



The Service Difference®

Syncor International Corporation

August 24, 2001

U.S. Nuclear Regulatory Commission
611 Ryan Plaza Drive
Suite 400
Arlington, TX 76011

Attention: Mr. Jim Montgomery

RE: Additional Information for Renewal of Radioactive Materials License Number 04-26507-01MD, Syncor International Corporation, Woodland Hills, CA.

Dear Mr. Montgomery:

As a follow up to your phone conversation with Tanya Ridgle on August 20, 2001, Syncor presents the following additional information in support of the above referenced license renewal:

1. Syncor confirms that we will only accept return of Syncor supplied "used" and "unused" radioactive material. Please refer to attachment A for a copy of item 10.7 of the NRC renewal application dated 4/26/01, "Customer Procedures for Return of Limited Quantity Shipments of Radioactive Materials to Syncor," confirming this statement.
2. Syncor requests that the amendment request dated June 22, 2001 be referenced as a tie down letter on the renewed license. A copy of the amendment request is included in attachment B for your reference.
3. Syncor employees who are likely to exceed a dose of 100 mrem in a year are trained on Parts 19 and 20 of the Nuclear Regulatory Commission's Rules and Regulations, Title 10 Code of Federal Regulations. At a pharmacy level, Pharmacy Managers, Radiation Safety Officers, or a designee of one the two may conduct the training. Syncor has created a pamphlet pointing out the most relevant sections of Parts 19 and 20. Employees are given this pamphlet for their reference. After training is completed, the trainee must complete and sign Syncor's RS 64 form acknowledging that they have received and familiarized themselves with the contents of the pamphlet. A video is also currently used to supplement this training. An exam supports this video and is referred to as RS 70. A copy of the RS 64 form, RS 70 form and the pamphlet summarizing Parts 19 and 20 is included in attachment C for your reference.
4. The Authorized Nuclear Pharmacist/Authorized User program is a formally structured program designed to teach the required theories and applications necessary to successfully perform the duties at a nuclear facility. The program is accredited by the University of Arkansas and is audited by the University annually.

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 4
FOIA-2008-127

6464 Canoga Avenue • Woodland Hills, CA • 91367 • 818-737-4000

ALL

468551

All full-time instructors are recognized through our external accreditation process with the University of Arkansas. Currently, each instructor holds adjunct faculty status with the University. Instructor credentials are evaluated by Syncor representatives for appropriateness in teaching specific sections of the program. While most instructors possess at least a Bachelors degree, there are exceptions. A skilled technician level employee might be used to teach hands-on applications such as how to properly conduct a wipe test. Occasionally guest lecturers are utilized based on their expertise in a particular field and their credentials are evaluated on a case-by-case basis.

The program format consists of lectures utilizing handouts, audiovisuals, demonstrations and discussions, including problem-solving sessions, supervised laboratory practice and homework assignments.

Participants are tested on material presented through the techniques listed above. The tested material consists of but is not limited to theories in Radiation Physics, Radiation Instrumentation, Radiation Safety, Radiochemistry, Quality Assurance, Clinical Radiopharmacy and Radiation Biology. The exam format varies, but all exams require problem solving skills and the ability to analyze the material learned in lecture. In addition to exams, participants are required to illustrate their knowledge of the instrumentation in a nuclear facility by passing a lab practical administered by the instructors. The lab practical allows instructors to observe the participants as they simulate use of instruments.

The program consists of six exams given in a six-week period. Participants must pass all exams with a minimum grade of 70 percent and must have a combined exam average of 75% to successfully complete the course. Participants are allowed to take one exam retake per three-week session. A minimum score of 70% must be made on the retest. The exact number of exams and pass points may vary slightly in the future based upon the instructors' evaluation of the program needs.

If you have any additional questions pertaining to this letter please contact Tanya Ridgle at 818-737-4651.

Sincerely,



David W. Pellicciarini, CHP
Program Director, Health Physics

Cc: NRC Pharmacy RSO's
NRC License File (2)

Attachment A

10.7 Customer Procedures for Return of Limited Quantity Shipments of Radioactive Materials to Syncor

We will provide the following information to all customers on the procedure to ship radioactive materials back to the pharmacy.

MEMO TO SYNCOR CUSTOMERS

The United States Department of Transportation (DOT) has specific regulations pertaining to the transportation of radioactive materials. It is Syncor's intent to follow all DOT requirements when accepting the return package from you for transport and while transporting the package back to the pharmacy.

In an effort to clarify these regulations, and to ensure compliance, we have implemented the following policy with respect to packaging and delivery of return shipments. We ask your cooperation in assisting us in complying with the applicable regulations.

Our system of service involves retrieving radioactive material from you, our customer. Because you will be returning radioactive material to the pharmacy, you now become a shipper of radioactive material. Syncor is providing you with a simple system to ensure you properly prepare your package for return.

Return shipments should be shipped as "Limited Quantity Shipments". DOT regulations under 49 CFR 173.421, state that if a package meets the following requirements, it is exempted from the specification packaging, marking, and labeling requirements and can be classified as a Limited Quantity Shipment:

1. 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 mrem 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). (6600 dpm/300cm²)
4. The package has the appropriate notice statement as required in 49 CFR 173.422.
5. Other provisions of this regulation are satisfied by Syncor's present packaging.

Syncor will accept return of both Syncor supplied "used" and "unused" unit dose syringes. To assure safety of our employees, Syncor has developed the SECURE Safety Insert System for transporting syringes. The SECURE Safety Insert System consists of a plastic insert placed inside the unit dose shield. A new dose is shipped to our customer with the syringe inside of the plastic insert. After the dose is injected, the used syringe is placed back into the plastic insert in the unit dose container. The customer must then place a red cap over the top of the plastic insert/used syringe, sealing the used syringe in a sharps container. The top of the unit dose container is then screwed on.

The following procedure will meet all of the above requirements and must be followed prior to Syncor accepting your material for return:

1. Ensure that the material being returned does not exceed the specified limits for "Limited Quantity Shipments". This can be determined by reviewing the attached table with activity limits for nuclides. The total quantity of activity being returned must not exceed the specified "Limited Quantity Shipment" activity whether you are returning used dose material or unused doses.

a) Example of estimating return activity for Tc-99m products.

- (1) **Used Products.** Assume 5% remains in the syringe after an injection. If the syringe is held for 24 hours (4 half lives), the remaining activity from a 30 mCi dose, is:

$$30 \text{ mCi} \times 0.05 \times 0.0625 = 0.094 \text{ mCi}$$

If ten unit dose syringes were returned, and all ten had been 30 mCi doses, the package would contain only 940 μCi , which is well below the 21.6 mCi limit in the attached table.

- (2) **Unused Products.** If an unused syringe of a 30 mCi dose is held for 24 hours (4 half lives), the remaining activity is:

$$30 \text{ mCi} \times 0.0625 = 1.9 \text{ mCi}$$

It can be seen that a maximum of eleven of these syringes could be returned and remain below the 21.6 mCi limit for Tc-99m.

b) **Limited quantity activity limits for shipments of mixed radionuclides.**

- (1) When shipping more than one radionuclide in the same package, the limit on the radioactivity that may be shipped is the lowest activity assigned (see attached table) for the radionuclide shipped.
 - (2) Example: If Tc-99m and I-131 were being shipped in the same package, only 1.35 mCi of total activity could be shipped.
2. Ensure that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr.
 3. Ensure 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., 6600 dpm when wiped over a 300 cm^2 area.
 4. Ensure the Syncor provided card for the shipping container is turned to indicate the Limited Quantity Shipment information.
 5. Place in the predetermined area for pickup.

Syncor employees are instructed not to accept any package for return that has not met the above criteria.

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

Attachment B



The Service Difference

Syncor International Corporation

June 22, 2001

U.S. Nuclear Regulatory Commission
611 Ryan Plaza Drive
Suite 400
Arlington, TX 76011
Attention: Mr. James Montgomery
C/o Ms. Colleen Murpahan

RE: Amendment Request for Radioactive Materials License 04-26507-01MD, Syncor International Corporation, Woodland Hills, CA.

Dear Mr. Montgomery,

Please amend the above referenced licenses to include the use of the new set of labels described in the following pages. Container labels listed in previous correspondences, i.e. license applications and amendment requests, will also be used. If you have any questions regarding this request please contact Tanya Ridgle at 818-737-4651.

Sincerely,

A handwritten signature in black ink, appearing to read "David W. Pellicciarini", with a long horizontal flourish extending to the right.

David W. Pellicciarini, CHP
Program Director, Health Physics

Tdr

Cc: NRC Pharmacy RSO's
NRC Amendment Request File
Mr. James Montgomery, NRC Region IV Field Office

The following page contains a sample of container labels, which will be used according to the following guidelines.

REQUIRED CONTAINER LABELING:

1. **Syringes** will be labeled with label C.
2. **Vials** will be labeled with the manufacturer's original label or with label C.
3. **Unit dose container shields** will be labeled with label D.
4. **Vial shields** will be labeled with the manufacturers' original label and/or label D.

In addition to the container, syringe, and vial labels, the customer is supplied with a prescription (A) for their records that are not used as container labels. An additional copy of the prescription (B), is retained by Syncor for our records.

Label E is used as an identifier on the top of the unit dose container shield. It is used for sorting purposes and may or may not be included on all containers.

This Area Is Not Included On Final Label



Syncor International Corporation

Run: 1 Rte: 1 Order Date: 04/04/00
Rx#: 820394 Dispense Date: 04/04/00

St. Elsewhere Hospital



210 Derantno Way • Ameri, CA 91219

Dr. Eversole

Patient: Per Physician Order

Patient Injected: _____

Tc 99m Sodium Pertechnetate DC

Procedure: MUGA Scan

Lot: TcO406-0095-101

Qty. Disp: 100.00 mCi +/-10%

Assay: 50.00 mCi/ml

As Of: 04/04/00 10:00

Volume: 2.00 ml

Expires: 04/04/00 24:00

Estimated Price
\$10.00

Administer Intravenously
Product of Fission Mo99

Mo99 < 0.15 uCi/mCi Tc99m @ expiry

Customer Copy



Syncor International Corporation

Run: 1 Rte: 1 Order Date: 04/04/00
Rx#: 820394 Dispense Date: 04/04/00

St. Elsewhere Hospital

Dr. Eversole

210 Derantno Way Ameri, CA 91219

Patient: Per Physician Order

Tc 99m Sodium Pertechnetate DC

Procedure: MUGA Scan

Lot: TcO406-0095-101

Qty. Ord: 100.00 mCi

Quantity Dispensed

Assay: 208.33 mCi/ml

100.00 mCi

As Of: 04/04/00 at 10:00

QS to 2.00 ml

Volume: 0.48 ml

Entered By: JDS

Dispensed By: _____

Administer Intravenously
Product of Fission Mo99

Mo99 < 0.15 uCi/mCi Tc99m @ expiry

Expires: 04/04/00 24:00

Pharmacy Notes

Pharmacy Copy



Syncor International Corporation

St. Elsewhere Hospital

Dr. Eversole

210 Derantno Way • Ameri, CA 91219

Patient: Per Physician Order

Patient: _____

Tc 99m Sodium Pertechnetate

Rx#: 820394

Procedure: MUGA Scan

Lot: TcO406-0095-101

Qty Disp: 100.00 mCi +/-10%

As Of: 04/04/00 10:00

Qty Ord: 100.00 mCi

Assay: 50.00 mCi/ml

Volume: 2.00 ml

Expires: 04/04/00 24:00

Assay Activity: _____ Date: _____ @ _____ By: _____

Admin Activity: _____ Date: _____ @ _____ By: _____

Administer Intravenously
Product of Fission Mo99

Mo99 < 0.15 uCi/mCi Tc99m @ expiry



St. Elsewhere Hospital

210 Derantno Way • Ameri, CA 91219

Patient: Per Physician Order

Run: 1 Rte: 1

Delivery Date: 04/04/00

Rx#: 820394

Dr. Eversole

Tc 99m Sodium Pertechnetate DP

Procedure: MUGA Scan Lot: TcO406-0095-101

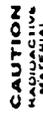
Qty Disp: 100.00 mCi +/-10% Volume: 2.00 ml

As Of: 04/04/00 10:00 Assay: 50.00 mCi/ml

Qty Ord: 100.00 mCi Expires: 04/04/00 24:00

Administer Intravenously Product of Fission Mo99

Mo99 < 0.15 uCi/mCi Tc99m @ expiry



CAUTION
RADIOACTIVE
MATERIAL

04/04/00

Syncor #820394

Tc 99m Sodium Pertechnetate

Patient: Per Physician Order

Procedure: MUGA Scan

2176 West 190th Street • Torrance, CA 90504

04/04/00

Syncor #820394

Tc 99m Sodium Pertechnetate

Patient: Per Physician Order

Procedure: MUGA Scan



This Area Is Not Included On Final Label

Attachment C

8.64 EMPLOYEE ACKNOWLEDGMENT FORM FOR RECEIPT OF THE
EMPLOYEES' GUIDE TO CFR TITLE 10, PARTS 19 AND 20 OR EQUIVALENT
AGREEMENT STATE REGULATIONS (RS-64)

This Section describes Form RS-64, the Employee Acknowledgment Form for Receipt of the Employees' Guide to CFR Title 10, Parts 19 and 20 or Equivalent Agreement State Regulations. A copy of this form is shown in FIGURE 8.64-1.

8.64.1 When to Complete the RS-64

The RS-64 should be completed when a new employee is hired or when an employee is transferred to a new location.

8.64.2 Special Instructions for the RS-64

It is important to have the RS-64 forms for all current employees readily available for an NRC or state inspection.

FIGURE 8.64-1

RS-64 (11/14/97)

**EMPLOYEE ACKNOWLEDGMENT FORM FOR RECEIPT OF
THE EMPLOYEES' GUIDE TO CFR TITLE 10, PARTS 19 AND 20
OR EQUIVALENT AGREEMENT STATE REGULATIONS (RS-64)**

Name: _____ Location No.: _____

Employee File No.: _____

Job Title: _____

In signing this form, I acknowledge that:

1. I have received and familiarized myself with the contents of the pamphlet entitled, "What You Should Know about Parts 19 and 20 of the Nuclear Regulatory Commission's or Equivalent Agreement State's Rules and Regulations."
2. My supervisor has satisfactorily answered any questions I had concerning this material.

Signed: _____ Date: _____

8.70 OVERVIEW OF RADIATION SAFETY, TRAINING FOR INDIVIDUALS
WORKING IN OR FREQUENTING RESTRICTED AREAS,
COMPETENCY EVALUATION (RS-70)

This Section describes Form RS-70, the Overview of Radiation Safety, Training for Individuals Working In or Frequenting Restricted Areas, Competency Evaluation. A copy of the form is shown in FIGURE 8.70-1.

8.70.1 Use of the RS-70

The RS-70 is based on the training video module entitled "Training for Individuals Working In or Frequenting Restricted Areas." This training module was developed for all pharmacy personnel and covers procedures for safe handling of radioactive materials. It is necessary for the employee to see the video program before taking the test.

Note that the video is a supplement to face-to-face training. The video alone does not provide a complete training module. The video must be supplemented with individual training and experience in your pharmacy, and an opportunity for the employee to ask questions and discuss the material presented.

This program is provided to comply with NRC rules and regulations, 10 CFR 19.12 (or equivalent Agreement State regulations) "Instructions to Workers." Participation in this program is required of all employees working in or frequenting any portion of a restricted area, and any other employees occupationally exposed to ionizing radiation.

8.70.2 When to Complete the RS-70

The RS-70 must be completed when a new employee is hired or is transferred to a new location, and annually thereafter.

8.70.3 Special Instructions for the RS-70

The minimum acceptable score on the RS-70 is 75% correct. The entire program is to be readministered and the employee retested until the requirement is met. A discussion of the test results should be conducted with the employee being tested.

See Section 9.2, Training Program, for additional information regarding the use of the competency evaluations.

FIGURE 8.70-1

**RADIATION SAFETY
COMPETENCY EVALUATION**

RS-70
Page 1 of 2

NAME: _____ DATE: _____ SCORE: _____

*Sequence 1: OVERVIEW OF RADIATION SAFETY; TRAINING FOR INDIVIDUALS
WORKING IN OR FREQUENTING RESTRICTED AREAS*

Part A: For all employees

INSTRUCTIONS

Provide a short answer to each of the following questions.

1. Describe three properties of radiation.
2. Where is the restricted area in your pharmacy?
3. Who is the RSO for your pharmacy?
4. What does ALARA stand for?
5. Name three ways that you can keep your exposure ALARA.
6. What is your responsibility when working around or with radioactive materials?
7. Where do you keep your badges and why?
8. Name the three basic principles of radiation safety.
9. Where are the regulations and the radioactive materials license for your pharmacy kept?
10. Where are the dosimetry reports for your badge readings?

FIGURE 8.70-1 (cont.)

Sequence 1: OVERVIEW OF RADIATION SAFETY (cont.)

RS-70
Page 2 of 2

INSTRUCTIONS : Circle **ALL** correct answers. There may be more than one right answer to each question.

1. Limiting radiation exposure is the responsibility of:
 - A. the employee (you)
 - B. the Radiation Safety Officer
 - C. the company (Syncor)
 - D. others working with you
2. Film badges:
 - A. are required **only** when you enter the restricted area
 - B. measure the amount of radiation you have been exposed to
 - C. are **not** sensitive to heat or moisture, only radioactivity
 - D. are changed every month
3. Areas where you would expect the highest exposure levels include:
 - A. the generator or elution room
 - B. the blood labeling room
 - C. the iodine room
 - D. the set-up area
4. When you notice unsafe conditions it is your obligation to:
 - A. report the condition to your radiation safety officer
 - B. report the condition to the pharmacy manager in writing
 - C. report the condition to the corporate offices
 - D. report the condition to your state radiologic health

Listed below are examples of safe handling of radioactive materials. Mark each example with the safety principle used to reduce exposure.

- | | |
|--------------|-----------------|
| A. Distance | B. Time |
| C. Shielding | D. Common sense |
5. ___ Use tongs to transfer syringes into the calibrator
 6. ___ Surround a radioactive source with lead
 7. ___ Stay in the iodine room only as long as needed to complete your task
 8. ___ Ask the pharmacist in charge when you see something unusual returned in the ammo can
 9. ___ Keep the waste bin lid closed when not in use



Syncor International Corporation

What You Should Know About

Parts 19 & 20

**of the Nuclear Regulatory Commission's
Rules and Regulations**

CONTENTS

Introduction	1
Posting Notices	2
Training and Instruction	2
Obtaining Your Exposure Reports	3
Inspections	3
Definitions	4
Units of Radiation Dose	4
Units of Radioactivity	4
Occupational Dose Limits	5
Radiation Dose to an Embryo/Fetus	5
Radiation Standards for Unrestricted Areas	5
Personnel Monitoring	6
Caution Signs and Labels	6
Picking up, Receiving and Opening Packages	6
Reporting Exposures to the NRC	7

INTRODUCTION

This is **YOUR GUIDE** to Parts 19 and 20 of the Nuclear Regulatory Commission's Rules and Regulations (Title 10, Chapter 1, Code of Federal Regulations-ENERGY).

Parts 19 and 20 establishes **YOUR RIGHTS & RESPONSIBILITIES**.
And...

Our responsibility to ensure **YOUR SAFETY** on the job.

This guide points out the most relevant sections in Parts 19 and 20, and how our Radiation Safety Program operates to ensure a safe work place.

Your supervisor is always available to discuss any questions you may have about Parts 19 and 20, or any potential problems you may encounter related to safe working conditions.

Part 19

Part 19 establishes requirements for posting notices, providing employees training, NRC inspections and obtaining your exposure reports.

POSTING NOTICES

- section 19.11

The following documents - or a notice describing them and where they are kept - are posted in a conspicuous place in our facility.

- ▶ Parts 19 and 20
- ▶ Our license
- ▶ Any notice of violation or penalties
- ▶ Form NRC-3, "Notice to Employees"

TRAINING AND INSTRUCTION

- section 19.12

Our company provides ongoing training and instruction to ensure that your radiation dose levels remain as low as reasonably achievable. Some of the areas in which we provide training and instruction are:

- ▶ Storage, use and transfer of radioactive material
- ▶ Health problems associated with exposure to radioactive material and radiation
- ▶ Minimizing your exposure
- ▶ Protective devices
- ▶ Responding to unusual and emergency conditions involving radioactive material and radiation
- ▶ Your responsibility to report any violation of regulations

OBTAINING YOUR EXPOSURE REPORTS - section 19.13

We provide your exposure reports to you:

- ▶ Annually
- ▶ At your request, should you terminate your employment with us
- ▶ Automatically, in the event of an overexposure

INSPECTIONS - sections 19.14 through 19.16

Parts 19 and 20 and our Radiation Safety Program require ongoing - and unscheduled - inspections by our own staff, by our own corporate Health Physics staff, and by the NRC.

- ▶ It is everyone's responsibility to immediately report anything that appears unsafe to a supervisor, or
- ▶ Request a formal inspection by the Health Physics staff, or the NRC, if the condition requires.
- ▶ It is against the policy of this company and the NRC to discriminate against anyone solely on the basis of that person requesting an inspection.

Part 20

Part 20, "Standards for Protection Against Radiation," contains the following important information:

DEFINITIONS

- section 20.1003

Understanding these terms will be especially helpful to you in minimizing your exposure:

- ▶ Radiation
- ▶ Radioactive material
- ▶ By-product material
- ▶ Licensed material
- ▶ Occupational dose
- ▶ Restricted areas
- ▶ Unrestricted areas

UNITS OF RADIATION DOSE

- section 20.1004

This section describes how human radiation exposure is measured in:

- ▶ REMS, and
- ▶ RADS

UNITS OF RADIOACTIVITY

- section 20.1005

This section establishes the basic units for the measurement of the radioactivity of radioactive materials, using:

- ▶ Disintegrations per second (dps)
- ▶ Disintegrations per minute (dpm)
- ▶ Curies, Microcuries, and Millicuries

OCCUPATIONAL DOSE LIMITS - sections 20.1201 through 20.1207

Our company maintains strict standards for control, possession, use and transfer of radioactive material so that your radiation dose does not exceed the following allowable levels.

<u>Part of Body</u>	<u>Rems per Year</u>
Whole body	5 rem
Lens of the eye	15 rem
Extremities - hands/forearms, feet and ankles	50 rem
Skin of whole body	50 rem
Any individual organ or tissue except lens of the eye	50 rem

RADIATION DOSE TO AN EMBRYO/FETUS - section 20.1208

Our company maintains strict standards to ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman does not exceed the following allowable level.

Exposure to an embryo/fetus during entire pregnancy	0.5 rem
---	---------

RADIATION STANDARDS FOR UNRESTRICTED AREAS - sections 20.1301 and 20.1302

Radiation in the unrestricted areas of our facility are maintained below the level that might cause your exposure to exceed the following acceptable levels:

- ▶ 2 millirems in any one hour
- ▶ 0.05 REM in any one year

PERSONNEL MONITORING

- sections 20.1501 through 1502

Our company supplies your dosimeters and maintains records of your exposure.

- ▶ You are required to wear your dosimeters at ALL times in restricted areas in order for us to maintain accurate records of your exposure.
- ▶ Should an overexposure occur, we will take immediate action to minimize your exposure.

CAUTION SIGNS and LABELS

- section 20.1901 through 20.1902

This section establishes the requirements for identifying restricted areas and containers used for radioactive material, and includes discussion of:

- ▶ "Caution Radioactive Material" signs
- ▶ "Caution Radioactive Material" labels
- ▶ "Caution Radioactive Area" signs

PICKING UP, RECEIVING and OPENING PACKAGES

- section 20.1906

Our company employs safe procedures for handling packages used in shipping and receiving radioactive material.

- ▶ All employees whose duties include picking up, receiving and opening such packages receive specific safety training and instruction in those tasks.

REPORTING EXPOSURES TO THE NRC - sections 20.2203 through 20.2206

Our company reports directly to the NRC:

- ▶ In the event your radiation dose exceeds an allowable level.
- ▶ Any occurrences of excessive levels of radiation or excessive concentration of radioactive material in our facility.

Parts 19 and 20 -- and our company's radiation safety program -- have been established for YOUR SAFETY on the job.

For the employees of: Syncor International Corporation

Published by: Quality & Regulatory

Syncor International Corporation

6464 Canoga Avenue

Woodland Hills, CA 91367

(818) 737 4000

(800) 999 9098

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Syncor International Corporation



The Service Difference

Syncor International Corporation

August 9, 2001

U.S. Nuclear Regulatory Commission
611 Ryan Plaza Drive
Suite 400
Arlington, TX 76011



Attention: Mr. Jim Montgomery

RE: Additional Information for Renewal of Radioactive Materials License Number 04-26507-01MD, Syncor International Corporation, Woodland Hills, CA.

Dear Mr. Montgomery:

As a follow up to our meeting of June 14-15, Syncor presents the following additional information in support of the above referenced license renewal:

- 1. Syncor uses a variety of methods to ensure compliance with applicable air emissions regulations and 10 CFR 20.1101(d)(the "Constraint Rule"). Syncor uses the COMPLY computer code to calculate the dose to members of the public from airborne emissions. (Note: Syncor requests continued authorization of a release factor of 10^-5 for technetium-99m and thallium-201 for use in the COMPLY program.) Air monitoring is performed at facilities that compound iodine-131 and calculations for permissible xenon-133 concentrations are performed for those facilities that handle xenon-133.
2. Syncor confirms that the requested possession limit for iodine-131 at the Bristol, PA location is 5 curies.
3. Please note the following address corrections:

Table with 2 columns: Facility Location and Correct Address. Rows include Indianapolis, IN; Glastonbury, CT; Griffith, IN; Kansas City, MO; and St. Louis, MO.

Handwritten number 468551

4. Please refer to attachment A for revised floor plans of the Indianapolis, IN and Kansas City, MO facilities that indicate the location of the cesium-137 sealed sources.
5. Please refer to attachment B for the revised floor plan of the Wauwatosa, WI. The restricted area is outlined in black.
6. Please refer to attachment C for additional information about the performance of sealed source leak testing as a customer service. This includes a more thorough description of the sealed source leak test kit to be used as well as instructions to the customer. This supplements the information presented in Appendix C of the original application. The information included in Appendix C of the original application is also attached for your reference.
7. Please see attachment D for an outline of Syncor's Authorized Nuclear Pharmacist training program. Syncor's Authorized Nuclear Pharmacists may also receive training from other accredited Authorized Nuclear Pharmacist training programs.
8. As described in Syncor's license application, under Syncor's ALARA Program, Investigational Levels have been established for personnel exposure and for airborne radioactivity levels. Syncor's ALARA Program is partly based upon the model ALARA Program contained in Appendix G to NRC Regulatory Guide 10.8, *Guide for the Preparation of Applications for Medical Use Programs*. At the time of the submission of Syncor's original license application in 1993, Task FC 410-4, *Guide for the Preparation of Applications for Nuclear Pharmacy Licenses*, was in draft form and was the "de facto" licensing guidance. However, it did not contain a model ALARA Program that would be acceptable to NRC. Although Syncor is not a medical use licensee, absent a model program in Task FC 410-4, NRC Regulatory Guide 10.8 seemed like a reasonable place to start based on at least similar types of radioactive material being handled at Syncor as compared to medical use licensees.

Section 6 of Appendix G to Regulatory Guide 10.8 discusses the establishment of investigational levels in order to monitor occupational radiation exposure. Section 6.d. specifically discusses the reestablishment of the Investigational Levels to higher levels in certain cases, given justification and RSC approval. This philosophy has been adopted into Syncor's ALARA Program from the regulatory guide. The model ALARA Program in Regulatory Guide 10.8 did not contain any provisions regarding radionuclide concentrations in air, so Syncor developed an ALARA Program for airborne radioactivity levels that was analogous to the model program for occupational exposure. As part of this, the concept of the reestablishment of Investigational Levels in certain circumstances, given justification and RSC approval, was carried over. This is the basis for Syncor's ALARA Program containing provisions to reestablish in certain cases Investigational Levels to higher levels than were initially established.

