NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 19

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 1, 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 Medical Services Group 2. 7446 Derry Street Harrisburg, Pennsylvania 17111	In accordance with letter dated November 27, 1992, 3. License number 37-19586-01MD is amended in its entirety to read as follows: 4. Expiration date December 31, 1997 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. 19

(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C. Any byproduct material authorized under paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987)	C. Any sealed source listed in paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or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
SUPPLEMENTARY SHEET

License number: 37-19586-01MD

Docket or Reference number: 030-18920

Amendment No. 19

(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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 37-19586-01MD
Docket or Reference number: 030-18920
Amendment No. 19

(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
SUPPLEMENTARY SHEET

License number: 37-19586-01MD
Docket or Reference number: 030-18920
Amendment No. 19

(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.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 7446 Derry Street, Harrisburg, Pennsylvania and 8181 President's Drive, Hummelstown, 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.

(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
SUPPLEMENTARY SHEET

License number: 37-19586-01MD

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Amendment No. 19

(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; or notwithstanding 10 CFR 32.72(a)(2), the licensee may prepare radiopharmaceuticals in accordance with the specific departures authorized in License Condition 17 of License Number 34-16654-01MD, provided that the licensee has all current specific departure directions and equipment required by License Condition 17 of License Number 34-16654-01MD nd they are available for inspection by the Commission.

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 37-19586-01MD
Docket or Reference number 030-18920
Amendment No. 19

(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. Notwithstanding 10 CFR 32.72(a)(2), the licensee may make departures to prepared iodine 131 (as sodium iodide) therapy dose radiopharmaceuticals, provided that the departures are made in accordance with License Condition 24 of License Number 34-16654-01MD and that the licensee has all current specific departure directions and required equipment and they are available for inspection.

23. 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. Letter dated April 4, 1991
    B. Letter dated July 30, 1991
    C. Letter dated August 13, 1991
    D. Application dated September 27, 1991
    E. Letter dated August 26, 1992
    F. Letter dated November 23, 1992
    G. Letter dated November 27, 1992

For the U.S. Nuclear Regulatory Commission

Original Signed By:
Thomas K. Thompson

Date FEB 0 5 1993

By
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

THE ATTACHED DOCUMENTS ARE TO BE PROCESSED AS ONE MATERIALS LICENSING PACKAGE UNDER.....

LICENSE NUMBER: 37-19586-01 MD

DOCKET NUMBER: 030-18920

CONTROL NUMBER: 117503

250043

FEB 0 5 1993

License No. 37-19586-01MD
Docket No. 030-18920
Control No. 117503

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

Dear Mr. Comer:

Please find enclosed an amendment to 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."

Prior to release of your old facility for unrestricted use you should be sure that the facilities meet the criteria in the enclosed "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct Source, or Special Nuclear Material." You should submit a report of the results of the surveys you performed to this office and refer to this letter.

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. 19
2. Requirements for Materials Licensees
3. Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material

DRSS:RI	DRSS:RI
Weidner/mlb	Thompson
1/25/93	2/2/93

030-18920

November 27, 1992

Address Change

Medical Licensing Section
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Amendment request for NRC Radioactive Material License Number 37-15986-01MD , Syncor International Corporation, Harrisburg, PA 17111

Attention Licensing:

Please amend the above referenced NRC Radioactive Material License Number 37-15986-01MD, Harrisburg, PA for authorization to move our nuclear pharmacy location to:

Syncor International Corporation
8181 President's Drive
Hummelstown, PA 17036

and to submit a decontamination survey for release of the facility we presently occupy for general use.

The attached information with respect to facilities, equipment, and use of Xenon-133 is submitted in support of this request.

Syncor confirms that all other commitments and procedures will be identical to our previously submitted license application dated 9/27/91 and any subsequent amendments.

Your consideration in this matter is appreciated.

Sincerely,

Frank M. Comer/gpw

Frank M. Comer
Program Director, Regulatory Support

Log	
Remitter	
Check No.	
Amount	
Fee Category	
Type of Fee	
Date Check Rec'd	
Date Completed	
By:	

cc: Robert Grobinski, Manager, RSO
License File

cy to MRV
SC

117503

OFFICIAL RECORD COPY ML 10

DEC 07 1992

FACILITIES AND EQUIPMENT

Site Description

1. This Syncor facility will be located in a commercially zoned area at: 8181 President's Drive, Hummelstown, PA 17036. This single story, freestanding building, utilizes brick and steel frame construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system. The restricted area has its own HVAC system.

2. Please see the attached site plan.

3. This building will have dead-bolt locks or mechanical combination locks on all entrances to the restricted area. A centrally monitored security system combining motion detectors and door contacts will be used for security.

4. The fume hood stack will extend five (5) feet above the roof line, and will be over 30 feet from the nearest point of access to the building or any unrestricted area.

5. We confirmed that operation of a nuclear pharmacy does not conflict with local codes and zoning laws.

6. Please see the attached letter which is sent to the police and fire departments unless the local Fire Marshall's office inspects the facility annually.

November 27, 1992

Address

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

Gentlemen:

We are required by the Nuclear Regulatory Commission and/or Agreement State to notify you that we are utilizing radioactive materials under NRC or Agreement State license at:

