE SHOULD BE STORED "TIGHTLY SEALED" TO ASSURE FRESHNESS. BY LEAVING THE JAR UNCAPPED FOR EXTENDED PERIODS OF TIME DEFEATS THE PURPOSE OF "BEING ANHYDROUS".

(2) SIZE #1 GELATIN CAPSULES

(SPECIAL NOTE) GELATIN CAPSULES SHOULD NOT BE BRITTLE. THEY SHOULD WE PLIABLE TO THE TOUCH. THE CAPSULES WILL BECOME BRITTLE WITH AGE; AND BRITTLE IF STORED NEXT TO EXCESSIVE HEAT.

(3) LATEX GLOVES

(SPECIAL NOTE) BY WEARING LATEX GLOVES NOT ONLY DO YOU PROTECT YOUR SKIN FROM THE SODIUM PHOSPHATE, THE GLOVES PROTECT THE CAPSULES FROM THE MOISTURE OF YOUR SKIN.

(4) GLASS PILL TILE / SPATULA

(SPECIAL NOTE> IF A GLASS PILL TILE OR OINTMENT SLAB IS NOT AVAILABLE IT IS NOT NECESSARY TO PURCHASE ONE. YOU CAN IMPROVISE BY USING A FLAT COUNTER TOP WITH A SHEET OF WAXED PAPER.

(5) AIR-TIGHT STORAGE CONTAINER

(SPECIAL NOTE) A CAPPED 20 DRAM PLASTIC RX VIAL FITS NICELY INSIDE A 40 DRAM PLASTIC RX VIAL. THIS METHOD OF STORAGE PROTECTS THE CAPSULES FROM MOISTURE.

## SODIUM PHOSPHATE CAPSULE PREPARATION

### * * * FILLING PROCEDURE * * *

(1) ON A CLEAN GLASS PILL TILE PLACE A SMALL PORTION OF SODIUM PHOSPHATE POWDER.

(2) USE A SPATULA (OR PIECE OF WAXED PAPER) TO PACK DOWN THE POWDER. BE SURE THE SODIUM PHOSPHATE POWDER IS PACKED TIGHTLY.

(3) WEARING LATEX GLOVES, FILL THE LONG END OF THE #1 CAPSULE WITH AS MUCH SODIUM PHOSPHATE POWDER AS POSSIBLE. (THE PIGGY-BACK FILLING METHOD OFTEN TAUGHT IN PHARMACY SCHOOL IS NOT THE PREFERRED METHOD SINCE IT DOES NOT ALLOW YOU TO PACK THE CAPSULES THE FULLEST YOU POSSIBLY CAN) INSTEAD BE SURE TO HOLD THE CAPSULE DIRECTLY IN YOUR HAND AND PUNCH UNTIL THE CAPSULE IS FULL. FILL THE SHORTER-HALF CAPSULE APPROXIMATELY TWO-THIRDS FULL. PLACE THE TWO ENDS FIRMLY TOGETHER AND BE SURE THE CAPSULE FEELS VERY HARD WHEN PRESSED BETWEEN YOUR FINGERS.

(4) MAKE TWENTY (20) OR MORE SODIUM PHOSPHATE CAPSULES DEPENDING ON YOUR USAGE. STORE IN AN AIR-TIGHT CONTAINER IN THE FREEZER.

(SPECIAL NOTE) WHEN A LIQUID REACTS WITH SODIUM PHOSPHATE ANHYDROUS AN "EXOTHERMIC" REACTION OCCURS, HEAT IS RELEASED THEREFORE BY STARTING WITH A VERY COLD SODIUM PHOSPHATE CAPSULE YOU REDUCE THE CHANCE OF MELTING THE GELATIN CAPSULE UPON INJECTION OF LIQUID SODIUM IODIDE.

# SODIUM IODIDE I-131 CAPSULE PREPARATION

## * * * MATERIALS NEEDED * * *

(1) CIS I-131 TX SOLUTION

(2) SODIUM PHOSPHATE SIZE #1 CAPSULES

(3) B-D LO DOSE (0.5 CC INSULIN) SYRINGES

(4) DISPENSING CONTAINER

(5) LEAD DISPENSING/SHIPPING CONTAINER

(6) LEAD "CAPSULE HOLDER" ( See diagram "A")

(7) 1 CC TUBERCULIN SYRINGE SHIELD

(8) TONGS

(9) "BROWER'S" MODIFIED STRAW (USED TO PICK UP CAPSULE SHELL)

(10) LATEX GLOVES

(11) SHOULDER LENGTH PLASTIC GLOVES
One Commercially available product:
1. LAB SAFETY SUPPLY "DISPOSABLE POLYETHYLENE GLOVES" Order No. 3217

## LEAD CAPSULE HOLDER

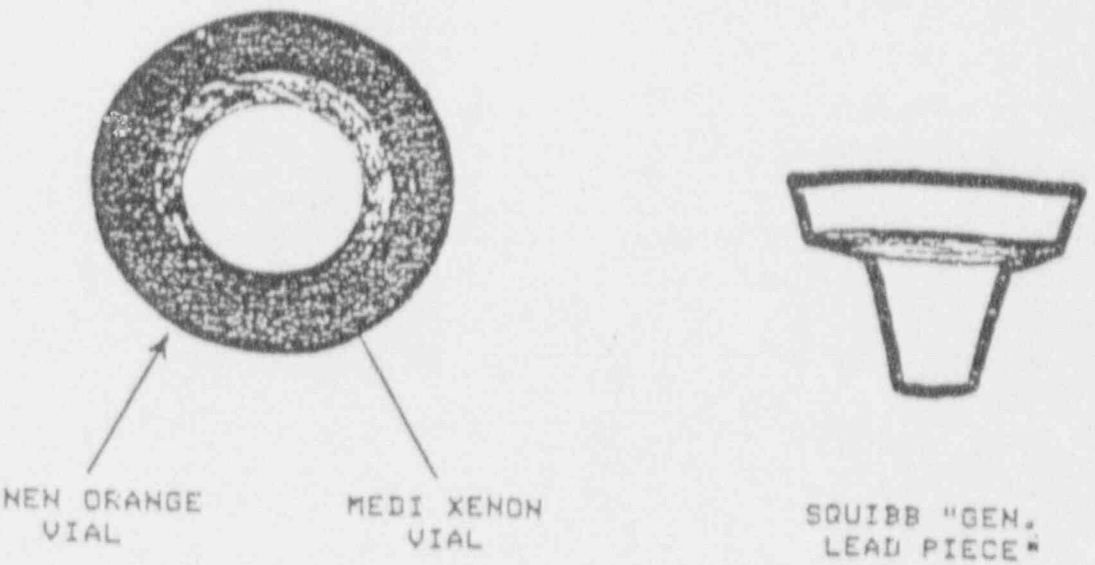
MATERIALS NEEDED: ONE ORANGE DUPONT LEAD CONTAINER
( DUPONT GA-67 LEAD CONTAINER )

ONE MEDI-PHYSICS XENON LEAD CONTAINER

ONE SQUIBB "GENERATOR LEAD PIECE"
( Scavenged lead portion from the Squibb generator's needle adaptor assembly )

INSERT THE MEDI LEAD XENON CONTAINER INTO THE ORANGE DUPONT LEAD CONTAINER. HAMMER THE XENON LEAD CONTAINER UNTIL IT IS ALL THE WAY INTO THE ORANGE ONE. PLACE THE SQUIBB "GENERATOR LEAD PIECE" ON TOP OF THE ORANGE LEAD CONTAINER.

( DIAGRAM A )

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## SODIUM IODIDE I-131 CAPSULE PREPARATION

### * * * COMPOUNDING PROCEDURE * * *

(1) TURN ON THE FUME HOOD AND I-131 GLOVE BOX IF NOT ALREADY OPERATING. CHECK TO MAKE SURE THE EQUIPMENT IS OPERATING PROPERLY.

(2) TURN ON THE VACUUM PUMP FOR AIR MONITORING IF NOT ALREADY OPERATING. CHECK TO MAKE SURE THE GAUGES AND VACUUM PUMP ARE OPERATING PROPERLY.

(3) WEAR TWO (2) PAIR(S) OF GLOVES. FIRST, PUT ON A PAIR Of SHOULDER LENGTH PLASTIC GLOVES. NEXT, PUT ON A PAIR OF LATEX GLOVES OVER THE SHOULDER LENGTH GLOVES YOU ARE WEARING.

(4) PERFORM AN AREA SURVEY OF THE I-131 GLOVE BOX AND WORK AREA TO SURE THAT IT IS CONTAMINATION FREE. IF NOT, DECONTAMINATE THE WORK AREA BEFORE YOU START. ALWAYS USE ALARA PRINCIPLES!

( SPECIAL NOTE ) A SURVEY METER EQUIPPED WITH A PANCAKE PROBE IS IDEAL FOR ISOLATING I-131 CONTAMINATION. THIS PROBE IS EXTRA SENSITIVE TO BETA-RADIATION; MORE SO THAN A GM SIDEWALL PROBE.

(5) CALCULATE THE AMOUNT OF I-131 SOLUTION NEEDED TO FILL THE PRESCRIPTION. REMEMBER TO TAKE INTO CONSIDERATION "DECAY" IF THE THERAPY CAPSULE IS FOR THE NEXT DAY. ALSO THE RESIDUAL VOLUME LEFT IN THE LO-DOSE SYRINGE WILL BE APPROXIMATELY 200-400 uCi. THIS MUST ALSO BE TAKEN INTO CONSIDERATION ESPECIALLY WHEN VERY LOW MILLICURIE CAPSULES ARE MADE.

(6) IN THE IODINE GLOVE BOX VENT THE I-131 SOLUTION THROUGH A CHARCOAL SYRINGE. NEXT, DRAW UP THE ACTIVITY NEEDED IN A SHIELDED LO-DOSE SYRINGE AND ASSAY. (SPECIAL NOTE) DO NOT EXCEED CAPSULE VOLUME CAPACITY. IF THE PRESCRIBED DOSE EXCEEDS THIS, A SECOND CAPSULE SHOULD BE MADE. IN ADDITION, ONLY FILL THE SYRINGE WITH THAT AMOUNT OF SOLUTION TO BE INJECTED INTO A SINGLE CAPSULE.

(7) PLACE THE SHIELDED I-131 LO-DOSE SYRINGE AND I-131 SOLUTION IN THE FUME HOOD SO IT IS OUT OF THE WAY.

(8) SET UP THE ORANGE DUPONT LEAD VIAL WITH THE SQUIBB GEN. LEAD PIECE ON TOP. THIS SET-UP WILL BE REFERRED TO AS THE "LEAD CAPSULE HOLDER".

(9) TAKE A SMALL PIECE OF SARAN WRAP (APPROX. 3" X 3" ) AND PLACE ON TOP OF THE LEAD CAPSULE HOLDER.

(10) SEPARATE A SIZE "0" GELATIN CAPSULE. TAKE THE LONG END AND PUSH THE PLASTIC WRAP INTO THE LEAD CAPSULE HOLDER.

(11) PLACE A SODIUM PHOSPHATE CAPSULE (FROM THE FREEZER) INTO THE SHIELDED SIZE "0" CAPSULE.

(12) TAKE AN EMPTY LO-DOSE SYRINGE AND BORE A PILOT HOLE THROUGH THE CENTER

TOP OF THE SODIUM PHOSPHATE CAPSULE. (SPECIAL NOTE) THIS PROCEDURE WILL PREVENT CORING WHICH VERY OFTEN CLOGS THE NEEDLE.

(13) INSERT THE NEEDLE OF THE SHIELDED I-131 DOSE INTO THE HOLE AS FAR AS IT WILL GO. INJECT THE CAPSULE WITH A SLOW BUT CONSTANT INJECTION. (SPECIAL NOTE) IF YOUR INJECTION IS MADE TOO SLOWLY, YOU INCREASE THE CHANCES THAT THE SODIUM PHOSPHATE POWDER WILL HARDEN PREMATURELY BEFORE YOU ARE ABLE TO MAKE THE ENTIRE INJECTION. IF YOUR INJECTION IS MADE TOO QUICKLY, THE SODIUM PHOSPHATE'S ABILITY TO ABSORB THE SOLUTION WILL BE EXCEEDED. THIS WILL BE OBVIOUS BY THE DISTORTED APPEARANCE OF THE FINISHED CAPSULE.

(14) ONCE THE INJECTION IS COMPLETE, REMOVE THE NEEDLE FROM THE CAPSULE AND CAP. PLACE THE EMPTY I-131 SYRINGE IN ITS HOLDER AND STORE IN THE FUME HOOD OUT OF THE WAY.