9. Please see attachment E for Syncor's molybdenum-99 breakthrough procedures.
10. Syncor confirms that it will comply with the provisions of 10 CFR 20.1208 and NRC regulatory guide 8.13 both of which pertain to fetal dose and declared pregnant worker training. Please refer to attachment F for a description of Syncor's fetal dose and declared pregnant worker training program.

11. Syncor uses a correction factor to address differences between calculated and measured values when assaying unit doses of pure beta emitting radionuclides. This correction factor was mentioned in a letter dated December 17, 1999 in reply to a Technical Assistance Request. The NRC subsequently authorized the use of this correction factor on January 5, 2000 (license condition 23 WW.). For A copy of Syncor's request to the NRC dated December 17, 1999 is included in attachment G for your reference.

12. Please see attachment H for the revised sections from item 10 of the original license. Included in attachment H are section 10.6, Procedures for Returning Radioactive Materials from Customers; section 10.7, Customer Procedures for Return of Limited Quantity Shipments of Radioactive Materials to Syncor; and 10.10, Distribution Procedures.

If you have any questions pertaining to the information in this letter please contact Toli Mikell at 818-737-4678 or Tanya Ridgle at 818-737-4651.

Sincerely,

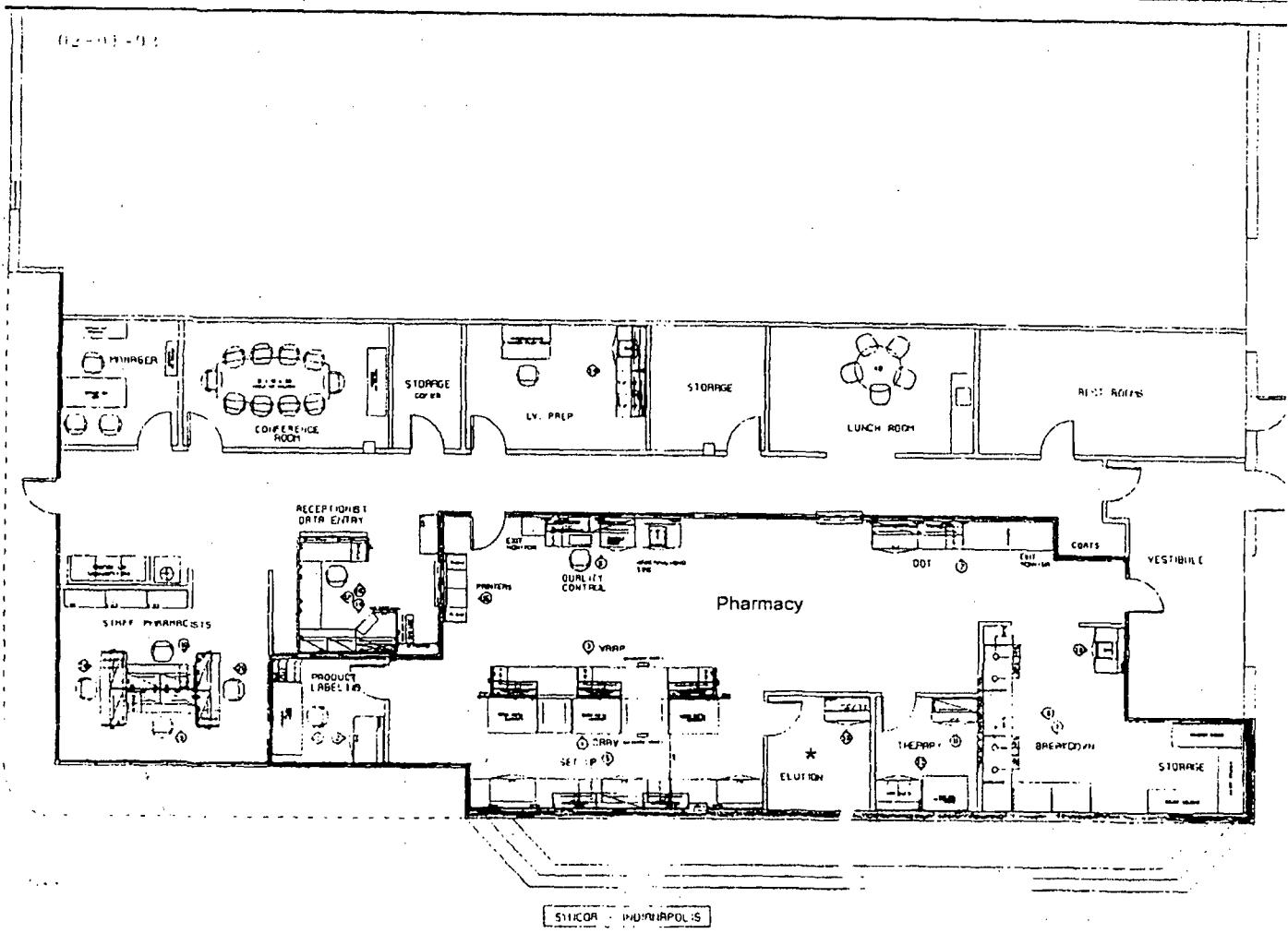


David W. Pellicciarini, CHP
Program Director, Health Physics

Tdr

Cc: All NRC Pharmacy RSO's
NRC License File (Application)
Mr. Jim Montgomery
Region IV Field Office

ATTACHMENT A



* = Cs-137 Source Location

Figure 2 Facility Floor Plan The restricted area is outlined in black

Sincor International Corporation

INDIANAPOLIS, IN
Date: 04/26/2001

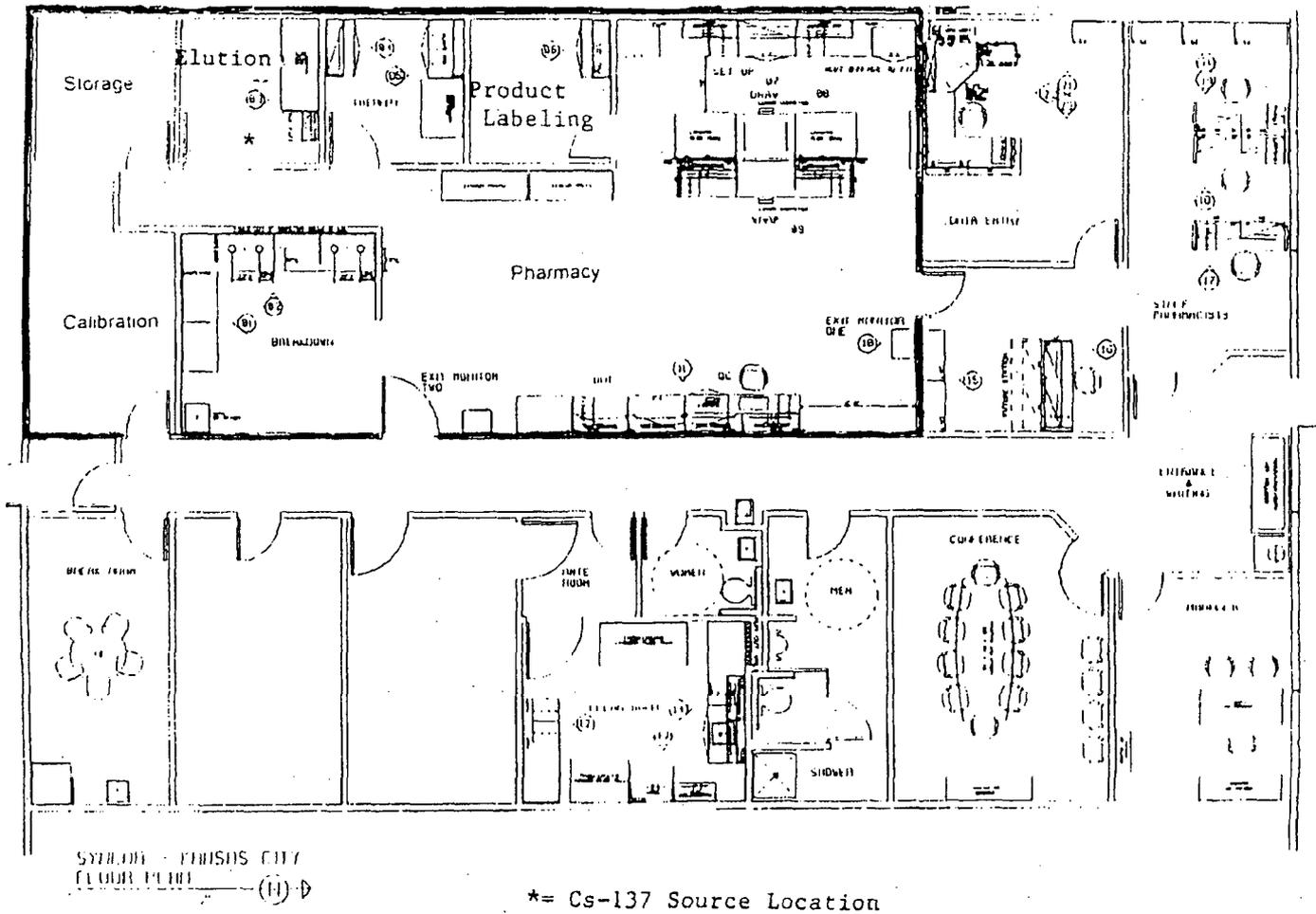
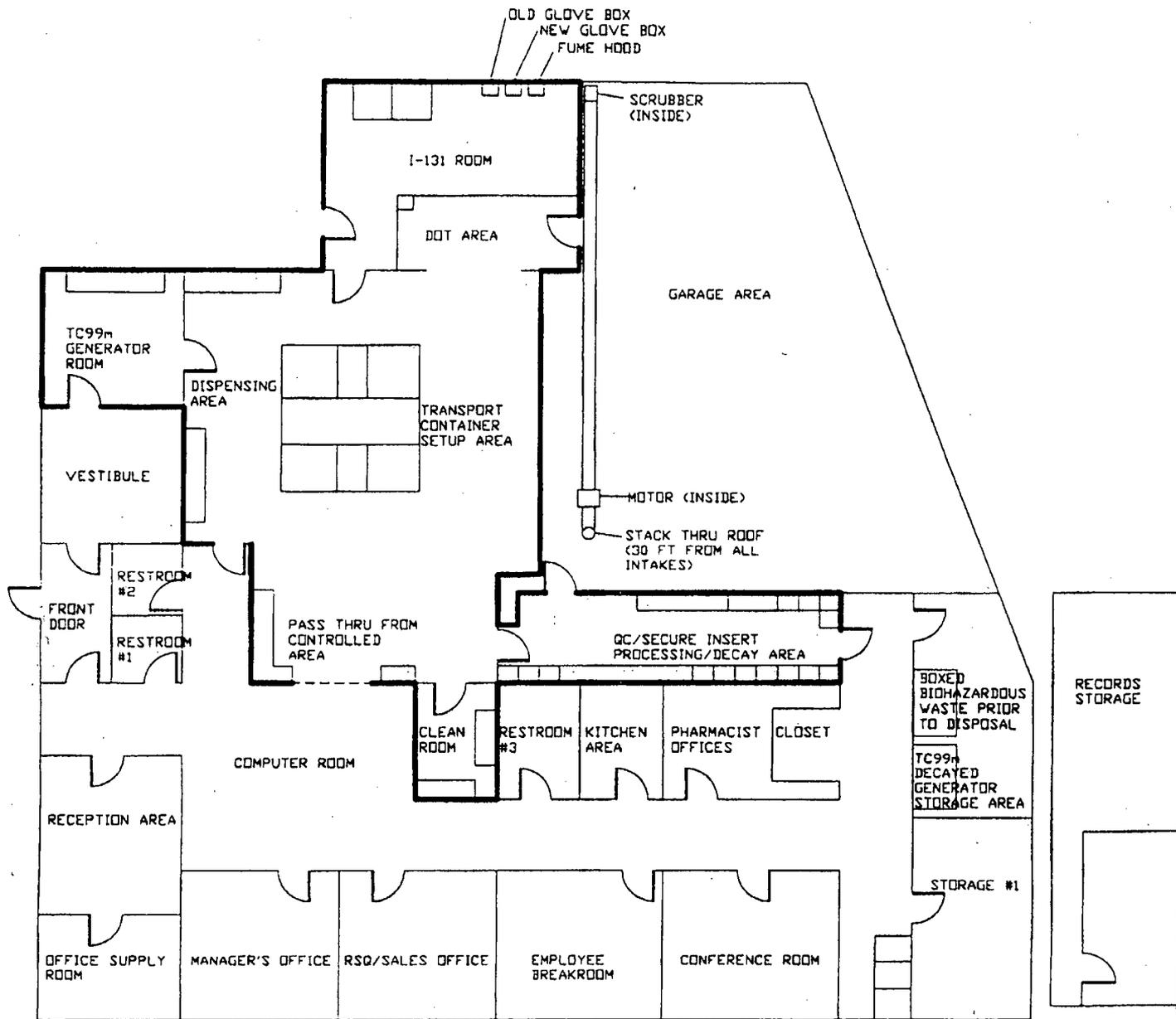


Figure 2 Facility Floor Plan The restricted area is outlined in black.

Syncor International Corporation

KANSAS CITY, MO
Date: 04/26/2001

ATTACHMENT B



CONTROLLED AREA MAP OF LOCATION #64

ATTACHMENT C

Protocol for Sealed Source Leak Testing as a Customer Service

A. Obtaining Samples

Syncor customers requiring leak testing of their sealed sources will be provided with a Syncor Leak Test Kit, or will have their sources leak tested by authorized Syncor personnel. The Syncor Leak Test Kit consists of the following:

1. Self-adhesive label
2. Cotton-tipped applicator or alcohol swab
3. Plastic test tube with cap
4. Pair of disposable gloves
5. Instruction sheet

B. Counting Samples

All samples will be counted in a well counter with a NaI detector. The efficiency of the counting system will be calibrated using the same isotope as the sealed source being leak tested, e.g. Cs-137 sealed source leak test samples will be evaluated using the efficiency obtained from a Cs-137 standard reference source

C. Evaluation and Reporting Results

All leak test results will be approved by either an authorized user or authorized nuclear pharmacist. If the test results indicate less than 0.005 microcuries, a certificate will be issued to the customer. If the test results indicate the presence of 0.005 microcuries or more of removable contamination, then the customer will be immediately notified and advised to withdraw the source from service. The customer will also be advised to notify the regulatory agency within five days.

D. Instructions for Customers

The following instructions are included in the Syncor Leak Test Kit :

1. Wear disposable gloves when leak testing sealed sources. Change gloves between sources when testing several sources.
2. Moisten the cotton-tipped applicator with water or alcohol.
3. Wipe the accessible surface of the source. Include the top, bottom, and the seal around the cap.
4. Place the cotton-tipped applicator into the test tube and cap the test tube.
5. Place the capped test tube into the zip-lock bag and seal.

6. Complete the self-adhesive label and affix to the outside of the zip lock bag.
7. Use a survey meter to determine if gross contamination exists.
8. Return the bag and its contents to Syncor International Corporation within 24 hours using Syncor's delivery service.

NOTE: SOURCES (CALIBRATION STANDARD VIALS) SHOULD BE HANDLED BEHIND ADEQUATE LEAD SHIELDING.

Appendix C Health Physics Services

Syncor International Corporation wishes to perform the following health physics services for its customers:

1. Sealed source leak testing
2. Calibration of survey meters

Sealed Source Leak Testing

Sealed sources will be leak tested according to the following procedure:

A. Equipment Required

Filter paper, cotton tip applicators
Appropriate calibration standards
Forceps or hemostat

Counting vials (test tubes)
Multichannel Analyzer
Disposable gloves

B. Procedure for Obtaining Wipe Sample

1. Wear disposable gloves when leak testing sealed sources. Change gloves between sources when testing several sources.
2. Moisten the cotton-tipped applicator with water or alcohol.
3. Wipe the accessible surface of the source. Include the top, bottom, and the seal around the cap.

C. Procedure for Assessing Test Results

1. All samples will be counted using a multi-channel analyzer (MCA) and a Well Counter with a NaI crystal.
2. If an efficiency for the isotope being tested has not been calculated during the current quarter or since repair of the system, establish and record the well efficiency factor in cpm/mCi using a reference source. This reference source will either be the same radionuclide or one with similar energy characteristics. This source shall either be NIST traceable or compared to a NIST standard and shall be accurate to within $\pm 5\%$ of the stated value.
3. Establish and record the minimum detectable activity (MDA). The MDA must be 0.005 μCi or less.
4. Count a background and the sample, each for 2 minutes.
5. Calculate and record results. Maintain records of leak tests for a minimum of 3 years.

D. Action Levels

If the test reveals the presence of 0.005 μCi or more of leakage or contamination obtained from a sealed source, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with NRC/State regulations. A report describing the equipment involved, the test results, and the corrective actions taken shall be filed within five (5) days to regulatory authorities.

E. Records

The following is a sample of the certificate to be given to Syncor's customers:

Sealed Source Leak Test Certificate

Syncor International Corp.

Facility:

*
*

Contact Person:

Test Date: _____ Performed by: _____

Wipe Date: _____ Wipe Performed By: _____

Next Leak Test Due: _____

Sample #	Radionuclide	Manufacturer/ Model #	Serial #	Source Activity	Net CPM	Removable Contamination (μCi)
1						
2						
3						
4						
5						

Description of Method: Each source was wiped with a wet swab or cotton tipped applicator and counted with a NaI well counter.

Maintain this Leak Test on file as proof of compliance with your Radioactive Materials License.

Test completed by Syncor.

ACTION LEVEL: If removable contamination is greater than $0.005\mu\text{Ci}$, the source should be removed from use and stored, repaired, or disposed of according to your Radioactive Materials License.

Signature of Radiation Safety Officer: _____ Date: _____

ATTACHMENT D

SYNCOR INTERNATIONAL CORPORATION
AUTHORIZED NUCLEAR PHARMACIST & AUTHORIZED USER TRAINING PROGRAM

SESSION I:
(Prerequisite plus 3 weeks of Didactic Training)

Prerequisite:	Introduction to Authorized User Training Program:Part I Mathematics Review and Problem Sets Introduction to Survey Meters Introduction to MCA Introductory Radiation Physics
Health Physics I:	Basic Physics, Chemistry, Biology and Mathematics Review Atomic Structure Nuclear Structure Nuclear Decay Process Half Life and Decay Equation Generators Interaction of Radiation with Matter Shielding Occupational Dosimetry and Personnel Dose Calculations Handling of Radionuclides Counting Statistics
Health Physics II:	Radiation Detection Instrumentation Gas-filled Detectors Scintillation Detectors Efficiency, LLD, MDA MCA/Energy Calibration SCA Calibration Air Monitoring Bioassay Emergency Procedures Physics of SPECT and PET
Radiation Safety:	Policy Statement Pharmacist Responsibility Radiation Safety Committee RAM Licenses Site and Facility Instrumentation Requirements Operations Employee Training Internal Program Audits Miscellaneous Procedures and Information

SYNCOR INTERNATIONAL CORPORATION
AUTHORIZED NUCLEAR PHARMACIST & AUTHORIZED USER TRAINING PROGRAM

SESSION II:

(Prerequisite plus 3 weeks of Didactic)

Prerequisite:	Introduction to Authorized User Training Program:Part II Mathematics Review and Problem Sets Radiopharmaceutical Quality Control Exercises Generator Elution Exercise and Problem Set NM Departmental Operations Awareness Program Radiopharmaceutical Clinical Case Presentation
Radiation Biology:	Properties of Ionizing Radiation Ionizing Radiation and Biological Systems Radiation, Cancer and Genetic Effects Health Effects of Low Level Radiation Exposure Concerns for Nuclear Pharmacists Prenatal Radiation Exposure Internal Dosimetry Pediatric Patient Dosimetry
Radiopharmaceutical Chemistry	Coordination Chemistry Review Hydrolysis and Colloid Formation Production of Radionuclides Clinical Selection of Radiopharmaceuticals Categories of Radiopharmaceuticals Radionuclide Generators Technetium chemistry Iodine Chemistry Indium Chemistry Positron Emission Tomography
Quality Assurance:	1984 Nuclear Pharmacy Guideline Nuclear Pharmacy Practice Standards Pharmacy Practice Policy & Procedure Manual Potential Formulation Errors-99mTc Chromatography of 99mTc Radiopharmaceuticals 131-I Compounding
Clinical Pharmacy:	Review of radiopharmaceuticals by organ system or class Altered biodistribution Radiopharmaceutical Clinical Case Presentations NM Instrumentation and Scan Interpretation Pediatric Dose Calculations

ATTACHMENT E

Molybdenum-99 Breakthrough Procedures

Syncor's RS-50 form or an equivalent form is currently used to document generator elution information. The form included in this attachment is subject to change as long as it meets the requirements outlined below. The procedure for Completion of the RS-50 form is below.

Procedures for Completion of RS-50

1. Set the dose calibrator to assay for molybdenum-99.
2. Slowly insert the moly shield assembly into the dose calibrator well. Record this reading as background. Remove moly shield assembly from dose calibrator.

NOTE: Some units require that the well liner be removed for this determination. Check the dose calibrator instruction manual to find out whether this is required, or whether a correction factor is used when measuring Mo-99.

3. Using appropriate precautions, place the Tc-99m eluate vial into the molybdenum breakthrough shield and place cover on vial.
4. Insert the moly shield assembly containing the eluate into the dose calibrator well and obtain the moly reading from the dose calibrator. The determination thus obtained must have the background value subtracted to give the net Mo-99 value. Record this value on the RS-50. If necessary, correct the measured value by manufacturer's correction factors, if any.
5. Remove the molybdenum breakthrough shield with elution vial from the dose calibrator.
6. Set the dose calibrator to assay for technetium-99m.
7. Obtain background measurement for this calibration setting.
8. Using appropriate precautions, place the Tc-99m eluate vial into the well and obtain the technetium-99m reading from the dose calibrator. Record this value on the RS-50.

NOTE: In lieu of assaying the whole vial, an aliquot method may be employed to reduce radiation exposure and to minimize handling large quantities of Tc-99m unshielded. Using appropriate precautions, place the Tc-99m eluate vial back into the elution shield and place cover on vial. Obtain Tc-99m activity by removing a 1 ml aliquot of eluate and assaying it in the dose calibrator. Obtain total Tc-99m activity by multiplying the aliquot activity in mCi/ml by the total volume in ml.

9. Divide the results of the determination of molybdenum-99 activity by the results of the determination of technetium-99m activity.

Example:
$$\frac{\text{net molybdenum-99 activity (uCi)}}{\text{net technetium-99m activity (mCi)}} = \frac{\text{uCi Mo-99}}{\text{mCi Tc-99m}}$$

10. Record the above value and the time that this determination was made along with your initials on the RS-50. This initial uCi Mo-99/mCi Tc-99m ratio is defined as the eluate **N** value.

Special Instructions for the RS-50 - Limits

1. Technetium-99m containing more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m shall not be administered to patients. These limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.
2. To ensure that no radiopharmaceutical exceeds the limit of 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of patient dose administration, a table listing a series of uCi Mo-99 / mCi Tc-99m ratios will be consulted. This table lists a series of uCi Mo-99 / mCi Tc-99m ratios calculated at one hour intervals (see table on following page).

Tc-99m Technetium Expiration Times
Following Generator Elution

Initial uCi Mo-99/ mCi Tc-99m	Expires (hr)	Initial uCi Mo-99/ mCi Tc-99m	Expires (hr)
0.135	1	0.034	14
0.122	2	0.031	15
0.109	3	0.028	16
0.098	4	0.025	17
0.089	5	0.023	18
0.080	6	0.020	19
0.072	7	0.018	20
0.065	8	0.016	21
0.058	9	0.015	22
0.052	10	0.013	23
0.047	11	0.012	24
0.042	12	0.0108	25
0.035	13		

At the time of radiopharmaceutical preparation, the **N** value of the elution being used to prepare the radiopharmaceutical is compared to the table. The **N** value of the elution is used to establish the point at which the limit of 0.15 uCi Mo-99/mCi Tc-99m would be exceeded.

For example, if the **N** value of the elution was 0.062 (0.062 uCi Mo-99/mCi Tc-99m at the time of elution), then the maximum expiration time would be a time 8 hours after the time of the generator elution.

ATTACHMENT F

Declared Pregnancy Training

All Syncor employees will be training against the NRC Regulatory Guide 8.13 and 10 CFR 20.1208 pertaining to the monitoring of an embryo or fetus. This training will also include the following information:

- A. Employees who wish to declare their pregnancy to Syncor must do so in writing. Included in this written declaration will be the employees name, declaration of pregnancy and the estimated date of conception.
- B. If an employee declares her pregnancy, she will be required to wear a fetal dosimeter to measure the exposure to the fetus. The dose to the fetus will be monitored against Syncor's ALARA Program.
 - 1. An ALARA investigational level of 90 mrem has been established. To more closely monitor this, the level stated below has also been established.
 - 2. If the fetal badge reads greater than 10 mrem in one month, an investigation will follow to determine the appropriate action.
- C. The lower dose limit will stay in effect until the employee withdraws her declaration in writing or informs her supervisor in writing that she is no longer pregnant.
- D. Job duties for a declared pregnant employee frequently working in the restricted area may be altered on a case-by-case basis. This decision will be based upon input from Human Resources, Legal, and Quality and Regulatory.

ATTACHMENT G



The Service Difference

Syncor International Corporation

December 17, 1999

U.S. Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive
Suite 400
Arlington, TX 76011
Attn: Mr. James Montgomery, Senior Health Physicist

Re: Reply to Technical Assistance Request Response for Syncor International Corporation,
License No. 04-26507-01MD, Control No. 467069.

Dear Mr. Montgomery:

Four quality control measures were suggested within the response to the Technical Assistance Request (TAR) dated November 9, 1999, for Syncor's ability to assay pure beta emitting radionuclides. Syncor's response to the requested additional quality control-measures follows.

1. *Each calibration standard must have a NIST traceable certificate of calibration.*
The procedure will be modified to indicate that the activity in the calibration standard must be traceable to NIST standards.
2. *For each calibration vial, the procedure should provide a mechanism for documenting the volume of the radiopharmaceutical, vial type (make/model if applicable), and vial size.*
The procedure includes a means for documenting the initial volume in the manufacturer's vial by instructing the operator to record the initial volume, or **IV**. Additional instructions will be added to the procedure for the operator to record the vial type as **VT** and the vial size as **VS**.
3. *The procedure should reflect a reasonable action level when comparing the calculated activity (BF2) vs. the measured activity (R4) of the material in the syringe.*
The difference between the **BF2** and **R4** values will differ depending on the geometry or type and size of the syringe used to hold the pure beta emitting radionuclide. An action level for the difference between the two values is unnecessary because the **BF3** factor corrects for the inconsistency between the **R4** and **BF2** values. The **BF3** correction factor will be used for measuring all subsequent syringes for unit doses.
4. *Unless the difference can be experimentally shown to be negligible, the procedure should reflect the method that the licensee will use to determine that the needle is uniformly filled (or not) with material, and that this level is consistent as practical among the filled syringes.*
Uniform filling or flushing of needles will be added to the procedure, unless it can be experimentally shown to be negligible.

Mr. J. Montgomery
December 17, 1999
Page 2

If you have any further questions, please contact Kory Kodimer at (818) 737-4491.

Sincerely,

A handwritten signature in black ink, appearing to read "David W. Pellicciarini". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

David W. Pellicciarini, CHP
Manager, Health Physics

kak

cc: NRC Pharmacy Radiation Safety Officers
NRC License File

ATTACHMENT H

10.6 Procedures for Returning Radioactive Materials from Customers

Syncor requests authorization to collect items from customers that contain, or are contaminated with, radioactive materials supplied by a Syncor Pharmacy.

A. Type of radioactive materials.

Syncor will only accept radioactive material that is authorized by our radioactive material license. Radioactive Materials picked up will be comprised of Syncor supplied items such as plastic syringes, needles, needle covers, vials, and depleted sealed sources that have been used by customers serviced by Syncor. Most of these items represent solid materials that contain residual radioactive material.