Syncor International Corporation
8181 President's Drive
Hummelstown, PA 17036

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

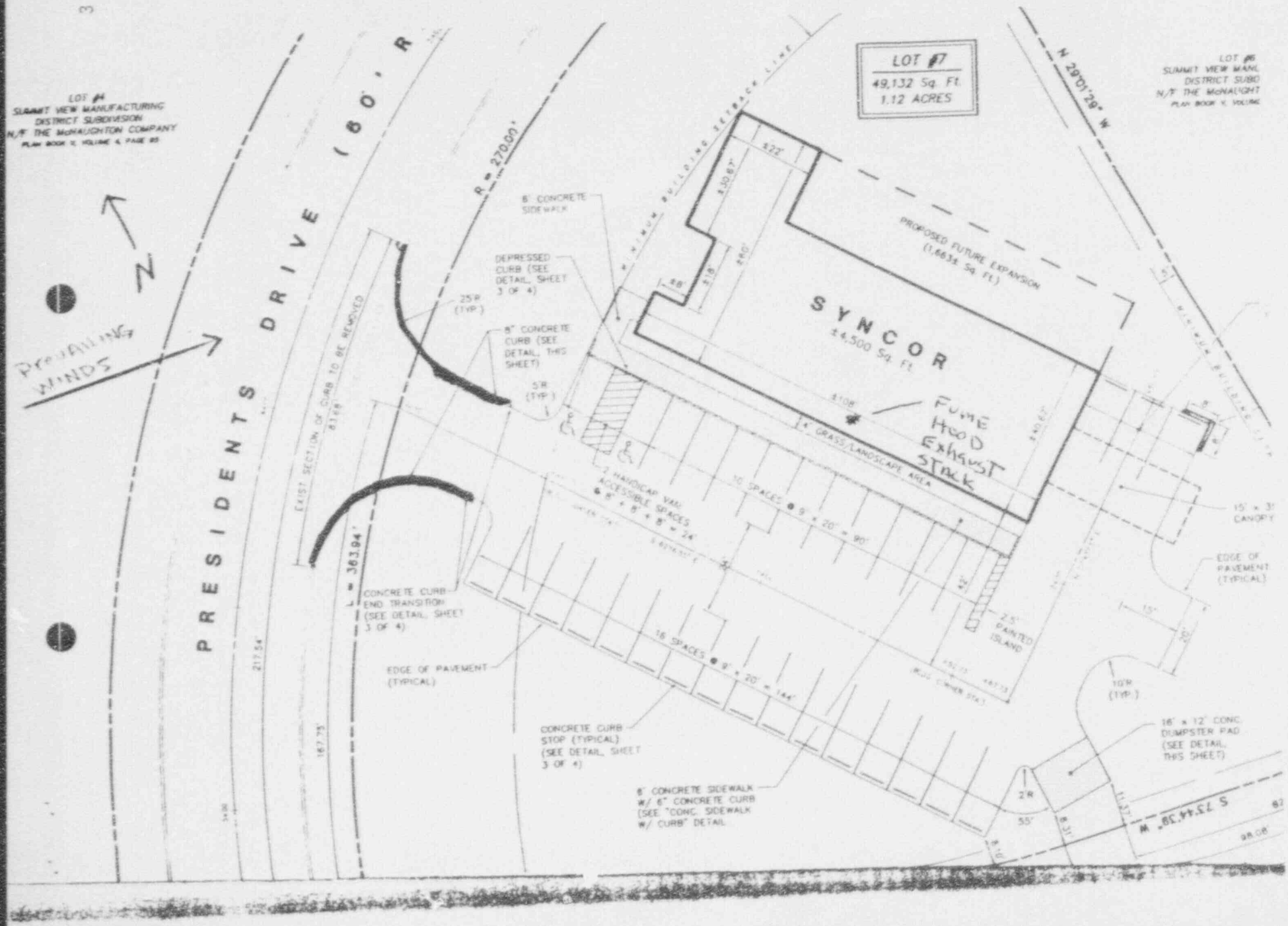
The material with which we work is for use by physicians for medical purposes, and, therefore, is comprised of short-lived radiopharmaceuticals.

Very little danger would exist in case of a fire or disaster; however, precaution should be exercised by fire fighting personnel should it be necessary to enter the room in which the radioactive material is stored. In the case of a fire, the non-volatile material would remain confined to this room, due to the nature of this building's construction.

Should it become necessary and possible to enter the pharmacy area, survey instruments are readily available, located in rooms adjacent to the radioactive storage room. Also, personnel trained in the use of survey instruments and familiar with hazardous radiation levels would be 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, do not hesitate to contact us.

The above letter is mailed to the Police Chief and Fire Chief with the appropriate information filled in specifically for our location.


LOT #4
SUMMIT VIEW MANUFACTURING DISTRICT SUBDIVISION
N/F THE McNAUGHTON COMPANY
PLAN BOOK X, VOLUME 4, PAGE 85
LOT #7
49,132 Sq. Ft.
1.12 ACRES
LOT #6
SUMMIT VIEW MANU. DISTRICT SUBD
N/F THE McNAUGHT
PLAN BOOK X, VOLUME
PRESIDENTS DRIVE (60' R
R = 270.00'
N 29°01'29" W
S 73°44'38" W
PROPOSED FUTURE EXPANSION (1,663± Sq. Ft.)
SYNCOR
±4,500 Sq. Ft.
FUME HOOD EXHAUST STACK
4' GRASS/LANDSCAPE AREA
2 HANDICAP VAN ACCESSIBLE SPACES
16 SPACES @ 9' x 20' = 144'
2.5' PAINTED ISLAND
15' x 3' CANOPY
EDGE OF PAVEMENT (TYPICAL)
10'R (TYP.)
16' x 12' CONC. DUMPSTER PAD (SEE DETAIL, THIS SHEET)
8' CONCRETE SIDEWALK
DEPRESSED CURB (SEE DETAIL, SHEET 3 OF 4)
25'R (TYP.)
8" CONCRETE CURB (SEE DETAIL, THIS SHEET)
5'R (TYP.)
EXIST. SECTION OF CURB TO BE REMOVED
CONCRETE CURB END TRANSITION (SEE DETAIL, SHEET 3 OF 4)
CONCRETE CURB STOP (TYPICAL) (SEE DETAIL, SHEET 3 OF 4)
8' CONCRETE SIDEWALK W/ 6" CONCRETE CURB (SEE "CONC. SIDEWALK W/ CURB" DETAIL
PREVAILING WINDS
N

General Description of Facility

Syncor International Corporation has leased approximately 4500 square feet of space for use as a radiopharmacy in a single story, freestanding building located in a commercially zoned area. Sketches of the floor plan and equipment placement are attached to this written description.

UNRESTRICTED AREA

See attached sketch.

RESTRICTED AREA -1300 square feet

Elution Room - 90 square feet

This area will be used for storage of ongoing, used radiopharmaceuticals, including Mo99/Tc99m generators. Benches are provided for generator storage and elution. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary.

Iodine Room - 90 square feet

This room will house the fume hood and glove box type fume hood. All volatile substances will be stored and handled in this area. A negative pressure will be maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent will be located in this room. These measures are taken to ensure that no air from this room may be circulated to other areas of the facility. 1/2" thick lead barrels will also be used in this room for storing Iodine 131 waste in sealed containers, i.e., zip-lock plastic bags.

Radiopharmaceutical Dispensing Area (Pharmacy) - 690 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Drawing stations will be located as shown on the attached sketch. The drawing stations will consist of: a leaded glass L-block, a dose calibrator, and one 12" forceps. The L-block shields will be a minimum of 1" thick lead with leaded glass viewing windows.

Radiopharmaceutical Dispensing Area (continued)

Technetium and technetium products will be eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers, all of which have a minimum of 1/4" thick lead. Quality control, as well as shipping and packaging, will be done in this area. A refrigerator is also located in this area for storing radiopharmaceuticals and cold kits which require refrigeration.