(15) USING A "BROWER'S" MODIFIED STRAW, PICK UP THE OTHER SIZE "0" CAPSULE HALF AND PLACE ON THE CAPSULE IN THE LEAD CAPSULE HOLDER. INVERT THE STRAW AND TAP IT DOWN TIGHTLY.

(16) REMOVE THE CAPSULE BY INJECTING THE SQUIBB GEN. LEAD PIECE ONTO A SECOND ORANGE LEAD CONTAINER THAT HAS A "DISPENSING CONTAINER" WITHIN. WITH AN EMPTY LO-DOSE SYRINGE PUSH THE CAPSULE THROUGH THE SQUIBB GEN. LEAD PIECE SO IT DROPS INTO THE DISPENSING CONTAINER.

(17) REMOVE THE SQUIBB GEN. LEAD PIECE AND CAP THE DISPENSING CONTAINER INSIDE. COVER THE ORANGE LEAD CONTAINER WITH IT'S LEAD TOP.

(18) ASSAY THE I-131 THERAPY CAPSULE; ACCOUNT FOR DECAY; AND ASSURE THAT THE FINISHED CAPSULE STRENGTH IS NOT GREATER THAN 10% WHICH WAS ORDERED.

(18-A) CLEAR WORK AREA.

(19) REMOVE YOUR LATEX GLOVES AND REPLACE WITH NEW ONES. (MAKE THIS STEP A PART OF YOUR NORMAL ROUTINE) (SPECIAL NOTE) IF FOR ANY REASON YOUR OUTER GLOVES ARE CONTAMINATED IT IS IMPORTANT TO CHANGE THEM NOW TO ASSURE THAT YOU DON'T CONTAMINATE THE LEAD SHIPPING CONTAINER;

(20) DISPENSE THE I-131 THERAPY CAPSULE IN A HEAVY LEAD CONTAINER. (SPECIAL NOTE) IT IS RECOMMENDED THAT A WET SMEAR BE PERFORMED ON THE LEAD CONTAINER TO ASSURE THAT THERE IS NO REMOVABLE CONTAMINATION.

(21) REMOVE THE SHIELDED I-131 SYRINGE FROM THE FUME HOOD AND PLACE IN THE I-131 GLOVE BOX. RINSE THE SYRINGE INTO A SHIELDED 10cc OR 20cc SALINE "WASH VIAL". STORE THE I-131 "WASH VIAL" IN THE FUME HOOD FOR FUTURE USE. DISPOSE OF THE I-131 SYRINGE IN THE APPROPRIATE RADIOACTIVE WASTE BIN.

(SPECIAL NOTE) THIS RINSE PROCEDURE WILL HELP CONTAIN THE I-131 IF IT BECOMES VOLATILE AND THEREFORE HELP REDUCE AIRBORNE I-131 CONTAMINATION.

(22) PERFORM AN AREA SURVEY OF THE I-131 GLOVE BOX AND OTHER IMMEDIATE WORK

AREAS TO ASSURE IT IS CONTAMINATION FREE. DECONTAMINATE IF NECESSARY !

(23) FOLLOW THE AIR MONITORING PROCEDURE AS OUTLINED IN YOUR NRC OR AGREEMENT STATE LICENSE.

(24) FOLLOW THE THYROID BIOASSAY PROCEDURE AS OUTLINED IN YOUR NRC OR AGREEMENT STATE LICENSE.

REVISED 5-3-87

Discussion: We are now using I-131 therapy solution which comes in sealed containers. The I-131 solution is very high concentration material, so if any contamination exist as a result of handling this material, the contamination can contribute to volatile Iodine levels, which we may not have experienced before.

The diagnostic capsules are shipped, so that, when we receive them, they are in a sealed container. If any volatilization occurs in shipping, (capsules do volatilize), then you may find some volatile Iodine escaping when you open the container and you may find some contamination on the shielding material.

Because of all of the above, steps must be taken to prevent or limit the amount of volatile I-131 that is released into our pharmacy or to the environment.

The following precautions must be taken for receipt and handling of this material:

A. CHECK IN PROCEDURE

1. Follow routine procedures for receipt of radioactive material.

2. When performing the wipe test on the inner source container, the sealed tin can should be thoroughly wipe tested.

3. Use an alcohol moistened 1" x 1" swipe and wipe the entire surface of the can.

4. Count it in (not on your well counter).

5. If no contamination is found on this sealed tin can > 0.01 uCi, (22,000 DPM), place it in storage until it becomes necessary to use it. If significant contamination is found, report your findings to the RSO and double seal the container and place it in storage. (Zip lock or heavy plastic bags are recommended.)

NOTE: If the tin can is not contaminated and remains sealed, it should be stored sealed until ready to use. All I-131, regardless of whether it is sealed or unsealed, must be stored in accordance with the conditions stated in your NRC/Agreement State license application.

B. PREPARATION FOR USE

1. For both therapy solution and diagnostic capsules, open the sealed tin can in you charcoal filtered I-131 glove box.

2. Remove the lead shield and perform a wipe test on it. If significant contamination is found, then this shield shall be replaced with an uncontaminated shield. The contaminated shield shall be double sealed and placed in waste storage along with the tin can, since it will also be contaminated.

3. Store your diagnostic capsules in the standard laboratory fume hood in a sealed plastic bag.

4. To prevent the possibility of volatile I-131 escaping from the therapy solution, and as a precaution to prevent contamination, release the partial pressure over the liquid I-131 by venting it through a 10 cc or larger charcoal filled syringe barrel.

   a. To prepare this syringe, add a cotton pledget to the syringe, fill with charcoal, and add a cotton pledget to the top of the charcoal.

5. If you do not require a high concentration of I-131, you may wish to buffer the solution or use a buffer as a diluent when preparing liquid I-131 therapy doses.

C. CONTAMINATION CONTROL

1. After each use of I-131 solution, the area where this material was handled must be cleaned up and decontaminated immediately. Since we are dealing with a highly concentrated I-131 solution, contamination significantly contributes to volatile I-131. Attached are procedures for handling and clean up procedures for use with an I-131 fume hood.

2. After use, make sure you clean the vial septum thoroughly with an alcohol swab. Rinse out the I-131 syringe into a sealed vial containing saline at least 10 times to insure that the syringe will be decontaminated prior to being stored.

3. It is highly recommended that liquid I-131 be handled in a double charcoal filtered glove box, which is located outside of your standard laboratory fume hood. The effluent from this glove box should be piped to the lab fume hood, thereby, insuring that MPC levels are not exceeded and contamination is isolated to the glove box area. In this matter, you prevent cross contamination between the area where you handle and the area where you store volatile materials. Since we are anticipating more extensive use of I-131 in the future, you should purchase a glove box and <u>two</u> filters at this time. This I-131 hood is the Atomic Products Model No. 190-210.

RSO PROCEDURES FOR CONTAMINATED SOURCES

1. In case of a contaminated I-131 shipment of therapy solution or diagnostic caps, you must make a decision whether you wish to use the material or place it in storage for decay. If you choose to use the material, you must proceed through steps B.1 and B.2 to insure that potential sources of volatile Iodine 131 are kept to a minimum.

2. Any regulatory requirements, with respect to incident or package opening procedures, must be implemented.

I. Use and Maintenance of I-131 Glove Box

NOTE: At installation and prior to use, the linear flow across the arm ports 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 laboratory fume hood on. Quarterly measurements will be obtained and documented to insure that the unit continues to operate at this base line level determination, with respect to negative linear flow.

a. Procedures for Use

1. Put on disposable gloves.

2. Turn on exhaust fan and adjust to maximum flow to insure negative pressure in the system. Check flow with the velometer.

3. Set up apparatus, vials, shields, etc., in hood behind L-block shield ready for I-131 transfer to insure that transfer time is minimal.

4. Placed sealed stock solution of I-131 Iodine in hood behind the L-block shield on the absorbent pad.

5. The air sampling system must be on during this procedure.

6. Transfer I-131 Iodine from stock solution to prescribed unit dose form. Make sure to recap or seal vials immediately after transfer.

7. Using forceps or a remote handling device, assay unit dose in dose calibrator.

8. Prepare for shipping.

9. Replace stock I-131 in storage.

10. With a low level survey meter and pancake probe, survey the I-131 glove box and record on form provided.

11. Clean up and change absorbent pad, if necessary (survey meter

readings will indicate if the pad is contaminated).

12. After glove box clean up, survey again, and record on form provided.

NOTE: If initial survey, with a pancake probe, indicated radiation levels no greater than background or no contamination, it is unnecessary to survey after clean up. If contamination was present on initial survey and on the after clean up survey, perform wipe test and decontaminate Iodine Hood until removable contamination is less than 2200 DPM/100 cm.

NOTE: Liquid I-131 used by Syncor is obtained from a sealed system (similar to a multi-dose vial for parenteral use).

b. Maintenance Procedures

NOTE: Very little maintenance is necessary on this unit, since it has only a UL approved induction type motor and potentiometer.

1. When performing charcoal filter surveys, observe the fan motor. If dusty or dirty, clean with a dry cloth.

2. To insure that the system is operating properly, a determination of linear flow at the arm ports will be taken quarterly using an anemometer. This value will be compared to the base line determination obtained at installation. If flow decreases below 20% of the base line values, the filter(s) will be changed to insure proper operation.

c. Procedure for Survey and Change of Filter

1. Disconnect exhaust pipe connector to fume hood.

2. Lift filter housing lid.

3. Put on disposable gloves.

4. Remove top filter and survey with low level survey meter and pancake probe, and record mr/hr or CPM on form provided.

5. Set filter on absorbent pad provided in standard laboratory fume hood.

6. Remove bottom filter and survey with low level survey meter. Record mr/hr or CPM on form provided.

7. Calculate the ratio of the radiation level on the top filter to the radiation level on the bottom filter, and express it as a percentage.

When the top filter radiation level is equal to or greater than 10% of the bottom filters radiation level, then the bottom filter should be discarded into RAM waste storage (make sure you seal the charcoal filter in a plastic bag before discarding into RAM waste).

8. Replace top charcoal filter in unit. This filter now becomes the bottom filter.

9. Replace new (unused) filter into unit (top filter) close baffle housing lid and reconnect unit to fume hood.

*NOTE: The charcoal filters in this device are surveyed weekly, however, the bottom filter is replaced as necessary only when the top filter indicates that the bottom filter allows greater than 10% of the I-131 to pass through it.*

# ITEM 10 - NRC 313

## RADIATION SAFETY PROGRAM

### Item 10.1 PERSONNEL MONITORING PROGRAM

We confirm that we have established and agree to implement written personnel monitoring procedures. As a minimum, these written procedures will require:

a. That whole body film badges be provided to personnel who enter restricted areas under the circumstances described in 10 CFR 20.202.

b. That whole body film badges and finger extremity monitors (e.g., thermoluminescence dosimeter, also called "TLD") be provided to personnel who elute, prepare, assay, or dispense millicurie quantities of radioactive material.

c. That whole body and extremity monitor badges be exchanged for processing at least monthly.

d. That whole body and extremity monitor badges be processed by a commercial dosimetry service company and/or a processor accredited by the National Voluntary Laboratory Accreditation Program.

e. That any pocket dosimeters used to measure exposure from licensed material be calibrated and tested for drift at least annually.

### Item 10.2 INSTRUMENTATION

Syncor will have in its possession and available for use at the time that it begins operation the instrumentation specified in (1) through (4) of Item 10.2.2 of the "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" dated August, 1985.

### Item 10.3 CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

X 1. Survey instruments will be calibrated, before use, annually and following repair.

X 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ±10 percent of the calculated or known values for each point checked. Readings within ±20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ±10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated:

X a. By the manufacturer.

___ b. At the licensee's facility.

1. Calibration source:
Manufacturer:
Model No.:
Activity:
Accuracy:
Traceability to primary standard:

2. The calibration procedures in Section I of Appendix D of the USNRC's "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" (dated August 1985) will be used.

X c. By the following licensed consultants or outside firms which are licensed to provide instrument calibration services to other licensees.

1. SYNCOR INTERNATIONAL CORPORATION
5347 West 86th Street
Indianapolis, IN 46268
NRC License #13-19229-01MD

2. SYNCOR INTERNATIONAL CORPORATION
6301 Winchester Avenue
Kansas City, MO 64133
NRC License #24-16617-01MD

3. SYNCOR INTERNATIONAL CORPORATION
16141 Leadwell Street
Van Nuys, CA 91406
California Radioactive Material License #3822-70

4. SYNCOR INTERNATIONAL CORPORATION
2612 North 7th Street
Phoenix, AZ 85006
Arizona Radioactive Material License #7-123

c. Syncor will maintain records of each calibration for at least two (2) years after each calibration.