B. Procedures for the safe handling of radioactive material.

1. The majority of material that will be returned will be residual radioactive material in unit dose syringes used by the customer supplied by Syncor. A majority of the unit doses sold by Syncor will be provided with the Secure Safety Insert™ which is a plastic container within the unit dose shield that will enable us to handle returned syringes without touching the syringe. Vials retrieved will represent a very small portion of the items accepted for return. An example of a returned vial would be an I-131 oral therapy vial. Each unit dose syringe or vial is identified by prescription number and radiopharmaceutical, therefore, returned, used materials will be easily identifiable.
2. The following is the procedure for receiving returned materials at Syncor Pharmacies:
 - a) Put on disposable gloves
 - b) Open the unit dose shield and identify the material (by Rx label).
 - c) Dump the unit dose directly from the shield into the bin provided. If the unit dose is not contained in the Secure Safety Insert™, touch only the outside of the unit dose shield.
 - d) Survey the unit dose shield for contamination with a low level survey meter. If a unit dose shield demonstrates activity levels greater than background, remove it from service, and place it in the storage area for decay to background levels. When surveying unit dose shields for reuse, any unit dose shield that is found to be greater than background must be placed into storage for decay or decontaminated to background levels.
3. Material returned to Syncor is shipped in the shields and shipping containers provided by our facilities. Shipping containers meet all Department of Transportation requirements for shipping hazardous materials.
4. All returned radioactive material will be transported by a third party carrier or in our vehicles by delivery personnel employed by Syncor. Only material that has been properly packaged will be picked up for return.

- C. The Syncor employee handling the radioactive material at the nuclear pharmacy will be trained on the above procedure for safe handling of radioactive materials. Delivery personnel will also be trained on our procedure for picking up materials from a customer and the applicable DOT requirements. Procedures for handling and disposal of radioactive materials 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 for all training will be completed stating the subject matter covered.

- D. Customers are notified that Syncor will only accept material that results from our own supplied radioactive material. Any radioactive material not resulting from Syncor supplied material is returned to the customer for disposal.

- E. See the following procedures for customers returning materials to Syncor.

10.7. Customer Procedures for Return of Limited Quantity Shipments of Radioactive Materials to Syncor

We will provide the following information to all customers on the procedure to ship radioactive materials back to the pharmacy.

MEMO TO SYNCOR CUSTOMERS

The United States Department of Transportation (DOT) has specific regulations pertaining to the transportation of radioactive materials. It is Syncor's intent to follow all DOT requirements when accepting the return package from you for transport and while transporting the package back to the pharmacy.

In an effort to clarify these regulations, and to ensure compliance, we have implemented the following policy with respect to packaging and delivery of return shipments. We ask your cooperation in assisting us in complying with the applicable regulations.

Our system of service involves retrieving radioactive material from you, our customer. Because you will be returning radioactive material to the pharmacy, you now become a shipper of radioactive material. Syncor is providing you with a simple system to ensure you properly prepare your package for return.

Return shipments should be shipped as "Limited Quantity Shipments". DOT regulations under 49 CFR 173.421, state that if a package meets the following requirements, it is exempted from the specification packaging, marking, and labeling requirements and can be classified as a Limited Quantity Shipment:

1. 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 mrem 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). (6600 dpm/300cm²)
4. The package has the appropriate notice statement as required in 49 CFR 173.422.
5. Other provisions of this regulation are satisfied by Syncor's present packaging.

Syncor will accept return of both "used" and "unused" unit dose syringes. To assure safety of our employees, Syncor has developed the SECURE Safety Insert System for transporting syringes. The SECURE Safety Insert System consists of a plastic insert placed inside the unit dose shield. A new dose is shipped to our customer with the syringe inside of the plastic insert. After the dose is injected, the used syringe is placed back into the plastic insert in the unit dose container. The customer must then place a red cap over the top of the plastic insert/used syringe, sealing the used syringe in a sharps container. The top of the unit dose container is then screwed on.

The following procedure will meet all of the above requirements and must be followed prior to Syncor accepting your material for return:

1. Ensure that the material being returned does not exceed the specified limits for "Limited Quantity Shipments". This can be determined by reviewing the attached table with activity limits for nuclides. The total quantity of activity being returned must not exceed the specified "Limited Quantity Shipment" activity whether you are returning used dose material or unused doses.
 - a) Example of estimating return activity for Tc-99m products.
 - (1) **Used Products.** Assume 5% remains in the syringe after an injection. If the syringe is held for 24 hours (4 half lives), the remaining activity from a 30 mCi dose, is:

$$30 \text{ mCi} \times 0.05 \times 0.0625 = 0.094 \text{ mCi}$$

If ten unit dose syringes were returned, and all ten had been 30 mCi doses, the package would contain only 940 μCi , which is well below the 21.6 mCi limit in the attached table.

- (2) **Unused Products.** If an unused syringe of a 30 mCi dose is held for 24 hours (4 half lives), the remaining activity is:

$$30 \text{ mCi} \times 0.0625 = 1.9 \text{ mCi}$$

It can be seen that a maximum of eleven of these syringes could be returned and remain below the 21.6 mCi limit for Tc-99m.

b) Limited quantity activity limits for shipments of mixed radionuclides.

- (1) When shipping more than one radionuclide in the same package, the limit on the radioactivity that may be shipped is the lowest activity assigned (see attached table) for the radionuclide shipped.

- (2) Example: If Tc-99m and I-131 were being shipped in the same package, only 1.35 mCi of total activity could be shipped.

2. Ensure that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr.
3. Ensure 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., 6600 dpm when wiped over a 300 cm² area.
4. Ensure the Syncor provided card for the shipping container is turned to indicate the Limited Quantity Shipment information.
5. Place in the predetermined area for pickup.

Syncor employees are instructed not to accept any package for return that has not met the above criteria.

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

10.10 Distribution Procedures

Syncor proposes to operate a centralized nuclear pharmacy that will prepare, compound and dispense radioactive materials for medical use on a unit dose or multiple dose basis. Preparation and transfer of radioactive drugs will be in compliance with 10 CFR 32.72 (or equivalent Agreement State Regulations).

Syncor commits that the nuclear pharmacy will maintain a current State Board of Pharmacy License and is therefore subject to laws and regulations set forth by the State Board of Pharmacy. Radioactive drugs for human use will be compounded/prepared in accordance with the standards of practice as regulated by the State Board of Pharmacy.

Syncor does not propose to manufacture generators or reagent kits for distribution. It is our intention to compound/prepare radioactive drugs and to transfer these to licensees authorized to possess them. The labeling and dispensing of radioactive drugs will meet the requirements of the State Board of Pharmacy and the requirements as specified in 10 CFR 32.72 (or equivalent Agreement State Regulations).

Syncor may also transfer some radioactive materials for non-human use. Radioactive materials for non-human use will be transferred to licensees of the Nuclear Regulatory Commission or an Agreement State. Examples may include transfers to universities for research purposes, transfers of sealed sources to other licensees, or transfers to veterinarians for their use in the practice of veterinary medicine.

Radioactive drugs for medical use which are distributed will be either:

- A. initially distributed by a manufacturer licensed pursuant to 10 CFR 32.72 (or equivalent agreement state regulations); or
- B. prepared by either an authorized nuclear pharmacist or an individual under the supervision of an authorized nuclear pharmacist.

Used generators to be redistributed will be packaged according to the following procedure:

A. Prepare the generator

- 1. Swab the septa of the needle cover vials with an alcohol wipe
- 2. Place the vials over the needles
- 3. Replace the plastic cover over the top of the generator
- 4. Wipe test the generator

B. Prepare the shipping carton

- 1. Remove or deface the "cargo aircraft only" sticker
- 2. Ensure that all internal lead shielding that originally came with the carton (lead circular plate on top and lead cylinder bucket on bottom) is in place
- 3. Affix a new, correctly filled out DOT shipping label indicating Mo-99 and the activity in GBq
- 4. Include a package insert in the shipping foam

C. Closing the carton

1. Place the generator in the foam insert (lead bucket)
2. Place the top foam over the generator
3. Close the carton and place a paper security seal where flaps meet
4. Seal entire package using 2" wide plastic tape (clear or fiber reinforced)
5. Wipe test the carton
6. Measure the exposure rate on contact of all 6 sides of the package
7. Measure the exposure rate at one meter from the highest contact exposure rate to determine the Transport Index (TI)
8. Using the exposure rates from contact and at one meter, determine the correct DOT label and place the label on the box
9. Record the TI on the DOT label
10. Label the carton with the recipient's name and address
11. Using the Rx generated for the transfer, generate a bill of lading

In addition to the above procedures for safely repacking the generators, Syncor confirms to the following:

- The manufacturer's packaging and labeling will not be altered;
- The generator will not be distributed beyond the expiration date shown on the generator label;
- The redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator; and
- Only generators used in accordance with the manufacturer's instructions will be redistributed.



Syncor International Corporation

The Service Difference

March 29, 2001

30 2001

U.S. Nuclear Regulatory Commission
Region IV Office
611 Ryan Plaza Drive
Suite 400
Arlington, TX 76011

Attention: Ms. Colleen Murnahan,
Mr. James Montgomery

RE: Renewal of Radioactive Material License 04-26507-01MD, Syncor International Corporation, Woodland Hills, CA

Dear Mr. Montgomery:

Per our recent telephone conversation, please find enclosed Form 313 for the renewal of the above referenced license. This letter with the attached form indicates Syncor's intention to renew this license. Syncor requests an additional thirty (30) days from the receipt of this letter to provide further information in support of our renewal application.

If there are any questions with this correspondence, please contact Toli Mikell at (818) 737-4678.

Sincerely,

David W. Pellicciarini, CHP
Program Director, Health Physics

tpm

cc: Region IV Walnut Creek Field Office
NRC License Amendment Request Binder
Pharmacies Listed on Syncor's NRC License



NRC FORM 313 (8-2000) 10 CFR 30, 32, 33, 34, 35, 38, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120	EXPIRES: 08/31/2002
<h2 style="margin: 0;">APPLICATION FOR MATERIAL LICENSE</h2>			
Estimated burden per response to comply with this mandatory collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0000), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.			

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 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: LICENSING ASSISTANT SECTION NUCLEAR MATERIALS SAFETY BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415 ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: SAM NUNN ATLANTA FEDERAL CENTER U. S. NUCLEAR REGULATORY COMMISSION, REGION II 61 FORSYTH STREET, S.W., SUITE 23185 ATLANTA, GEORGIA 30303-8831	IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 801 WARRENVILLE RD. LISLE, IL 60532-4351 ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING SECTION U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-9064
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PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>04-26507-01MD</u>	2. NAME AND MAILING ADDRESS OF APPLICANT (include ZIP code)
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED 	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION TELEPHONE NUMBER _____

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 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 EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY _____ AMOUNT ENCLOSED \$ _____

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

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, 38, 39, 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 82 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE David W. Pellicciarini, CHP Program Dir.	SIGNATURE 	DATE 3/29/01
--	----------------------	------------------------

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		468551
APPROVED BY _____				DATE _____	

TABLE OF CONTENTS

Application for Radioactive Material License.....	
Item 5 Radioactive Material Data.....	5-1
Item 6 Purpose(s) for Which Licensed Material Will Be Used	6-1
Item 7 Individual(s) Responsible for Radiation Safety and Their Training Experience.....	7-1
Item 8 Training for Individuals Frequenting Restricted Areas.....	8-1
Item 9 Facilities and Equipment	
9.1 Site Description.....	9-1
9.2 Adequacy of Facility for Handling Xenon-133	9-3
9.3 Special Equipment for Handling Millicurie Quantities of Liquid Radioiodine.....	9-7
9.4 Procedures for Completion of Iodine-131 Monitoring.....	9-11
Item 10 Radiation Safety Program	
10.1 Program for Maintaining Occupational Radiation Exposures ALARA.....	10-1
10.2 Procedures for Receiving Shipments Containing Radioactive Material.....	10-6
10.3 Procedures for Safely Opening Packages Containing Radioactive Material.....	10-7
10.4 General Procedures for the Safe Use of Radioactive Material	10-9
10.5 Emergency Procedures.....	10-10
10.6 Procedures for Returning Radioactive Waste from Customers.....	10-12
10.7 Customer Procedures for Return of Limited Quantity Shipments of Radioactive Materials to Syncor	10-14
10.8 Precautionary Measures for Handling Millicurie Quantities of Radioiodine	10-17
10.9 Area Survey Procedures.....	10-19
10.10 Distribution Procedures.....	10-10
10.11 Prescription Form and Container Labels.....	10-22
10.12 Product Shielding.....	10-26
10.13 Procedures for Packaging and Transporting Radiopharmaceuticals.....	10-33

TABLE OF CONTENTS

10.14	Emergencies Involving Motor Vehicles Acting as Carriers of Radioactive Materials.....	10-35
10.15	Independent Audit Program and Corporate Radiation Safety Program.....	10-37
10.16	Leak Testing.....	10-39
10.17	Radiation Detection Instrumentation and Calibration.....	10-40
10.18	Personnel Monitoring.....	10-45
Item 11	Waste Disposal.....	11-1
Appendix A	NRC Exemptions	
Appendix B	Procedure for Assaying Beta Emitters	
Appendix C	Health Physics Services	
Appendix D	Syncor's Audit Form	
Appendix E	Individual Site and Floor Plans	
Appendix F	Syncor Organizational Charts	



Syncor International Corporation

April 26, 2001

U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064
Attention: Mr. Jim Montgomery

RE: Renewal Application for Radioactive Materials License 04-26507-01MD, Syncor International Corporation, Woodland Hills, CA.

Dear Mr. Montgomery:

Please find enclosed the renewal application for the above referenced license. If you have any questions or concerns regarding this application, please contact Tanya Ridgle at 818-737-4651 or Toli Mikell at 818-737-4678.

Sincerely,

David W. Pellicciarini, CHP
Program Director, Health Physics

tdr

cc: All NRC Pharmacy RSO's
NRC License File (Application)
Mr. Jim Montgomery
Region IV Field Office

Encl: Check for Renewal Fees



**Item 5
Radioactive Material**

Radioactive Material	Chemical and/or Physical Form	Maximum Activity Requested
A. Molybdenum-99	A. Any molybdenum-99 technetium-99m generator initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent agreement state regulations.	A. 200 Ci
B. Technetium-99m	B. Any unsealed form	B. 200 Ci
C. Any unsealed byproduct material, except iodine-131, technetium-99m and xenon-133	C. Any unsealed byproduct, for medical use material except iodine-131, technetium-99m and xenon-133.	C. 1 Ci
D. Xenon-133	D. Unit dose containers of gas or gas in solution initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations.	D. 5 Ci
E. Iodine-131	E. Any unsealed form	E. 990 mCi
F. Iodine-131	F. Any unsealed form	F. 3 Ci (See Item 6 F)
G. Iodine-131	G. Any unsealed form	G. 10 mCi (See Item 6 G)
H. Any byproduct material listed in 10 CFR 35.400	H. Sealed source	H. 500 mCi
I. Any byproduct material listed in 10 CFR 35.500	I. Sealed source	I. 4.5 Ci total and no single source to exceed 1.5 Curies
J. Cesium-137	J. Sealed sources (3M 4P6E 4F6H, 4D6L, or 4F6S; U.S. Nuclear 375; Isotope Products 193; Amersham X.9 and X.8; Industrial Research Labs 2-4 2-10; J.L. Shepherd Model 6810)	J. 1 Ci For the Kansas City, MO facility only

K. Cesium-137

K. Sealed source (Technical Operations Model 773)

K. 165 mCi for the Indianapolis, IN facility only

L. Any byproduct material authorized under 10 CFR 35.57(a)

L. Sealed Source

L. 50 mCi

M. Uranium (depleted in the isotope Uranium 235)

M. Metal encased in stainless steel

M. 220 kilograms

N. Any byproduct material with atomic numbers 2-83 inclusive

N. Analytical Samples

N. As needed

Item 6
Purpose(s) for Which Licensed Material Will Be Used

- A. through E. Preparation and distribution of radioactive drugs (includes Mo-99/Tc-99m generators) to authorized recipients. Also transfer to authorized recipients for non-medical use.
1. 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 NRC or Agreement State regulations.
 2. Each redistributed generator will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that describes the procedures to be followed and the equipment and shielding to be used in using the generator.
 3. Unused generators will be redistributed without opening or altering the manufacturer's packaging.
 4. Used generators will be redistributed using the manufacturer's packaging and labeling. Please see Item 10.10 for a description of the procedures for repackaging generators. Used generators will not be distributed beyond the expiration date shown on the generator label.
- F. To be used as described in E. at Syncor's facilities in Griffith, IN, St. Louis, MO, Wauwatosa, WI, Sharon Hill, PA, Pittsburgh, PA and Seaford, DE.
- G. To be used as described in E. at Syncor's facilities in Appleton, WI, and Bradford, PA.
- H and I. Redistribution of sealed sources for brachytherapy and diagnosis in accordance with the following:
1. Sources will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements.
 2. The manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.
- J. To be used in a J.L. Shepherd and Associates Model 28-6A calibrator at the Kansas City, MO facility for instrument calibration including calibration of survey meters as a service for customers and other clients.
- K. To be used in a Victoreen Gamma Survey Instrument calibrator at the Indianapolis, IN facility for instrument calibration including calibration of survey meters as a service for customers and other clients.
- L. For redistribution of calibration and reference sealed sources in accordance with the following:
1. Sources to be redistributed will be obtained from a manufacturer authorized to distribute these sources in accordance with a specific license issued pursuant to NRC or Agreement State regulations.

2. The manufacturer's packaging, labeling, and shielding will not be altered and redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

M. To be used for shielding of Mo-99/Tc-99m generators.

N. Possession incident to the performance of swipe testing of customer's sealed sources.

Item 7

Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

Radiation Safety Committee

Syncor's Radiation Safety Committee (RSC) was established to periodically assess the effectiveness of the radiation safety program and to recommend required changes to policies and procedures. The RSC's purpose is to ensure the safe handling and use of radioactive material at Syncor.

The RSC consists of individuals from senior management, the Corporate Radiation Safety Officer, the Program Director of Compliance Assessment, a Human Resources representative, a Legal representative, and Operations representatives. To establish a quorum, at least one-half of the RSC's membership shall be present, including the Corporate Radiation Safety Officer (or designee) and a senior management representative (or designee).

The RSC meets on a trimesterly basis. The RSC reviews pharmacy Quality and Regulatory (Q&R) audit results, regulatory agency inspection results, summarized personnel dosimetry data, the overall radiation safety program (annually) and the ALARA program (annually). The RSC also reviews and approves Authorized Nuclear Pharmacists and Pharmacy RSOs in NRC States, and if allowed by license conditions, in Agreement States.

Radiation Safety Officers

The corporate radiation safety officer (CRSO) will be David W. Pellicciarini, CHP. Mr. Pellicciarini is currently listed as an authorized user on this license. Additionally, Mr. Pellicciarini is the Radiation Safety Officer for Syncor's training facility in Woodland Hills, CA. A copy of his resume and Syncor's Woodland Hills, CA Radioactive Materials License is included for your reference.

The responsibilities of the CRSO are as follows:

1. Manage the Corporate Radiation Safety Program.
2. As the Radiation Safety Officer named on Syncor's NRC license, coordinate reports from and directs local pharmacy RSOs and Q&R Audit staff with regard to radiation safety, compliance assessment, and regulatory issues.
3. Provide 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.
4. Furnish consulting services on all aspects of radiation protection to personnel at all levels of responsibility.
5. 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.
6. Exercise the authority to terminate immediately any project or procedure that is found to be hazardous to the health, welfare, or safety of any employee or the public.
7. Hold voting membership on the Syncor Radiation Safety Committee.

In addition to Syncor's corporate radiation safety officer, each Syncor facility will have its own pharmacy radiation safety officer (PRSO).

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

1. General surveillance over all activities involving radioactive material, including routine monitoring and special surveys.
2. Ensuring compliance with NRC/Agreement State regulations as well as conditions of the Radioactive Material 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 PRSO, authorized users must assume the duties of the PRSO and ensure compliance with NRC/Agreement State regulations as well as conditions of the Radioactive Material License.

Authorized Users

Syncor wishes to have the following individuals listed as Authorized Users on this license:

The following individuals are currently listed on this license as Authorized Users. A copy of this license is included in support of this request:

Tony Adamo
T. John Alexander
Jack L. Coffey
Edward A. Corros
W. Robert Davis
Tara J. Domiter
Colleen M. Glynn
Cheryl Holmes

Matthew Komornik
Robert E. Lewis
Brenda K. Norkosky
Michele Panichi-Egberts
David W. Pellicciarini, CHP
Wes Rogers
Dan Schmitz
Mark Vorhees
David Wilson
Michael Young
Adam J. Fleshner

In addition to the above list, Syncor wishes to have the following individuals listed as Authorized Users. Copies of their training and experience and/or radioactive materials licenses of broad scope are included in support of this request:

James Chimielewski
Kory Kodimer, Ph.D.
Toli Mikell
Willie Regits, Ph.D.
Corey Woods

Authorized Nuclear Pharmacists

See Appendix A, Requested Exemptions.

Resume for David Pellicciarini

David W. Pellicciarini

EXPERIENCE

Program Director, Health Physics, Syncor International Corp., Woodland Hills, CA 1/01 to Present
Serve as Syncor's Corporate Radiation Safety Officer, overseeing a global radiation safety program encompassing over 120 nuclear pharmacies, 60 medical imaging facilities, and several manufacturing facilities. Ensure general surveillance over all Syncor activities involving radioactive material and radiation producing machines, including problem identification, personnel dosimetry, regulatory agency interaction, training, and emergency response. Responsible for advising senior management on all matters related to radiation protection; for reviewing and approving all proposed uses, and locations of proposed use, of radioactive materials; and for guiding the Quality and Regulatory Department in carrying out Syncor's radiation safety program. Supervise a six person staff.

Manager, Health Physics, Syncor International Corp., Woodland Hills, CA 10/98 to 1/01
Develop, implement and manage all technical and logistical aspects of Syncor's Radiation Safety Program for the day-to-day and long-term operation of all domestic radiopharmacies (120), international radiopharmacies (16), and medical imaging facilities (40). Ensure Syncor's operations are conducted in accordance with the regulations of the Nuclear Regulatory Commission, Department of Transportation, Environmental Protection Agency, and numerous Agreement States. Provide technical information regarding health physics, regulatory concerns, emergencies, and decontamination operations. Audit facilities for radiation safety/regulatory compliance. Coordinate the presentation of, and teach in, Syncor's health physics, radiation safety and radiation biology courses in a six week authorized nuclear pharmacist training program. Supervise a six person staff.

Program Manager, Health Physics, Syncor International Corp., Woodland Hills, CA 6/95 to 10/98
Manage the health physics program for 120 U.S. radiopharmacies, eight international radiopharmacies, and four cyclotrons. Other duties and responsibilities similar to above. Supervise a five person staff.

Health Physicist, Syncor International Corp., Chatsworth, CA 11/92 to 6/95
Coordinate the radioactive material licensing program for 118 radiopharmacies and four cyclotrons. Radiation Safety Officer for corporate laboratory. Teach Health Physics and Radiation Safety in an Authorized User training course. Provide technical information regarding health physics, regulatory concerns, emergencies, and decontamination operations. Audit facilities for radiation safety/regulatory compliance. Wrote numerous radioactive material license applications and amendment requests.

Lieutenant, United States Navy Reserve 10/92 to Present

Lieutenant, U. S. Navy 1/89 to 9/92

Assistant to Squadron Engineer

Assisted in managing the material condition of a squadron of nuclear powered submarines. Included auditing/maintaining records, coordinating maintenance activities involving multiple organizations, and providing technical support to the Squadron Engineer regarding the operation, maintenance and repair of Naval nuclear power plants.

Reactor Controls Division Officer

In charge of operating, maintaining, and repairing all electronic and mechanical equipment associated with reactor control, monitoring reactor plant parameters and reactor safety. Supervised a division of ten personnel. Administered Engineering Department training regarding reactor safety/control. Assigned, scheduled, and coordinated maintenance and repairs. Responsible for divisional training/technical advancement, administration & personnel issues.

EXPERIENCE (cont.)

Engineering Officer of the Watch/Engineering Duty Officer

Managed a watch section of ten personnel. Supervised the safe operation of a Naval nuclear power plant. At sea, responsible for maintaining continuity of electrical power, propulsion, casualty control, and reactor safety. In port, supervised major maintenance and repair jobs of the nuclear power plant.

Firefighter, Truck Operator/Driver

Groton Long Point Volunteer Fire Dept., Groton Long Point, CT

4/91 to 6/9

Carson City Volunteer Fire Dept., Carson City, NV

6/86 to 6/8

Bureau of Land Management, Carson City, NV

5/88 to 8/8

Responded to emergency medical/rescue calls, hazardous materials spills, structure/wildland fires, small plane crashes, etc. Operator/driver of a ladder truck (100 ft. aerial platform).

EDUCATION

MBA Candidate, University of California, Los Angeles, Anticipated graduation of June 2003

Graduate-level Coursework in Physics, California State University Northridge

Bachelor of Science, Physics, minor in math - University of Nevada Reno.

Naval Nuclear Power School - Orlando, FL: General/Nuclear/Electrical Engineering, Radiological Controls, Chemistry, Reactor Dynamics, Aspects of Reactor Plant Operation.

Nuclear Prototype Training Unit - Idaho Falls, ID: Applied the education gained in Naval Nuclear Power School to an operating nuclear power plant. Qualified to supervise the operation, maintenance and repair of Naval nuclear power plants.

Naval Submarine School - New London, CT: Indoctrination to submarines/associated systems, personnel management/administration, leadership training.

Officer Candidate School - Newport, RI: Courses in Naval Science, personnel management and administration, leadership training.

TEACHING EXPERIENCE

Adjunct Associate Professor of Bionucleonics
Butler University, Indianapolis, IN

1/93 to 6/99

Adjunct Lecturer
University of Arkansas, Little Rock, AR

6/99 to Present

CERTIFICATION/RADIOACTIVE MATERIAL LICENSURE

Certified Health Physicist (by the American Board of Health Physics).
Authorized user on Syncor NRC Materials License No. 04-26507-01MD.
Authorized user and RSO on Syncor CA Radioactive Materials License No. 4853-19.

PROFESSIONAL MEMBERSHIPS

Health Physics Society - National
Health Physics Society - Southern California Chapter
American Academy of Health Physics, Plenary Member

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 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	In accordance with letter dated March 13, 2001
1. Syncor International Corporation	3. License number 04-26507-01MD is amended in its entirety to read as follows:
2. 6464 Canoga Avenue Woodland Hills, California 91367	4. Expiration date March 31, 2001
	5. Docket No. 030-33224 Reference No.