Waste Storage and Break Down Area - 132 square feet

This waste storage room will be used for the storage and decay of waste materials. Waste will be stored in lead barrels 16" in diameter, 24' high and 3/8" thick. Ample lead bricks 2" x 4" x 8" are provided for additional shielding, as necessary. This area will also be used for receipt and handling of radiopharmaceutical deliveries.

Storage -220 square feet

This area will be used for storage of supplies and waste which has been decayed to low levels i. e. less than 2 milli-roentgen/hour prior to final decay and transfer to the medical waste hauler.

Labeling (WBC Tagging Area) - 84 square feet

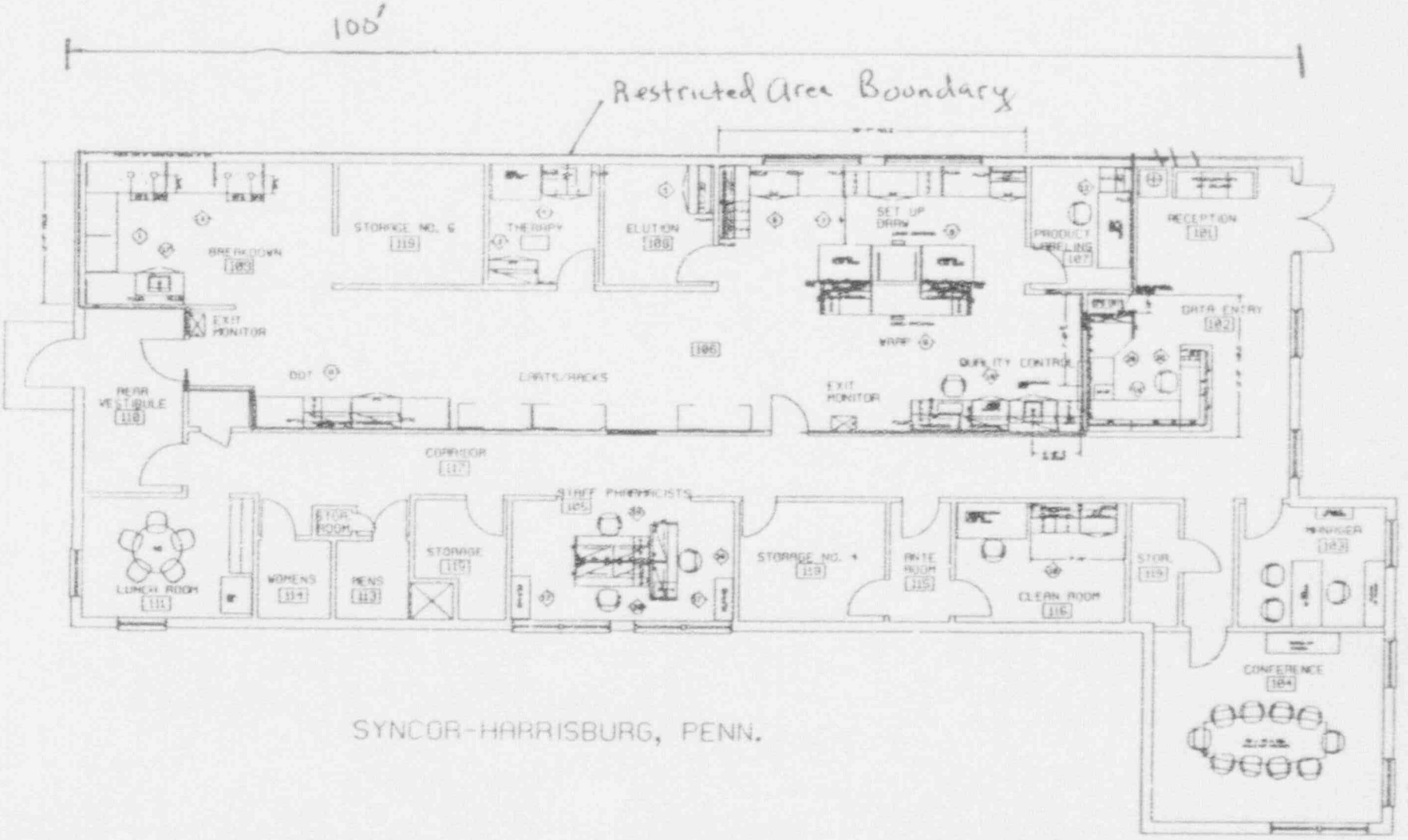
This are will house the biohazards hoods and be used for blood cell component tagging.

NOTE: After hours delivery will be made to the rear door in the room labelled Vestibule. This area is a heated area. Common carriers will be instructed to lock the outside door on completion of the delivery. The common carrier will not have access to the nuclear pharmacy area proper.