As an option we request authorization to have survey meters calibrated by any consultant or outside firm licensed to provide instrument calibration services to other licensees.

Item 10.4 CALIBRATION OF DOSE CALIBRATORS

Syncor has adopted the dose calibrator calibration program describe in appendix E of the "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" dated August 1985.

Item 10.5 PROCEDURES FOR RECEIVING SHIPMENTS CONTAINING RADIOACTIVE MATERIAL

Syncor has adopted the package receipt procedures described in appendix F of the "Guide for the Preparation of Applications for a Nuclear Pharmacy License" dated August, 1985.

Item 10.6 PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Syncor has adopted the package opening procedure described in appendix G of the "Guide for the Preparation of Applications for a Nuclear Pharmacy License" dated August, 1985.

Item 10.7 GENERAL PROCEDURES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

Syncor has adopted the general rules for safe use of radioactive material described in appendix H of the "Guide for the Preparation of Applications for a Nuclear Pharmacy License" dated August 1985.

Item 10.8 EMERGENCY PROCEDURES

Syncor has adopted the emergency procedures described in appendix I of the "Guide for the Preparation of Applications for a Nuclear Pharmacy License" dated August, 1985.

## Item 10.9 PROCEDURES FOR RETURNING RADIOACTIVE WASTE FROM CUSTOMERS

Request for Authorization to Collect Radioactive Waste

1. Packaging and pick up from customers.

   A. Type of radioactive waste.

      Radioactive waste picked up will be comprised of plastic syringes, needles, needle covers, vials, and depleted sealed sources which have been used by nuclear medicine departments serviced by Syncor. These items will represent solid waste which has contained radio-pharmaceutical substances, which are listed in our Materials License.

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

      1. It must be emphasized that unit dose material represents very low level radioactive waste. With the exception of vials, which have contained radiopharmaceuticals, the syringes will have been flushed out with patient blood in the process of injecting the patient. Also, because of the routine of a nuclear pharmacy, these materials will be retrieved 24 hours after use; therefore, the Tc-99m products will have decayed at the user's site for at least three half-lives. Those vials retrieved as waste represent a very small portion of the waste in this system. Examples of vial waste would be I-131 oral therapy vials, and I-131 IHSA vials. This represents 5% of the waste retrieved from the customer. It must also be pointed out that each unit dose syringe or vial is identified by prescription number and radiopharmaceutical. This is required by state pharmacy regulations. Therefore, returned, used materials are easily identifiable.

      2. See following procedures for returning used unit dose containers to Syncor Corp.

      3. The following is the procedure for receiving waste at Syncor:

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

         a. Open unit dose, identify material (by Rx label).

         b. Dump used unit dose container directly from shield into bin provided. Touch only the outside of the unit dose shield.

         c. Survey unit dose container for contamination with a low level survey meter. If a unit dose shield demonstrates activity levels greater than background, remove from service, and place in storage area for decay to background levels. When surveying unit dose shields for reuse, any unit dose shield which demonstrates a survey meter response greater than background must be wipe tested. If wipe test samples demonstrate contamination levels greater than

200 dpm/100 $cm^2$, the unit dose shield should be decontaminated until less than 200 dpm/100 $cm^2$ contamination is detected.

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

All radiopharmaceuticals will be transported by courier or in our vehicles by delivery personnel employed by Syncor. Only waste syringes, needles, needle covers, and vials will be accepted for pick up, if they have been returned to their original containers after use, and placed in the cases for return to the nuclear pharmacy.

D. The individual handling the radioactive waste will be a trained nuclear technologist at the hospital or clinic. The individual handling the radioactive waste at the nuclear pharmacy will meet that criteria for training established in Item 10.9 of this application. If delivery personnel, these individuals will be trained by the pharmacist in the proper techniques for handling this return waste material. Procedures for handling and disposal of radioactive waste found in this section will be used for this training. These individuals will also be trained in the proper use of, and how to read a low level survey meter. A form will be completed stating the subject matter covered, the amount of time spent in training, and certification by the pharmacist that the individual trained is competent to perform the assigned task.

E. Customers are notified that Syncor will only accept waste which results from Syncor supplied radioactive material. Any radioactive waste not resulting from Syncor supplied material is returned to the customer for disposal.

## PROCEDURE FOR RETURNING USED UNIT DOSE CONTAINERS TO SYNCOR

Syncor Corporation has been licensed by the Nuclear Regulatory Commission to pick up those materials, which after use, represent radioactive waste. Only those materials supplied to you by Syncor Corporation may be returned to the medical services center as waste.

A. Syringes, Needles, and Needle Covers:

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

2. Place the unit dose shield in the case provided for return to the Medical Services Center.

B. Unit Dose Vials; Depleted Calibration Sources:

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

2. In those situations (usually iodine-131 therapy doses) where material has been delivered to you in appropriate DOT packaging, return the vial to its container, replace in packing and seal.

C. Returning Packages:

1. Ensure that radioactivity quantities returned are equal to or less than those specified on the attached table.

2. Ensure that the radiation levels at all points on the surface of the package are equal to or less than 0.5 millirem/hr.

3. Ensure that the removable contamination does not exceed 22 $dpm/cm^2$ over a 300 $cm^2$ area.

4. Slip the over cover onto the package, or reverse the card to indicate that the package is a "Limited Quantity Shipment".

D. If you are presently using DOT shipping papers, you may wish to continue that practice as an option.

Note: A copy of the following memo will be given to all accounts:

The United States Department of Transportation adopted new regulations which bring their regulations in line with international standards for the transportation of radioactive material. NRC has also rewritten their regulations to be compatible with those of DOT.

As a result of these changes and further action by NRC, state agencies, and DOT, several regulations which affect you, our customers, are now being enforced. All packages must be transported in accordance with Department of Transportation Regulations.

In an effort to clarify these regulations, and to implement their requirements, Syncor proposes to make the following policy changes with respect to packaging, delivery, and return shipments. We ask your cooperation to make it possible for us to implement these changes.

Our system of service involves retrieving waste material from you, our customers. Because you will be returning your radioactive waste to Syncor, you now become a shipper of radioactive material.

We have looked at the new DOT regulations with respect to transporting limited shipment quantities of RAM, and because of a suggestion by a member of the DOT staff, we recommend that you utilize the provisions of this regulation (49 CFR 173.421).

Under the provisions of this regulation, the task you must perform will be minimized, and to aid you in performing these tasks, Syncor will make available to you an over cover which may be slipped over the Syncor packaging or a reversible plastic card to indicate that the return package is a "Limited Quantity Shipment".

49 CFR 173.421 states that if a package meets the following requirements, it is exempted from the specification packaging, marking, and labeling requirements.

1. That the amount of radioactivity in the package does not exceed a specified amount. (A table is attached to this letter specifying that limit for each commonly used radiopharmaceutical.)

2. The radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour.

3. The non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limited specified in 49 CFR 173.443(a).

4. Other provisions of this regulation are satisfied by Syncor's present packaging.

The tasks which must be performed are:

1. That you ensure that the waste being returned does not exceed the specified limits for "Limited Quantity Shipments".

2. That you determine that the radiation level at any point on the surface of the package does not exceed 0.5 mr/hr.

3. That you determine that the non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a), i.e., 22 dpm/$cm^2$ when wiped over a 300 $cm^2$ area.

4. That you slip the over cover, with the limited shipment quantity information on it, over the package, or reverse the card with this same information on it.

For those customers presently making our shipping papers, you may wish to continue that practice as an option.

For used Tc-99m products, the activity being returned can be estimated as shown in the example.

EXAMPLE: Assume 5% remaining in the syringe following by a 24-hour (4 half lives) decay:

$$5\% \times (1/2)^4 = 0.05 \times 0.0625 = 0.003$$

Thus, the activity from a 30 mCi dose, which normally is the maximum, is:

$$30 \text{ mCi} \times 0.003 = 0.09 \text{ mCi}$$

If ten unit dose syringes were returned (the number which fit in a case), and all had been 30 mCi doses, the package would therefore contain only 900 µCi.

The specified limited shipment quantity for Tc-99m is 10 mCi.

It may be necessary to hold unused Tc-99m doses for 48 hours (8 half lives), but depending upon the quantity of the unused dose, it may be possible to return them within 24 hours.

The total quantity of activity being returned must not exceed the specified "Limited Quantity Shipment" whether you are returning used dose material or unused doses.

For your information, we have enclosed a copy of the procedure to be followed in returning waste material to Syncor, and a copy of 49 CFR 173.421. We suggest that this procedure be posted for easy reference.

# LIMITED SHIPMENT QUANTITIES FOR EACH COMMONLY USED RADIOPHARMACEUTICAL

| RADIONUCLIDE | LIMITED SHIPMENT QUANTITY (mCi) $A_2 \times 10^{-4}$ |
|---|---|
| Co-57 | 9 |
| Co-58 | 2 |
| Cr-51 | 60 |
| Ga-67 | 10 |
| I-123 | 5 |
| I-125 | 7 |
| I-131 | 1 |
| In-111 | 2.5 |
| Mo-99 | 2 |
| P-32 | 3 |
| Se-75 | 4 |
| Tc-99m | 10 |
| Tl-201 | 20 |
| Xe-133 (uncompressed, $A_2 \times 10^{-3}$) | 1,000 |

The above values have been calculated using information from 49 CFR 173.423 Table 7, and 49 CFR 173.435 Table of $A_1$ and $A_2$ values for radionuclides.

When shipping more than one type of radioactive material in the same package, the limit on the radioactivity that may be shipped is determined by the lowest Ci quantity assigned for the items shipped.

EXAMPLE: If Tc-99m and Se-75 were being shipped in the same package, only 4 mCi of total activity could be hipped.

# RADIOACTIVE WASTE HANDLING AND DISPOSAL

A. Waste Generated

1. All waste generated in a medical services center is related to radiopharmaceuticals used by the medical profession. Since none of the radioactive materials used have long half-lives, Syncor has established a waste classification system to be used for segregating various types of material according to half-life, and the quantity of waste generated. Waste should be segregated according to the following classifications.

   a. very short half-life: Tc-99m waste. (≈94%)

   b. short half-life: Xe-133, Ga-67, Tl-201, etc., waste. (≈2%)

   c. long half-life: I-125, Co-57, etc., waste. (≈1%)

   d. generator cores: Mo-99 waste. (≈2%)

   e. I-131 Iodine waste: (≈1%)

2. Methods for Holding Waste

   a. Two ⅛" lead barrels with a diameter of 16", 24" high, mounted on 1/4" lead plates on casters. A ¼" lead plate is used as a lid. This type of barrel is now used for initial storage of short-lived isotopes. When full, the sharps containers in the barrels are removed to concrete bins for final decay. The concrete bins measure 38" x 48" x 12' x 12" thick. These bins are used for decay storage of all returned radioactive waste.

   b. A container emptying rotation cycle is established to ensure that all material has been stored for a minimum of ten (10) half-lives, or until it has reached background levels.

   c. When a container is filled, it is sealed, the date is placed on the container, and the radiation level at the surface of the container is determined.

   d. When all containers are filled, the container which has the earliest date sealed is disposed of, provided its activity level has returned to background level when measured with a low level survey meter.

B. Waste Disposal Procedures

1. Used Generators Returned to Manufacturer or Stored

   a. Return Mo-99, Tc-99m generator to original shipping container.

   b. Perform wipe test on surface of container.

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

NOTE: Used generators will be stored in their original shipping containers until returned to manufacturer or until they have decayed to levels suitable for dismantling for core storage. Those which will not decay out will be stored or disposed of through a licensed waste disposal firm.

2. Receiving Waste Returned From Customer.

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

   a. Open unit dose shield, identify material by Rx label and/or color coding, if needed.

   b. Dump contents of unit dose shield directly into bin provided. Touch only the outside of the unit dose shield.

   c. Survey unit dose container for contamination with a low level survey meter. If a unit dose shield demonstrates activity levels greater than background, remove from service, and place in the storage area for decay to background levels. When surveying unit dose shields for reuse, any unit dose shield which demonstrates a survey meter response greater than background must be wipe tested. If wipe test samples demonstrate contamination levels greater than 200 dpm, the unit dose shield should be decontaminated until less than 200 dpm of contamination is detected.

3. Survey Procedures for Disposal of Waste into Normal Trash.

   NOTE: Always wear disposable gloves when handling waste.

   a. Check survey meter to make sure it is operating properly.

   b. Record background of survey meter on waste disposal record.
      1. Obtain background in low background area.

   c. Select waste from container that indicates that waste has decayed for at least 10 half-lives.

   d. Remove plastic bag from lead container.

   e. Measure radiation level over the entire surface of bag with the survey meter. If waste contains beta emitters, make sure beta shield is open.

   f. If RAM waste measures background:
      1. Remove all radioactive tags or obliterate RAM labels.
      2. Dispose of into normal trash.

   g. If RAM waste measures above background, return to lead waste container for further decay in storage.

   h. Record all findings on "Radioactive Waste Disposal Record".