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
Maximum amount per licensed facility identified in Condition 10		
A. Any unsealed byproduct material, except iodine-131, technetium-99m and xenon-133 used to prepare radioactive drugs for medical use.	A. Any unsealed byproduct material used to prepare radioactive drugs for medical use, except iodine-131, technetium-99m and xenon-133.	A. 1 Curie
B. Molybdenum-99	B. Any molybdenum-99/technetium-99m generator initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations	B. 200 curies
C. Technetium-99m	C. Unsealed	C. 200 curies
D. Xenon-133	D. Unit dose containers of gas or gas in solution initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations	D. 5 curies

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

04-26507-01MD

Docket or Reference Number

030-33224

Amendment No. 37

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
E. Iodine-131	E. Any unsealed byproduct material used to prepare radioactive drugs for medical use	E. 990 millicuries (also see Condition 21)
F. Iodine-131	F. Sodium iodide, liquid or capsule, and/or sodium iodohippurate (Hippuran)	F. 5 curies for Bristol, Pennsylvania facility only
G. Any byproduct material listed in 10 CFR 35.400	G. Any sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations	G. 500 millicuries
H. Any byproduct material listed in 10 CFR 35.500	H. Any sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations	H. 4.5 curies total and no single source to exceed 1.5 curies
I. Cesium-137	I. Sealed sources (3M 4P6E, 4F6H, 4D6L, or 4F6S; U.S. Nuclear 375; Isotope Products 193; Amersham X.9 and X.8; Industrial Research Labs 2-4 and 2-10; J.L. Shepherd Model 6810)	I. 1 curie for the Kansas City, Missouri facility only

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

04-26507-01MD

Docket or Reference Number

030-33224

Amendment No. 37

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. Cesium-137	J. Sealed source (Technical Operations Model 773)	J. 165 millicuries for the Indianapolis, Indiana facility only
K. Any byproduct material listed in 10 CFR 31.11(a)	K. Prepackaged units for <u>in vitro</u> diagnostic tests	K. 50 millicuries
L. Any byproduct material authorized under 10 CFR 35.57(a)	L. Any sealed source listed in 10 CFR 35.57(a) that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations	L. 50 millicuries
M. Uranium (depleted in the isotope Uranium 235)	M. Metal encased in stainless steel	M. 220 kilograms
N. Any byproduct material with atomic numbers 2-83, inclusive	N. Analytical samples	N. As needed (see Item 9.N)

9. Authorized use:

- A. through F. Preparation and distribution of radioactive drugs (includes Mo99/Tc99m generators) to authorized recipients.
- G and H. 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

04-26507-01MD

Docket or Reference Number

030-33224

Amendment No. 37

- I. To be used in a J.L. Shepherd and Associates Model 28-6A calibrator at the Kansas City, Missouri facility for instrument calibration including calibration of survey meters as a service for customers and other clients.
- J. To be used in a Victoreen Gamma Survey Instrument Calibrator at the licensee's Indianapolis, Indiana facility for instrument calibration including calibration of survey meters as a service for customers and other clients.
- K. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the *packaging and labelling remain unchanged*.
- L. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR 32.74, the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 35.57(a) or under equivalent licenses of Agreement States.
- M. Shielding for Mo99/Tc99m generators
- N. Possession incident to the performance of swipe testing of customer's sealed sources.

Pursuant to 10 CFR 32.72 and 32.74, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through M. of this license to persons licensed pursuant to Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of 10 CFR Part 35, or under equivalent licenses of Agreement States.

CONDITIONS

- 10. Licensed material identified in Items 6.A through 6.M shall be used only at the licensee's facilities located at:
 - A. 420 East Northland Avenue, Appleton, Wisconsin 54915
 - B. 2444 Brodhead Road, Suite F, Bethlehem, Pennsylvania 18017
 - C. 200 Rittenhouse Circle, Unit 9 East, Bristol, Pennsylvania 19057
 - D. 3432 Route 764, Sugar Run Plaza, Building 1, Duncansville, Pennsylvania 16835
 - E. 3800 West 12th Street, Erie, Pennsylvania 16505
 - F. 628 Hebron Avenue, Building 4, Glastonbury, Connecticut 06033
 - G. 8181 President's Drive, Hummelstown, Pennsylvania 17036
 - H. #1 Syncor Drive, University Heights, U.S. Route 60 East, Huntington, West Virginia 25705
 - I. 7920 Georgetown Road, Suite 100, Indianapolis, Indiana 46268
 - J. 1864 Pine Ridge Drive, #A, Jenison, Michigan 49428
 - K. Marion Ridge Business Park, 9668 Marion Ridge, Kansas City, Missouri 64137
 - L. 130 Market Street, Kenilworth, New Jersey 07033

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
04-26507-01MD

Docket or Reference Number
030-33224

Amendment No. 37

- M. 1610 30th Avenue South, Moorhead, Minnesota 56560
- N. 1094 Globe Avenue, Mountainside, New Jersey 07092
- O. 70 33rd Street, Suite A, Pittsburgh, Pennsylvania 15201
- P. 1500 Tomlyn Street, Richmond, Virginia 23230
- Q. Rd 3, Box 367, Route 20 West, Seaford, Delaware 19973
- R. 650 Elmwood Avenue, Sharon Hill, Pennsylvania 19079
- S. 21681 Melrose Avenue, Southfield, Michigan 48075
- T. 3040 East Elm Street, Springfield, Missouri 65802
- U. 1045 Westgate Drive, Suite 100, St. Paul, Minnesota 55114
- V. 1909 Beltway Drive, St. Louis, Missouri 63114
- W. 28 Omega Drive, Building #7, Stamford, Connecticut 06907
- X. 5370 Miller Road, Suite #25, Swartz Creek, Michigan 48473
- Y. 230 Clearfield Avenue, Suite 125, Virginia Beach, Virginia 23462
- Z. 11829 W. Ripley Avenue, Wauwatosa, Wisconsin 53226
- AA. 212 South Ivanhoe Court, Griffith, Indiana 46319-3454
- BB. 201 West 6th Street, Marshfield, Wisconsin 54449

11. Licensed material identified in Item 6.N may be used at the licensee's facilities listed in Condition 10 and at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.
12. A. Licensed material shall be used by, or under the supervision of a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) and (3).
- B. Licensed material for other than radiopharmaceutical use shall be used by or under the supervision of:

Tony Adamo	Cheryl Holmes	Wes Rogers
T. John Alexander	Joseph Jerkins	Dan Schmitz
Carlos Barrientos	Matthew Komornik	Mark Vorhees
Jack L. Coffey	Robert E. Lewis	David Wilson
Edward A. Corros	Brenda K. Norkosky	Michael Young
W. Robert Davis	Michele Panichi-Egberts	Adam J. Fleshner
Tara J. Domiter	David W. Pellicciarini	James T. Chimelewski, Jr.
Colleen M. Glynn	Corey W. Woods	

- C. The Radiation Safety Officer for this license is David W. Pellicciarini, CHP

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

04-26507-01MD

Docket or Reference Number

030-33224

Amendment No. 37

13. Notwithstanding the requirements of 10 CFR 32.72(b)(2)(ii), the licensee may approve authorized nuclear pharmacists in accordance with letter dated January 19, 1995:
14. 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 specified by the certificate of registration referred to in 10 CFR 32.210.
- 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.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive 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 transferred 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.
- E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately 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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

04-26507-01MD

Docket or Reference Number

030-33224

Amendment No. 37

- F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
17. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
18. 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 ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
19. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in letter dated January 18, 1996.
20. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
21. A. Notwithstanding Item 8.E, the Iodine-131 possession limit for the licensee's Appleton, Wisconsin facility shall not exceed 10 millicuries.
- B. Notwithstanding Item 8.E, the Iodine-131 possession limit for the licensee's St. Louis, Missouri, Griffith, Indiana, Seaford, Delaware, Wauwatosa, Wisconsin, Pittsburgh, Pennsylvania and Sharon Hill, Pennsylvania facilities shall not exceed 3 curies.
22. Notwithstanding the requirements of 10 CFR 32.72(c), the licensee may re-distribute alpha-, beta-, or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier licensed pursuant to 10 CFR 32.72, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and label.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

04-26507-01MD

Docket or Reference Number

030-33224

Amendment No. 37

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 U.S. 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 May 31, 1993
 - B. Letter dated January 19, 1995
 - C. Letter dated January 18, 1996
 - D. Letter dated February 19, 1996
 - E. Letter dated March 6, 1996
 - F. Letter dated March 21, 1996
 - G. Letter dated March 25, 1996
 - H. Letter dated April 25, 1996
 - I. Letter dated April 26, 1996
 - J. Letter dated June 6, 1996
 - K. Letter dated September 9, 1996
 - L. Letter dated November 22, 1996
 - M. Letter dated January 29, 1997
 - N. Letter dated February 6, 1997
 - O. Letter dated May 12, 1997
 - P. Letter dated May 19, 1997
 - Q. Letter dated August 7, 1997
 - R. Facsimile dated August 18, 1997
 - S. Letter dated September 23, 1997
 - T. Letter dated October 29, 1997
 - U. Letter dated November 5, 1997
 - V. Letter dated December 8, 1997
 - W. Letter dated January 28, 1998
 - X. Letter dated February 6, 1998
 - Y. Letter dated February 24, 1998
 - Z. Letter dated March 11, 1998
 - AA. Facsimiles (2) dated March 25, 1998
 - BB. Letter dated May 29, 1998
 - CC. Letter dated June 22, 1998
 - DD. Letter dated June 26, 1998
 - EE. Letter dated July 6, 1998
 - FF. Letter dated August 5, 1998
 - GG. Letter dated October 16, 1998
 - HH. Letter dated December 30, 1998
 - II. Letter dated March 8, 1999
 - JJ. Facsimile dated March 23, 1999

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

04-26507-01MD

Docket or Reference Number

030-33224

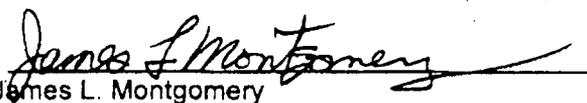
Amendment No. 37

KK. Letter dated April 2, 1999
LL. Letter dated April 13, 1999
MM. Letter dated May 28, 1999
NN. Letter dated June 1, 1999
OO. Letter dated July 14, 1999
PP. Letter dated August 27, 1999
QQ. Letter dated September 20, 1999
RR. Letter dated September 21, 1999
SS. Facsimile dated October 20, 1999
TT. Letter dated October 21, 1999
UU. Letter dated October 25, 1999
VV. Letter dated November 17, 1999
WW. Letter dated December 17, 1999
XX. Letter dated December 29, 1999
YY. Letter dated January 17, 2000
ZZ. Letter dated January 26, 2000
AAA. Letter dated February 8, 2000
BBB. Letter dated February 18, 2000
CCC. Letter dated May 15, 2000
DDD. Letter dated May 17, 2000
EEE. Letters (2) dated July 5, 2000
FFF. Letter dated September 28, 2000
GGG. Letter dated October 5, 2000
HHH. Letter dated October 11, 2000
III. Letter dated October 16, 2000
JJJ. Letter dated March 13, 2001

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date April 18, 2001

By



James L. Montgomery
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011

NOV 02 2000

RADIOACTIVE MATERIAL LICENSE

O & F

In accordance with the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee	Syncor International Corporation	3. License Number	4853-19	Amendment Number	0
2. Address	6464 Canoga Avenue Woodland Hills, CA 91367	4. Expiration date	April 24, 2002		(C)
Attention	David W. Pellicciarini, CHP Radiation Safety Officer	5. Inspection agency	Los Angeles County Department of Health Services		

In response to the letter dated October 12, 2000, signed by David W. Pellicciarini, CHP, License Number 4853-19, hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Any radionuclide with atomic numbers 1-83, except Rubidium-81, Krypton-81m, Molybdenum-99, Technetium-99m, Iodine-123, 125, and 131, and Xenon-133.	A. Any	A. 1 curie per radionuclide and 2 curies total.
B. Rubidium-81	B.-C. Any	B.-C. Total not to exceed 200 millicuries.
C. Krypton-81m		
Molybdenum-99	D.-E. Any	D.-E. Total not to exceed 5 curies.
E. Technetium-99m		
F. Iodine-123, 125, and 131	F. Any	F. Total not to exceed 400 millicuries.
G. Xenon-133	G. Any	G. Total not to exceed 100 millicuries.
H. Gold-198 Indium-192 Iodine-125 Palladium-103	H. Seeds for brachytherapy.	H. 1 millicurie per source. Total not to exceed 4.5 curies.
I. Samarium-153	I. Liquid source manufactured, labeled, packaged, and distributed in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State.	I. Total not to exceed 15 millicuries.

9. Authorized Use

- A.-G. Preparation and distribution of radioactive drugs including compounding of Iodine-123, 125, and 131 and redistribution of used and unused Molybdenum-99/Technetium-99m generators to authorized recipients in accordance with CCR Title 17, Section 30210.2. Preparation and distribution of radioactive drugs and radiochemicals including compounding of Iodine-123, 125, and 131 and redistribution of used and unused Molybdenum-99/Technetium-99m generators to authorized recipients for non-medical use. Also labeling blood components, analysis of labeled or tagged biological samples.

RADIOACTIVE MATERIAL LICENSE

License Number: 4853-1

Amendment Number: 2

- H. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.7 or equivalent Agreement State requirements. Redistribution of sealed sources that have been registered either with U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed to persons specifically authorized by the U.S. Nuclear Regulatory Commission or Agreement State to receive, possess, and use the devices/sources.
- I. To be used for calibration of instruments.

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following location:
- (a) 6464 Canoga Avenue, Woodland Hills, CA.
11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.
12. Radioactive material shall be used by, or under the supervision and in the physical presence of, the following individuals:
- (a) Louis E. Baca
(b) Jack L. Coffey
(c) David W. Pellicciarini, CHP
(d) Tara J. Domiter
(e) Korj Kodimer, Ph.D
(f) Toli Mikell
(g) Willie Regits, Ph.D.
(h) Any authorized user or authorized nuclear pharmacist authorized under U.S. Nuclear Regulatory Commission License Number 04-26507-01 MD, issued to Syncor Corporation.
13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- (a) The application with attachments dated March 22, 1994, as modified by the letter with attachments dated August 14, 1995, both signed by David W. Pellicciarini.
- (b) The letter dated August 17, 1994 signed by David W. Pellicciarini, relative to use of TLD dosimeters which are to be exchanged in quarterly basis or more frequently.
- (c) The letter dated January 26, 1996, signed by David W. Pellicciarini, regarding labeling products.
- (d) The letter with attachments dated October 17, 1996 signed by David W. Pellicciarini, regarding the notification to relocate the facility and provide an exit survey of the old location upon vacating.
- (e) The letter dated February 3, 1997 regarding closeout survey for the Chatsworth facility and letter dated February 5, 1997 with a revised floor plan of the Woodland Hills facility, both signed by David W. Pellicciarini.
- (f) The letter dated September 23, 1998 signed by Tara J. Domiter regarding the clarification of the fume hood exhaust as being in the north HVAC system on the fourth floor training facilities.

RADIOACTIVE MATERIAL LICENSE

License Number: 4853-

Amendment Number:

- (g) The letter dated September 28, 1999, signed by David W. Pellicciarini, regarding a change to Optical Stimulated Luminescence whole body badges by Landauer.
- (h) The letter dated November 17, 1999, signed by Tara J. Domiter, regarding authorization to process, store, and redistribute I-125 and Pd-103 in the form of brachytherapy seeds.
- (i) The letter dated August 24, 2000, signed by Kory Kodimer, Ph.D., regarding alternate procedures for receiving and opening packages.
14. (a) The Radiation Safety Officer in this program shall be David W. Pellicciarini, CHP.
(b) The Alternate Radiation Safety Officer in this program shall be Kory Kodimer, Ph.D.
15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17 California Code of Regulations, Section 30275 (c).
16. Quantitative analytical assays for the purpose of tests for leakage and/or contamination of sealed sources shall be performed only by persons specifically authorized to perform that service.
17. Sealed sources described in Subitem A. of this license shall be tested for leakage and/or contamination at intervals not to exceed six months, following the test method described in 13 (a).
- Records of leak test results shall be kept in units of microcuries and maintained for inspection. Records may be disposed of following Department inspection. Any leak test revealing the presence of 0.005 microcuries or more of removable radioactive material shall be reported to the Department of Health Services, Radiologic Health Branch, 601 N. Tenth Street, P.O. Box 942732 - MS 178, Sacramento, CA 94234-7320, within five days of the test. The report shall include a description of the defective source or device, the results of the test, and the corrective action taken.
19. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services:
- (a) The Radiation Safety Officer
(b) Qualified individuals designated in writing by the Radiation Safety Officer
20. Where users or their assistants are engaged in elution of pertechnetate-99m from generators, the exposure to the fingers or hands shall be monitored as required by Title 10, Code of Federal Regulations, Part 20 Section 20.1502 (a).
21. The licensee shall distribute only sealed sources and/or devices for which a Sealed Source and Device Registry Certificate has been issued by the California Department of Health Services, the U.S. Nuclear Regulatory Commission, or other Agreement State. Sealed sources and/or devices distributed must adhere to the design specifications described in the Sealed Source and Device Registry Certificate. Any changes in the design or specifications of these sealed sources and/or devices require the manufacturer to apply for and receive an amendment to the Sealed Source and Device Registry Certificate prior to distribution. The licensee may distribute sources and/or devices without a Sealed Source and Device Registry Certificate provided the recipient is authorized to possess such items by license condition or applicable State or Federal regulations and laws.
22. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.

RADIOACTIVE MATERIAL LICENSE

License Number: 4853-1

Amendment Number:

23. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at ~~6464~~ Canoga Avenue, Woodland Hills, CA.

For the State Department of Health Services

Date: October 26, 2000

By: *David Wesley*

Radiologic Health Branch
P.O. Box 942732-MS 178, Sacramento, CA 94234-7320

Training and Experience Records for James Chimelewski

RADIOISOTOPE HANDLING EXPERIENCE

Name: James T. Chmielewski, Jr.

Date: 01/19/01

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1.2.3.4.5.6.7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
Mo-99	15 Ci	1,5,7	01/25/99 to 10/13/00 >2000 Hours	Syncor International Corporation Syracuse, NY
Tc-99m	5 Ci	1,2,3,4,5,6		
I-131	50 mCi	1,5,6	11/6/00 to 12/01/00 160 Hours	
Xe-133	20 mCi	1,3,4,5,6	12/25/00 to 01/19/01 160Hours	
I-123	6 mCi	1,3,4,5		
Ga-67	40 mCi	1,3,4,5		
Tl-201	80 mCi	1,3,4,5		
Co-57	5 mCi	2	>2320 Total Hours	
Cs-137	250 μ Ci	2		

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
3. Calculating, assaying and safely preparing dosages for patients or human research subjects
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests
7. Eluting Tc-99m from generator systems, assaying the eluate for Tc-99m and for Mo-99 contaminations, and processing the eluate with reagent kits to prepare Tc-99m labeled radioactive drugs

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

James Chmielewski, Jr.

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
SYNCOR INT'L CORPORATION, WOODLAND HILLS, CA	10/16/2000 to 11/3/2000 AND 12/4/2000 to 12/21/2000	SYNCOR AUTHORIZED NUCLEAR PHARMACIST TRAINING PROGRAM	227	92	50	24	25	36
*Note Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)			TOTAL HOURS 227	92	50	24	25	36

SYNOR INTERNATIONAL CORPORATION

certifies that

James Chmielewski, Jr.

successfully completed the

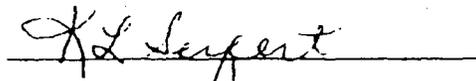
Authorized Users Training Program

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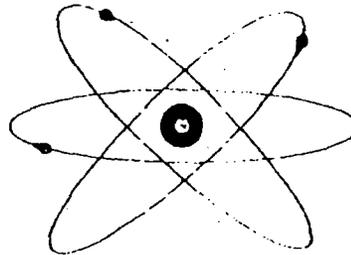
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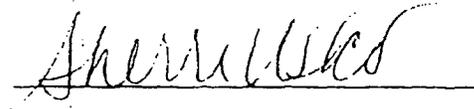
Chairman of the Board



Director, Regulatory



President and Chief Executive Officer



Program Manager, Educational Resources



The Service Difference®

Syncor Pharmacy Services

DOCUMENTATION OF AUTHORIZED USER TRAINING

I hereby certify that the technician listed below has been satisfactorily trained and that the individual has achieved a level of competency sufficient to operate a nuclear pharmacy.

Technician Name (print) JAMES CHARLES JR

Technician Signature [Signature] Date 1-17-01

Preceptor Name (print) DAN PALMQUIST

Preceptor Signature [Signature] Date 1/17/01

Location 1080

Training and Experience Records for Corey Woods

RADIOISOTOPE HANDLING EXPERIENCE

Name: Corey Woods

Date: 11/27/00

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below: 1.2.3.4.5.6.7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
Mo-99	15 Ci	1,5,7	11/24/86 to 01/14/00 >2000 Hours 02/07/00 to 03/10/00 200 Hours 04/03/00 to 11/22/00 1300 Hours >2000 Total Hours	Syncor International Corporation Charlotte, NC
Tc-99m	13 Ci	1,3,4,5,6,7		
I-131	250 mCi	1,3,4,5,6		
Xe-133	1Ci	1,3,4,5,6		
I-123	5 mCi	1,3,4,5		
Ga-67	50 mCi	1,3,4,5		
Tl-201	120 mCi	1,3,4,5		
Co-57	10 mCi	2		
Cs-137	200 uCi	2		

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
3. Calculating, assaying and safely preparing dosages for patients or human research subjects
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests
7. Eluting Tc-99m from generator systems, assaying the eluate for Tc-99m and for Mo-99 contaminations, and processing the eluate with reagent kits to prepare Tc-99m labeled radioactive drugs

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Corey Woods

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radio-activity	Radiation Biology	Radio-pharmaceutical Chemistry
SYNCOR INT'L CORPORATION, WOODLAND HILLS, CA	1/17/2000 to 2/4/2000 AND 3/13/2000 to 3/30/2000	SYNCOR AUTHORIZED NUCLEAR PHARMACIST TRAINING PROGRAM	227	92	50	24	25	36
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)			TOTAL HOURS 227	92	50	24	25	36



The Service Difference™

Syncor Pharmacy Services

DOCUMENTATION OF AUTHORIZED USER TRAINING

I hereby certify that the technician listed below has been satisfactorily trained and that the individual has achieved a level of competency sufficient to operate a nuclear pharmacy.

Technician Name (print) Corey W. Woods

Technician Signature [Handwritten Signature]

Date 1/15/01

Preceptor Name (print) Michael A. Rubetta (PharmD)

Preceptor Signature [Handwritten Signature]

Date 1/15/01

Location 1083

5464 Canoga Avenue • Woodland Hills, CA 91367 • 818-737-4000

SYNCON INTERNATIONAL CORPORATION

certifies that

Corey Woods

successfully completed the

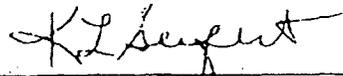
Authorized Users Training Program

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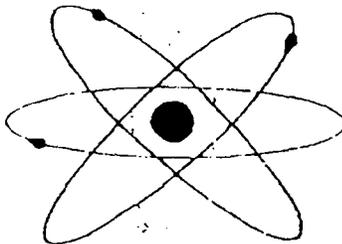
March 30, 2000



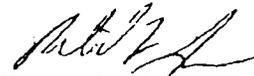
Chairman of the Board



Director, Regulatory



President and Chief Executive Officer



Program Manager, Educational Resources

Item 8

Training for Individuals Working in or Frequenting Restricted Areas

Occupationally Exposed Workers

- A. Individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem will be instructed in the items specified in NRC/Agreement State regulations before an employee assumes duties with or in the immediate vicinity of radioactive materials or whenever a significant change occurs in duties, regulations, or terms of the NRC/Agreement State license, and at least annually thereafter. The extent of the instructions will be commensurate with potential radiological health protection problems in the work place. This instruction will include:
1. Information on the storage, transfer or use of radiation and/or radioactive material.
 2. Health protection problems associated with exposure to radiation or radioactive material, and precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed.
 3. Applicable provisions of NRC/Agreement State regulations and licenses for the protection of personnel for exposure to radiation or radioactive material.
 4. Responsibility to report promptly to the RSO any condition that may lead to or cause a violation of NRC/Agreement State regulations and licenses or unnecessary exposure to radiation or radioactive material.
 5. Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.
 6. Right to be informed of their radiation exposure and bioassay results.
 7. Locations where Syncor Pharmacies have 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 the NRC/Agreement State regulations.
- B. This information will be provided initially at pharmacy employee orientation sessions and at least annually thereafter at in-service meetings.

Personnel Involved in Package Preparation and Transport

Syncor confirms that we have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, including but not limited to:

- 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/Agreement State and DOT 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; and
- I. Their right to be informed of their radiation exposure and bioassay results.

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 they have made a delivery with an experienced driver, they must check that account off of the list.

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

- A. The sequence of hospital delivery;
- B. The number of cases to be delivered to each hospital;
- C. Retrieval and return of all cases;
- D. Making sure that upon leaving a vehicle all windows are closed and all doors are locked;
- E. 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 where we supply. These instructions will include:
 - 1. Where to park upon arrival at the hospital;
 - 2. What entrance to enter the hospital by;
 - 3. Whether or not to check in with security;
 - 4. Route to take from entry into the hospital to Nuclear Medicine;
 - 5. Area where doses may be left during off-duty hours, if not Nuclear Medicine;
 - 6. Any special instructions, such as checking in at desk, special area in Nuclear Medicine to leave doses having security personnel unlock doors, etc.

F. Having in their vehicle the instructions that we supply in case of an accident; and

G. Their responsibility to maintain the security and control of radioactive material at all times.

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:

- A. You may not pick up any radioactive waste from our customers who are not comprised of material delivered by Syncor to this customer.
- B. All materials must have been returned to its original shipping container and packaging before you are authorized to collect it. You may not accept any loose material, syringes, needles, vials, etc., for transport.
- C. 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

**Item 9
Facilities and Equipment**

9.1 General Provisions

1) (b)(4)

Ex 4

- 2) We confirm that all Syncor facilities have been issued a board of pharmacy license from their respective states. We also confirm that a new Syncor facility will not operate as a nuclear pharmacy until the board of pharmacy license has been obtained.
- 3) We confirm that operation of a nuclear pharmacy does not conflict with local codes and zoning laws for each location.
- 4) We confirm that the fume hood stack will extend at least 5 feet above the roofline and will be at least 30 feet from the nearest building air intake.
- 5) Please see the attached letter that is sent out to the police and fire departments unless the local Fire Marshal's office inspects the facility annually.

Date:

Address:

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

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

Syncor International Corporation
Street Address *
City, State, Zip *
Business Hours Phone: *
Emergency Phone (after business hours) *

This notification is for your information in case of a fire or disaster that 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 appropriate information will be filled in specifically for each location.

Figure 9-2 Letter mailed to the Police Chief and Fire Chief.

9.2 Adequacy of Facility for Handling Xenon-133

A. Quantities

The desired possession limit is 5 Ci of xenon-133. The rubber septums on the sealed vials will not be punctured nor the contents of the vials altered in any way.

B. Distribution and Storage

If the manufacturer's shielding container is opened, the xenon-133 vial(s) will be assayed in a dose calibrator and repackaged for distribution to authorized recipients. If the manufacturer's shielding container is unopened, the xenon-133 vial(s) will be dispensed under the manufacturer's assay. The xenon-133 vials will be shielded and stored in a fume hood.

C. Ventilation

Exhaust will be 300 CFM or greater from the fume hood, with no return vents in the room. This room will remain under constant negative pressure. Xenon-133 will not be used in the pharmacy; it will be stored in the fume hood only.

The fume hood will be checked every six months and after maintenance with an anemometer to determine if the fume hood is operating adequately.

Syncor commits to having a minimum of eight zones for the fume hood and corrective actions will be taken if the linear velocity drops below 50 ft/min

Syncor confirms that airflow checks will be made immediately after any maintenance of the fume hood or fan to confirm proper direction and volume of fume hood airflow.

D. Emergency Procedures in Case of Xenon-133 Release

1. Immediately evacuate all personnel in the area of the spill.
2. Notify all personnel, close all doors, and evacuate the room for * minutes (determined on the following page). 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 * minutes (same as above) or until normal background levels are measured in the facility.
4. Notify the Radiation Safety Officer and document the incident.

EXAMPLE

The amount of time adequate for the xenon-133 concentration to return below 1×10^{-4} $\mu\text{Ci/ml}$ ($100 \mu\text{Ci/m}^3$) if a unit dose is broke is given by

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

where

$$\begin{aligned} t &= \text{time in minutes} \\ V &= \text{room volume in milliliters} \end{aligned}$$

- Q = room exhaust rate in ml/min
 A = activity of gas possible to spill in μCi
 C = permissible air concentration for the volatile substance in $\mu\text{Ci/ml}$

Example:

If a 40 mCi vial of xenon-133 was dropped and broken the evacuation time could be determined as follows:

$$\begin{aligned}
 V &= (16 \text{ ft} \times 9 \text{ ft} \times 9 \text{ ft}) \times (2.83 \times 10^4 \text{ ml/ft}^3) \\
 &= 3.67 \times 10^7 \text{ ml}
 \end{aligned}$$

$$\begin{aligned}
 Q &= (300 \text{ ft}^3/\text{min}) \times \left(2.83 \times 10^4 \frac{\text{ml}/\text{min}}{\text{ft}^3/\text{min}} \right) \\
 &= 8.49 \times 10^6 \text{ ml/min}
 \end{aligned}$$

$$C = 1.0 \times 10^{-4} \mu\text{Ci/ml for restricted area}$$

$$A = 40,000 \mu\text{Ci}$$

$$\begin{aligned}
 t &= -\frac{3.67 \times 10^7}{8.49 \times 10^6} \times \ln \left(1.0 \times 10^{-4} \times \frac{3.67 \times 10^7}{40000} \right) \\
 &= 10.3 \text{ minutes}
 \end{aligned}$$

After 10.3 minutes, the concentration of Xenon-133 in this area would have returned to below the DAC.