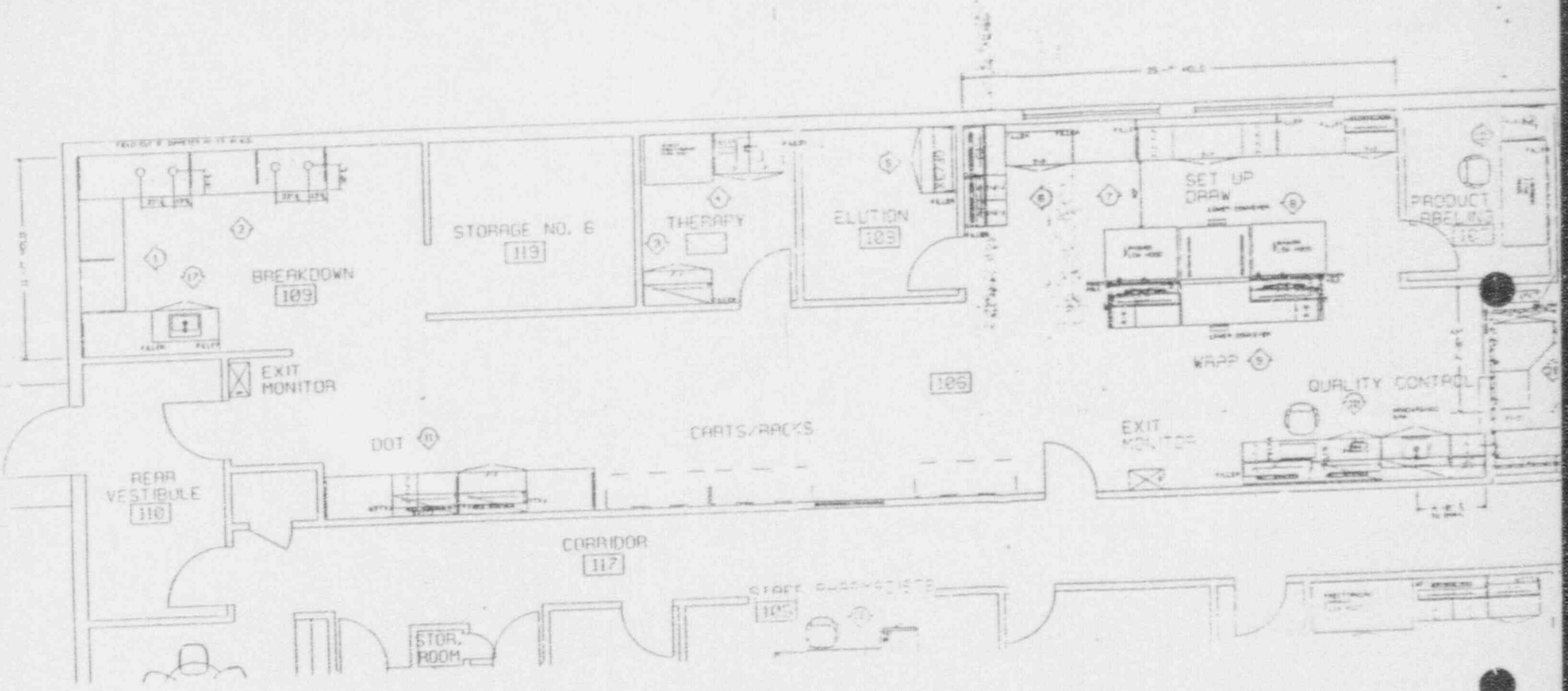
SHIELDING

Generator Area:	Manufacturer's shielding 1/2" lead "Shield" around each generator plus additional lead shielding as necessary.
Refrigerator:	Manufacturer's shielding, 1/2" lead around isotope storage.
Isotope Storage:	Manufacturer's shielding, plus 2" x 4" x 8" lead bricks.
Waste Storage:	10-1/2" & 2-3/4" thick lead barrels, 18.5 in diameter, 24" high mounted on casters. 2" x 4" x 8" lead bricks, where necessary.

Scale:


100'
Restricted Area Boundary
BREAKDOWN
105
STORAGE NO. 6
119
THERAPY
ELUTION
106
SET UP
DRAW
PRODUCT
RELEASING
107
RECEPTION
101
DATA ENTRY
102
EXIT
MONITOR
WAFF
QUALITY CONTROL
DDT
CARTS/RACKS
REAR
VESTIBULE
110
EXIT
MONITOR
CORRIDOR
117
STAFF PHARMACISTS
105
LUNCH ROOM
111
WOMENS
114
MENS
113
STORAGE
118
STORAGE NO. 4
119
ANTE
ROOM
115
CLEAN ROOM
116
STOR.
MANAGER
103
CONFERENCE
104
SYNCOR-HARRISBURG, PENN.

N



SCALE: 1" = 8.53'
Restricted Area

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 area

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 the Xenon-133. Please see attached floor plan diagram for the location of the fume hood. The nearest unrestricted controlled area is the entrance to the dispensing area from the hallway which is over 20 feet away.

2. Describe the ventilation in all areas where Xenon-133 is stored and dispensed. Exhaust > 300 CFM from fume hood, supply 150 cfm with no return vents. This room remains under constant negative pressure.

Xenon-133 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. The fume hood has a rated air flow of >300 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 20.106 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 ordered 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 or increasing the ventilation of the area.

Procedure

This pharmacy has an exclusive heating and cooling system.

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

2. Notify all personnel, close all doors, and evacuate the room for 15 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 15 minutes or until normal background levels are measured in the facility.

4. Notify the Quality and Regulatory Department and document the incident.

These calculations demonstrate that fourteen (14) minutes is adequate for Xenon-133 concentration to return below 1×10^{-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 if the evacuation time for the volatile substance handling room if a 40 millicurie vial of Xenon-133 was dropped and broken?

$V = 10 \times 9 \times 9\ ft^3 \times 2.83 \times 10^4\ ml/ft^3 = 2.29 \times 10^7\ ml$

$Q = 300\ ft^3/min \times 2.83 \times 10^4\ ml/min/ft^3/min = 8.49 \times 10^6\ ml/min$

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

A = 40,000 uCi

$$t = \frac{-2.29 \times 10^7}{8.49 \times 10^6} \times \ln \left(1 \times 10^{-5} \times \frac{2.29 \times 10^7}{4 \times 10^4} \right)$$

$$t = -2.70 \times \ln \left(1 \times 10^{-5} \times 5.73 \times 10^2 \right)$$

t = 13.9 minutes

After 14 minutes, the concentration of Xenon-133 in this area would have returned to a permissible level in uCi/ml.

E. Air concentrations of Xenon-133 for unrestricted areas.

1. All Xenon-133 gas will be handled and dispensed in the fume hood.

   a. Estimate the maximum amount of activity to be user 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 in mCi is 1,500. This will be the maximum amount stored in the fume hood.

3. We have recently completed a study which indicates that the leakage from Xenon-133 vials is more realistically 0.05% per vial per day rather than 0.5% submitted by NEN at an earlier date. See data enclosed in our license application from our study. 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 1,500 mCi on hand seven days a week (both assumptions are excessive), then:

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

4. The exhaust across the fume hood is 300 cubic feet per minute. Calculating (V) in metric terms:

   $$V = \frac{300 \text{ cubic ft}}{\text{minutes}} \times \frac{60 \text{ min}}{\text{hours}} \times \frac{24 \text{ hrs}}{\text{day}} \times \frac{7 \text{ days}}{\text{week}}$$

   $$\times \frac{1728 \text{ cubic in}}{\text{cubic feet}} \times \frac{16.39 \text{ ml}}{\text{cubic in}}$$

   $$V = 8.56 \times 10^{10} \text{ ml/wk}$$

5. For unrestricted areas, 10 CFR 20, Appendix B, Table II requires that the maximum allowed concentration is:

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

In our case:

$$\frac{A \times f}{V} = \frac{1.5 \times 10^{6} \text{ uCi}}{8.56 \times 10^{10} \text{ ml/wk}} \times \frac{3.5 \times 10^{-3}}{\text{wk}} = 6.10 \times 10^{-8} \frac{\text{uCi}}{\text{ml}}$$

F. Methods for Xenon-133 disposal

1. Xenon-133 vials not marketed to hospitals 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 shows the vials to be at background radiation levels.