## Item 10.10 PRECAUTIONARY MEASURES FOR HANDLING MILLICURIE QUANTITIES OF LIQUID RADIOIODINE

Thyroid Bioassay will be performed in accordance with the provisions of NRC Regulatory Guide 8.20, with respect to action levels, i.e., 0.04 microcuries and the frequency specified in this guide or more frequently. All individuals handling an open form of quantities of radioactive Iodine that are equal to or exceeds those quantities shown in Table 1 of NRC Guide 8.20 shall be required to have thyroid bioassay. Any worker sufficiently close to the handling process (within a few meters, and in the same room as the worker handling the material) will also have thyroid bioassay procedures performed. Individuals compounding Iodine 131 capsules will perform bioassay weekly.

In Vivo Thyroid Bioassay

1. Equipment:
   a. scintillation counting system with
   b. thyroid neck phantom
   c. I-131 capsule

2. Procedure:
   I-131 energy = 364 kev
   Analyzer window = 100 kev

   With the I-131 capsule, peak the analyzer by adjusting the detector voltage until maximum count rate is achieved.

   a. Obtain background of counting system

   b. Obtain standard count by placing neck phantom containing capsule centered on detector face.

   c. Obtain counts over the thyroid. Place the detector against the front of the neck at midline in three vertical positions. For your calculations use the positions which gives you the highest count rate.

   d. Calculate thyroid activity from:

$$\frac{THYROID}{BURDEN} = \frac{(CPM_{neck} - CPM_{bkg})}{(CPM_{capsule} - CPM_{bkg})} \times \frac{CAPSULE}{ACTIVITY}$$

3. Since NRC Guide 8.20 specifies an action level with respect to thyroid burden of 0.04 µCi, it will be necessary for you to determine the sensitivity of your equipment, and the thyroid counting time necessary to demonstrate a level of 0.04 µCi in the thyroid. This may be done in the following manner:

   a. From the data obtained when counting the I-131 capsule for thyroid bioassay, express the sensitivity of your counting system in cpm/µCi.

      EXAMPLE: a 5.0 µCi 131-I capsule is counted in the thyroid neck phantom on the detector face and counts 20,000 cpm, then:

$$CF = \frac{20,000\ cpm}{5\ \mu Ci} = 4,000\ \mu Ci$$

b. Sample calculations: Minimum detectable activity

Prior to any thyroid bioassay procedure, it is necessary to verify that the requisite MDA can be achieved. The MDA is given by:

$$MDA = 3.3 \times \frac{\sqrt{2R_B / T_B}}{CF}$$

$R_b$ = the background counting rate

$T_b$ = time taken to count the background

CF = calibration factor, i.e., cpm/μCi of a standard source

In the above example, CF = 4000 cpm/μCi.

If background was counted for 1 minute and yielded 290 total counts, then the MDA is:

$$MDA = 3.3 \times \frac{\sqrt{2 \times 290\ \frac{counts}{1\ min}}}{4000 cpm/\mu Ci} = 0.018\ \mu Ci$$

which satisfies the requisite sensitivity.

This thyroid counting system would be capable of detecting quantities of I-131 below that required for adequate monitoring of health and safety.

The quantity of radioactive material (Q) deposited in the thyroid is simply:

$$Q = \frac{THYROID}{BURDEN} = \frac{(CPM_{neck} - CPM_{bkg})}{CF}$$

4. For our bioassay programs, action levels, frequency of bioassay, and actions to be taken if those levels are exceeded will be in accordance with U.S. Nuclear Regulatory Guide 8.20, Application for Bioassay for I-125 and I-131. Bioassays for thyroid uptake will be obtained with a Ludlum 2200 single channel analyzer with a 1" probe. Measurements of the thyroid will be compared to an Iodine-131 capsule housed in an appropriate thyroid phantom to take into account tissue attenuation from the employee's neck.

A record of bioassay results on the above test will be maintained. Records will contain the name of the individual, results of testing, and date. All positive bioassay results will be investigated. Corrective actions taken to prevent further uptake will be documented in accordance with 10 CFR 20.103.

*LLD Formula is available in Radiation Safety Manual supplied to each pharmacy.

## *DERIVATION OF MDA FORMULAE

A. $$LLD = \frac{2.71}{T_s} + 3.3 \times \sqrt{\frac{R_b}{T_b} + \left(1 + \frac{T_b}{T_s}\right)}$$

Where: $T_s$ = sample count time

$T_b$ = background count time

$R_b$ = background count time (cpm)

LLD = lowest level detectable activity in cpm

When $T_s = T_b$ the term $2.71/T_s$ may be neglected and the above formulae becomes:

B. $$LLD = 3.3 \times \sqrt{2 \times \frac{R_b}{T_b}}$$

Also:

C. $$MDA = \frac{LLD}{2.22 \times 10^6 \frac{dpm}{\mu Ci} \times F_e}$$

where: $F_e$ = efficiency factor of counting system

MDA = minimum detectable activity

However, $(2.22 \times 10^6) \times F_e = CF$, where CF = cpm/pCi of a standard source

Therefore, MDA may be expressed as:

D. $$MDA = \frac{3.3 \times \sqrt{2 \times R_b / T_b}}{CF}$$

when $T_b = T_s$

*HASL Procedures Manual (HASL-300, Suppl-2)

RS14 (1.0) Syncor Corp # 003

Bioassay Test Record

---

Location Id :
Date/Time : :
Soc Sec# :
Performed By :

Thyroid Test Equipment :

Serial # :
Make :
Model # :
Descr :

"Bkg" cpm :

Comments :

Thyroid Test Results :
Actual Thyr cpm :
"Net" Thyroid cpm :
Actual Src cpm :
Src / Lot Number:
Source Actv uCi:
"Net" Source cpm :
Thyroid uCi :

## Item 10.11 AREA SURVEY PROCEDURES

Syncor has adopted the area survey procedures described in Appendix J of the "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" dated August 1985.

## Item 10.12 DISTRIBUTION PROCEDURES

Syncor proposes to continue operation of a centralized nuclear pharmacy which will compound and dispense radiopharmaceuticals to a number of nuclear medicine departments on a unit dose or multi-dose basis. Criteria for this purpose has been published by the NRC and is contained in the NRC "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" dated August 1985.

The nuclear pharmacy is licensed by the State Board of Pharmacy and is therefore subject to laws and regulations set forth by the State Board of Pharmacy. The nuclear pharmacy will be required to comply with the applicable provisions of the Federal Food, Drug, and Cosmetic Act. The FDA has made available a guideline to assist nuclear pharmacies in determining if they must register under Section 510 of the Act. This publication "Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment" is dated May 1984.

Requests for radiopharmaceuticals from physicians (M.D. or D.O.) holding licenses issued by the Nuclear Regulatory Commission or Agreement State, and who also hold a license to practice medicine in this state or an adjoining state, will be handled and treated as a prescription. Only these radiopharmaceuticals which the physician is licensed to possess will be dispensed.

Syncor does not, at this time, propose to manufacture generators or reagent kits or any other radiopharmaceuticals starting with raw materials. It is our intention to prepare radiopharmaceuticals which have been manufactured by manufacturers such as Squibb, Mallinckrodt, New England Nuclear, Medi- Physics, Amersham, and others, and to distribute these products in dose form to nuclear medicine departments licensed to use them. The labeling and dispensing of these doses meets FDA requirements as specified in the Federal Food, Drug, and Cosmetic Act, Section 503 & 501(g)(1).

Should Syncor anticipate the manufacture and distribution of generators or reagent kits, the normal procedures for meeting FDA and NRC/Agreement State requirements would be followed, such as applying to the FDA for an IND and applying to the NRC/Agreement State for a license amendment.

Radiopharmaceuticals distributed for human use shall be:

1. Repackaged or distribution from radiopharmaceuticals that are the subject of an FDA-approved NDA or for which an IND has been accepted by the FDA.

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

If IND radiopharmaceuticals and radiopharmaceuticals prepared from generators or reagent kits that are under IND status, these drugs will be dispensed:

1. In accordance with directions provided by the sponsors of the IND, and

2. Only the physicians who have been accepted by the sponsors of the IND to participate to clinical evaluations of the drug, and

3. With the understanding that the physician is responsible to the sponsors of the IND for use of the drug in accordance with protocols and information obtained through the use of the drug.

# STATE PHARMACY LICENSE

DISPLAY THIS CERTIFICATE PROMINENTLY - NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

COMMONWEALTH of PENNSYLVANIA
DEPARTMENT of STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
P.O. BOX 1753, HARRISBURG, PA. 17105-1753

CLASSIFICATION

PHARMACY PERMIT

| CERTIFICATE NUMBER | CERTIFICATION DATE | ISSUED | EXPIRES |
|---|---|---|---|
| PP-412318-L | NOV 20 1980 | JUL 17 1991 | AUG 31 1993 |

THIS LICENSE IS VALID ONLY FOR THE NAME/ADDRESS SHOWN

ISSUED TO

SYNCOR CORP APOTHECARY
ROBERT E GROBINSKI JR
7446 DERRY STREET
HARRISBURG PA 17111

Robert E. Grobinski Jr.
SIGNATURE

George L. Sheridan
COMMISSIONER OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

THIS DOCUMENT IS PRINTED ON BLUE SAFETY PAPER

Item 10
Date: 09/27/91

# REQUIRED CONTAINER LABELING

1. VIALS:

   Vials will be labeled with the manufacturers' original label or with label C.

2. SYRINGES:

   Syringes will be labeled with Rx label C.

3. VIAL SHIELDS:

   All vial shields will be labeled with the manufacturers' original label and/or label B.

4. UNIT DOSE CONTAINER SHIELDS:

   Unit dose containers will be labeled with label B.

5. GENERATORS:

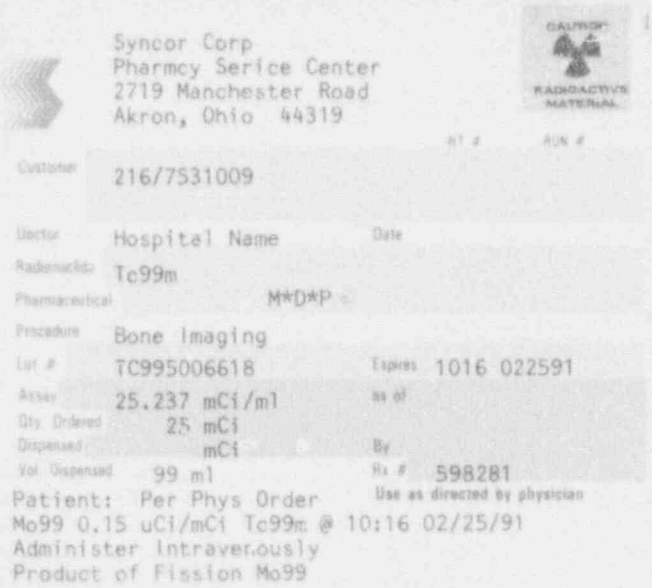
   Generators will be labeled with label A and the manufacturer's original label. The manufacturers leaflet or brochure will remain with the generator, and will contain the statement required by 10 CFR 32.72(a)(5)(ii).

   Each package of radiopharmaceutical transported will be accompanied by a packing list which will contain the following statement:

   This radiopharmaceutical is approved for distribution to persons licensed by the U.S. Nuclear Regulatory Commission to use Byproduct Material listed in 10 CFR 35.100, 35.200, or 35.300 as appropriate or under an equivalent license of an Agreement State.