E. Air Concentrations of Xenon-133 for Unrestricted Areas

1. All xenon-133 gas will be handled 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 will be 5 Ci. This will be the maximum amount stored in the fume hood.
3. Using a value of 0.05% per day for the leakage from xenon-133 vials, the following calculations are submitted.

If we have a leakage of 0.05% per day and we assume that we will continually have 5 Ci on hand seven days a week, then:

$$F = \frac{0.0005}{\text{day}} \times \frac{7 \text{ days}}{\text{week}}$$

$$= \frac{3.5 \times 10^{-3}}{\text{week}}$$

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

$$V = \frac{300 \text{ ft}^3}{\text{min}} \times \frac{60 \text{ min}}{\text{hr}} \times \frac{24 \text{ hr}}{\text{day}} \times \frac{7 \text{ day}}{\text{week}} \times \frac{1728 \text{ in}^3}{\text{ft}^3} \times \frac{16.39 \text{ ml}}{\text{in}^3}$$

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

5. For unrestricted areas, the maximum allowed concentration is $5 \times 10^{-7} \mu\text{Ci/ml}$. In our case:

$$\begin{aligned} \text{Maximum Concentration} &= \frac{A \times F}{V} \\ &= \frac{(5 \times 10^6 \mu\text{Ci}) \times (3.5 \times 10^{-3} \text{ wk}^{-1})}{8.56 \times 10^{10} \text{ ml/wk}} \\ &= 2.04 \times 10^{-7} \mu\text{Ci/ml} \end{aligned}$$

NOTE: These calculations are a "worst case scenario" to demonstrate the ability to comply with the DAC limits. Our locations will generally be much below the calculated value. These calculations demonstrate that at 16 feet downstream, the effluent concentration level will be well below the limits.

PHARMACY EVACUATION TIMES IN THE CASE OF A XENON-133 SPILL

LOC. #	Location Name	STATE	H (feet)	W (feet)	L (feet)	V (ml)	t (minutes)
2	Southfield	MI	8.0	11.0	10.0	2.5E+07	8.1
4	Richmond	VA	9.0	9.5	11.0	2.7E+07	8.5
7	Virginia Beach	VA	9.0	10.0	10.0	2.5E+07	8.3
10	Indianapolis	IN	9.0	9.0	10.0	2.3E+07	7.7
13	Glastonbury	CT	8.0	8.0	12.0	2.2E+07	7.5
16	Griffith	IN	9.5	11.0	10.0	3.0E+07	9.1
19	Kenilworth(proposed)	NJ	10.0	10.0	11.0	3.1E+07	9.4
24	Allentown	PA	8.0	8.0	12.0	2.2E+07	7.5
25	Swartz Creek	MI	9.0	8.0	11.0	2.2E+07	7.6
28	Kansas City	MO	9.0	10.0	10.0	2.5E+07	8.3
29	Pittsburgh	PA	8.0	12.0	24.0	6.5E+07	13.9
30	St. Louis	MO	12.0	8.0	8.0	2.2E+07	7.5
38	St. Paul	MN	8.0	10.0	10.0	2.3E+07	7.7
39	Moorhead	MN	9.0	9.0	9.0	2.1E+07	7.2
64	Wauwatosa	WI	9.5	9.5	18.0	4.6E+07	11.7
72	Sharon Hill	PA	9.0	10.0	14.0	3.6E+07	10.2
73	Hummelstown	PA	9.0	9.0	10.0	2.3E+07	7.7
88	Stamford	CT	9.0	9.0	10.0	2.3E+07	7.7
96	Girard	OH	10.0	8.0	10.0	2.3E+07	7.7
97	Bristol	PA	8.0	9.0	10.0	2.0E+07	7.1
106	Appleton	WI	9.0	9.0	10.0	2.3E+07	7.7
109	Huntington	WV	9.0	8.0	12.0	2.4E+07	8.1
115	Duncansville	PA	9.0	8.0	18.0	3.7E+07	10.3
120	Springfield	MO	9.0	7.0	13.0	2.3E+07	7.8
125	Erie	PA	8.0	10.0	14.0	3.2E+07	9.5
128	Seaford	DE	9.0	8.0	13.0	2.7E+07	8.5
142	Marshfield	WI	9.0	8.0	8.0	1.6E+07	6.1

$Q = 8.49E+06 \text{ ml/min} = \text{Total room exhaust} = 300 \text{ CFM}$
 $A = 40,000 \text{ } \mu\text{Ci} - \text{Activity of Xe-133}$
 $C = 1E-04 \text{ } \mu\text{Ci/ml} - \text{Derived Air Concentration (DAC) from 10 CFR 20, Appendix B}$
 $t = V/Q \times \ln(C \times V/A)$

NOTE: Please also note that future changes to the evacuation times per each pharmacy will not include calculations, but will be on file for review or inspection.

9.4 Special Equipment for Handling Millicurie Quantities of Sodium Iodide-131

The handling and storage system at Syncor facilities consists of a standard laboratory (main) fume hood, and a smaller, radioiodine (glove box type) fume hood. The radioiodine hood is sometimes referred to as a glove box, although there are no attached gloves.

The standard laboratory fume hood, similar to the one shown in Figure 9-5 will be used for the storage of volatile or gaseous radioactive materials and will run continuously. The standard laboratory fume hoods in use vary in size, but are generally around 4 ft long by 3 ft wide by 5 ft tall. They are all rated with a volume flow rate in excess of 300 CFM. No filtration is used in this hood, and the effluent is vented outside of Syncor's facility.

The correct fume hood sash position will be determined during the semi-annual flow check performed on the fume hood. This flow check is documented on Syncor's Form RS-56, Fume Hood and Restricted Area Ventilation Check Record. Records of Syncor's Form RS-56 will be kept for a period not to exceed three years.

A velometer or anemometer is used to calculate fume hood performance. Fume hood air flow is determined on a semi-annual basis. The opening(s) is(are) divided into a number of zones, and the linear velocity is measured for each zone. These values are averaged, and then multiplied by the area of the opening(s) to find the total volume flow rate.

To ensure that staff members are aware of and able to determine the proper sash position when compounding iodine products, the position will be marked on the side of the hood. This will be the position that yields both an adequate volume flow rate and face velocity.

The radioiodine compounding hood similar to the one shown in Figure 9-5 will be utilized for dispensing liquid I-131 sodium iodide and compounding iodine-131 therapy capsules. The effluent from this fume hood will be directed into the standard laboratory fume hood exhaust.

The radioiodine fume hood is 24" long by 20" wide by 36" tall. Two charcoal filters are used to filter the effluent from this device. They are each 12" x 12" x 1", and are stacked on top of one another to ensure a trapping efficiency of 90%. The effluent from this device is routed either to the main exhaust stack, i.e., the exhaust stack rising from the standard laboratory fume hood, or into the side of the standard laboratory fume hood. The radioiodine effluent stream then joins the effluent from the standard laboratory fume hood and is exhausted outside of Syncor's facility. Measurements of air flow with an anemometer at the arm ports for this fume hood will show a linear air flow of at least 50 feet/min. 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. The air flow measuring equipment will be calibrated annually.

The efficiency of the trapping system by the charcoal filters will be checked weekly. The filters are removed and the radiation level at their surfaces is measured. When the measured level of the top filter is equal to or greater than 10% of the measured level of the bottom filter (provided that the bottom filter is greater than 10 times background), the bottom filter will be replaced with the top filter, and a new top filter will be inserted.

To aid in our efforts to reduce effluent levels, additional charcoal filtration may be placed inline with the effluent system. Air sampling for volatile I-131 will be performed in conjunction with the use of the filtration systems. The air sampling system measures the air concentration of iodine-131 in the effluent released outside of Syncor's facility, and in the breathing zone of a person compounding iodine-131 products inside Syncor's facility. In general, the effluent sample is collected in the main exhaust stack, downstream from where the radioiodine fume hood exhaust connects. A sampling probe is placed in the main exhaust stack to collect a sample. The air is drawn through a TEDA impregnated charcoal

cartridge, which is exchanged periodically and counted for iodine-131. The restricted area sample is collected in the breathing zone of the person operating the radioiodine fume hood. Air is drawn through an open face charcoal cartridge holder. The TEDA impregnated charcoal cartridge is exchanged periodically and counted for iodine-131. Please see the following pages for the step by step air sampling procedure.

The above procedure and those listed in the remaining pages of this section are necessary only when sodium iodide-131 is handled or stored.

Note: There are additional models of radioiodine fume hoods in use at some Syncor facilities. The only differences are that they have slightly different dimensions such as they are slightly larger, has slightly larger arm ports, and are produced by a different manufacturer. They each connect into the system in the exact same manner.

HEALTH PHYSICS SUPPLEMENT TO I-131 COMPOUNDING PROCESS

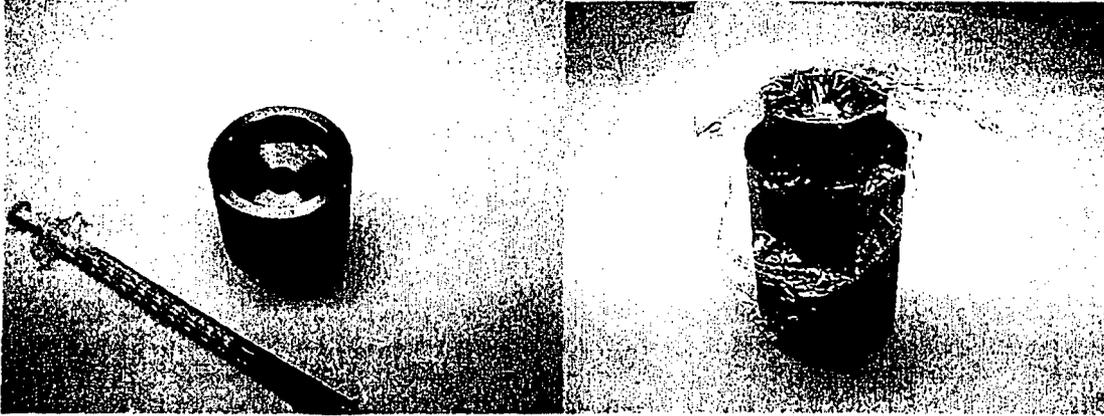
Below is a list of additional procedural items pertaining to radiation safety that must be followed during I-131 Compounding:

1. Check to ensure that the standard laboratory fume hood is operating properly.
2. Confirm that the air flow of the radioiodine compounding fume hood is 50-70 lfm or greater.
3. All procedures require double gloving. The shoulder length gloves or Tyvec sleeves must be used with appropriate disposable gloves (i.e. latex, vinyl, etc.)
4. Survey the radioiodine compounding fume hood for contamination before beginning the compounding procedure. Use the face of a pancake probe without the plastic cap to conduct this survey. Decontaminate if necessary.
5. During the compounding procedure, survey your gloves for contamination and change them if contamination is detected.
6. When compounding capsules, a Gotti cup capsule holder/shield must be used. An example of a Gotti cup is attached.
7. Once the patient dose is assayed, perform a wipe survey of the patient dose shield before removing it from the iodine compounding area to ensure that cross contamination is minimized.
8. Survey the radioiodine compounding fume hood and immediate work areas after the compounding procedure and decontaminate as needed.
9. Upon completion of the compounding procedure and surveys of the immediate work area, survey yourself thoroughly to ensure you are free of contamination. If personnel contamination exists, follow the Emergency Procedure for Personnel Exposed to I-131 posted in your compounding area.
10. Follow the air monitoring procedure as outlined in your NRC/Agreement State license.
11. Follow the thyroid bioassay procedure as outlined your NRC/Agreement State license.

Gotti Cup

The Gotti cup is used to increase the level of shielding available during the capsule compounding process. Below is an example of one type of Gotti cup capsule holder/shield. This new Gotti cup constructed of tungsten was designed to fit in the Piglet₂ for use in capsule compounding.

Another example of a Gotti cup used by Syncor utilizes a portion of lead off old Squibb generators. The lead generator portion is placed on top of a lead DuPont Ga-67 pig.



9.5 Procedures for Completion of Iodine-131 Air Monitoring

A TEDA-impregnated carbon cartridge will be used. 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. We confirm that sampling will be done on a continual basis. Air sampling cartridges will be exchanged every 7 days.

A. Equipment

1. Vacuum pump with air flow gauge (rotameter)
2. Teflon tubing
3. Charcoal cartridge holder
4. TEDA impregnated charcoal cartridge
5. Scintillation counting system and barium-133 cartridge standard

B. Operating Procedure for Air Cartridges

1. Effluent sampling must be done in the exhaust duct on the down stream side of any additional air filtering system.
2. The sample cartridge will be counted and exchanged every 7 days.

NOTE: In the event of a spill the sample cartridge will be counted immediately.

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

- a) Put on disposable gloves.
- b) Place the barium-133 cartridge standard directly on the scintillation probe housing. Obtain a count on the standard. Remove the standard and obtain a background count. Record the background and standard counts.
- c) Place the sample cartridge on the scintillation probe in the same geometrical configuration as the barium-133 standard source.
- d) Obtain a count of the sample cartridge. Make sure that an efficiency factor (F_e) for the barium-133 standard with the I-131 correction factor has been calculated for the proper analyzer setting.
- e) Record the sample count.

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

5. Record the μCi quantity of the barium-133 standard.

C. Procedure for Calculating the Concentration of Volatile Iodine

The following calculations may be used to determine the concentration of volatile iodine in $\mu\text{Ci/ml}$ in the restricted and unrestricted areas. See the worksheet in Figure 9-4.

1. Calculate "pump on duration" from the pump on and off times.

2. Determine the activity of iodine-131 present on the cartridge in μCi using:

$$A = \frac{(\text{Net cpm for the cartridge}) \times e^{\lambda t}}{F_e}$$

where:

A = activity of I-131 in μCi
t = one half of the sampling period
 F_e = efficiency for the Ba-133 standard in $\text{cpm}/\mu\text{Ci}$
 $e^{\lambda t}$ = correction factor for decay

A simplifying assumption is to back-decay the activity for one half of the sampling time to correct for sample decay.

3. Multiply the pump flow data in ml/min by the sampling time in minutes to calculate the air flow through the sampling pump in ml .
4. Calculate the iodine-131 concentration in $\mu\text{Ci}/\text{ml}$ using the following formula:

$$\text{Concentration} = \frac{\text{Activity of I-131 (from step 2)}}{\text{Total air flow (from step 3)}}$$

5. The regulatory limits for iodine-131 are:

- a) Effluent Concentration = $2 \times 10^{-10} \mu\text{Ci}/\text{ml}$
- b) Occupational DAC = $2 \times 10^{-8} \mu\text{Ci}/\text{ml}$

Syncor confirms that completed monitoring worksheets or computer printouts will be maintained at each location to document the concentration of I-131 in restricted and unrestricted areas in accordance with 10 CFR 20.2103. Syncor also confirms that these records will include determinations of the counting system's minimum detectable activity (MDA) and lower limit of detection (LLD).

WORK SHEET FOR IODINE-131 AIR MONITORING

A. Determine the activity of Iodine-131 in the cartridge

1. Well counter background (bkg) = _____ cpm

2. Gross sample count (cartridge) = _____ cpm

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

4. Ba-133 Standard Activity = _____ μ Ci

5. $F_e = \frac{\text{Net Ba - 133} \times R_p}{\text{Ba - 133 Standard Activity}} = \frac{\text{A.3.}}{\text{A.4.}} = \text{_____ cpm}/\mu\text{Ci}$

6. I-131 Activity = $\frac{\text{Net Cartridge Count} \times e^{\lambda t^{**}}}{F_e} = \frac{(\text{A.2.} - \text{A.1.}) \times e^{\lambda t}}{\text{A.5.}} = \text{_____ } \mu\text{Ci}$

B. Determine the total flow through the sampling pump

1. Measured Sample Pump Flow Rate = _____ ml/min

2. Pump-on Duration = _____ min

3. Pump Flow = (Pump Flow Rate) x (Pump-on Duration) = B.1. x B.2. = _____ ml

C. Determine the concentration of I-131 in air

I-131 Concentration in Air = $\frac{\text{I-131 Activity}}{\text{Pump Flow}} = \frac{\text{A.6.}}{\text{B.3.}} = \text{_____ } \mu\text{Ci/ml}$

Instrument _____

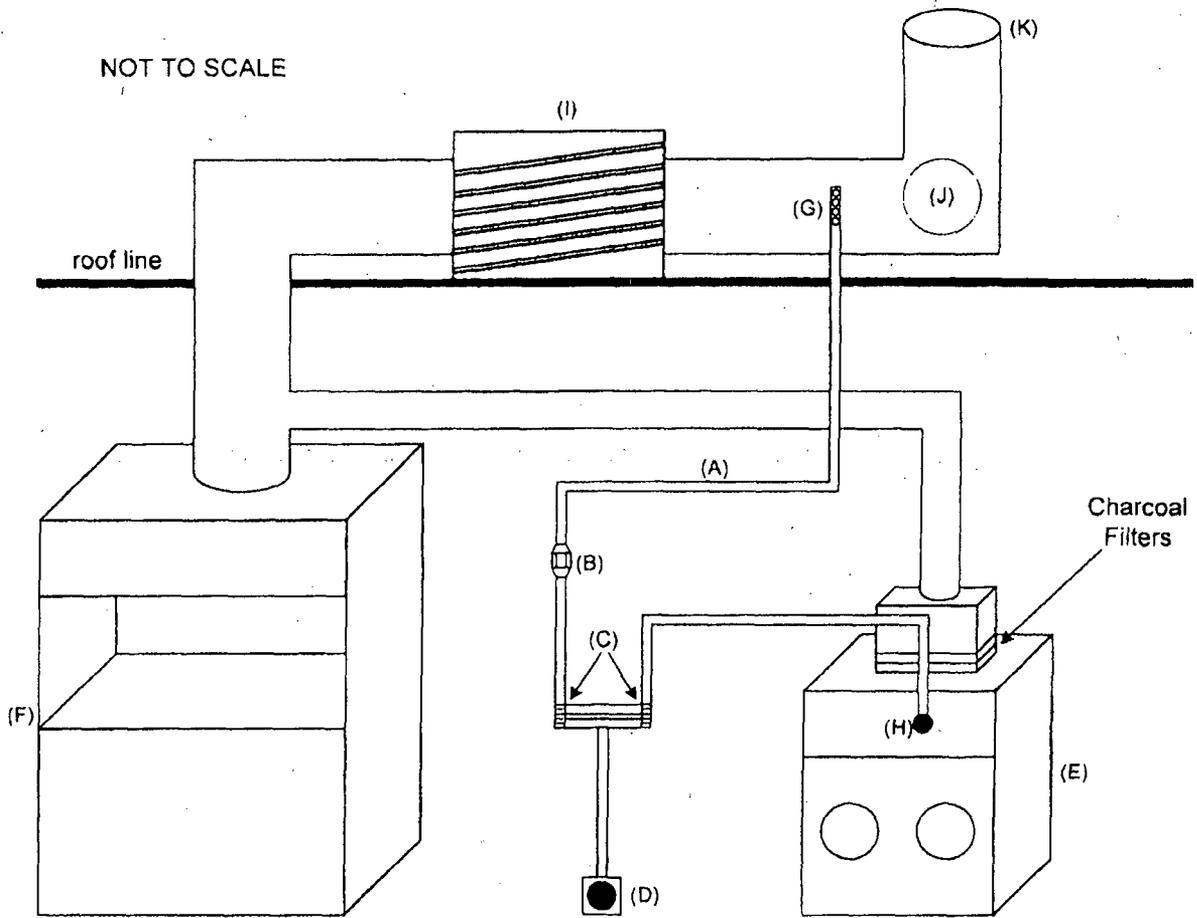
Analyzer Setting _____ keV to _____ keV

Signature _____ Date _____

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

** $e^{\lambda t}$ = decay correction where t equals half the time between samples

Figure 9-4 Worksheet for I-131 air monitoring.



- | | |
|--|---|
| A. Teflon Tubing | G. Sampling Probe |
| B. Unrestricted Air Sampling Cartridge | H. Restricted Area Air Sampling Cartridge |
| C. Rotameter | I. Charcoal Filtration Unit (optional) |
| D. Vacuum Pump | J. Fan Motor |
| E. Radioiodine Hood | K. Exhaust Stack |
| F. Fume Hood | |

Note: The relative position between the radioiodine hood and the fume hood may vary. Also, the exhaust for the radioiodine hood may actually go into the top of the fume hood as opposed to the bottom of its exhaust stack.

Figure 9-5 Volatile substance handling and sampling system.

Item 10
Radiation Safety Program

10.1 Program for Maintaining Occupational Radiation Exposures ALARA

I. Management Commitment to ALARA

- A. The management of Syncor is committed to the program described herein for keeping exposure (individual and collective) **as low as reasonably achievable (ALARA)**. In accordance with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policies, procedures, and instructions to foster the ALARA concept within Syncor. The organization will include a Radiation Safety Committee (RSC) and a Corporate Radiation Safety Officer (CRSO). Each Syncor facility will have a Pharmacy Radiation Safety Officer (PRSO).
- B. The Radiation Safety Committee will perform a documented formal review of the corporate radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, audits, etc., and consultation with the Quality and Regulatory personnel (radiation protection staff).
- C. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposure unless the cost is considered to be unjustified. Syncor will be able to demonstrate, if necessary, that modifications have been implemented where reasonable. Where modifications or additions have been recommended but not implemented, Syncor will be prepared to describe the reasons for not implementing them.
- D. In addition to maintaining doses to individuals as far below the limit as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limits if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Committee

A. Review of Proposed Uses

The Radiation Safety Committee will review all types and quantities of use which may vary from routine recommended procedures to ensure measures are included to maintain exposures ALARA.

B. Delegation of Authority

The RSC will delegate authority to the CRSO for enforcement of the ALARA concept. This committee will also delegate authority through the CRSO to the Pharmacy Radiation Safety Officer (PRSO).

The RSC will support the CRSO and PRSO when it is necessary for either to assert authority. If the RSC has overruled the CRSO, it will record the basis for its action in the minutes of the trimester meeting.

C. Review of The ALARA Program

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

The RSC will perform a trimesterly review of occupational radiation exposure with particular attention to instances in which the investigation levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigation levels are exceeded.

Table 1. Investigation levels for exposure during a calendar year.

	Level I	Level II
WHOLE BODY (TEDE)	0.5 rem (= 0.005 Sv)	1.5 rem (= 0.015 Sv)
EXTREMITY (Shallow Dose Equiv.)	25 rem (= 0.25 Sv)	40 rem (= 0.40 Sv)
EYE (Eye Dose Equivalent)	1.5 rem (= 0.015 Sv)	4.5 rem (= 0.045 Sv)

The RSC will evaluate each location's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the CRSO, PRSO, authorized users, and workers, as well as those of management.

III. Corporate Radiation Safety Officer (CRSO)

A. Annual and Quarterly Review

1. Annual review of the radiation safety program. The CRSO will perform an annual review of the corporate radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
2. Quarterly review of occupational exposures. The CRSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of established investigation levels.
3. Quarterly review of records of radiation surveys. The PRSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter.
4. An extremity exposure analysis is performed quarterly for all personnel dispensing doses*, at all locations, and a report is presented to the RSC at its trimester meeting.

B. Education Responsibilities for ALARA Program

1. The CRSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
2. The CRSO and PRSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the CRSO are committed to implementing the ALARA concept.

C. Cooperative Efforts for Development of ALARA Procedures

1. Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
2. The CRSO will be in close contact with the PRSO who in turn will be in close contact with his

* Extremity exposure analysis calculates for the left and right hand:

- a) Average exposure received by a dispenser.
- b) Average exposure received by a dispenser/100 scripts.
- c) Total exposure/100 scripts for dispensers as a group.

facilities users and workers. ALARA procedures for working with radioactive materials will be developed using information from the PRSO, users and workers.

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

D. Reviewing Instances of Deviation from Good ALARA Practices

The CRSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes in the program to maintain doses ALARA.

IV. Pharmacy Radiation Safety Officers

Every Syncor radiopharmacy has a designated PRSO. Further information regarding the role of the PRSO is available in the Item number naming the PRSO in the Syncor license application.

V. Authorized Users

A. New Methods of Use Involving Potential Radiation Doses

1. The authorized user will consult with the CRSO and/or RSC during the planning stage before using radioactive materials for new uses.
2. The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

B. Authorized User's Responsibility to Supervised Individuals

1. The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
2. The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

VI. Individuals Who Receive Occupational Radiation Doses

- A. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
- B. Workers will be instructed in resources available if they feel that ALARA is not being promoted on the job.

VII. Investigation Levels To Monitor Occupational External Radiation Doses

- A. Syncor International Corporation has established investigation levels for occupational external radiation doses which, when exceed, will initiate review or investigation by the RSC and/or the CRSO. These investigation levels are listed in Table 1. These levels apply to the exposure of individual workers.
- B. The Syncor Quality and Regulatory Department reviews all dosimetry records. The following actions will be taken at the investigation levels as stated in Table 1:
 1. Personnel dose less than Investigation Level I.

Except when deemed appropriate by the CRSO, no further action will be taken in those cases

where an individual's dose is less than Table 1 values for the Investigation Level I.

2. Personnel dose equal to or greater than Investigation Level I but less than Investigation Level II.

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

3. Personnel dose equal to or greater than Investigation Level II.

The CRSO and PRSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigation Level II and, if warranted, will take actions. A report of the investigation, any actions taken and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

4. Reestablishment of investigation levels to levels above those listed in Table 1.

In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigation level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigation levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigation levels.

VIII. ALARA Levels For Radionuclide Concentrations In Air

- A. Syncor International Corporation has established investigation levels for radionuclide concentrations in air which, when exceeded, will initiate review or investigation by the RSC and/or the PRSO and CRSO. These investigation levels are listed in Table 2.

The RSC will evaluate each location's overall efforts for maintaining radionuclide concentrations in air ALARA on an annual basis. This review will include the efforts of the CRSO, PRSO, authorized users, and workers, as well as those of management.

Table 2. Investigation Levels For Air for a given radionuclide

	Level I	Level II
OCCUPATIONAL VALUE (for Restricted Area)	10% of DAC	30% of DAC
EFFLUENT VALUE (for Unrestricted Areas)	20% of value given in Table II, Appendix B, 10 CFR 20	40% of value given in Table II, Appendix B, 10 CFR 20

- B. The following actions will be taken at the investigation levels as stated in Table 2:

1. Radionuclide concentrations in air less than Investigation Level I.

Except when deemed appropriate by the CRSO, no further action will be taken in those cases where the radionuclide concentration is less than Table 2 values for the Investigation Level I.

2. Radionuclide concentration in air equal to or greater than Investigation Level I but less than Investigation Level II.

The CRSO will review the radionuclide concentration in air when it equals or exceeds Investigation Level I and will report the results of the reviews at the first RSC meeting following the quarter when the radionuclide concentration in air was recorded. If the concentration does not equal or exceed Investigation Level II, no action related specifically to the radionuclide concentration in air is required unless deemed appropriate by the RSC. The RSC will, however, review each such effluent concentration in comparison with those of other locations with similar workloads and facilities as an index of ALARA program quality and will record the review in the RSC minutes.

3. Radionuclide concentration in air equal to or greater than Investigation Level II.

The CRSO and PRSO will investigate in a timely manner the causes of all radionuclide concentrations in air equaling or exceeding Investigation Level II and, if warranted, will take actions. A report of the investigation, any actions taken and a copy of the radiopharmacy's air monitoring data will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

4. Reestablishment of investigation levels to levels above those listed in Table 2.

In cases where a radiopharmacy's radionuclide concentration in air exceeds an investigation level, a new, higher investigation level may be established for that radiopharmacy on the basis that it is consistent with good ALARA practices. Justification for new investigation levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigation levels.