G. Please note that Xenon-133 will not be used in the radiopharmacy. It will be assayed in a dose calibrator and repackaged in its original shipping container and distributed to authorized recipients.

H. The exhaust stack from the fume hood is exclusive for this fume hood, is located over 30 feet from the nearest air intake.

August 19, 1985

Mr. Frank Comer
Syncor International Corporation
Health Physics Group
3939 First Avenue
Paramount, CA 92103

Dear Frank:

Enclosed is the result of the Xenon leakage study we did on the NEN xenon vials. We used 10 x 10 mCi and 8 x 20 mCi Xe-133 vials. The vials were assayed when they were received and then returned to their containers. After a week the vials were assayed again. The Final Calculated Activity was determined based on the Initial Assayed Activity. There was hardly any amount lost. Even the few that did show a difference were probably just fluctuations of the dose calibrator reading.

Sincerely,

Verne

encl.

XENON-133 LEAKAGE DATA SHEET

Dose Calibrator CAPINTEC Serial # 10859

Calibration Factor Xenon-133 Background 0.1 uCi

Activity Loaded 523.8 mCi Date 5/31/85 Time 12:00

DATE	TIME of FILTER REMOVAL & REPLACEMENT	#1 (uCi)	#2 (uCi)	#3 (uCi)	TOTALS
6/1/85	12:00	0.3	0.1	0.3	0.7 uCi
6/2/85	12:00	0.1	0.1	0.2	0.4 uCi
6/3/85	12:00	3.2	1.2	0.7	5.1 uCi
6/4/85	12:00	2.0	1.3	0.8	4.1 uCi
6/5/85	12:00	2.6	1.5	1.7	5.8 uCi
6/6/85	12:00	6.3	5.5	3.8	15.6 uCi
6/7/85	12:00	6.1	4.8	3.7	14.6 uCi
TOTALS		20.6 uCi	14.5 uCi	11.2 uCi	46.3 uCi

COMMENTS: THE ABOVE VALUES WERE FROM 10 X 10 mCi AND 8 X 20 mCi MEDI-PHYSICS XENON VIALS.

Signature signed by Verne Y. Tabacon

Date 6/7/85

MEDI-PHYSICS 10 mCi & 20 mCi Xe-133 VIALS

Xenon-133 Leakage Start: 5/31/85 End: 6/7/85

SOURCE	INITIAL ASSAYED ACTIVITY (mCi)	FINAL ASSAYED ACTIVITY (mCi)	CALCULATED FINAL ACTIVITY (mCi)	ACTIVITY LOST in 7 DAYS (mCi)
A	21.9	8.43	8.45	0.020
B	21.0	8.16	8.15	- 0 -
C	20.7	8.06	8.03	- 0 -
D	19.8	7.68	7.68	- 0 -
E	20.2	7.87	7.84	- 0 -
F	20.8	8.06	8.07	0.010
G	20.4	7.95	7.92	- 0 -
H	21.6	8.40	8.38	- 0 -
I	21.7	8.39	8.42	0.030
J	21.1	8.22	8.19	- 0 -
K	39.1	15.25	15.17	- 0 -
L	38.9	15.24	15.09	- 0 -
M	42.4	16.68	16.45	- 0 -
N	38.5	14.96	14.94	- 0 -
O	41.4	16.12	16.06	- 0 -
P	38.3	14.85	14.86	0.010
Q	38.7	15.12	15.02	- 0 -
R	37.3	14.55	14.47	- 0 -
			203.24 mCi	0.070 mCi

$$\% \text{ LOSS IN 7 DAYS} = \frac{0.070}{203.24} \times 100 = 0.0344\%$$

AVERAGE LOSS PER DAY = 0.0049%

Signature signed by Verne Y. Tabacon

Date 6/7/85

XENON-133 LEAKAGE DATA SHEET

Dose Calibrator CAPINTEC Serial # 10859

Calibration Factor Xenon-133 Background _____ uCi

Activity Loaded 428.1 mCi Date 6/28/85 Time 10:00

DATE	TIME of FILTER REMOVAL & REPLACEMENT	#1 (uCi)	#2 (uCi)	#3 (uCi)	TOTALS (uCi)
6/29/85	10:00	12.9	3.9	3.8	20.6
6/30/85	10:00	10.6	9.1	9.7	29.4
7/1/85	10:00	30.6	11.3	10.4	52.3
7/2/85	10:00	44.4	17.2	9.1	70.7
7/3/85	10:00	62.2	44.2	10.3	116.7
7/4/85	10:00	15.6	2.3	0.2	18.1
7/5/85	10:00	25.0	2.1	1.1	28.2
TOTALS		201.3	90.1	44.6	336.0

COMMENTS: 10 X 10 mCi and 8 X 20 mCi NEN XENON VIALS.

Signature signed by Verne Y. Tabacon

Date 7/5/85

NEN 10 mCi & 20 mCi Xe-133 VIALS

Xenon-133 Leakage Study Start: 6/28/85 End: 7/5/85

SOURCE	INITIAL ASSAYED ACTIVITY (mCi)	FINAL ASSAYED ACTIVITY (mCi)	CALCULATED FINAL ACTIVITY (mCi)	ACTIVITY LOST in 7 DAYS (mCi)
A	16.8	6.45	6.52	0.07
B	16.7	6.42	6.48	0.06
C	16.6	6.42	6.44	0.02
D	16.6	6.39	6.44	0.05
E	16.8	6.45	6.52	0.07
F	15.7	6.04	6.09	0.05
G	16.5	6.36	6.40	0.04
H	16.6	6.40	6.44	0.04
I	16.2	6.27	6.28	0.01
J	16.1	6.23	6.25	0.02
K	32.6	12.56	12.65	0.09
L	32.7	12.56	12.68	0.12
M	33.1	12.71	12.84	0.13
N	33.4	12.79	12.96	0.17
O	33.1	12.74	12.84	0.10
P	33.0	12.71	12.80	0.09
Q	33.3	12.89	12.95	0.06
R	32.3	12.39	12.53	0.14
			166.11 mCi	1.33 mCi

$$\% \text{ LOSS IN 7 DAYS} = \frac{1.33}{166.11} \times 100 = 0.8006\%$$

AVERAGE LOSS PER DAY = 0.114%

Signature signed by Verne Y. Tabacon

Date 7/5/85

XENON-133 LEAKAGE DATA SHEET

Dose Calibrator CAPINTEC Serial # 10859

Calibration Factor Xenon-133 Background _____ uCi

Activity Loaded 417.38 mCi Date 7/5/85 Time 10:00

DATE	TIME of FILTER REMOVAL & REPLACEMENT	#1 (uCi)	#2 (uCi)	#3 (uCi)	TOTALS (uCi)
7/6/85	10:00	40.4	7.3	0.3	48.0
7/7/85	10:00	13.3	0.9	0.0	14.2
7/8/85	10:00	12.0	1.2	0.4	13.6
7/9/85	10:00	57.5	36.5	4.0	98.0
7/10/85	10:00	50.8	14.7	11.7	77.2
7/11/85	10:00	28.8	17.7	10.8	57.3
7/12/85	10:00	36.9	23.0	9.3	69.2
TOTALS		239.7	101.3	36.5	377.5

COMMENTS: 10 X 10 mCi and 8 X 20 mCi NEN XENON VIALS.