## Item 10.13 PRODUCT LABELS

A. Generator label


Syncor Corp
Pharmcy Serice Center
2719 Manchester Road
Akron, Ohio 44319

CAUTION RADIOACTIVE MATERIAL

RT # RUN #

Customer 216/7531009

Doctor Hospital Name Date

Radionuclide Tc99m

Pharmaceutical M*D*P

Procedure Bone Imaging

Lot # TC995006618 Expires 1016 022591

Assay 25.237 mCi/ml as of

Qty Ordered 25 mCi

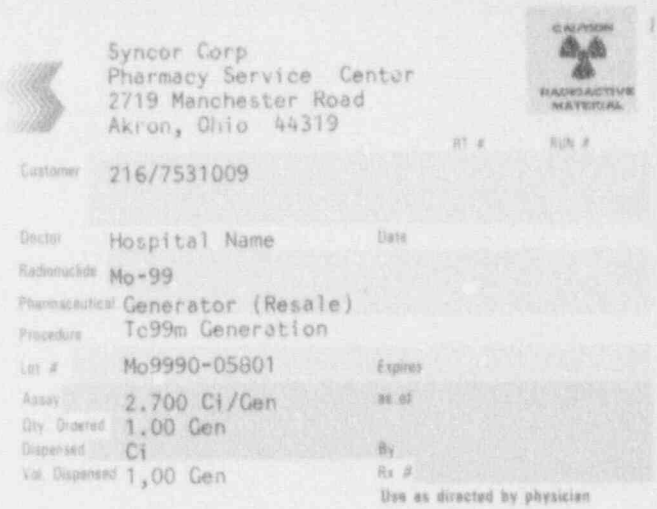
Dispensed mCi By

Vol. Dispensed 99 ml Rx # 598281

Use as directed by physician

Patient: Per Phys Order
Mo99 0.15 uCi/mCi Tc99m @ 10:16 02/25/91
Administer Intravenously
Product of Fission Mo99

B. Rx label


Syncor Corp
Pharmacy Service Center
2719 Manchester Road
Akron, Ohio 44319

CAUTION RADIOACTIVE MATERIAL

RT # RUN #

Customer 216/7531009

Doctor Hospital Name Date

Radionuclide Mo-99

Pharmaceutical Generator (Resale)

Procedure Tc99m Generation

Lot # Mo9990-05801 Expires

Assay 2.700 Ci/Gen as of

Qty Ordered 1.00 Gen

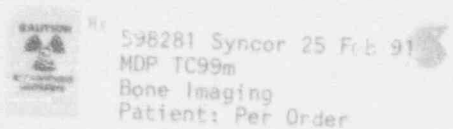
Dispensed Ci By

Vol. Dispensed 1,00 Gen Rx #

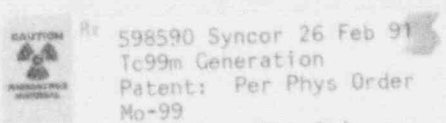
Use as directed by physician

Patent: Per Phys Order
Comment: For Resale!!

C.


Rx 598281 Syncor 25 Feb 91
MDP TC99m
Bone Imaging
Patient: Per Order

C.


Rx 598590 Syncor 26 Feb 91
Tc99m Generation
Patent: Per Phys Order
Mo-99
Generator (Resale)

These are sample labels. Each individual pharmacy will have its address printed on the labels which it uses.

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## Item 10.14 PRODUCT SHIELDING

F. In accordance with 10 CFR 32.72(a)(3)and 10 CFR 20.1(c) or equivalent agreement state regulations.

The applicant submits information on the radionuclide, chemical and physical form, packaging (including maximum activity per package) and shielding provided by the packaging of the by-product material that is appropriate for safe handling and storage of radiopharmaceutical of group licensees:

| | Chemical/ Physical Form | Max Activity per Vial or Syringe | Shield to be used for Dispensing | IC-008 | IC-004 | Heavier |
|---|---|---|---|---|---|---|
| I-131 | Sodium Iodide Sol'n/Cap/Tagged Drug | 5.0 mCi | X* | | | |
| I-131 | Tagged Drug Sol'n | 300.0 mCi | IC-004 | | 6.0 | |
| I-125 | Tagged Drug Sol'n | 2.0 mCi | IC-008, -004, X* | 0.03 | 0.03 | 0.03 |
| Cr-51 | Sodium Chromate Sol'n | 2.0 mCi | IC-008, -004, X* | 0.03 | 0.03 | 0.03 |
| Ga-67 | Gallium Citrate | 10.0 mCi | IC-004, X* | --- | 26.0 | <26.0 |
| Tl-201 | Thallous Chloride | 4.0 mCi | IC-004, X* | --- | 0.5 | <0.5 |
| I-123 | Sodium Iodide | 5.0 mCi | | --- | <1.0 | <1.0 |
| In-111 | Indium Chloride, DTPA, or Oxine | 3.0 mCi | IC-004 | --- | --- | --- |
| Ru-81/ Kr-81 | Special Form/ Gas | 25.0 mCi | X* | --- | --- | --- |
| Co-57 | Cyanocobalamin | 10.0 µCi | IC-008, -004, X* | <0.5 | <0.2 | --- |
| Tc-99m | Sodium Pertechnetate, Tagged Drug Sol'n | 500.0 mCi | IC-008, -004, X* | 2.2 | 0.1 | 0.05 |
| Tc-99m | Tagged Drug Sol'n | 200.0 mCi | IC-008, -004, X* | 0.5 | 0.07 | 0.05 |
| Tc-99m | Tagged Drug Sol'n | 100.0 mCi | IC-008, -004, X* | 0.4 | 0.06 | 0.05 |
| Tc-99m | Tagged Drug Sol'n | 50.0 mCi | IC-008, -004, X* | 0.3 | 0.05 | 0.05 |

* X has more shielding than IC-004 (manufacturer's shield).

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

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

Maximum Surface Radiation for this shield:

99m-Tc 10.0 curies 5.0 mR/hr

* These therapy doses and 133-Xenon will be shipped in manufacturer's containers and shielding devices as supplied by the commercial manufacturers.

Therapeutic quantities of Phosphorous-32 will be ordered for the hospitals on a demand basis. For this reason, they will be dispensed in their original containers.

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

| Syringe Carrier No. | Without Gasket Leakage | With Gasket |
|---|---|---|
| 1 C-006 | 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-006 | 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-006 | 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 RA, Croft R: 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 12-33.

4. *The Federal Register, 49CFR, Dept. of Transportation Materials Transportation Bureau Part 172*, Washington, DC, The National Archives of the United States: parts 171-177, 1978

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




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## Results

As shown in Table 1, carrier I C-004 contains 50% (by weight) more lead than 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 | 1.18 | 0.63 | 0.39 | 1.11 |
| I C-004 | 1538 | 0.63 | 1.11 | 0.85 | 0.63 | 1.27 |
| Ia | 1364 | 0.78 | 0.71 | 0.78 | 0.63 | 0.63 |
| Ib | 1516 | 0.71 | 0.78 | 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 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 | 8.5 | 25.0 | 0.50 | 0.05 |
| I C-004 | 0.20 | 2.0 | 8.5 | 0.35 | 0.05 |
| Ia | 0.25 | 3.5 | 9.0 | 0.65 | 0.05 |
| Ib | 0.30 | 2.0 | 9.0 | 0.45 | 0.10 |

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

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

| Carrier No. | Top | Junction | Middle | Bottom | at 1 m (T.I.) |
|---|---|---|---|---|---|
| | Surface Readings | | | | |
| I C-008 | 0.45 | 8.0 | 55.0 | 1.00 | 0.15 |
| I C-004 | 0.20 | 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 |

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

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

| Carrier No. | Top | Junction | Middle | Bottom | at 1 m (T.I.) |
|---|---|---|---|---|---|
| | Surface Readings | | | | |
| I C-008 | 0.10 | 0.20 | 0.40 | 0.04 | 0.04 |
| I C-004 | 0.06 | 0.40 | 0.05 | 0.04 | 0.04 |
| Ia | 0.07 | 0.30 | 0.10 | 0.06 | 0.05 |
| Ib | 0.04 | 0.065 | 0.06 | 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).

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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.

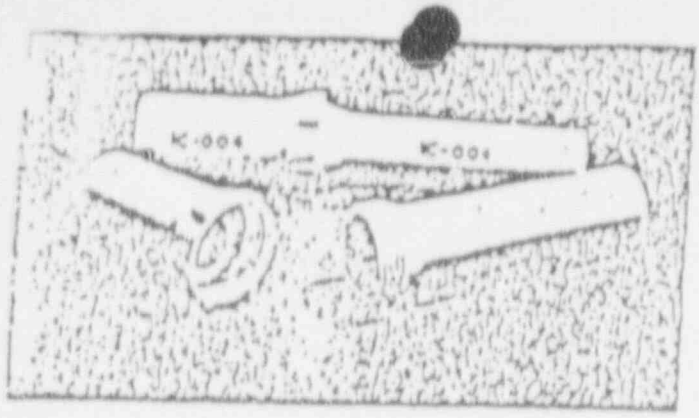


FIG. 2. Syringe carrier shield, 1C-004 with screw-on top, continuous plastic coating.

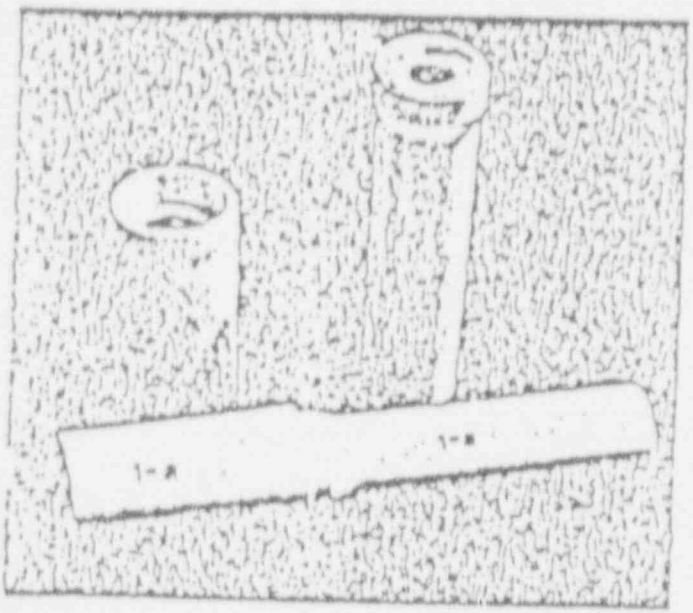


FIG. 3. Syringe carrier shield, 1a with slip-on top, plastic coating.

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

## Materials and Methods

Four different syringe carriers were evaluated: the 1C-008 (Fig. 1) and the 1C-004 (Fig. 2) (General Design Development, Albuquerque, NM), and the 1a (Fig. 3) and 1b (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 the 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.

# 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.

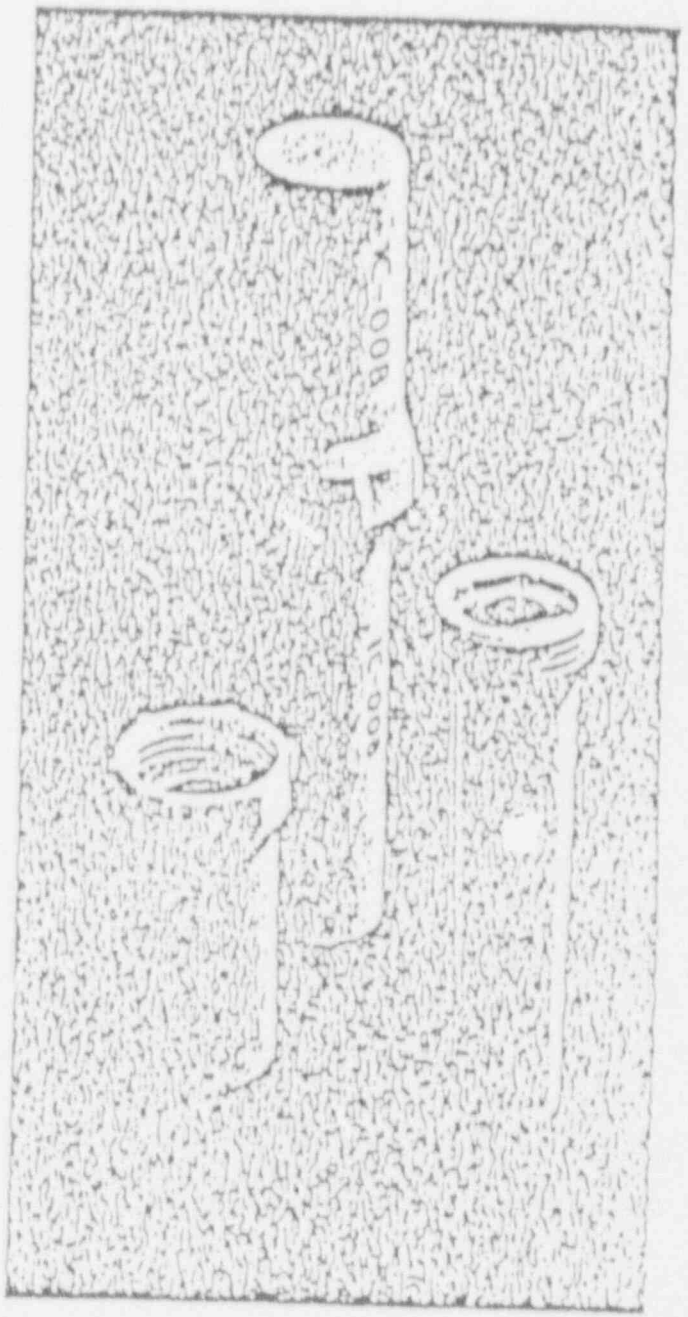

FIG. 1. Syringe carrier shield, 1 C-008 with screw-on top and continuous plastic coating.