10.2 Procedures for Receiving Shipments Containing Radioactive Material

- A. An authorized nuclear pharmacist/authorized user, or their designee, will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
- B. The receiving area will be located so that the radiation levels in areas outside of the pharmacy's control do not exceed the limits specified in the NRC/Agreement State regulations.
- C. When the nuclear pharmacy is open, carriers will be instructed to deliver radioactive packages directly to the receiving area of the nuclear pharmacy.
- D. When the nuclear pharmacy is closed, delivery firms will have written instructions to place packages in the receiving area of the nuclear pharmacy. If the carrier notices that the package is wet or appears to be damaged, he will be instructed to immediately contact the nuclear pharmacist on call who will then come to the nuclear pharmacy to inspect the package. The carrier will be asked to remain at the nuclear pharmacy until it can be determined that neither the carrier nor the delivery vehicle is contaminated. Carriers will not have access to the restricted area of the nuclear pharmacy.

The following letter will be given to each carrier service:

TO: Any carrier service delivering radioactive materials to Syncor Pharmacy

FROM: Manager/RSO, Syncor Pharmacy

RE: Delivery of packages containing radioactive material

Any packages containing radioactive material that are to be delivered to our nuclear pharmacy after normal hours of operation are to be placed in the designated "receiving area." Be sure to lock the door upon leaving.

If the package is wet or appears damaged, immediately contact the nuclear pharmacist on call. Remain at the nuclear pharmacy until it can be determined that neither you nor the delivery vehicle is contaminated.

10.3 Procedures for Safely Opening Packages Containing Radioactive Material

Syncor confirms that we have developed, and will implement and maintain written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906.

Package receipt and check-in procedures will be in accordance with the NRC/Agreement State regulations.

The following steps will be performed for all incoming packages containing radioactive material that contain Type A quantity or greater and for White I, Yellow II, or Yellow III labeled packages.

1. Packages will be monitored for surface contamination and external radiation levels as soon as practicable after receipt, but no later than three (3) hours after receipt if received during normal working hours or three (3) hours from the beginning of the next working day if received after normal working hours.
2. Put on waterproof gloves to prevent hand contamination.
3. Visually inspect the package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop and notify the Radiation Safety Officer (RSO).
4. Measure the exposure rate at 1 meter from the package surface and record it. If greater than 10 mR/hour, stop the procedure and notify the RSO.
5. Measure the surface exposure rate and record it. If greater than 200 mR/hour, stop the procedure and notify the RSO.
6. Wipe the external surface of the package and remove the wipe to a low-background area. Check wipes with appropriate instrumentation and take precautions against the spread of contamination, as necessary. Record the results.
7. Open the outer package (following manufacturer's directions, if supplied), and remove the packing slip.
8. Open the inner package and verify that the contents agree with those on the packing slip. Compare the requisition, packing slip, and label on the bottle.
9. Check the integrity of the final source container (i.e., inspect for broken seals or vials, loss of liquid, and discoloration of packaging material).
10. Check that the shipment does not exceed possession limits.
11. Wipe the external surface of the final source container shield and remove the wipe to a low-background area. Check wipes with an appropriate instrument and take precautions against the spread of contamination, as necessary.

12. Monitor the packing material and packages with appropriate instrumentation for contamination before discarding.
 - A) If contaminated, treat as radioactive waste.
 - B) If not contaminated, obliterate the radiation labels before discarding in the non-radioactive trash.
13. The appropriate regulatory agency and the final delivering carrier will be notified, by telephone or telegraph, if removable contamination exceeds 22 dpm per cm² on the external surfaces of the package, or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 1 meter.
14. Records of exposure rate and contamination surveys in Items 4, 5 and 6 will be maintained as required by NRC/Agreement State regulations.

10.4 General Procedures for the Safe Use of Radioactive Material

Syncor confirms that we have developed and will implement and maintain written procedures for the safe use of radioactive materials.

- A. Always wear laboratory coats or other protective clothing in areas where radioactive materials are used.
- B. Always wear disposable gloves when handling radioactive materials.
- C. Monitor hands and clothing for contamination before leaving the restricted area.
- D. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
- E. Do not store food, drink, or personal effects with radioactive material.
- F. Always use syringe shields and vial shields for preparing and dispensing radiopharmaceuticals.
- G. Always wear your assigned personnel monitoring devices in areas where radioactive materials are used or stored. These devices are to be worn at chest level (preferably on the shirt collar). Personnel monitoring devices, when not being worn to monitor occupational exposures, are to be stored in the designated low-background area.
- H. Always wear finger badges when eluting the generator and preparing, assaying, or dispensing mCi quantities of radioactive material.
- I. Never pipette by mouth.
- J. Dispose of radioactive waste only in specially designated and properly shielded receptacles.
- K. Survey the generator, kit preparation, and dose dispensing areas for contamination after each procedure or at the end of the day. Decontaminate, if necessary.
- L. Conduct inventory of sealed sources at least semi-annually.
- M. Confine radioactive solutions in covered containers that are clearly identified and labeled with the name of the compound, radionuclide, date, and activity.
- N. Always transport radioactive material in shielded containers.

In addition to the above general procedures, Syncor further confirms that license material accountability and control will be maintained by the following:

1. Licensed material in storage will be secured from unauthorized access or removal.
2. Licensed material not in storage will be maintained under constant surveillance and control.
3. Records of receipt, transfer, and disposal of licensed material will be maintained.

10.5 Emergency Procedures

Introduction

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surface contamination, as well as the radiotoxicity of the spilled material.

To determine if the spill is major or minor, the amount of radioactivity spilled should be estimated. Guidance for determining whether to initiate a major or minor spill procedure maybe based on the following dividing line. Spills above these values may be considered major, below may be considered minor: Please refer to table below for determining values.

Radionuclide	Millicuries	Radionuclide	Millicuries
F-18	10	Y-90	10
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Co-60	1	I-131	1
Ga-67	100	Sm-153	10
Sr-85	10	Tl-201	100
Sr-89	1		

Spill Procedures

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

A. Minor Spills

1. NOTIFY: Notify persons in the area that the spill has occurred.
2. PREVENT THE SPREAD: Cover the spill with absorbent paper.
3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper. Insert into a plastic bag. Also, insert into the plastic bag all other contaminated materials, such as disposable gloves. Put the plastic bag into the radioactive waste container.
4. SURVEY: With a low-range, thin-window GM survey meter or other appropriate meter, check the area around the spill, hands, and clothing for contamination.
5. A decontamination kit is located * _____.
6. REPORT: Report the incident to the Radiation Safety Officer (RSO).

B. Major Spills

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

RADIATION SAFETY OFFICER: _ *

OFFICE PHONE: _ *

HOME PHONE: _ *

NAMES AND TELEPHONE NUMBERS OF ALTERNATES DESIGNATED BY THE RSO:*

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

10.6 Procedures for Returning Radioactive Materials from Customers

Syncor requests authorization to collect items from customers that contain, or are contaminated with, radioactive materials supplied by a Syncor Pharmacy.

A. Type of radioactive materials.

Syncor will only accept radioactive material that is authorized by our radioactive material license. Radioactive Materials picked up will be comprised of items such as plastic syringes, needles, needle covers, vials, and depleted sealed sources that have been used by customers serviced by Syncor. Most of these items represent solid materials that contain residual radioactive material.

B. Procedures for the safe handling of radioactive material.

1. The majority of material that will be returned will be residual radioactive material in unit dose syringes used by the customer. A majority of the unit doses sold by Syncor will be provided with the Secure Safety Insert™ which is a plastic container within the unit dose shield that will enable us to handle returned syringes without touching the syringe. Vials retrieved will represent a very small portion of the items accepted for return. An example of a returned vial would be an I-131 oral therapy vial. Each unit dose syringe or vial is identified by prescription number and radiopharmaceutical, therefore, returned, used materials will be easily identifiable.
2. The following is the procedure for receiving returned materials at Syncor Pharmacies:
 - a) Put on disposable gloves.
 - b) Open the unit dose shield and identify the material (by Rx label).
 - c) Dump the unit dose directly from the shield into the bin provided. If the unit dose is not contained in the Secure Safety Insert™, touch only the outside of the unit dose shield.
 - d) Survey the unit dose shield for contamination with a low level survey meter. If a unit dose shield demonstrates activity levels greater than background, remove it from service, and place it in the storage area for decay to background levels. When surveying unit dose shields for reuse, any unit dose shield that is found to be greater than background must be placed into storage for decay or decontaminated to background levels.
3. Material returned to Syncor is shipped in the shields and shipping containers provided by our facilities. Shipping containers meet all Department of Transportation requirements for shipping hazardous materials.
4. All returned radioactive material will be transported by a third party carrier or in our vehicles by delivery personnel employed by Syncor. Only material that has been properly packaged will be picked up for return.

- C. The individual handling the radioactive material at the nuclear pharmacy will be trained on the above procedure for safe handling of radioactive materials. Delivery personnel will also be trained on our procedure for picking up materials from a customer and the applicable DOT requirements. Procedures for handling and disposal of radioactive materials 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 for all training will be completed stating the subject matter covered.

- D. Customers are notified that Syncor will only accept material that results from our own supplied radioactive material. Any radioactive material not resulting from Syncor supplied material is returned to the customer for disposal.

- E. See the following procedures for customers returning materials to Syncor.

10.7 Customer Procedures for Return of Limited Quantity Shipments of Radioactive Materials to Syncor

We will provide the following information to all customers on the procedure to ship radioactive materials back to the pharmacy.

MEMO TO SYNCOR CUSTOMERS

The United States Department of Transportation (DOT) has specific regulations pertaining to the transportation of radioactive materials. It is Syncor's intent to follow all DOT requirements when accepting the return package from you for transport and while transporting the package back to the pharmacy.

In an effort to clarify these regulations, and to ensure compliance, we have implemented the following policy with respect to packaging and delivery of return shipments. We ask your cooperation in assisting us in complying with the applicable regulations.

Our system of service involves retrieving radioactive material from you, our customer. Because you will be returning radioactive material to the pharmacy, you now become a shipper of radioactive material. Syncor is providing you with a simple system to ensure you properly prepare your package for return.

Return shipments should be shipped as "Limited Quantity Shipments". DOT regulations under 49 CFR 173.421, state that if a package meets the following requirements, it is exempted from the specification packaging, marking, and labeling requirements and can be classified as a Limited Quantity Shipment:

1. 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 mrem 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). (6600 dpm/300cm²)
4. The package has the appropriate notice statement as required in 49 CFR 173.422.
5. Other provisions of this regulation are satisfied by Syncor's present packaging.

Syncor will accept return of both "used" and "unused" unit dose syringes. To assure safety of our employees, Syncor has developed the SECURE Safety Insert System for transporting syringes. The SECURE Safety Insert System consists of a plastic insert placed inside the unit dose shield. A new dose is shipped to our customer with the syringe inside of the plastic insert. After the dose is injected, the used syringe is placed back into the plastic insert in the unit dose container. The customer must then place a red cap over the top of the plastic insert/used syringe, sealing the used syringe in a sharps container. The top of the unit dose container is then screwed on.

The following procedure will meet all of the above requirements and must be followed prior to Syncor accepting your material for return:

1. Ensure that the material being returned does not exceed the specified limits for "Limited Quantity Shipments". This can be determined by reviewing the attached table with activity limits for nuclides. The total quantity of activity being returned must not exceed the specified "Limited Quantity Shipment" activity whether you are returning used dose material or unused doses.

a) Example of estimating return activity for Tc-99m products.

- (1) **Used Products.** Assume 5% remains in the syringe after an injection. If the syringe is held for 24 hours (4 half lives), the remaining activity from a 30 mCi dose, is:

$$30 \text{ mCi} \times 0.05 \times 0.0625 = 0.094 \text{ mCi}$$

If ten unit dose syringes were returned, and all ten had been 30 mCi doses, the package would contain only 940 μ Ci, which is well below the 21.6 mCi limit in the attached table.

- (2) **Unused Products.** If an unused syringe of a 30 mCi dose is held for 24 hours (4 half lives), the remaining activity is:

$$30 \text{ mCi} \times 0.0625 = 1.9 \text{ mCi}$$

It can be seen that a maximum of eleven of these syringes could be returned and remain below the 21.6 mCi limit for Tc-99m.

b) Limited quantity activity limits for shipments of mixed radionuclides.

- (1) When shipping more than one radionuclide in the same package, the limit on the radioactivity that may be shipped is the lowest activity assigned (see attached table) for the radionuclide shipped.
- (2) Example: If Tc-99m and I-131 were being shipped in the same package, only 1.35 mCi of total activity could be shipped.

2. Ensure that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr.
3. Ensure 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., 6600 dpm when wiped over a 300 cm² area.
4. Ensure the Syncor provided card for the shipping container is turned to indicate the Limited Quantity Shipment information.
5. Place in the predetermined area for pickup.

Syncor employees are instructed not to accept any package for return that has not met the above criteria.

For your information, we have enclosed a copy of the procedure to be followed in returning radioactive 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	21.6
Co-58	2.7
Cr-51	81.1
F-18	13.5
Ga-67	16.2
I-123	16.2
I-125	5.41
I-131	1.35
In-111	5.41
Mo-99	2
P-32	0.811
Sm-153	1.35
Sr-89	1.35
Tc-99m	21.6
Tl-201	27
Xe-133 (uncompressed, $A_2 \times 10^{-3}$)	541
Y-90	5.41

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 mCi quantity assigned for the items shipped.

For example, if Tc-99m and Y-90 were being shipped in the same package, only 5.41 mCi of total activity could be shipped.

10.8 Precautionary Measures for Handling Millicurie Quantities of Radioiodine

Thyroid bioassay will be performed in accordance with the provisions of U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.20, *Applications of Bioassay for I-125 and I-131*, with respect to action levels, i.e., 0.04 μCi 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 exceed those quantities shown in Table 1 of NRC Regulatory 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 bioassays weekly.**

In Vivo Thyroid Bioassay

I. Equipment

- A. scintillation counting system
- B. thyroid neck phantom
- C. standard source (I-131 capsule or Ba-133 rod source)

II. Procedure

- A. Note the characteristic energy of the nuclide. For I-131 the energy is 364 keV.
- B. If using a single channel analyzer, calibrate to 100 keV/turn and adjust the instrument to count in a 100 keV window around the 364 keV photopeak. If using a multichannel analyzer, perform an energy calibration, and set a 100 keV wide region of interest around the 364 keV photopeak.
- C. Obtain a background count for the counting system.
- D. Obtain a standard count by placing the neck phantom containing the standard source centered on the detector face.
- E. Obtain counts over the thyroid. Center the detector against the front of the neck in three vertical positions. The calculations will use the position that gives the highest count rate.
- F. The thyroid activity is calculated from:

$$\frac{\text{THYROID BURDEN}}{\text{CAPSULE ACTIVITY}} = \frac{(\text{CPM}_{\text{neck}} - \text{CPM}_{\text{bkg}})}{(\text{CPM}_{\text{capsule}} - \text{CPM}_{\text{bkg}})}$$

III. Since NRC Regulatory Guide 8.20 specifies an action level with respect to thyroid burden of 0.04 μCi , it will be necessary to determine the sensitivity of the equipment.

- A. From the data obtained when counting the standard source for thyroid bioassay, the sensitivity of the counting system is expressed in cpm/ μCi .

- B. The MDA is given by:
$$\text{MDA} = \frac{3.3\sqrt{2R_b/T_b}}{\text{CF}}$$

where R_b is the background counting rate, T_b is the time taken to count the background and CF is the calibration factor, i.e., cpm/ μCi of a standard source.

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

$$Q = \frac{\text{THYROID}}{\text{BURDEN}} = \frac{(\text{CPM}_{\text{neck}} - \text{CPM}_{\text{bkg}})}{\text{CF}}$$

V. For our bioassay program, action levels, frequency of bioassay, and actions to be taken if those levels are exceeded will be in accordance with NRC Regulatory Guide 8.20. Bioassays for thyroid uptake will be obtained with a scintillation counting system. Measurements of the thyroid will be compared to an iodine-131 capsule or barium-133 source rod 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.

DERIVATION OF MDA FORMULAE*

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

where T_s is the sample count time, T_b is the background count time, R_b is the background count rate (cpm) and LLD is the lowest level detectable activity in cpm.

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

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

Also:

$$C. \text{ MDA} = \frac{\text{LLD}}{2.2 \times 10^6 \frac{\text{dpm}}{\mu\text{Ci}} \times F_e}$$

where F_e is the efficiency factor of counting system and MDA is the minimum detectable activity.

However, $(2.22 \times 10^6 \text{ dpm}/\mu\text{Ci}) F_e = \text{CF}$, where $\text{CF} = \text{cpm}/\mu\text{Ci}$ of a standard source. Therefore, when $T_b = T_s$, the MDA may be expressed as:

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

Note: Syncor confirms that records of the assay method's minimum detectable activity evaluation will be available for review during NRC inspections. This evaluation is documented on Syncor's form RS-35, Quarterly Gamma Well Efficiency Test.

10.9 Area Survey Procedures

- A. All elution, preparation, assay, and dispensing areas will be surveyed daily with a low range survey meter and decontaminated if necessary. Daily surveys in which no abnormal exposures are found, only the date, the name of the person performing the survey, and the survey results will be recorded.
- B. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.
- C. Waste storage areas and all other laboratory areas will be surveyed weekly.
- D. The weekly and monthly surveys will consist of:
 - 1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 milliroentgen per hour.
 - 2. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 220 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other high-background areas will be removed to a low background area for measurement.
- E. Records of all survey results, will be kept for 3 years after each survey. The record will include:
 - 1. The initials of the person who performed the survey.
 - 2. A drawing of the area surveyed identifying relevant features such as active storage areas, active waste areas, etc.
 - 3. Measured exposure rates (in units of milliroentgen per hour) keyed to locations on the drawing.
 - 4. Detected contamination levels (in units of dpm or μCi) keyed to locations on the drawing.
 - 5. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
- F. The area will be either cleaned or posted and restricted from use if the contamination level exceeds 2200 dpm per 100 cm^2 .
- G. The area will be covered, cleaned, or identified to all employees if the contamination level exceeds 220 dpm per 100 cm^2 but is less than 2200 dpm per 100 cm^2 .

10.10 Distribution Procedures

Syncor proposes to operate a centralized nuclear pharmacy that will prepare, compound and dispense radioactive materials for medical use on a unit dose or multiple dose basis. Preparation and transfer of radioactive drugs will be in compliance with 10 CFR 32.72 (or equivalent Agreement State Regulations).

Syncor commits that the nuclear pharmacy will maintain a current State Board of Pharmacy License and is therefore subject to laws and regulations set forth by the State Board of Pharmacy. Radioactive drugs for human use will be compounded/prepared in accordance with the standards of practice as regulated by the State Board of Pharmacy.

Syncor does not propose to manufacture generators or reagent kits for distribution. It is our intention to compound/prepare radioactive drugs and to transfer these to licensees authorized to possess them. The labeling and dispensing of radioactive drugs will meet the requirements of the State Board of Pharmacy and the requirements as specified in 10 CFR 32.72 (or equivalent Agreement State Regulations).

Syncor may also transfer some radioactive materials for non-human use. Radioactive materials for non-human use will be transferred to licensees of the Nuclear Regulatory Commission or an Agreement State. Examples may include transfers to universities for research purposes, transfers of sealed sources to other licensees, or transfers to veterinarians for their use in the practice of veterinary medicine.

Radioactive drugs for medical use which are distributed will be either:

- A. initially distributed by a manufacturer licensed pursuant to 10 CFR 32.72 (or equivalent agreement state regulations); or
- B. prepared by either an authorized nuclear pharmacist or an individual under the supervision of an authorized nuclear pharmacist.

Used generators to be redistributed will be packaged according to the following procedure:

- A. Prepare the generator
 - 1. Swab the septa of the needle cover vials with an alcohol wipe
 - 2. Place the vials over the needles
 - 3. Replace the plastic cover over the top of the generator
 - 4. Wipe test the generator
- B. Prepare the shipping carton
 - 1. Remove or deface the "cargo aircraft only" sticker
 - 2. Ensure that all internal lead shielding that originally came with the carton (lead circular plate on top and lead cylinder bucket on bottom) is in place
 - 3. Affix a new, correctly filled out DOT shipping label indicating Mo-99 and the activity in GBq
 - 4. Include a package insert in the shipping foam

C. Closing the carton

1. Place the generator in the foam insert (lead bucket)
2. Place the top foam over the generator
3. Close the carton and place a paper security seal where flaps meet
4. Seal entire package using 2" wide plastic tape (clear or fiber reinforced)
5. Wipe test the carton
6. Measure the exposure rate on contact of all 6 sides of the package
7. Measure the exposure rate at one meter from the highest contact exposure rate to determine the Transport Index (TI)
8. Using the exposure rates from contact and at one meter, determine the correct DOT label and place the label on the box
9. Record the TI on the DOT label
10. Label the carton with the recipient's name and address
11. Using the Rx generated for the transfer, generate a bill of lading

REQUIRED CONTAINER LABELING:

1. **Vials** will be labeled with the manufacturer's original label or with label A.
2. **Syringes** will be labeled with label A.
3. **Vial shields** will be labeled with the manufacturers' original label and/or label C.
4. **Unit dose container shields** will be labeled with label C.
5. **Generators** will be labeled with the manufacturer's original label.

In addition to the container, syringe, and vial labels, the customer is supplied with a prescription (PRESCRIPTION FORM) and label (LABEL B) for their records that are not used as container labels.

A blank area is located in the upper right hand corner to identify the radiopharmaceutical being dispensed. This area is completed in large letters and has been placed on the form to aid in preventing errors in dispensing compounded or prepared radiopharmaceuticals.

The following page contains a sample of the second possible set of prescription forms and self-adhesive container labels, which will be used according to the following guidelines.

REQUIRED CONTAINER LABELING:

- 1. Syringes** will be labeled with label A.
- 2. Vials** will be labeled with the manufacturer's original label or with label A.
- 3. Unit dose container shields** will be labeled with label D.
- 4. Vial shields** will be labeled with the manufacturers' original label and/or label D.

In addition to the container, syringe, and vial labels, the customer is supplied with a prescription (E) and label (C) for their records that are not used as container labels.

Label B is used as an identifier on the top of the unit dose container shield. It is used for sorting purposes and may or may not be included on all containers.

Comments can be printed here

Syncor Rx #820394 04 Apr 00

Tc 99m Sodium Pertechnetate
 Patient: Per Physician Order
 Procedure: MUGA Scan

2176 West 190th Street • Torrance, CA 90504

100 mCi
TcO4
10:00

Syncor Syncor International Corporation
 2176 West 190th Street • Torrance, CA 90504

210 Derantno Way
 Ameri, CA 91219 Delivery Date: 04/04/00

Tc 99m Sodium Pertechnetate
 Procedure: MUGA Scan

Qty Dsp: 100.00 mCi +/- 10% As Of: 04/04/00 10:00
 Qty Ord: 100.00 mCi Lot: TcO406-0095-101
 Volume: 0.48 ml Assay: 12.590 mCi/ml
 QS to _____ Expires: 12/10/97 24:00
 Administered By: _____ Time: _____

Administer Intravenously
 Product of Fission Mo99 Mo99 < 0.15 uCi/mCi Tc99m @ expiry

Patient: _____ Dr. Eversole

Syncor Syncor International Corporation
 2176 West 190th Street • Torrance, CA 90504

Run: 1 Rte: 1 Delivery Date: 04/04/00

210 Derantno Way
 Ameri, CA 91219

Tc 99m Sodium Pertechnetate
 Procedure: MUGA Scan

Qty Dsp: 100.00 mCi +/- 10% As Of: 04/04/00 10:00
 Qty Ord: 100.00 mCi Lot: TcO406-0095-101
 Volume: 0.48 ml Assay: 12.590 mCi/ml
 QS to _____ Expires: 12/10/97 24:00
 Dispensed By: MGD / _____ Entered By: _____

Administer Intravenously
 Product of Fission Mo99 Mo99 < 0.15 uCi/mCi Tc99m @ expiry

Patient: _____ Dr. Eversole

Syncor Syncor International Corporation
 2176 West 190th Street • Torrance, CA 90504

Run: 1 Rte: 1 Delivery Date: 04/04/00

Patient: Per Physician Order Rx#: 820394

Tc 99m Sodium Pertechnetate
 Procedure: MUGA Scan

Lot: TcO406-0095-101 Qty. Ord: 100.00 mCi

Qty Dsp: _____

Assay: 12.590 mCi/ml Expires: 12/10/97 24:00

As Of: _____

Volume: _____ QS to _____ ml

Dispensed By: MGD / _____ Entered By: JDS

Administer Intravenously
 Product of Fission Mo99 Mo99 < 0.15 uCi/mCi Tc99m @ expiry

210 Derantno Way
 Ameri, CA 91219 Dr. Eversole

St. Elsewhere Hospital

The following page contains a sample of container labels, which will be used according to the following guidelines.

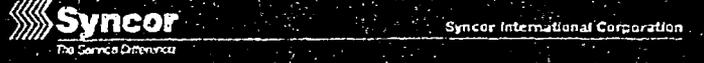
REQUIRED CONTAINER LABELING:

1. **Syringes** will be labeled with label C.
2. **Vials** will be labeled with the manufacturer's original label or with label C.
3. **Unit dose container shields** will be labeled with label D.
4. **Vial shields** will be labeled with the manufacturers' original label and/or label D.

In addition to the container, syringe, and vial labels, the customer is supplied with a prescription (A) for their records that are not used as container labels. An additional copy of the prescription (B), is retained by Syncor for our records.

Label E is used as an identifier on the top of the unit dose container shield. It is used for sorting purposes and may or may not be included on all containers.