Signature signed by Verne Y. Tabacon

Date 7/12/85

NEN 10 mCi & 20 mCi Xe-133 VIALS

Xenon-133 Leakage Study Start: 7/5/85 End: 7/12/85

SOURCE	INITIAL ASSAYED ACTIVITY (mCi)	FINAL ASSAYED ACTIVITY (mCi)	CALCULATED FINAL ACTIVITY (mCi)	ACTIVITY LOST in 7 DAYS (mCi)
A	16.50	6.53	6.54	0.01
B	16.58	6.56	6.58	0.02
C	17.0	6.70	6.74	0.04
D	16.81	6.62	6.67	0.05
E	17.10	6.77	6.78	0.01
F	16.69	6.59	6.62	0.03
G	16.67	6.61	6.61	- 0 -
H	17.03	6.75	6.75	- 0 -
I	16.48	6.51	6.54	0.03
J	16.72	6.62	6.63	0.01
K	30.7	12.17	12.18	0.01
L	30.9	12.20	12.25	0.05
M	31.1	12.21	12.33	0.12
N	31.1	12.30	12.33	0.03
O	30.2	11.96	11.96	0.02
P	32.5	12.87	12.89	0.02
Q	32.1	12.70	12.73	0.03
R	31.2	12.36	12.37	0.01
			165.52 mCi	0.49 mCi

$$\% \text{ LOSS IN 7 DAYS} = \frac{0.49}{165.52} \times 100 = 0.296\%$$

AVERAGE LOSS PER DAY = 0.042%

Signature signed by Verne Y. Tabacon

Date 7/12/85

NEN 10 mCi & 20 mCi Xe-133 VIALS

Xenon-133 Leakage Study Start: 8/2/85 End: 8/9/85

SOURCE	INITIAL ASSAYED ACTIVITY (mCi)	FINAL ASSAYED ACTIVITY (mCi)	CALCULATED FINAL ACTIVITY (mCi)	ACTIVITY LOST in 7 DAYS (mCi)
A	15.0	5.97	5.95	- 0 -
B	15.0	5.96	5.95	- 0 -
C	15.1	5.99	5.99	- 0 -
D	15.0	5.97	5.95	- 0 -
E	14.7	5.81	5.83	0.02
F	16.0	6.37	6.35	- 0 -
G	16.3	6.46	6.46	- 0 -
H	16.3	6.48	6.46	- 0 -
I	16.5	6.54	6.54	- 0 -
J	15.8	6.30	6.27	- 0 -
K	31.5	12.53	12.49	- 0 -
L	31.8	12.60	12.61	0.01
M	31.3	12.41	12.41	- 0 -
N	31.5	12.48	12.49	0.01
O	32.0	12.71	12.69	- 0 -
P	31.8	12.63	12.61	- 0 -
Q	31.2	12.39	12.37	- 0 -
R	30.4	12.08	12.06	- 0 -
			161.48 mCi	0.04 mCi

$$\% \text{ LOSS IN 7 DAYS} = \frac{0.04}{161.48} \times 100 = 0.0248\%$$

AVERAGE LOSS PER DAY = 0.0035%

Signature signed by Verne Y. Tabacon

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.

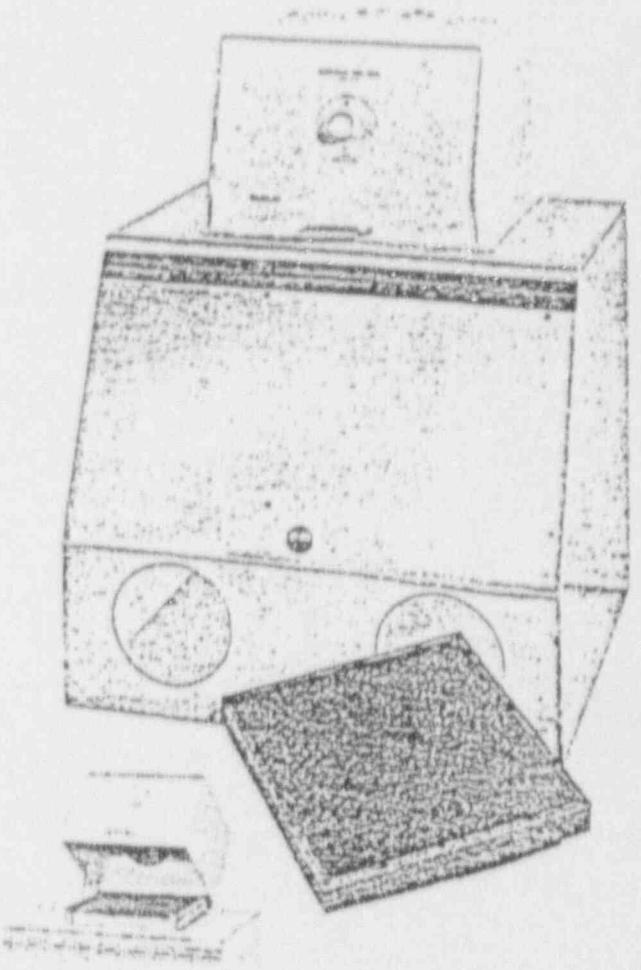
The efficiency of this trapping system is checked weekly. The filters are removed and the radiation level at their surfaces is measured with a pancake probe type survey meter or more sensitive device. When the measured level of the top filter is equal to or greater than 10% of the measured level of the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

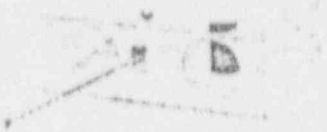


Constructed of 3/8" clear plexiglass, this rugged Radioiodine Fume Hood is designed to meet the problems associated with iodination procedures. The large internal work area and spacious arm ports allow maximum uninhibted manipulation of material within the unit. A 24" x 13" swing-away front door permits 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

EQUIPMENT AND STANDARDS

Item 1

A TEDA-impregnated carbon cartridge 2 1/4" in diameter and 1" high (HI-Q Environmental Products Co., La Jolla, CA, 619/549-2820, Catalog #TC-12) will be used with no pre-filter. The manufacturer's stated efficiency factor is 99% at 0.35 CFM or 10 liters per minute for worst case, i.e., for methyl iodide. Please see attached graph.