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Facsimile letter - Nu Medico Associates

NU MEDICO

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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 IC-004 SYRINGE SHIPPING CONTAINER

Method of Testing

The attenuation of I-131 and Cr-51 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 I-131.

Results

1. The average effective thickness of the sample was 0.92 cm. of lead. Less than 3σ 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.

## Item 10.15 PROCEDURES FOR PACKAGING AND TRANSPORTING RADIOPHARMACEUTICALS

The nuclear pharmacy will comply with applicable regulations for packaging and transportation of radioactive material as specified in 10 CFR 71, 49 CFR 170-189, and 14 CFR 103. All outgoing packages will be wipe tested in accordance with 49 CFR 173.443.

1. Packaging of radioactive material for transport by a common carrier:

   a. The radioactive material will be placed into appropriate shielding, i.e., General Design Development, Model IC-008 or IC-004 or original manufacturer's shielding.

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

   c. The wrapped unit dose container will be put into a plastic bag and sealed.

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

   e. The appropriate radioactive label will be applied to the outside of the box. Determination of the transport index is accomplished by placing the package one meter distant from a calibrated survey meter, then reading the transport index on the scaler in mR/hr. Determination of the radioactive White I, radioactive Yellow II, or radioactive Yellow III, is accomplished by taking a surface reading of the package as well as the T.I. The following criteria is used:

      T.I. = NA ..... RL < 0.5 mrem/hr ..... White-I
      T.I. < 1.0 .... 0.5 mrem/hr < RL < 50 mrem/hr ..... Yellow-II
      1.0 < T.I. ..... 50 mrem/hr < RL ..... Yellow-III

   f. Shipping papers for radioactive material will be effected and attached to the package.

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

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

2. Packaging of radioactive material for transport to immediate area hospitals

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

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

c. The inside of the transport cases contain an insert which has been cut to conform to the molded shape of the unit dose containers. This material will prevent movement of unit dose containers, will absorb a great amount of shock, and will act as an absorbent material in the event of an accident. A security seal will be present in accordance with 49 CFR 173.412(b).

d. Therapy and multi-dose materials will be transported in the lead shielding containers utilized by the manufacturer, or heavier shielding.

e. The label affixed to each package of the radiopharmaceutical will contain information as to the radionuclide, its apparent chemical form, the quantity and the date of assay. The label affixed to each package or the leaflet or brochure which accompanies each package will contain a statement that the radiopharmaceutical is licensed by the U. S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 10 CFR 35.100, 35.200 or 35.300 as appropriate or under an equivalent license of an Agreement State. All labeling requirements set forth by DOT will be met.

3. Vehicle

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

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

c. The Transport Index for all packages of radioactive material in a vehicle will never exceed a Transport Index of 50.

d. Packages of radioactive material bearing "Radioactive Yellow II" or "Radioactive Yellow III" will not be placed closer to passengers than is specified in 49 CFR 177.842.

4. Miscellaneous directives

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

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

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

# TRAINING PROGRAM FOR DELIVERY PERSONNEL

Individuals who deliver radiopharmaceuticals and who collect radio-active residue from our customers and transport it to our facility will be required to attend training sessions before assuming their duties with, or in the vicinity of radioactive materials, annually for refresher training, and whenever there is a significant change in duties, regulations, or terms of the license. The training program will be of sufficient scope to ensure that all personnel will receive proper instruction in the items specified in 10 CFR 19.12.

A. Areas where radioactive material is used or stored;

B. Potential hazards associated with radioactive materials;

C. Radiological safety procedures appropriate to their respective duties;

D. Pertinent NRC regulations.

E. The rules and regulations of the license;

F. The pertinent terms of the license;

G. Their obligation to report unsafe conditions;

H. Appropriate response to emergencies and unsafe conditions.

I. Their right to be informed of their radiation exposure and bioassay results.

Individuals hired as delivery personnel will have little or no experience; however, they will be trained with respect to delivery by an experienced radiopharmacist. All initial deliveries and retrieval of used material will be by the pharmacist who will train the delivery personnel on the job. As delivery personnel gain experience, they will train new drivers, with respect to delivery routes and customer drop-off procedures.

All new drivers will accompany an experienced driver to each customer we service. A list of accounts will be given to each new driver, and when he has made a delivery with an experienced driver, he must check that account off of the list.

In addition to verbal instructions, each driver must be given written instructions. These instructions must include:

1. The sequence of hospital delivery.

2. The number of cases to be delivered to each hospital.

3. Retrieval and return of all cases.

4. Making sure when you leave your vehicle that all windows are closed and that all doors are locked.

5. Delivering all doses to the Nuclear Medicine Department, unless directed otherwise. In consideration of the above, each driver is to be furnished

with written instructions for proper delivery to each institution which we supply. These instructions shall include:

a. Where to park upon arrival at the hospital;
b. What entrance by which to enter the hospital;
c. Whether or not to check in with security;
d. Route to take from entry into the hospital to Nuclear Medicine;
e. Area where doses may be left during off-duty hours, if not Nuclear Medicine;
f. Any special instructions, such as checking in at desk, special area in Nuclear Medicine to leave doses, having security personnel unlock doors, etc.

6. Having in his vehicle the instructions which we supply in case of an accident.

7. Carrying on his person a company card with the pharmacy's address and phone number.

In addition to the above, these individuals will be given the following written instructions. They will be required to read them and document that they understand and will follow them.

Instructions for individuals collecting radioactive waste from our customers:

1. You may not pick up any radioactive waste from our customers which is not comprised of material delivered by Syncor to this customer.

2. All materials must have been returned to its original shipping container and packaging before you are authorized to collect it. No loose material, syringes, needles, vials, etc., shall be accepted by you for transport.

3. You shall not open any unit dose syringe shield, manufacturer's shipping container, or packaging containing the above during collection or transport to the pharmacy.

It is our company policy that all new accounts are set up by an experienced radiopharmacist and that, from time to time, deliveries are made by the pharmacist. This is to establish a working rapport with the accounts, Nuclear Medicine personnel, and to stay abreast of any changes in procedures, etc., which may affect delivery, unit dose levels, licensing or change of established procedures.

## EMERGENCIES INVOLVING MOTOR VEHICLES ACTING AS CARRIERS OF RADIOACTIVE MATERIALS

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

a. Immediate notification is to be given by telephoning the following in order: Local Police and/or Highway Patrol, Radiation Safety Officer. Caller must relate his/her name, location, what happened, when, where, who was involved, and what has been done to control or confine the radioactive materials. Have someone maintain security over the vehicle and radioactive material and keep bystanders away while calls are being made.

Phone numbers:

1. Police: 911
   Fire: 911

2. Nuclear Pharmacist on call, or Radiation Safety Officer.
   Office: 717/564-5052 Home: 717/561-4531

b. 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. If radioactive material is spilled, passage through areas should be prevented unless absolutely necessary. If the right-of-way must be cleared and the fire department is present, the spill may be washed to shoulders of right-of-way with minimum dispersal of wash water, or covered with at least four inches of earth or sand.

c. If radioactivity has escaped its primary container, the nearest Nuclear Regulatory Commission Office should be notified as soon as possible.

Phone - 24-hour USNRC Operational Center: 301/951-0550

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

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

f. Contaminated injured should be removed from the area of the accident with as little contact as possible and held at a transfer point. All life-saving measures should be performed promptly, but elective first aid and surgical procedures should be delayed until advice or help can be obtained from a physician familiar with radiation medicine. Except in extreme emergency,

patients should not be moved to local hospital or doctor's office before a radiological survey has been made.

g. 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. Suspected material should not be handled until it has been monitored and released by monitoring personnel. Clothing and tools used at the fire should be segregated until they can be checked by the monitoring teams.

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

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

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

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

ON THE ACTUAL COPY THAT IS CARRIED IN THE VEHICLE, THIS INFORMATION WILL BE FILLED IN AND UPDATED AS NECESSARY.

Item 10.16 INDEPENDENT AUDIT PROGRAM

## CORPORATE RADIATION SAFETY PROGRAM

The Quality and Regulatory Department, a division of Syncor International, has assumed responsibility for the Syncor Radiation Safety Program. This program will be generic in nature and a centralized approach to regulatory compliance, training, and health physics practices will be utilized. A comprehensive radiation safety manual has been developed and distributed to each pharmacy manager. The basic premise of this radiation safety program is compliance with NRC/Agreement State regulations and conditions of our NRC/Agreement State licenses. To this end, each manager is expected to be conversant with the details of his or her license, and to operate his or her pharmacy in full compliance with NRC regulations and the conditions of the license.

An ongoing audit is performed quarterly or semi-annually by members of this staff. A comprehensive compliance survey form is utilized by the Quality and Regulatory Department to ensure compliance with NRC and/or Agreement State regulations (see attached compliance survey form).

In addition, the Quality and Regulatory Department has developed a standard set of documentation forms which are incorporated into the computer software programs. This Department has established a program for routine monitoring of these forms to ensure compliance with regulatory requirements.

This Department has established a trend analysis program to monitor film badge reports, audit reports, and NRC and state inspection reports. The personnel dosimetry trend analysis will be used to evaluate program effectiveness.

This Department has established a hazard reporting system whereby individual Syncor employees can submit reports of potential unsafe working conditions. Regulatory, technical, and corporate policy information is provided through the company newsletter. This Department has established a comprehensive, corporate-wide radiation safety program to achieve full and continuing compliance with NRC and/or Agreement State requirements.

Audits are performed by the Quality and Regulatory staff. All radiopharmacies will be audited quarterly for the first year of operation. If it is determined by the Quality and Regulatory staff and corporate management that a particular pharmacy is in compliance, with good record of health physics practices and a good record of regulatory agency inspections, the audit frequency will be reduced to a semi-annual frequency.

Audits are performed by members of the Quality and Regulatory staff. These individuals are not closely associated with or working at the facility that is being audited. After the initial audit conducted by the Quality and Regulatory, audits may be conducted on an unannounced basis. The audit is an examination of activities conducted under the license as they relate to radiation safety and to compliance with the NRC and/or agreement state rules and regulations and the condition of the license. The audit consists of examinations of procedures and representative records, interviews with personnel, measurements, and observations. The accompanying compliance survey form is utilized to perform this audit.

Prior to performing an audit, the auditor receives from the corporate data analysis center and from his own files results of previous audits, information regarding personnel exposure and submitted documentation. Previously identified items which could represent poor health physics practices or items of non-compliance are noted and special attention is given to these areas during the audit.

A schedule has been established for audit visits. This schedule is submitted to the corporate RSO so that the appropriate pre-audit information is made available to the health physicist performing the audit.

After the audit is performed, copies of the completed compliance survey, plus the auditors' deficiency letter to the pharmacy manager, are submitted to the Corporate Radiation Safety Officer. If the auditor who performs the audit feels that an item needs immediate attention, a telephone conference is immediately initiated with the corporate RSO and/or corporate management.

If poor health physics practices or items which may represent items of non-compliance are identified, the pharmacy manager is required to submit the following to the Quality and Regulatory Department:

1. Corrective steps which have been taken and the results achieved.

2. Corrective steps which will be taken to avoid further items of non-compliance.

3. The date when full compliance was achieved.

At the conclusion of each inspection audit, an exit interview is held with the day to day RSO. Those problems which have been identified are discussed and immediate corrective action is initiated when possible. The day to day RSO is still required to submit a report on the form provided indicating the corrective measures taken to the Quality and Regulatory office.

CORPORATE RADIATION SAFETY OFFICER RESPONSIBILITIES

1. Manage the Corporate Radiation Safety Program.

2. General surveillance over all corporate activities involving radioactive material, including problem identification, personnel dosimetry exposure, and trend analysis, documentation monitoring, regulatory license preparation and site visit audits.

3. Furnish consulting services on all aspects of radiation protection to personnel at all levels of responsibility.

4. Supervise and aid in developing training programs for all levels of personnel, to include proper procedures for use of radioactive material prior to use and at periodic intervals, as required by changes in procedures, equipment, regulations, etc.

5. Exercise the authority to terminate immediately any project or procedure that is found to be hazardous to the health, welfare, or safety or any employee or the public.

COMPLIANCE SURVEY
(Rev 09/21/90)

Location:_____ Date:_____
License No:_____ Time:_____
Auditor Name:_____

Last NRC/Agreement State Inspection:_____

The inspection was an examination of the activities conducted under the above license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's rules and regulations and the conditions of the above license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations. The findings, as a result of this inspection, are attached in the following survey.