This Area Is Not Included On Final Label



A Run: 1 Rte: 1 Order Date: 04/04/00
 Rx#: 820394 Dispense Date: 04/04/00
St. Elsewhere Hospital
 210 Derantno Way • Ameri, CA 91219 Dr. Eversole
 Patient: Per Physician Order
 Patient Injected: _____

Tc 99m Sodium Pertechnetate DC

Procedure: MUGA Scan

Lot: TcO406-0095-101

Qty. Disp: 100.00 mCi +/-10%

Assay: 50.00 mCi/ml

As Of: 04/04/00 10:00

Volume: 2.00 ml

Expires: 04/04/00 24:00

Estimated Price \$10.00

Administer Intravenously
Product of Fission Mo99

Mo99 < 0.15 uCi/mCi Tc99m @ expiry

Customer Copy

B Run: 1 Rte: 1 Order Date: 04/04/00
 Rx#: 820394 Dispense Date: 04/04/00
St. Elsewhere Hospital Dr. Eversole
 210 Derantno Way Ameri, CA 91219

Patient: Per Physician Order

Tc 99m Sodium Pertechnetate DC

Procedure: MUGA Scan

Lot: TcO406-0095-101

Qty. Ord: 100.00 mCi

Assay: 208.33 mCi/ml

As Of: 04/04/00 at 10:00

Volume: 0.48 ml

Entered By: JDS

Dispensed By: _____

Administer Intravenously
Product of Fission Mo99

Mo99 < 0.15 uCi/mCi Tc99m @ expiry

Expires: 04/04/00 24:00

Pharmacy Notes

Pharmacy Copy

D

St. Elsewhere Hospital Dr. Eversole
 210 Derantno Way • Ameri, CA 91219
 Patient: Per Physician Order
Tc 99m Sodium Pertechnetate Rx#: 820394
 Procedure: MUGA Scan Lot: TcO406-0095-101
 Qty Disp: 100.00 mCi +/- 10% As Of: 04/04/00 10:00
 Qty Ord: 100.00 mCi Assay: 50.00 mCi/ml
 Volume: 2.00 ml Expires: 04/04/00 24:00
 Assay Activity: _____ Date: _____ @ _____ By: _____
 Admin Activity: _____ Date: _____ @ _____ By: _____
 Administer Intravenously
Product of Fission Mo99
 Mo99 < 0.15 uCi/mCi Tc99m @ expiry

D C C

St. Elsewhere Hospital
 210 Derantno Way • Ameri, CA 91219
 Patient: Per Physician Order
 Run: 1 Rte: 1
 Delivery Date: 04/04/00
 Rx#: 820394 Dr. Eversole
Tc 99m Sodium Pertechnetate DP
 Procedure: MUGA Scan Lot: TcO406-0095-101
 Qty Disp: 100.00 mCi +/- 10% Volume: 2.00 ml
 As Of: 04/04/00 10:00 Assay: 50.00 mCi/ml
 Qty Ord: 100.00 mCi Expires: 04/04/00 24:00
 Administer Intravenously Product of Fission Mo99
 Mo99 < 0.15 uCi/mCi Tc99m @ expiry

CAUTION
 RADIOACTIVE
 MATERIAL

04/04/00
 #820394
 Tc 99m Sodium Pertechnetate
 Patient: Per Physician Order
 Procedure: MUGA Scan
 2175 West 180th Street • Torrance, CA 90504

#820394
 Tc 99m Sodium Pertechnetate
 Patient: Per Physician Order
 Procedure: MUGA Scan

CAUTION
 RADIOACTIVE
 MATERIAL

04/04/00
 #820394
 Tc 99m Sodium Pertechnetate
 Patient: Per Physician Order
 Procedure: MUGA Scan

CAUTION
 RADIOACTIVE
 MATERIAL

Tc04

This Area Is Not Included On Final Label

10.12 Product Shielding

The following containers will be used to distribute radioactive material:

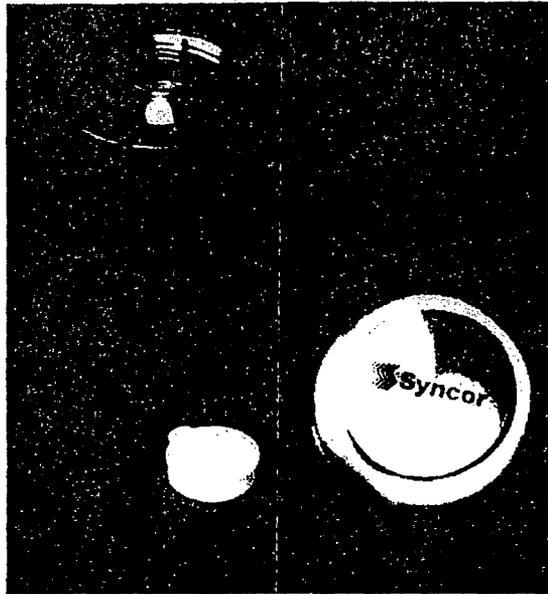
- A. Manufacturer supplied shielding or containers with shielding that provide equivalent or lower exposure levels than manufacturer's shielding
- B. One of the following containers (see attached photos):

Container Type	Side Thickness of Shielding	Nuclide	Nuclide Physical/Chemical form	Maximum Activity (mCi)	Exposure Rate (mR/hr)
Commercially Available Syringe Pig or Syncor Unit Dose Secure Insert™ Syringe Pig	6.4 mm Lead	Tc-99m	Sodium Pertechnetate, Tagged Drug Solution	440	0
		Tl-201	Thallous Chloride Solution	10.64	0.5
		Ga-67	Gallium Citrate Solution	14	5
		In-111	Any Liquid or Solid	10	1.5
		Cr-51	Sodium Chromate Solution	0.28	0.03
		Sm-153	Samarium Lexidronam	150	5
		I-131	Sodium Iodide Solid, Solution or Labeled Compounds	17.6	55
		Y-90	Any liquid or solid	32	40
		I-123	Any liquid or solid	1000	0
		I-125	Any liquid or solid	440	0
Syncor Tungsten Unit Dose Secure Insert™ Syringe Pig	4 mm Tungsten	Tc-99m	Sodium Pertechnetate, Tagged Drug Solution	440	0
		Tl-201	Thallous Chloride Solution	10.64	1
		Ga-67	Gallium Citrate Solution	14	10
		In-111	Any Liquid or Solid	10	4
		Cr-51	Sodium Chromate Solution	0.28	0.07
		Sm-153	Samarium Lexidronam	150	9.2
		I-131	Sodium Iodide Solid, Solution or Labeled Compounds	17.6	340
		Y-90	Any liquid or solid	32	100
		I-123	Any liquid or solid	1000	0
		I-125	Any liquid or solid	440	0
Co-57	Any liquid or solid	440	0		
Syncor Piglet™	21 mm Tungsten	I-131 or any γ -emitter <511 keV	Any Liquid or Solid	400	250
Syncor Piglet ₂ ™	16 mm Tungsten	I-131	Any Liquid or Solid	100	113
Syncor PETPig	23 mm Tungsten	Any γ -emitter <511 keV or positron emitters	Any Liquid	100	194
Syncor 10 cc PETPig	23mm Tungsten	Any γ -emitter <511 keV or positron emitters	Any Liquid	112.5	370
Syncor 30ml PET Dispensing Pig	35 mm Tungsten	Any γ -emitter <511 keV or positron emitters	Any Liquid	1000	71.4
Syncor 10ml PET Vial Shield	25 mm Tungsten	Any γ -emitter <511 keV or positron emitters	Any liquid	3000	375

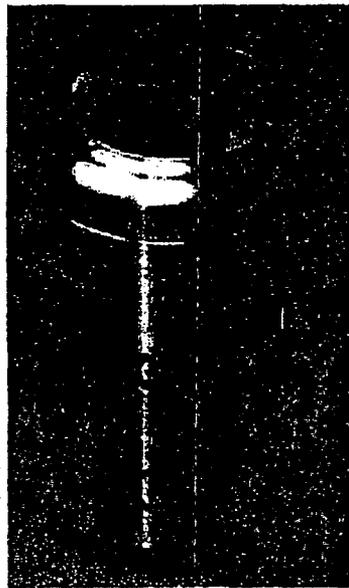
Notes:

1. Exposure rates for unit dose pigs are measured or estimated at the surface.
2. Xe-133 will be dispensed in the manufacturer's shielding, it's equivalent, or better.

Syncor's Piglet™



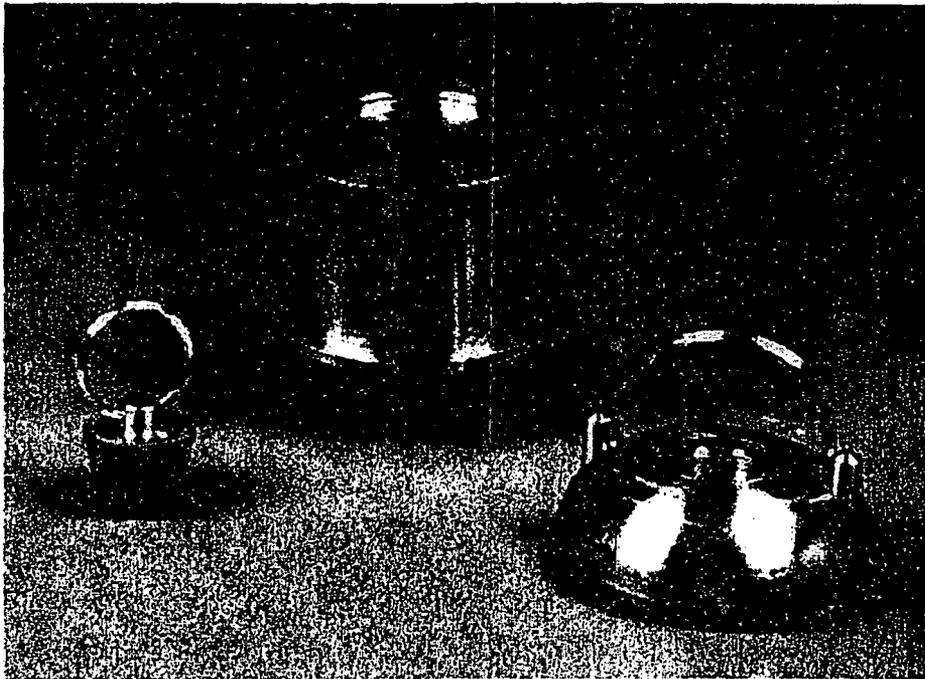
Syncor's Piglet₂™



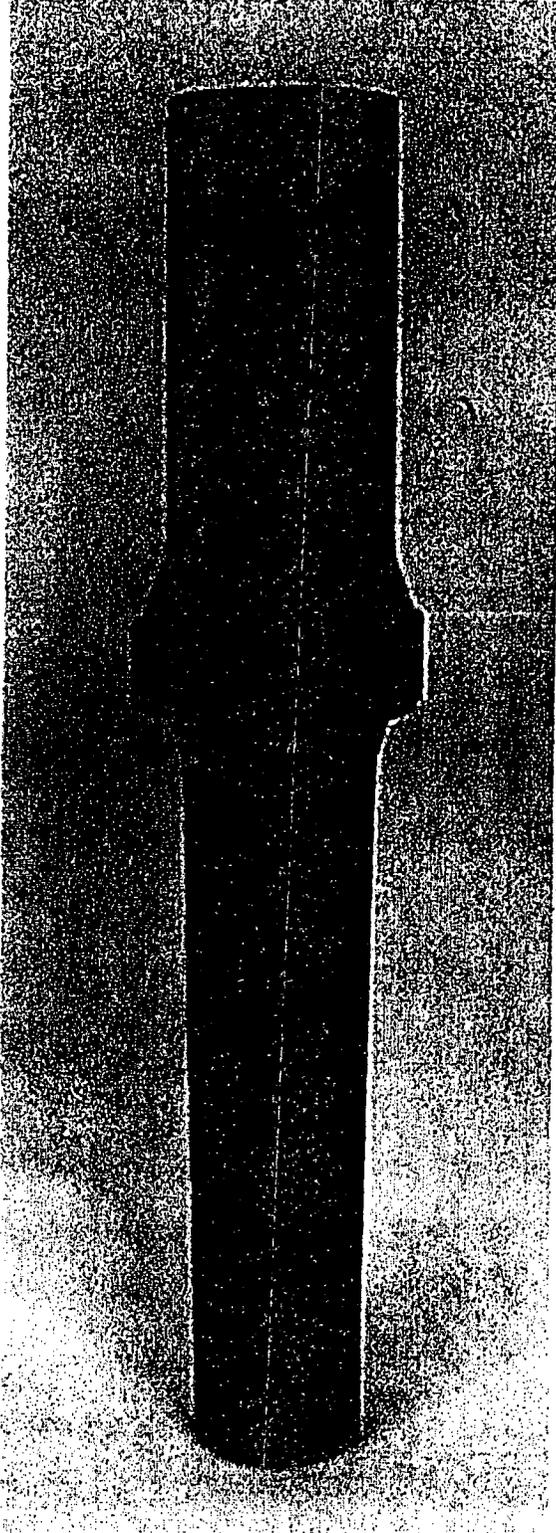
Syncor PETPig™



Syncor PET Dispensing Pig



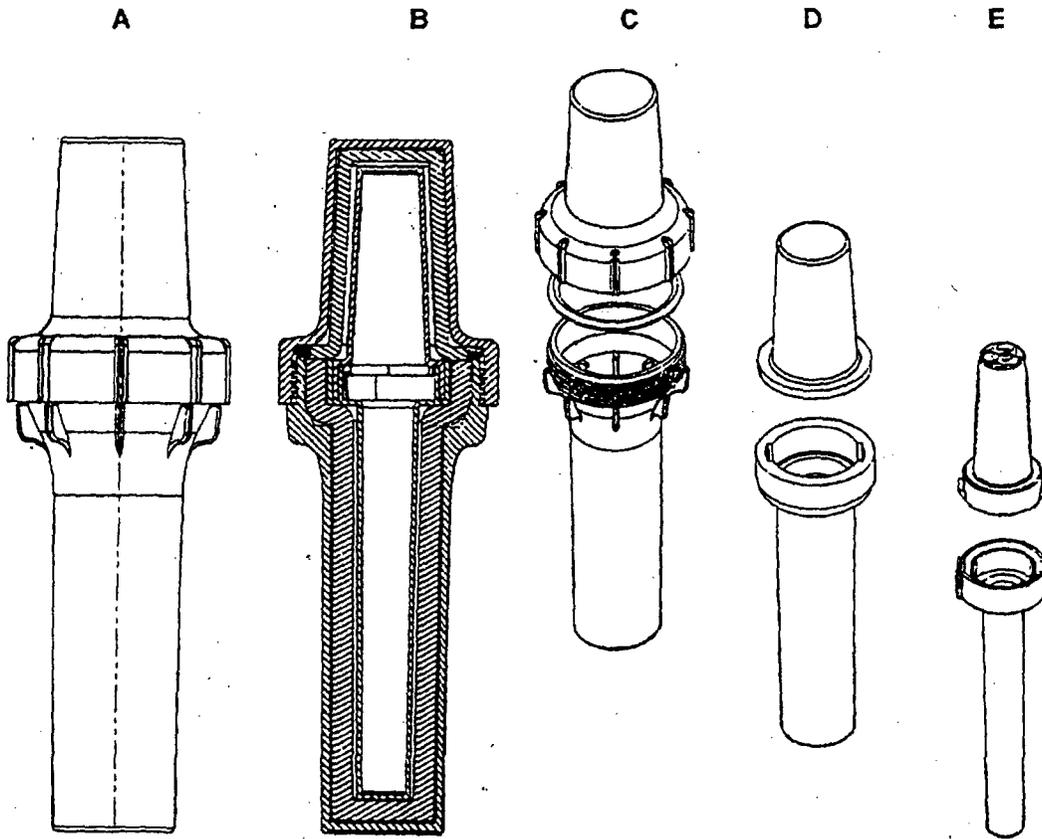
Commercially Available Unit Dose Carrier



Syncor Unit Dose Secure Insert™ Pig



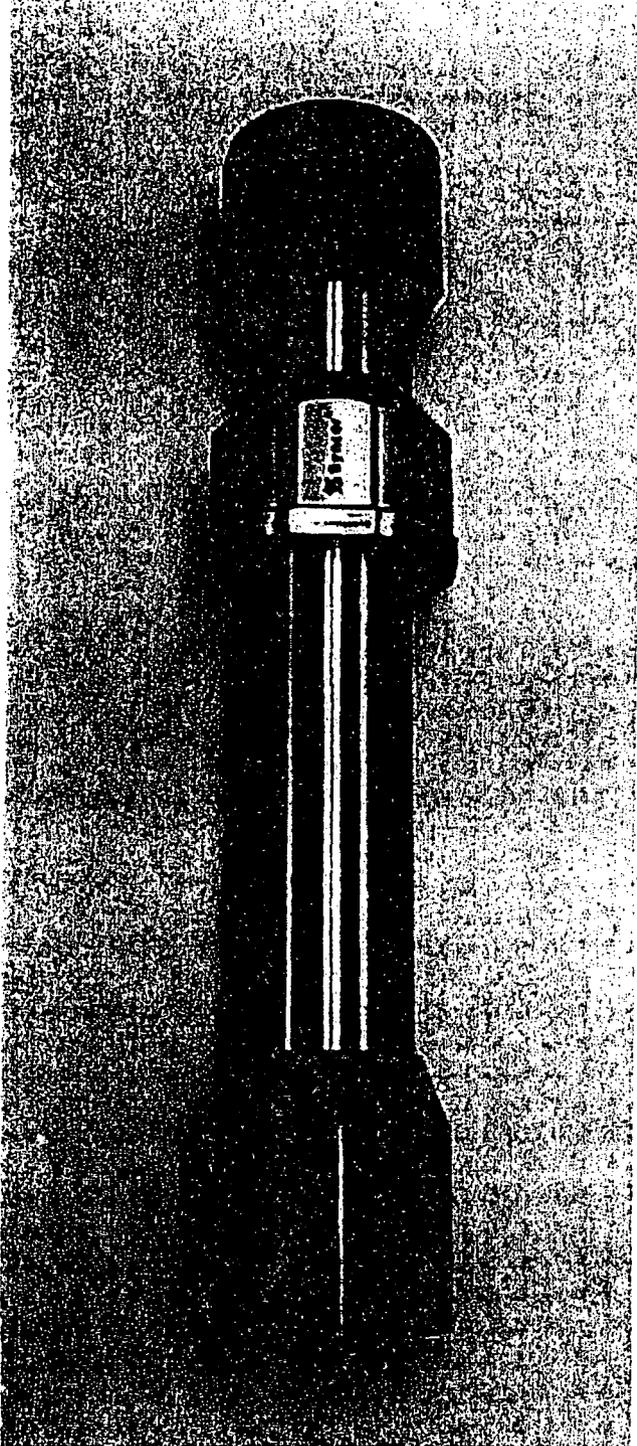
SECURE™ SAFETY INSERT SYSTEM



SCALE: Approximately 1 to 3

- A** Unit Dose Shield
- B** Cross Section of Unit Dose Shield with Disposable Insert
- C** Perspective View of Unit Dose Shield Outer Housing and O-Ring
- D** Perspective View of Unit Dose Shield Lead
- E** Perspective View of Disposable Insert

Syncor Tungsten Unit Dose Syringe Pig



10.13 Procedures for Packaging and Transporting Radiopharmaceuticals

Syncor will comply with applicable regulations for packaging and transportation of radioactive material as specified in NRC/Agreement State regulations and 49 CFR.

A. Packaging of radioactive material for transport by a common carrier or Syncor vehicles:

1. Only approved DOT 7A Type A packaging will be used for transport of Type A radioactive material. Each Type A package will be labeled and marked according to DOT requirements.
2. The appropriate radioactive label will be applied to the outside of the package when shipping Type A radioactive material. Determination of the transport index is accomplished by placing the package at a distance of one meter from a calibrated survey meter, then reading the transport index in mR/hr. The following criteria is used to determine the label:

Transport Index	Maximum Radiation Level at Any Point on the External Surface	Label Category
Less than or equal to 0.05	Less than or equal to 0.5 mrem/hr	White-I
Greater than 0.05 but less than or equal to 1.0	Greater than 0.5 mrem/hr but less than or equal to 50 mrem/hr	Yellow-II
Greater than 1.0 but less than or equal to 10	Greater than 50 mrem/hr but less than or equal to 200 mrem/hr	Yellow-III

3. Packages are wipe tested to ensure there is no removable contamination greater than 6600 dpm/ 300 cm².
4. Shipping papers for radioactive material will be generated for each labeled package.
5. Each package will show the name and address of the consignee if the package is to be transferred by a commercial carrier.
6. The outside of each package containing Type A radioactive material 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.

B. Syncor Delivery Vehicles

1. Appropriate placards will be displayed on the front, rear, and each side of transport vehicles when any radioactive material package on board bears a "Radioactive Yellow III" label.
2. Packages will be blocked and braced so that they cannot change position during conditions normally incident to transportation.
3. The combined Transport Index for all packages of radioactive material in a vehicle will never exceed 50.
4. 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.

C. Miscellaneous directives

1. All Syncor delivery personnel will be provided with instruction in proper handling of 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.
2. All Syncor delivery personnel will be instructed to lock their vehicle whenever it is left unattended.
3. All Syncor delivery personnel will be directed to ONLY leave packages in a secure place previously designated by the customer.
4. Each container shipped will have only one customer's order in it.

10.14 Emergencies Involving Motor Vehicles Acting as Carriers of Radioactive Materials

Due to the nature of these kinds of emergencies, the following is a completely self-contained set of instructions that will be carried in every Syncor vehicle used while transporting radioactive material. 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 telephone in 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 making calls.

Phone numbers:

1. Police: 911
Fire: 911

2. Nuclear Pharmacist on call, or Radiation Safety Officer.
Office: * Home: *

- 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 NRC or State Radiation Regulatory Agency should be notified as soon as possible.

Phone: *

- 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 non-injured 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. Injured persons who contacted released material may be a minor contamination problem to contacted persons, equipment, and facilities. Ensure that medical personnel are aware of the materials involved, and take precautions to protect themselves. All life-saving measures should be performed promptly. Priorities for rescue, life-saving, first aid, and control of fire and other hazards are of higher priority than measuring radiation levels.
- 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 that may have been in contact with material from the accident should not be used.
- I. Security and control of radioactive material must be maintained at all times.
- J. 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.

10.15 Independent Audit Program and Corporate Radiation Safety Program

The Quality and Regulatory Department (Q&R), a division of Syncor International Corporation, is responsible for the development and implementation of Syncor's Radiation Safety Program. This program is generic in nature and a centralized approach to regulatory compliance, training, and health physics practices is utilized. 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/Agreement State regulations and the conditions of the license.

An on-site audit is performed at least semi-annually by the Q&R staff. A comprehensive compliance survey form is utilized to ensure compliance with NRC and/or Agreement State regulations. This form is periodically updated to reflect changes in regulations and company policy.

Q&R has developed a standard set of documentation forms which are incorporated into computer software programs. Q&R has also established a trend analysis program to monitor dosimetry reports, audit reports, and NRC and state inspection reports. This information is used to evaluate radiation safety program effectiveness.

Q&R 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 company newsletters. A comprehensive, corporate-wide radiation safety program has been established to achieve full and continuing compliance with NRC and/or Agreement State requirements.

All radiopharmacies will be audited trimesterly (three times per year) for the first year of operation. If it is determined by the Q&R staff and corporate management that a particular pharmacy is in compliance, with a good record of health physics practices and a good record of regulatory agency inspections, the audit frequency may be reduced to a semi-annual frequency.

Audits are performed by members of the Q&R 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 Department, 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 conditions of the license. The audit consists of examinations of procedures and representative records, interviews with personnel, measurements, and observations.

After the audit is performed, a copy of the auditor's deficiency letter to the pharmacy manager is 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 potential items of non-compliance are identified, the pharmacy manager is required to submit the following to the Quality and Regulatory Department:

- A. Corrective steps that have been taken and the results achieved.
- B. Corrective steps that will be taken to avoid further items of non-compliance.
- C. The date when full compliance was achieved.

At the conclusion of each inspection audit, an exit interview is held with the pharmacy RSO or on-duty authorized nuclear pharmacist. Those problems that have been identified are discussed and immediate corrective action is initiated when possible. The pharmacy RSO is still required to submit a report to the Quality and Regulatory Department indicating the corrective measures taken.

The duties and responsibilities of the Corporate Radiation Safety Officer are:

- A. Manage the Corporate Radiation Safety Program.
- B. 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.
- C. Furnish consulting services on all aspects of radiation protection to personnel at all levels of responsibility.
- D. 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.
- E. Exercise the authority to terminate immediately any project or procedure that is found to be hazardous to the health, welfare, or safety of any employee or the public.

Please refer to appendix D for a copy of Syncor's Audit Form.

10.16 Leak Testing

Sealed sources need not be leak tested if they contain more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material.

A. Equipment Required

Filter paper, cotton tip applicators
Appropriate calibration standards
Forceps or hemostat

Counting vials (test tubes)
Multichannel Analyzer
Disposable gloves

B. Procedure for Obtaining Wipe Sample

1. Wear disposable gloves when leak testing sealed sources. Change gloves between sources when testing several sources.
2. Moisten the cotton-tipped applicator with water or alcohol.
3. Wipe the accessible surface of the source. Include the top, bottom, and the seal around the cap.

C. Procedure for Assessing Test Results

1. All samples will be counted using a multi-channel analyzer (MCA) and a Well Counter with a NaI crystal.
2. If an efficiency for the isotope being tested has not been calculated during the current quarter or since repair of the system, establish and record the well efficiency factor in cpm/mCi using a reference source. The reference source will either be the same radionuclide or one with similar energy characteristics. This source shall either be NIST traceable or compared to a NIST standard and shall be accurate to within $\pm 5\%$ of the stated value.
3. Establish and record the minimum detectable activity (MDA). The MDA must be 0.005 μCi or less.
4. Count a background and the sample, each for 2 minutes.
5. Calculate and record results. Maintain records of leak tests for a minimum of 3 years.

D. Action Levels

If the test reveals the presence of 0.005 μCi or more of leakage or contamination obtained from a sealed source, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with NRC/State regulations. A report describing the equipment involved, the test results, and the corrective actions taken shall be filed within five (5) days to regulatory authorities.

10.17 Radiation Detection Instrumentation and Calibration

Syncor wishes to comply with the appendix J of NUREG – 1556, Volume 13, published December 1998, titled Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration.

Calibration of Dose Calibrators

A dose calibrator will be used for the measurement of radioactive drugs.

The following procedure will be implemented for calibrating our dose calibrators, adapted from Appendix C to NRC Regulatory Guide 10.8, Revision 2, August 1987, and Appendix E to NRC Regulatory Guide Task FC 410-4, August 1985.

Tests

Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the Pharmacy Action Level of $\pm 5\%$. This Pharmacy Action Level is more restrictive than the regulatory limit of $\pm 10\%$ to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances:

- a) Constancy $\pm 5\%$ (each day of use prior to assay of patient doses)
- b) Linearity $\pm 5\%$ (at installation and at least quarterly thereafter)
- c) Geometry $\pm 5\%$ (at installation)
- d) Accuracy $\pm 5\%$ (at installation and at least annually thereafter)

The pharmacy RSO and/or pharmacy manager will review and sign the records of all geometry, linearity, constancy, and accuracy tests. A record of the results of each test will be maintained for 2 years from the date of the test.

Tests After Repairs

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

Constancy and Accuracy Measurements

Constancy means reproducibility in measuring a constant activity over a long period of time. *Accuracy* means that, for a given calibrated reference source, the indicated (measured) activity is equal to the activity determined by the National Institute of Standards and Technology (NIST) or by a supplier who has compared that source to a source that was calibrated by NIST.

ANNUAL ACCURACY PROCEDURE (annually and at installation, after repair/adjustment)

- A. The calibrated reference source must be a NIST traceable source of the most commonly used radionuclide for the facility (currently Tc-99m). Assay the calibrated reference source at the appropriate calibration factor setting. Measure background at the appropriate setting and subtract it, or confirm the proper operation of the automatic background subtract circuit if used.
- B. Record the background and measured activity of the standard on the computer-generated Constancy/Accuracy form (RS-31 or equivalent). The dose calibrator reading for the standard should be within $\pm 5\%$ of the certified activity of the reference source after decay correction.

- C. Enter into the computer the background for the setting checked and the activity of the source. The computer calculates the current net activity and compares it to the dose calibrator net reading.
- D. An action level or tolerance for each recorded measurement has been established that will alert the individual performing the test to notify the pharmacy RSO or Authorized User of suspected malfunction of the calibrator. This action level requires the daily measured activities to be within $\pm 5\%$ of the calculated activities and will be listed on the computer screen and generated hard copy report. A computer flag is used to indicate that the action levels have been exceeded. The established action level is more restrictive than those in the regulations to ensure that corrective actions are taken before the dose calibrator is outside of permissible tolerances. The regulation requires repair or replacement if the error exceeds 10%.

Daily Constancy/Accuracy Procedure

This procedure combines the daily Constancy and Accuracy tests into one process. The initial accuracy of the dose calibrator is determined at installation and annually thereafter using the "Annual Accuracy Procedure" (above). By comparing the cesium-137 source's reading at each of the dose calibrator's calibration factor settings on a daily basis, the accuracy test is performed. In effect, this procedure provides a daily accuracy in addition to a daily constancy.

- A. Assay the cesium-137 E-vial reference source on the cesium-137 setting. Measure the background and subtract it, or confirm the proper operation of the automatic background subtract circuit if used.
- B. Record the background and activity from Step (A) on the computer-generated Constancy/Accuracy form (RS-31 or equivalent). The cesium-137 E-vial should demonstrate a value within $\pm 5\%$ of the certified activity of the reference source after decay correction.
- C. Repeat Steps (A) and (B) with the cesium-137 E-vial for each commonly used calibration factor setting.
- D. Compare the cesium-137 E-vial's measured activity at each of the calibration factors settings to the cesium-137 E-vial's measured activity at the cesium-137 calibration factor setting. Enter these readings and the computer will calculate the ratios of these readings as follows:

$$\text{RATIO}_{\text{Setting X/Cs-137}} = \frac{\text{Cs-137 READING at CALIBRATOR SETTING for X}}{\text{Cs-137 READING at Cs-137 SETTING}}$$

For example:

$$\text{RATIO}_{\text{Tc-99m/Cs-137}} = \frac{\text{Cs-137 READING at Tc-99m SETTING}}{\text{Cs-137 READING at Cs-137 SETTING}}$$

- E. The calculated ratios of the cesium-137 E-vial at each of the calibration factors should be within $\pm 5\%$ of the previously calculated values.