Item 2

a. Syncor confirms that sampling will be done on a continual basis.

b. Air sampling cartridges will be exchanged every 7 days.

c. For outer dimensions of 2 1/4" diameter by 1" inch, the volume of the TEDA carbon is calculated using a 3/4" radius with a 3/4" thickness:

$$\frac{RESIDENCE}{TIME} = \frac{Volume\ of\ Absorber\ (ft^3)}{Sample\ Rate\ (ft^3/min)}$$

$$\frac{RESIDENCE}{TIME} = \frac{1.36 \times 10^{-3}\ ft^3}{0.35\ ft^3/min} = 3.9 \times 10^{-3}\ min = 0.23\ sec$$

d. Please see the attached example of the geometrical relationship between the sample cartridge/standard cartridge and the scintillation detector.

e. A Barium-133 standard will be placed on the scintillation probe in the same geometrical configuration as the sample cartridge. The analyzer transmission will be set between 300 keV and 430 keV (or in equivalent channels if an MCA is used), and the instrument will be peaked to obtain the maximum count rate for the standard. The standard will be counted for a minimum of 10,000 net CPM to insure an accuracy of 2% at 95% confidence level, i.e., two (2) standard deviations. This calibration will be performed each time the sample cartridge is counted and the activity of the standard in net CPM will be used in the determination of sample cartridge Iodine-131 activity. The following calibration sources will be available. An LLD and an MDA will be determined for the standards.

Isotope Products Laboratories (IPL)
1800 N. Keystone Street
Burbank, CA 91504
818/843-7000

IPL P/N EG-133-CH: Barium-133
0.5 uCi in Charcoal Cartridge.
Calibrated & NIST traceable.

Item 3

a. The equipment will be checked prior to use (every 7 days) with the Barium-133 standard to ensure accuracy of the system.

b. We have ordered tandem cartridge holders and will evaluate the second cartridge in-line each week for break through of the initial cartridge. This break through cartridge will be changed every four weeks.

c. The air flow measuring equipment will be calibrated annually using a mass flow calibrator which is calibrated annually for NIST traceability.

SKETCH OF METHOD FOR MOUNTING
AIR SAMPLING APPARATUS

STANDARD LABORATORY FUME HOOD

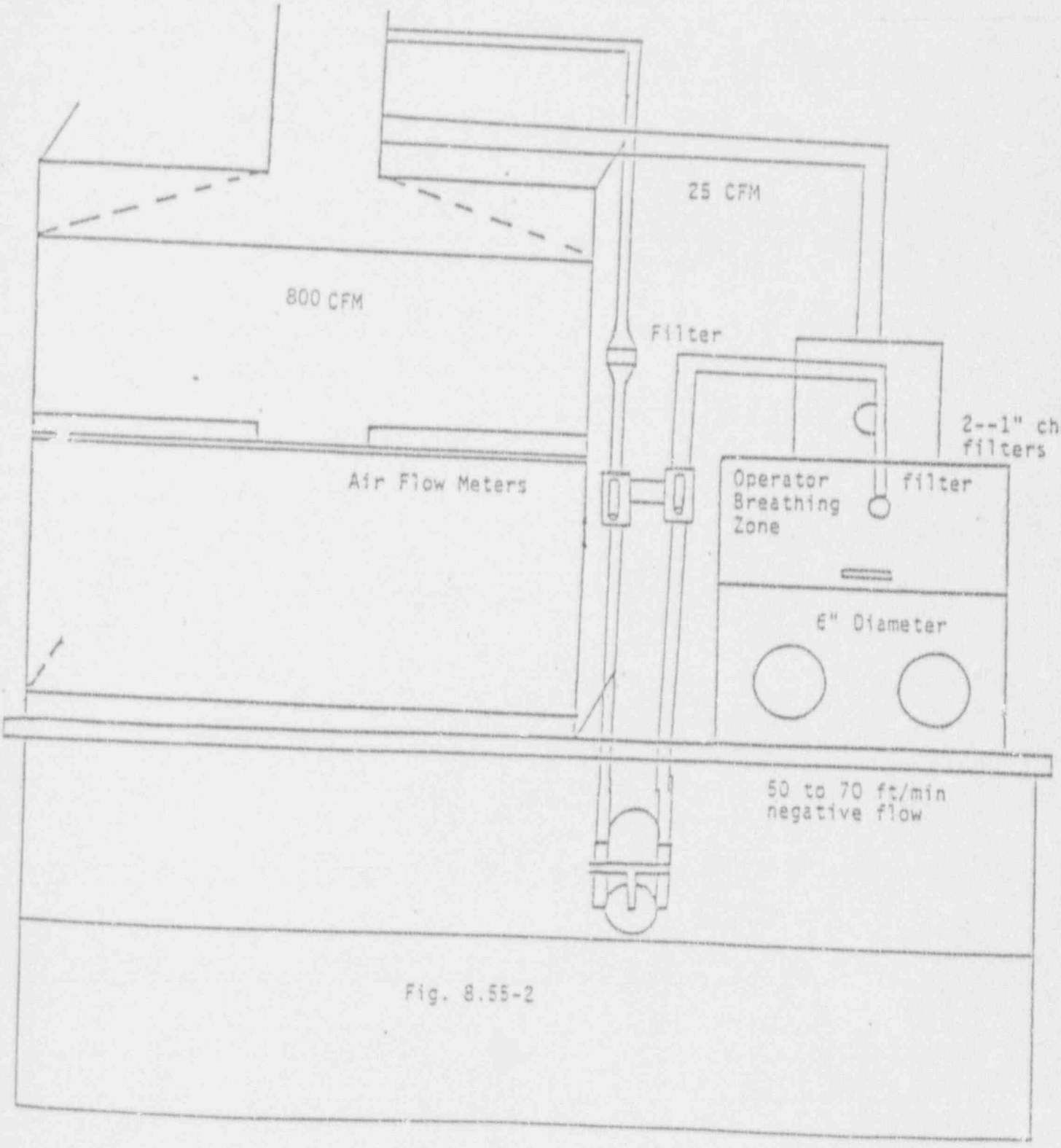


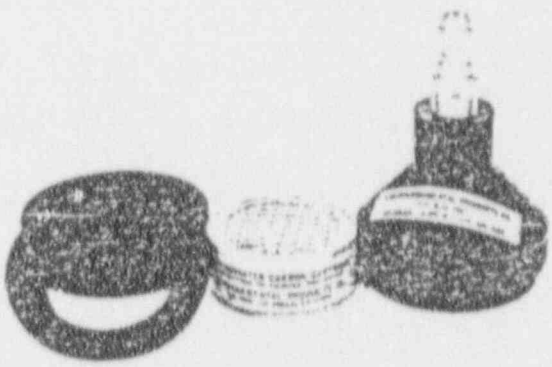
Fig. 8.55-2

CARBON CARTRIDGE TECHNICAL DATA

(HI-Q Environmental Products Company*, Catalog #TC-12 Cartridges)