**SYNCOR INTERNATIONAL CORPORATION**

KEY

Item Number: Reference to NRC Radioactive Material License Application

10 CFR: Nuclear Regulatory Commission Code of Federal Regulations

49 CFR: Department of Transportation Code of Federal Regulations

Condition #: References NRC Radioactive Material License

Appendix #: References Nuclear Pharmacy Licensing Guide

DOT $ Fine: Fine incurred as a result of DOT Citation

SL: Severity Level, Most Serious III > IV > V

Company Policy: As issued by written notice or memo

SEVERITY LEVEL REFERENCE 10 CFR, PART 2, APPENDIX C

SL III Most severe, leading to escalated enforcement. Includes therapy misadministrations, multiple diagnostic misadministrations. Penalties usually assessed.

SL IV 1. Violations related to more than minor safety or environmental significance.

2. Failure to implement 10 CFR parts (regulations) relative to our operations.

3. Failure to implement license conditions or license application commitments.

SL V Violations that have minor safety or environmental significance.

Repeat violations can move SL IV and SL V violations into the SL III level.

The number of violations can also be considered in assigning a severity level category.

SL III violations are also related to excessive exposure, willful disregard, breach of security,or lack of management oversight.

---

Syncor Assignment of numerical value to severity level violations

SL V = 1 Repeat = 2 Repeat Again = 5

SL IV = 2 Repeat = 4 Repeat Again = 5

SL III = 5 Repeat = Management Intervention

Greater than 5 violations = 5 Additional points + points assigned for each individual violation.

**RATINGS.** Q & R will assign a rating to each Pharmacy following each field audit it performs. Individual ratings will fall into one of the four categories listed below.

| Rating | Score |
|---|---|
| A - Excellent | 0 to 6 points |
| B - Acceptable | 7 to 11 points |
| C - Below Standard, Marginal | 12 to 16 points |
| D - Below Standard, Acute | 17 + points |

| Comment Number or Comment | Y | N | N/A |
|---|---|---|---|
| I. Laboratory Procedures (observations) | | | |
| A. Protective clothing used Nuclear Pharmacy Licensing Guide (NPLG), Appendix H Severity Level (SL) | | | |
| 1. Gloves worn when handling radioactive materials SL IV | ___ | ___ | _____ |
| 2. Lab coats worn and buttoned in restricted area SL V | ___ | ___ | _____ |
| 3. Gloves changed to prevent contamination SL V | ___ | ___ | _____ |
| B. Posting and labeling | | | |
| 1. Vial shields labeled in accordance with all federal and state requirements, proper reference to kit prep sheet 10 CFR 32.72 and 20.203 (f), SL IV | ___ | ___ | _____ |
| 2. All entrances to restricted and other areas posted as Radiation Area and Radioactive Materials 10 CFR 20.203, SL V | ___ | ___ | _____ |
| 3. Current "Notice to Employees" sign posted in a location visible to all employees 10 CFR 30.7 (e) and 19.11 (b), SL V | ___ | ___ | _____ |
| 4. Radioactive Material License posted or sign posted saying where it is located 10 CFR 19.11 (b), SL V | ___ | ___ | _____ |
| 5. Copy of notice of violation and response posted when applicable 10 CFR 19.11 (a) (4) (e), SL V | ___ | ___ | _____ |
| 6. Current pharmacy permit, intern and R.Ph licenses posted/available State Pharmacy Law, current: SL III, posted/available: SL IV | ___ | ___ | _____ |



| | Y | N | N/A or Comment |
|---|---|---|---|

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7. Current emergency procedures posted in restricted area
Item 10.8, Appendix I, SL IV ___ ___ _____

8. Timely renewal filed if pharmacy license will expire soon
State Law, SL IV ___ ___ _____

C. Dispensing

1. Molybdenum checks performed on every generator elution and documented
10 CFR 30.34 (g) and 35.204, SL III ___ ___ _____

2. Alumina checks performed on every generator elution and documented
10 CFR 30.34 (g) and 35.204, SL III ___ ___ _____

3. As per regulatory requirement each photon emitting dose is assayed in the dose calibrator prior to dispensing, except In-111 DTPA for cisternography. Item 10.7, Appendix H and
10 CFR 35.53 L III ___ ___ _____

4. Each photon emitting diagnostic dose assayed within +/- 10% of dose dispensed USP XXII, SL IV ___ ___ _____

5. Each photon emitting THERAPY does is assay within +/- 10% of dose prescribed before dispensing SL III ___ ___ _____

D Syringe and vial shields
Item 10.7, Appendix H, 10 CFR 35.60 and 35.61, ALARA Company Policy

1. Syringe shields used at all times, SL IV ___ ___ _____

2. Vial shields used at all times.
IV ___ ___ _____

3. Syringe and vial shields maintained in good condition, SL V ___ ___ _____

Page 3. I. Laboratory Procedures

| | Y | N | N/A or Comment |
|---|---|---|---|
| E. Contamination control procedures followed. Item 10.7, Appendix H | | | |
| 1. No smoking, eating, etc. allowed in restricted area, SL IV | ___ | ___ | _____ |
| 2. Work areas where contamination is possible covered with absorbent paper. Paper changed at a frequency to prevent exposure & or cross contamination, SL IV | ___ | ___ | _____ |
| 3. Hands and feet monitored before exiting restricted area, SL IV | ___ | ___ | _____ |
| F. Dosimetry devices worn properly by everyone in the restricted area Item 10.1, Appendix H, 10 CFR 20.201, | | | |
| 1. Film badge on the collar of all employees. SL IV | ___ | ___ | _____ |
| 2. Two ring badges worn facing toward palms by each dispenser. Ring badges worn by other handlers, SL IV | ___ | ___ | _____ |
| 3. Fetal badges worn when necessary. NRC Guide 8.13, ALARA, SL IV | ___ | ___ | _____ |
| 4. Required dosimeter worn, SL IV | ___ | ___ | _____ |
| G. Incoming package opening procedure 10 CFR 20.205 and Appendix G, | | | |
| 1. Incoming package opening procedure followed and documented on R3-22. SL IV | ___ | ___ | _____ |
| 2. Packages delivered to proper designated location, Item 9, SL IV | ___ | ___ | _____ |
| H. DOT procedures followed: DOT $ FINE ? | | | |
| 1. Delivery cases and packages properly surveyed 49 CFR 173.441 (b) (3) and 172.403, SL IV | ___ | ___ | _____ |
| 2. Shipping papers filled out properly 49 CFR 172.203 (d) and 173.411, SL IV | ___ | ___ | _____ |
| 3. Proper DOT labels and seals affixed to all outgoing RAM packages 49 CFR 172.203 (d) and 173.411 | ___ | ___ | _____ |

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page 4. I.Laboratory Procedures

| | Y | N | N/A or Comment |
|---|---|---|---|
| H. DOT procedures followed | | | |
| 4. Absorbent materials used in all outgoing packages and pigs containing liquid RAM's 49 CFR 173.412 (n)(2) SL V | ___ | ___ | _____ |
| 5. Delivery cases in good condition with the required information present and legible, 49 CFR 173.411, SL IV | ___ | ___ | _____ |
| 6. DOT Type 7A shipping containers always used, in same configuration as tested. 49 CFR 173.415, SL IV, DOT $ Fine | ___ | ___ | _____ |
| I. Packages delivered to authorized location in hospitals 10 CFR 20.207, Item 10.15 (4) or equivalent | | | |
| 1. Authorized location specified for each customer and documented in a drivers' manual SL IV | ___ | ___ | _____ |
| 2. Observation of correct locations by auditors SL IV | ___ | ___ | _____ |
| J. Waste, including returned waste, handled as outlined in license application. Item 10.9, 11, 10 CFR 20.302 | | | |
| 1. Limited quantity shipment return policy followed 49 CFR 173.421, SL IV, DOT $ Fine | ___ | ___ | _____ |
| 2. Waste segregated by half-life, SL V | ___ | ___ | _____ |
| 3. Waste monitored and container labels removed or obliterated prior to placing in clean trash 10 CFR 20.203 (f)(4), SL IV | ___ | ___ | _____ |
| 4. Proper disposal of used needles. Sharps containers used. SL III | ___ | ___ | _____ |
| 5. Waste disposal record documentation maintained SL IV | ___ | ___ | _____ |

Page 5. I. Laboratory Procedures

| | Y | N | N/A or Comment |
|---|---|---|---|
| K. Visitors' procedures followed | | | |
| 1. Cleaning staff escorted or trained (if applicable) 10 CFR 19.12, SL V | ___ | ___ | _____ |
| 2. Visitors' log properly filled out SL V | ___ | ___ | _____ |
| II. Facility Equipment and Instrumentation (observations) | | | |
| A. Pharmacy Item 9.1 | | | |
| 1. Floor plan complies to license application, SL IV | ___ | ___ | _____ |
| 2. Shielding adequate, all areas SL IV | ___ | ___ | _____ |
| 3. All restricted areas safeguarded from unobserved entry 10 CFR 20.207, SL III | ___ | ___ | _____ |
| 4. Flammable material stored in accordance with NFP codes SL V | ___ | ___ | _____ |
| B. Equipment | | | |
| 1. Fume hood continuously operational Item 9.3, SL IV | ___ | ___ | _____ |
| 2. Liquid iodine and xenon gas stored in fume hood Item 9.3, SL IV | ___ | ___ | _____ |
| 3. Refrigerator which contains radio-active material adequately shielded and posted. No food or drink stored in this refrigerator Item 9.2, Appendix H, SL IV | ___ | ___ | _____ |
| 4. Where applicable, laminar or bio-hazard hoods used and certified annually State Law, SL IV | ___ | ___ | _____ |

Page 6. II. Facility Equipment and Instrumentation

| | Y | N | N/A or Comment |
|---|---|---|---|
| B. Equipment | | | |
| 5. Area, hand and foot monitors monitors set at proper sensitivity. Items 10.2,10.3,10.11, Appendix H & J SL IV | ___ | ___ | _____ |
| 6. High range survey meter available. Back-up available 10 CFR 30.33, Item 10.2, SL IV | ___ | ___ | _____ |
| 7. Dedicated check source attached to survey meters. 10 CFR 35.51, SL IV | ___ | ___ | _____ |
| III. Health Physics Evaluation (observations and records review) | | | |
| A. Special Procedure - radioiodide handling I-131 Capsule Compounding Amendment, Item 9.4, 10 CFR 20.106 | | | |
| 1. Check in procedures followed for incoming packages containing radioiodides, SL IV | ___ | ___ | _____ |
| 2. Radioiodide waste in sealed bags and stored separate from other waste SL III | ___ | ___ | _____ |
| 3. Radioiodide vented through charcoal syringe, SL IV | ___ | ___ | _____ |
| 4. Used syringes, etc. cleaned before storage or disposal. Other contamination control procedures used, SL III | ___ | ___ | _____ |
| 5. Adequate shielding in glove box, SL III | ___ | ___ | _____ |
| 6. Capsule making procedure followed, SL III | ___ | ___ | _____ |
| 7. Glove box filter checks performed weekly, SL IV | ___ | ___ | _____ |
| 8. Glove box in proper working order Item 10 SL III | ___ | ___ | _____ |

| Page 7. III. Health Physics Evaluation | Y | N | N/A or Comment |
|---|---|---|---|
| B. Bioassay<br>Item 10.10, 10 CFR 20.108, and<br>NPLG 8.25 | | | |
| 1. Bioassay performed as required and bioassay results documented on RS-14 SL III | ___ | ___ | _____ |
| 3. Corrective actions taken when applicable according to NPLG 8.20 SL III | ___ | ___ | _____ |
| C. Air Monitoring<br>Item 9.4, 10 CFR 20.105 and 20.106 | | | |
| 1. Air monitors continuously operational and located in the proper areas, SL IV | ___ | ___ | _____ |
| 2. Proper frequency observed and air monitoring results properly documented on RS-55 for restricted and unrestricted areas SL IV | ___ | ___ | _____ |
| 3. Corrective actions taken when applicable. RS-55A generated whenever daily I-131 MPC exceeded SL III | ___ | ___ | _____ |
| D. Special Procedures - White Blood Cell and Platelet Labeling<br>Company Policy | | | |
| 1. Approved work sheet utilized. Copies on file, SL V | ___ | ___ | _____ |
| 2. Clear identification of patient's blood (patient name, color code, etc.) SL III | ___ | ___ | _____ |
| 3. Proper disinfection materials available and area disinfected after use SL V | ___ | ___ | _____ |