Iodide Retention Efficiency	>98% at 10 liters/minute for methyl iodide, ASTM D3803, Method A, 1979 Procedure.
Physical Description	2.25" diameter, 1" thick, high density polypropylene (plastic)
Raw Material	Coconut Shell Carbon
Surface Area	1200-1300 m^2/gm, typical
Activation Method	High Temperature Steam
Particle Type	Natural Grain
Carbon Adsorptive Properties	ASTM-D3467 (Carbon Tetrachloride Activity = 40%)
Particle Size	ASTM-D2862 (8-16 mesh)
Impregnant	Triethylene Diamine (Tertiary Amines) 4-5%
Impregnant Disbursion	Vapor Diffusion

(* HI-Q Environmental Products, San Diego, CA, 619/549-2820)



Procedures for Completion of 131-I Air Monitoring

The following pages give detailed instructions for performing Iodine-131 air monitoring including operating procedures for cartridges. 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 Xenon-133. 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 Iodine-131, Syncor 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 computer generated form.

b. Equipment

1. Vacuum pump with air flow gauge,(rotameter)

   Because we will operate our air sampling equipment continually, evaluation of the effluent concentration will be done every 7 days.

2. Appropriate teflon tubing

3. Charcoal Cartridge holder

4. TEDA-impregnated charcoal cartridge

5. Scintillation counting assembly and Barium-133 cartridge standard

c. Operating Procedure for Air Cartridges

1. Mount the air sampling apparatus in a manner which will insure that effluent being released to both restricted and unrestricted areas will be sampled. Sampling must 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 decreases the amount of volatile I-131 Iodine that will escape into the restricted area.

2. The charcoal cartridge will be counted and exchanged every 7 days.

3. To obtain the data necessary to determine the activity in the cartridge:

   (a) Put on disposable gloves.

   (b) Calibrate the counting system by placing the Barium-133 cartridge standard directly on the scintillation probe housing. Set the analyzer transmission with the lower discriminator at 300 keV and the upper discriminator at 430 keV and peak the instrument by adjusting the high voltage potentiometer or gain control. Obtain a count on the standard. Remove the standard and obtain a background count. Record the background and standard counts on RS-55 form or enter this data into the RS-55 computer program

   (c) Place the cartridge on the scintillation probe in the same geometrical configuration as the standard source; and,

   (d) Obtain a count on it. Make sure that an efficiency factor (F_e) for the Barium-133 standard with the 131-Iodine correction factor has been calculated for the analyzer setting in (b) above.

   (e) Record the 131-Iodine count on Form RS-55 or enter this data into the RS-55 computer program.

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

5. Record uCi quantity of Barium-133 Standard.

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 attached worksheet).

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

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

$$\text{Iodine-131 uCi} = \frac{\text{Net cpm } e^{\lambda t} * \text{ (cartridge)}}{(CF)} \quad \text{where}$$

CF = the Ba-133 standard in cpm/uCi corrected for photon yield and $e^{\lambda t}$ is the correction factor for decay.

(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.

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

(e) The maximum permissible concentrations are:

(i) Unrestricted area MPC = 1×10^{-10} uCi/ml
(ii) Restricted area MPC = 9×10^{-9} uCi/ml

2. Useful Conversion Factors are:

(a) 1 ft^3 = 2.832×10^{-2} m^3 = 2.832×10^4 ml
(b) 1 ft^3/min = 2.832×10^4 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 $\frac{\text{I-131}}{\text{Ba-133}} = R_p$

e. Procedures for Installation

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

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

* If a Barium-133 standard is used, CF may be corrected for photon yield, however, the actual correction factor is dependent on the equipment used to obtain your data. $e^{\lambda t}$ is the correction for decay of the I-131 trapped in the cartridge.

WORK SHEET FOR IODINE-131 AIR MONITORING

A. To determine uCi of Iodine-131 in cartridge:

1. Well counter background (bkg) = _____ cpm.

2. Sample count (cartridge) = _____ cpm.

3. Barium-133 x R_p = _____ cpm.*

4. Ba-133 Standard Activity = _____ uCi.

5. I-131 Activity (uCi) = $\frac{\text{Net Cartridge Count x } e^{\lambda t} \text{ (cpm)}}{\text{CF (cpm/uCi)}}$ = ___ uCi

6. Where: CF = $\frac{\text{Net Ba-133 Standard Count x } R_p \text{ (cpm)}}{\text{Activity of Ba-133 Standard (uCi)}}$ = ____cpm/uCi

B. Determine flow through sampling pump:

1. Measured sample pump flow = _____ ml/min.

2. Pump-on Duration = _____ min.

Pump Flow _____ ml/min x Pump-on Duration ____ min = ___ ml

C. Determine concentration in uCi/ml:

1. I-131 Concentration in Air (uCi/ml) = $\frac{\text{I-131 UCi from A5 above}}{\text{Flow through pump (ml)}}$

Instrument _____ Analyzer Setting ___
_____ keV to _____ keV

Signature _____ Date _____
_____

*Photon Yield Ratio (I-131/Ba-133) = R_p

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02500
STATUS CODE: 0
FEE CATEGORY: 3C 2B
EXP. DATE: 19911031
FEE COMMENTS: ----------
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: SYNCOR INTERNATIONAL CORPORATION
RECEIVED DATE: 921207
DOCKET NO: 3019920
CONTROL NO.: 117503
LICENSE NO.: 37-19586-01MD
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: #490.00
CHECK NO.: 33405

3. COMMENTS

SIGNED Rebecca J. Brown
DATE 12/8/92

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

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

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

3. OTHER ----------

SIGNED [signature]
DATE 12/23/92