Page 8. III. Health Physics Evaluation

| | Y | N | N/A or Comment |
|---|---|---|---|
| E. Surveys<br>Item 10.11, Appendix J, 10 CFR 20.201,<br>Item 19.12 | | | |
| 1. Personnel trained in survey techniques<br>Smear technique covers 100 $cm^2$ SL IV | ___ | ___ | _____ |
| 2. Restricted areas surveyed daily for radiation levels and contamination amounts. (include cold trash and random smear)<br>Results documented on RS-6 forms, SL IV | ___ | ___ | _____ |
| 3. Unrestricted areas surveyed weekly for radiation levels and contamination amounts. (include vehicle surveys). Results documented on RS-6 forms SL IV | ___ | ___ | _____ |
| 4. Well counter used for counting smears. LLD, MDA, and Fe calculated and documented. Action levels posted SL V | ___ | ___ | _____ |
| 5. Background consistently low and LLD sufficient to detect regulatory limits at time of measurement, SL IV | ___ | ___ | _____ |
| 6. Neighboring areas monitored<br>Item 9.2, SL IV | ___ | ___ | _____ |
| 7. Corrective actions and follow-up surveys made when needed<br>SL IV | ___ | ___ | _____ |
| F. Instrumentation and Repair<br>Item 10.3, 10 CFR 20.201 (b) | | | |
| 1. Survey meters, hand and foot monitors, and room monitors calibrated annually or as required by regulations, and records maintained, SL IV | ___ | ___ | _____ |
| 2. Pocket dosimeters calibrated as per license requirements and results documented, SL IV | ___ | ___ | _____ |

Page 9.

| III. Health Physics Evaluation<br>F. Instrumentation and Repair | Y | N | N/A or Comment |
|---|---|---|---|
| 3. Dose calibrators, Item 4, Appendix E | | | |
| a. Constancy checks performed at the beginning of each day of use and properly documented on RS-31, SL IV | ___ | ___ | _____ |
| b. Accuracy checks performed annually and documented on RS-31/RS-32, SL IV | ___ | ___ | _____ |
| c. Linearity tests carried out from at least 400 Mci to ten (10) microcuries every 13 weeks on all units and documented on RS-33 SL IV | ___ | ___ | _____ |
| d. Geometry testing performed at installation and after each repair and properly documented on RS-34 SL IV | ___ | ___ | _____ |
| 4. MCA or SCA calibrated and/or daily constancy check documented on RS-36. SL IV. | ___ | ___ | _____ |
| 5. Quarterly Fe documented on RS-35 SL V | ___ | ___ | _____ |
| 6. Iodine glove box airflow measured quarterly and meets license specifications. Properly documented on RS-56 Item 9.3, I-131 Compounding Amendment SL IV | ___ | ___ | _____ |
| 7. Fume hood airflow measured semiannually and meets license specifications. Properly documented on RS-56 SL IV | ___ | ___ | _____ |
| G. Leak tests<br>Specific NRC / State License Condition | | | |
| 1. All sealed sources with activity levels above exempt quantities leak tested semi-annually and documented on RS-40/certificate, SL IV | ___ | ___ | _____ |
| 2. Sealed source inventory performed quarterly and properly documented on RS-40. All sources on license accounted for, SL IV | ___ | ___ | _____ |

| Page 10. III. Health Physics Evaluation | Y | N | N/A or Comment |
|---|---|---|---|
| H. Quality Control NRC Region III / Agreement State License Commitments | | | |
| 1. Quality control performed according to company QC manual, SL III. | ___ | ___ | _____ |
| 2. All results properly documented on RS-25 or RSQC and available for review including signatures (initials), SL III | ___ | ___ | _____ |
| I. Exposures (Personnel Dosimeters) 10 CFR 20.101 | | | |
| 1. Personnel exposure readings available (dosimetry reports), SL IV | ___ | ___ | _____ |
| 2. Required documentation maintained when not within ALARA limits on RS-15, SL IV | ___ | ___ | _____ |
| 3. Current personnel exposure readings posted and initialed. SL V | ___ | ___ | _____ |
| 4. Badges for dispensers changed and processed weekly, SL IV | ___ | ___ | _____ |
| 5. Film badges stored properly in a low background area when not in use, SL IV | ___ | ___ | _____ |
| 6. Missing badges evaluated and properly documented on RS-18, SL IV | ___ | ___ | _____ |
| 7. Is there a reportable overexposure SL III | ___ | ___ | _____ |
| J. Computer Traceability and Inventory NRC Commitment | | | |
| 1. Pharmaceuticals can be traced to manufacturers' lot numbers Script #_____ traced, SL IV | ___ | ___ | _____ |
| 2. All isotopes within possession limits. Computer inventory matches physical inventory, SL IV | ___ | ___ | _____ |

| Page 11. III. Health Physics Evaluation | Y | N | N/A or |
|---|---|---|---|

Item 10
Date: 09/27/91

Comment

K. Pharmacy Law,

1. Rx initialed by dispensing pharmacist SL III ___ ___ _____

2. State Pharmacy Laws followed, if applicable, SL III

   a. Patient's name on prescription ___ ___ _____

   b. Physician's name on prescription ___ ___ _____

3. Telephone orders taken only by pharmacist or pharmacist intern Company Policy, SL III ___ ___ _____

4. Transfers are limited to unopened containers with manufacturer's instructions SL III ___ ___ _____

5. Pharmacy practice followed Company Policy

   a. Company guidelines followed for kit preparation SL III ___ ___ _____

   b. Calibration time of product will not exceed corporate kit preparation guidelines SL III ___ ___ _____

   c. Mixing products from different manufacturers is not allowed SL III ___ ___ _____

L. Vehicle Review

1. Bracing in all cars. Bracing adequate 49 CFR 177.84 (d), SL IV, DOT $ Fine ___ ___ _____

2. Current emergency notification signs on all cars and emergency procedures available in all cars Item 10.15, SL IV ___ ___ _____

| Page 12. III. Health Physics Evaluation<br>L. Vehicle Review | Y | N | N/A or Comment |
|---|---|---|---|
| 3. Vehicles placarded, driver qualifications current, supporting documentation sent to corporate, and emergency equipment available on vehicle when carrying DOT III shipments<br>49 CFR 172.504. DOT $ Fine SL III | ___ | ___ | _____ |
| 4. Security provided during loading of vehicles. Vehicles locked when unattended<br>10 CFR 20.207, SL III | ___ | ___ | _____ |
| 5. Accidents reported to corporate within 24 hours of occurrence.<br>10 CFR 20.403, SL V | ___ | ___ | _____ |
| 6. Tests results available on all DOT type 7A shipping containers that are used<br>49 CFR 173.461, DOT $ Fine, SL V | ___ | ___ | _____ |
| IV. Training (discussions with staff, records review)<br>10 CFR 19.121 | | | |
| A. Knowledge of staff members of license conditions and NRC Part 19.12. Proper documentation on RS-60, SL V | ___ | ___ | _____ |
| B. Knowledge of DOT requirements, emergency procedures and of the ALARA concept. Proper documentation RS-59, SL V | ___ | ___ | _____ |
| C. Female employees instructed in Regulatory Guide 8.13. Training properly documented on RS-60, SL V | ___ | ___ | _____ |
| D. Dispensers trained and tested in Moly/ alumina breakthrough testing. Training documented on RS-61a and proficiency documented on RS-61b<br>10 CFR 30.34 (g) and 35.204, SL V | ___ | ___ | _____ |
| E. Initial employment and periodic retraining programs conducted and documented on RS-59<br>Item 8, 10 CFR 19.12, SL IV | ___ | ___ | _____ |

| Page 13. IV. Training | | | N/A or |
|---|---|---|---|

| | Y | N | Comment |
|---|---|---|---|
| F. Training documentation available for personnel compounding I-131 therapy capsules. SL V | ___ | ___ | _____ |
| G. Personnel trained in the Bioassay procedure. Training documentation available, SL V | ___ | ___ | _____ |
| H. Personnel trained in Air Monitoring procedures. Training documentation available, SL V | ___ | ___ | _____ |
| I. Personnel trained in needle-less WBC procedure. Training documentation available, SL V | ___ | ___ | _____ |
| J. Contamination Smear training documentation available, SL V | ___ | ___ | _____ |

V. Regulatory (discussions with RSO)

| | | | |
|---|---|---|---|
| A. Pharmacy, State Law | | | |
| 1. Requested from the State Board of Pharmacy for advance approval of any remodeling, if appropriate, SL IV | ___ | ___ | _____ |
| 2. Advised the State Board of Pharmacy of any changes of Pharmacist in charge SL IV | ___ | ___ | _____ |
| 3. Misadministrations reported to corporate RSO and documented on RS-58 SL IV | ___ | ___ | _____ |
| 4. Technician duties clearly defined, documented, and in compliance with State Pharmacy Laws. SL III | ___ | ___ | _____ |
| 5. Used generators are not distributed for human use unless approved by RAM license, SL III | ___ | ___ | _____ |
| B. Personnel | | | |
| 1. Authorized user and pharmacist on site when radiopharmaceuticals are dispensed, labeled, handled, and/or packaged. License Condition 11, 12, SL III | ___ | ___ | _____ |

| B. Personnel | Y | N | Comment |
|---|---|---|---|
| 2. Customer license file current and complete, CFR 30.41 (d), SL IV | ___ | ___ | _____ |
| C. Radiation safety officer's functions 10 CFR 35.21 | | | |
| 1. Monthly regulatory audits performed, and copies sent to regulatory (Wayne, PA),SL IV | ___ | ___ | _____ |
| 2. Compliance program supervised to insure compliance by staff. All RS documents reviewed and initialed weekly by RSO, SL IV | ___ | ___ | _____ |
| D. Health physics correspondence | | | |
| 1. Copies of license, all amendments and correspondence organized and available. NPLG Section 1.2, SL V | ___ | ___ | _____ |
| 2. Current copies of State/NRC/DOT regulations available. Copy of pharmacy laws available, SL V | ___ | ___ | _____ |
| 3. All State/NRC inspection reports and corporate responses available and organized. 10 CFR 30.52, SL V | ___ | ___ | _____ |
| 4. All corporate audits (Management, Regulatory, Operations, etc.) available and organized. Company Policy, SL V | ___ | ___ | _____ |
| 5. Pharmacy in compliance with incident reporting requirements. SL V | ___ | ___ | _____ |
| 6. Letter to fire and police distributed and filed, if applicable. Item 9.1, SL V | ___ | ___ | _____ |

**INDEPENDENT SURVEYS:**

A. Radiation Surveys
Survey meter I.D.:
Last calibration date:
Background:_____

B. Contamination Surveys
Instrument I. D.:
Efficiency:
Last calibration date:
Background: _____

| AREA: | Net mR/HR | DPM | CORRECTIVE ACTION |
|---|---|---|---|
| 1. Generator room (at 1 foot) | | | |
| 2. Generator room (entrance) | | | |
| 3. Waste room (bins) | | | |
| 4. Waste room entrance | | | |
| 5. Laminar Flow Hood | | | |
| 6. Fume Hood | | | |
| 7. Floor around drawing station | | | |
| 8. Telephone, Analyzer knobs, etc. | | | |
| 9. Wrapping area | | | |
| 10. QC area | | | |

OTHER SERVICES: (in service training, reorganization of records, etc.)

Page 16.

COMMENTS: (List all comments by section number)

VIOLATIONS:

| ITEM NUMBER | POINTS |
|---|---|

TOTAL POINTS _____

RATING _____

FOLLOW-UP: Brief evaluation of follow-up needed to assist pharmacy to obtain full compliance:

_____ Signature of Auditor

_____ Signature of Manager after review of audit results with auditor

_____ Time of Completion

_____ Date

*ITEM 11 NRC - 313*

WASTE MANAGEMENT

Syncor confirms that they have established and agree to follow written procedures for disposal of radioactive waste by decay-in-storage and that these procedures include as requirements the criteria specified in 1 through 4 of Item 11.2.2 in the "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" dated August 1985.

*ITEM 11 NRC - 313*

WASTE MANAGEMENT

Syncor confirms that they have established and agree to fo'low written procedures for disposal of radioactive waste by decay-in-storage and that these procedures include as requirements the criteria specified in 1 through 4 of Item 11.2.2 in the "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" dated August 1985.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02500
STATUS CODE: 2
FEE CATEGORY: 3C
EXP. DATE: 19911031
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: SYNCOR CORPORATION
RECEIVED DATE: 910926
DOCKET NO: 3018920
CONTROL NO.: 115573
LICENSE NO.: 37-19586-01MD
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: $1400.00
CHECK NO.: 215521

3. COMMENTS

SIGNED Rebecca J. Brown
DATE 10/8/91

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

1. FEE CATEGORY AND AMOUNT: 3C $1400

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

3. OTHER

SIGNED Alto Jacques
DATE 10/17/91