The dose calibrator reference standards used will be of at least 50 μCi and have a calibration accuracy of $\pm 5\%$.

Geometry Measurements

Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cc plastic syringes and that the radiopharmaceutical kits are made in 30 cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

- A. In a small beaker or vial, mix 2 cc of a solution of technetium-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
- B. Draw 0.5 cc of the technetium-99m solution into the syringe and assay it. Record the volume and activity in millicuries indicated on the dose calibrator.
- C. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and activity in millicuries indicated.
- D. Repeat the process until you have assayed a 2.0 cc volume.
- E. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5% error lines above and below the chosen "standards volume".
- F. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence" and note the date of the test, the model number and serial number of the calibrator.
- G. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the technetium-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity in millicuries indicated.
- H. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and activity in millicuries indicated.
- I. Repeat the process until you have assayed a 19.0 cc volume. The entire process must be completed within 10 minutes (As an alternate, volumes of 2, 4, 8, 10, 20 and 25 cc may be used).
- J. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5% error lines above and below the chosen "standards volume".
- K. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence" and note the date of the test, the model number and serial number of the calibrator.
- L. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower energy radionuclides such as iodine-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Adequate

correction factors must be established for assaying iodine-125. An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

Linearity Measurements

Linearity means that the calibrator is able to indicate the correct activity over the range of the use of that calibrator. This test is done using a vial or syringe of technetium-99m with an activity at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dose syringe, or in a radiopharmaceutical therapy dose, whichever is largest.

Decay Method: This method documents percent variances with no graphing.

- A. Inspect the instrument to ascertain that the measurement chamber liner is in place and that the instrument zero is properly set (see manufacturer's instructions).
- B. Assay the technetium-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.
- C. Repeat step B at time intervals of approximately 6, 24, 30, 48, and 96 hours after the initial assay.
- D. Using the 30-hour activity measurement as a starting point, calculate the predicted activities for the 0, 6, 24, 48, and 96 hour measurements.
- E. **Example:** If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be $(15.625 \text{ mCi}) \times (15.8533) = 247.71 \text{ mCi}$ and $(15.625 \text{ mCi}) \times (0.1259) = 1.967 \text{ mCi}$, respectively. The half-life of $T_{1/2} = 6.02$ hours has been used in calculating these values.
- F. Compare the measured net activity (for each time interval) versus the calculated activity (for the same time interval).
- G. The activities should be within $\pm 5\%$ of the calculated activity if the instrument is linear and functioning properly. If variations greater than $\pm 5\%$ are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.
- H. If instrument linearity cannot be corrected, for routine assays it will be necessary to use either an aliquot of the eluate that can be accurately measured or the comparison in step F to relate measured activities to calculated activities.

Decay Method: This method utilizes graphing of decay measurements.

- A. Assay the technetium-99m vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to nearest minute, and net activity on the Dose Calibrator Linearity Test Form. This first assay should be done in the morning at a regular time (e.g., 8 AM).
- B. Repeat the assay at time intervals of 6, 24, 30, 48 and 96 hours after the initial assay or until the assayed activity is less than 30 μCi . For dose calibrators on which you select a range with a switch, select that range you would normally use for the measurement.
- C. Convert the time and date information you recorded to hours elapsed since the first assay.
- D. On a sheet of semi-log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

- E. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. $(A_{\text{observed}} - A_{\text{line}}) / (A_{\text{line}}) = \text{deviation}$.
- F. If the worst deviation is more than ± 0.05 , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

Shield Method

As an alternative to the decay method, several companies manufacture a set of lead lined tubes that can be inserted into the dose calibrator. The tubes may be arranged or inserted concentrically with the source in the center, thus allowing the operator to simulate different source strengths with only one source. The need for determining linearity by fractionating eluants or decaying the elution for several days while data is being collected is eliminated at a greatly reduced radiation exposure to personnel.

Dose calibrator linearity using the shield method will be performed with:

- a) the "Calicheck" (Calcorp, Inc., Cleveland, OH), or
- b) the "Lineator" (Atomic Products Corporation, Shirley NY), or
- c) similar commercially available products.

All linearity tests done using the shield method will be performed following the shield device manufacturer's instructions and applicable license conditions, regulations, etc.

10.18 Personnel Monitoring Program

We confirm that we will establish and implement written personnel monitoring procedures. As a minimum, these written procedures will require:

- A. That whole body dosimetry (film badges, TLD's* or OSL's†) be provided to personnel who enter restricted areas under the circumstances described in the NRC/Agreement State regulations;
- B. That whole body dosimetry (film badges, TLD's or OSL's) and finger extremity monitors (TLD or OSL) be provided to personnel who elute, prepare, assay, or dispense millicurie quantities of radioactive material;
- C. That whole body dosimetry be exchanged for processing at least monthly if film, quarterly if TLD or OSL, 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;

* Thermoluminescence Dosimeter

† Optically Stimulated Luminescence Dosimeter

Item 11 Waste Disposal

A. Waste Generated

Radioactive waste generated at the nuclear pharmacy is mostly short lived with half-lives less than 120 days. Syncor will segregate waste according to half-life for decay in storage. Any waste accumulated with a half-life greater than 120 days will be disposed of through a licensed radioactive waste disposal firm.

Radioactive waste accepted from customers typically consists of plastic syringes, needles, needle covers, vials, and depleted sealed sources. Radioactive waste generated at the nuclear pharmacy consists of any item contaminated with radioactive material resulting from the operation of the nuclear pharmacy such as gloves, absorbent material, vials, syringes, etc.

B. Waste Classification System

The pharmacy will use a waste classification system for segregating various types of materials according to half-life. Waste will be segregated according to the following classifications. The percent associated with the waste is the approximate volume at any one time.

1. very short half-life: Tc-99m waste. ($\approx 90\%$)
2. short half-life: Xe-133, Ga-67, Tl-201, etc. waste. ($\approx 6\%$)
3. long half-life: I-125, Co-57, etc., waste. ($\approx 1\%$)
4. generator columns: Mo-99 waste. ($\approx 2\%$)
5. I-131 waste. ($< 1\%$)

Syncor does not use byproduct materials with half-lives greater than 120 days with the exception of sealed sources. Waste sealed sources with half-lives greater than 120 days will be either returned to the manufacturer or transferred to a waste broker that is authorized to receive them.

C. Methods for Holding Waste

1. A sufficient number of lead barrels will be used to store waste. A lead plate will be used as a lid.
2. A container emptying rotation cycle will be established to ensure that all material has been stored for a minimum of ten half-lives.
3. When a container is filled it will be sealed, the date will be placed on the container, and the radiation level at the surface of the container will be determined.

D. Waste Disposal Procedures

No waste will be disposed to the sanitary sewer. Waste may be disposed of by transfer to another licensee. If this method of disposal is used Syncor will obtain a copy of that organization's materials license to confirm that they are authorized to receive the waste.

1. Used generators will either be returned to the manufacturer, stored for decay, or transferred to a licensed waste disposal firm.

2. Generator columns will be separated from other waste and held for decay.
3. Survey Procedures for Disposal of Waste as Non-radioactive
 - a. Always wear disposable gloves when handling waste.
 - b. Use a low level survey meter and ensure it is operating properly prior to use.
 - c. Record background of survey meter on waste disposal record. Obtain background in low background area.
 - d. Select waste from a container that has been held for at least ten half-lives.
 - e. Remove plastic bag (or fiberboard liner) from lead container.
 - f. Measure radiation level over the entire surface of plastic bag with the survey meter. If waste contains beta emitters, make sure beta shield is open.
 - g. If radioactive waste measures background:
 - i. Remove all radioactive tags or obliterate RAM labels.
 - ii. Dispose of into normal trash.
 - h. If radioactive waste measures above background and less than 2 mR/hr, it may be placed within the lead waste container or outside of the lead waste container for further decay in storage.
 - i. If radioactive waste measures above 2 mR/hour, return to lead waste container for further decay in storage.
 - j. Record all findings on the radioactive waste disposal record.
4. Records of waste disposal will be maintained until the termination of the license.

APPENDIX A
NRC EXEMPTIONS

Appendix A
Requested Exemptions

1. Syncor International Corporation wishes to have continued authorization to "self-approve" Authorized Nuclear Pharmacists without having to request and receive an amendment to this license prior to allowing the individual to work as an Authorized Nuclear Pharmacist. Syncor commits to following the criteria as specified in 10 CFR 35.972, 35.980 and 35.981.

The NRC originally granted this authorization on May 22, 1996.

2. Syncor International Corporation requests continued exemption from assaying products redistributed in the manufacturer's unopened container as has been authorized by NRC. Syncor realizes that the manufacturer must be properly licensed under 10 CFR 32.72 and that the products must not be manipulated prior to redistribution. Syncor confirms that there will not be any manipulation of any kind to the dose, including changes to the labeling.

The NRC originally approved this exemption on March 26, 1996.

APPENDIX B

PROCEDURE FOR ASSAYING BETA EMITTERS

Introduction

Several regulatory agencies have questioned the ability of the standard ion chamber type dose calibrator to assay pure beta minus (referred to herein as beta) emitters accurately. Rather than direct measurement of the photons emitted from an isotope, the ion chamber measures the bremsstrahlung x-rays created by the beta particle interactions in materials between the ion chamber and the source. A spectrum of x-ray energies is produced, where the maximum energy may be up to the originating beta particle energy. The average energy produced, however, is low in comparison to the original beta energy, making it easier for detection by the ion chamber.

Capintec, a manufacturer of dose calibrators, has produced an instrument to measure pure beta emitting isotopes. The machine, named the *Beta-C*, consists of a 1" sodium iodide (NaI) crystal detector in a shielded well and a control panel similar to that of standard ion chamber dose calibrators produced by Capintec. Although the *Beta-C* is a good instrument for measuring beta emitting isotopes, the high sensitivity of the NaI detector does not allow measurement of doses dispensed to patients (in excess of 20 mCi).

Until a device is developed that does not saturate upon measuring large quantities of beta emitting isotopes, the ion chamber type dose calibrator is currently the best tool for determining activities. Since the dose calibrator measures the bremsstrahlung x-rays created by beta interactions in materials surrounding the source, the measurement of such isotopes is geometry dependent. Additionally, manufacturers of dose calibrators do not typically include calibrator factors or numbers for pure beta emitting isotopes.

The Quality and Regulatory Department of Syncor International Corporation has developed a procedure to identify dose calibrator settings that will provide accurate assessment of the activity within a vial or syringe containing pure beta emitting radionuclides. In the absence of a direct dose calibrator setting, an alternative procedure is defined for developing a correction factor to be applied to the dose calibrator readings. The procedures discussed within may be modified in the future to meet the needs of a particular new product, providing similar comparison are made to account for geometric differences.

Geometry Dependence

The procedure included below must be repeated for any changes in geometry, such as volume of material or a change in syringe or vial size, type and shape. The procedure must also be repeated for each pure beta-emitting isotope, establishing a separate set of correction factors for each isotope.

Syringes will be assayed with the needle attached. The needle syringe system is considered to be a single geometrical configuration, for which correction factors are developed based on comparison to the manufacturer's vial. Bremsstrahlung x-rays production within the needle will be limited by the small volume of radioactive solution present within the needle. A typical needle used for patient injection is a one inch long, stainless steel, hollow cylinder with a diameter of approximately one hundredth of an inch. These dimensions dictate that the needle will contain less than five microliters of solution. If, for example, a unit dose is 3 milliliters of total volume with a concentration of 100 mCi per ml, the bulk of the activity is contained within the syringe rather than the needle. The primary source of bremsstrahlung x-rays will therefore be the syringe, not the needle.

The contribution of the material in the needle to the total assay has also been determined to be negligible through both experiments using pure beta minus emitters and Monte Carlo computer simulations. During the experiments, millicurie amounts of activity were drawn into a syringe and

measured in a standard dose calibrator. The needle on the syringe containing the material was then removed and replaced with a fresh needle. The measurement of the syringe with the fresh needle yielded the same result as the original syringe/needle combination. Contributions to the assay were also negligible when varying syringe volume in the Monte Carlo simulations.

Pure Beta Minus Assay Procedure - Calibration

The following procedure must be followed for each dose calibrator to be used as well as each geometrical configuration to be employed.

- Step 1. Calculate the current activity of the material in the manufacturer's vial (**MV**) by calculation or decay tables. Verify that the manufacturer's assay of the material is traceable to NIST standard. The paperwork included with the source must contain the certification.
- Step 2. Record calculated activity as **R1**.
- Step 3. Insert vial into dose calibrator.
- Step 4. Adjust the potentiometer setting or calibration number until the calculated activity is shown on the display. As an example, the calibration number for a Capintec CRC-15R is 71×10 for the vial containing the Y-90 supplied by Antisoma.
- Step 5. If the potentiometer can not be adjusted to display the proper activity, choose a setting.
- Step 6. Record the potentiometer setting or calibration number as **CN**.
- Step 7. Record the activity displayed on the dose calibrator as **R2**.
- Step 8. Record the initial volume contained within the **MV** as **IV**. Record the vial type as **VT** and the vial size as **VS**.
- Step 9. Record the total volume of liquid to be placed in syringe for distribution as **SV**. Transfer the volume, **SV**, of material into the syringe to be used for distribution. If there is not enough material, use saline solution to increase the volume to **SV**.
- Step 10. Add saline solution to the **MV** to achieve the original volume contained within the **MV**.
- Step 11. Mix the **MV** and re-measure, recording the value as **R3**.
- Step 12. Measure the syringe containing the dose and record as **R4**.

Pure Beta Minus Assay Procedure – Unit Doses

- Step 1. Draw required volume in syringe.
- Step 2. Place syringe in dose calibrator.
- Step 3. Adjust potentiometer or calibration number to **CN** determined above.
- Step 4. Multiply dose calibrator reading by **BF3** to obtain the activity.

Worksheet for Pure Beta Minus Assays

Use the table below to determine the required values and calibration factors. Note that this procedure must be repeated for any changes in geometry, such as syringe or vial size, type and shape. The procedure must also be repeated for each pure beta-emitting isotope.

Symbol	Meaning	Calculation	Value
R1	Current activity in vial (decay or back decay)	$A_0e^{-\lambda t}$ or $A_0e^{+\lambda t}$	
CN	Calibration number or potentiometer setting	-	
R2	Dose calibrator reading of manufacturer's vial	-	
BF1	Ratio of actual activity to measured (vial).	$R1 / R2$	
IV	Initial volume contained within manufacturer's vial.	-	
VT	Indicate the type of vial used (size, shape, color).		
VS	Indicate the size of the vial.		
SV	Total volume to be placed in syringe.	-	
R3	Dose calibrator reading of diluted manufacturer's vial.	-	
BF2	Calculated activity in syringe.	$(R2 - R3) * BF1$	
R4	Dose calibrator reading of filled syringe.	-	
BF3	Ratio of actual activity to measured (syringe).	$BF2 / R4$	

APPENDIX C
HEALTH PHYSICS SERVICES

Appendix C Health Physics Services

Syncor International Corporation wishes to perform the following health physics services for its customers:

1. Sealed source leak testing
2. Calibration of survey meters

Sealed Source Leak Testing

Sealed sources will be leak tested according to the following procedure:

A. Equipment Required

Filter paper, cotton tip applicators	Counting vials (test tubes)
Appropriate calibration standards	Multichannel Analyzer
Forceps or hemostat	Disposable gloves

B. Procedure for Obtaining Wipe Sample

1. Wear disposable gloves when leak testing sealed sources. Change gloves between sources when testing several sources.
2. Moisten the cotton-tipped applicator with water or alcohol.
3. Wipe the accessible surface of the source. Include the top, bottom, and the seal around the cap.

C. Procedure for Assessing Test Results

1. All samples will be counted using a multi-channel analyzer (MCA) and a Well Counter with a NaI crystal.
2. If an efficiency for the isotope being tested has not been calculated during the current quarter or since repair of the system, establish and record the well efficiency factor in cpm/mCi using a reference source. This reference source will either be the same radionuclide or one with similar energy characteristics. This source shall either be NIST traceable or compared to a NIST standard and shall be accurate to within $\pm 5\%$ of the stated value.
3. Establish and record the minimum detectable activity (MDA). The MDA must be 0.005 μCi or less.
4. Count a background and the sample, each for 2 minutes.
5. Calculate and record results. Maintain records of leak tests for a minimum of 3 years.

D. Action Levels

If the test reveals the presence of 0.005 μCi or more of leakage or contamination obtained from a sealed source, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with NRC/State regulations. A report describing the equipment involved, the test results, and the corrective actions taken shall be filed within five (5) days to regulatory authorities.

E. Records

The following is a sample of the certificate to be given to Syncor's customers:

Sealed Source Leak Test Certificate

Syncor International Corp.
*
*

Facility:

Contact Person:

Test Date: _____ Performed by: _____

Wipe Date: _____ Wipe Performed By: _____

Next Leak Test Due: _____

Sample #	Radionuclide	Manufacturer/ Model #	Serial #	Source Activity	Net CPM	Removable Contamination (μCi)
1						
2						
3						
4						
5						

Description of Method: Each source was wiped with a wet swab or cotton tipped applicator and counted with a NaI well counter.

Maintain this Leak Test on file as proof of compliance with your Radioactive Materials License.

Test completed by Syncor.

ACTION LEVEL: If removable contamination is greater than $0.005\mu\text{Ci}$, the source should be removed from use and stored, repaired, or disposed of according to your Radioactive Materials License.

Signature of Radiation Safety Officer: _____ Date: _____

Survey Meter Calibrations

Syncor will implement the model survey meter calibration program published in Appendix J to NUREG-1556 Vol. 13 "Program Specific Guidance About Radiopharmacy Licenses" dated September 1999.

APPENDIX D
SYNCOR'S AUDIT FORM



The Service DifferenceSM

Syncor International Corporation

COMPLIANCE SURVEY

Location: _____ Date: _____

License #: _____ Time: _____

Auditor: _____

Last NRC/Agreement State Inspection: _____ Points: _____

The inspection was an examination of the activities conducted under the above license as they relate to radiation safety and to compliance with NRC/Agreement State rules and regulations and the conditions of the above license. Include other areas of compliance also, i.e., agencies listed below. 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.

KEY: Yes No Not Audited Not Applicable

Text of audit item. SEVERITY LEVEL _____

EXAMPLE:

103 All radioactive material within possession limits. _____
SEVERE (NRC)

- NRC: Nuclear Regulatory Commission (10 CFR) or Agreement State
- BOP: State Board of Pharmacy
- DOT: Department of Transportation (49 CFR)
- OSHA: Occupational Safety & Health Administration (29 CFR)
- PNP: Policy or Procedure as issued by written notice, memo or published program.
- FDA: Food & Drug Administration (21 CFR)
- EPA: Environmental Protection Agency (40 CFR)
- UFC: Uniform Fire Code
- NFPA: National Fire Protection Association
- MED: State or Local Medical Waste Regulations

COMPLIANCE SURVEY

SEVERITY LEVELS:

- MINIMAL** Violations that have minor safety, environmental, or policy significance or deficiencies that may impact quality.
- MODERATE** Violations that have more than minor safety, environmental, or policy significance. These violations involve inadequate implementation of regulations, standards, or license conditions relative to operations.
- SEVERE** Violations that have major safety, environmental, or policy significance or deficiencies that may impact quality. Characteristics are: may lead to escalated enforcement by an outside regulatory agency, requires immediate resolution, may have heavy liability (may include financial impact), or negligence. SEVERE violations are also related to excessive exposure, willful disregard, breach of security, or lack of management oversight.
- CRITICAL** Most serious. SEVERE violations which are potentially life-threatening or result from willful or intentional disregard for regulations, policies, or standards.

POINTS & RATINGS:

- MINIMAL = 1** Repeat = 2 Repeat Again = 5
- MODERATE = 2** Repeat = 4 Repeat Again = 5
- SEVERE = 5** Repeat = Management Intervention
- CRITICAL = 7 point** Repeat = Management Intervention

Repeat violations can move MODERATE and MINIMAL violations into the SEVERE or CRITICAL level.

<u>RATING</u>	<u>POINTS</u>
Outstanding	0
Excellent	1 - 6
Acceptable	7 - 11
Below Standard, Marginal	12 - 16
Below Standard, Acute	17 +
Below Standards - Critical	Any + Critical

COMPLIANCE SURVEY

100	RECORDS	Y	N	N/A	N/Au	or Comment #
101	Copies of license, all amendments and correspondence organized and available. MINIMAL [NRC]					101
102	License commitments followed and regulatory agency inspection response commitments implemented and followed. Examples include adequate RSO oversight, floor plan, and commitments made in response to violations. MODERATE [NRC/BOP]					102
103	All radioactive material within possession limits. SEVERE [NRC]					103
104	Authorized user and pharmacist on site when radioactive materials are dispensed, labeled, handled, and/or packaged in accordance with local law. SEVERE [NRC/BOP]					104
105	All State/NRC inspection reports and corporate responses available and organized. MINIMAL [PNP]					105
106	All corporate audits available and organized. Timely response letter sent. MINIMAL [PNP]					106
107	Regulatory audits performed, as required. MINIMAL [NRC]					107
108	All RS documents and exposure reports reviewed and initialed at intervals not to exceed 7 days by RSO or RSO-designate. Errors and omissions in the RS forms highlighted, initialed by the reviewer and corrective actions initiated. MODERATE [NRC/PNP]					108
109	Restricted areas surveyed and wipe tested as required. Results documented on RS-6 forms. MINIMAL [NRC]					109
110	Unrestricted areas surveyed and wipe tested at intervals not to exceed 7 days. Results documented on RS-6 forms. MINIMAL [NRC]					110
111	Vehicles surveyed and wipe tested at intervals not to exceed 7 days. Results documented on RS-6 forms MINIMAL [NRC]					111
112	All trash is at background levels prior to removal from restricted area and documented on the RS-6 or equivalent. MODERATE [NRC]					112
113	Neighboring areas monitored per regulatory commitment. MINIMAL [NRC]					113
114	Corrective actions and follow-up surveys made if action levels met or exceeded. MODERATE [NRC]					114

COMPLIANCE SURVEY

Y N N/A N/Au or Comment #

115	Well counter used for counting all wipe tests. LLD, MDA, and efficiency calculated and documented. Action levels posted. Appropriate ROI used for dispensing activity. MINIMAL [NRC]					115
116	Background consistently low and LLD/MDA sufficient to detect regulatory limits at time of measurement. MINIMAL [NRC]					116
117	Proper bioassay procedure and frequency observed (intervals not to exceed 7 days), and bioassay results documented. MODERATE [NRC]					117
118	Corrective actions taken when applicable according to NRC/RG 8.20 (I-131 Action Level = 0.04 uCi). SEVERE [NRC]					118
119	Personnel exposure readings available and initialed by individuals (dosimetry reports). MINIMAL [NRC]					119
120	Dosimeters changed and processed according to appropriate frequency. Control badges sent with dosimeters. MODERATE [NRC]					120
121	DELETED.					
122	Extremity exposures greater or equal to 800 mrem/week per dosimetry device properly documented on RS-15 and investigated per policy. Appropriate corrective actions taken and documented. SEVERE [NRC]					122
123	Incoming RAM package opening procedure followed and documented on RS-22. MODERATE [NRC/PNP]					123
124	Incoming RAM packages delivered to properly designated location. MINIMAL [NRC]					124
125	Molybdenum checks performed on every Mo-99/Tc-99m generator elution and documented. SEVERE [NRC/BOP]					125
126	Mo-99/Tc-99m activity ratio within regulatory limits. CRITICAL [NRC/BOP]					126
127	DELETED.					
128	Pharmacy Practice Policy and Procedures Manual (P4M) guidelines followed for kit preparation and time of use. MODERATE [PNP]					128
129	Radiopharmaceutical quality control performed according to company P4M. MODERATE [NRC]					129

COMPLIANCE SURVEY

	Y	N	N/A	N/Au	or Comment #
130	All radiopharmaceutical quality control results properly documented on RS-25 or RSQC and available for review including signature (initials). Radiopharmaceuticals with QC results falling below Syncor's professional MAP, and above USP standards, evaluated. These radiopharmaceuticals may be dispensed under the discretion of the pharmacist (as outlined in the P4M manual). This approval must be documented for each kit on the kit prep sheet, or RSQC. MODERATE [NRC, PNP]				130
132	Each DIAGNOSTIC dose is assayed, except: manufacturer's unopened containers. Dispensed activity within +/-10% of prescribed dose, except: In-111 DTPA for cisternography, Co-57 & -58 capsules, I-125 RISA. MODERATE [NRC/BOP]				132
133	Each THERAPY dose is assayed, except: manufacturer's unopened containers. Dispensed activity within $\pm 10\%$ of prescribed dose. SEVERE [NRC/BOP]				133
134	Therapy log properly completed within: i) 1 hour of time when order is placed, or ii) before prescription is dispensed, whichever is sooner. SEVERE [PNP]				134
135	Prescription labels in accordance with Pharmacy law: MODERATE [BOP]				135
136	Survey meters, hand and foot monitors, and room monitors calibrated at intervals not to exceed 1 year or as required by regulations, and records maintained. MINIMAL [NRC]				136
137	Pocket dosimeters calibrated as per license requirements and results documented. MINIMAL [NRC]				137
138	Anemometer calibrated annually. MINIMAL [NRC]				138
139	Dose calibrator constancy checks performed at the beginning of each day of use, properly documented on RS-31, and corrective action taken if required. MINIMAL [NRC]				139
140	Dose calibrator accuracy checks performed at intervals not to exceed 1 year and documented on RS-31/RS-32, corrective actions taken if necessary. MINIMAL [NRC]				140

COMPLIANCE SURVEY

		Y	N	N/A	N/Au or Comment #
141	Dose calibrator linearity tests carried out from at least 10% above the highest activity added to a kit, but no less than 550 mCi, down to (30) microcuries (or 10 microcuries if required by license commitments). Linearity tests performed every 13 weeks on all dose calibrators and documented on RS-33. MINIMAL [NRC]				141
142	Dose calibrator geometry testing performed at installation and after each repair and properly documented on RS-34. MINIMAL [NRC]				142
143	Quarterly efficiency test documented on RS-35. MINIMAL [NRC]				143
144	Daily constancy performed on MCA, SCA, or scaler and documented on RS-36. MINIMAL [NRC]				144
145	All active sealed sources with activities above exempt quantities leak tested at intervals not to exceed 6 months and documented. MINIMAL [NRC]				145
146	Sealed source inventory (except check sources) performed at intervals not to exceed 13 weeks and properly documented. MINIMAL [NRC/PNP]				146
147	Physical inventory matches sealed source inventory documentation. MODERATE [NRC]				147
148	Transferred sources checked into inventory. Leak tests performed and documented. MINIMAL [NRC]				148
149	DELETED.				
150	Medical waste shipment records are maintained at each location per state & local regulations. At a minimum, the records shall include the following: Date of shipment, Quantity (by approximate weight), signature of the transporter's representative, "Certificate of Destruction", "Record of Treatment and Disposal," or equivalent record. MODERATE [MED]				150
151	Radioactive waste held for a minimum of ten half lives, monitored to ensure background, and results documented on RS-46 form or equivalent prior to removal from restricted area. MODERATE [NRC]				151
152	Medical waste is stored within local time limit requirements per federal, state and local regulations. MINIMAL [PNP]				152
153	Glove box filter checks performed at intervals not to exceed 7 days and documented on RS-54. Corrective actions taken when needed. MINIMAL [NRC]				153
154	Proper air monitoring procedure and frequency observed (intervals not to exceed 7 days), and air monitoring results properly documented for restricted and unrestricted areas. MODERATE [NRC]				154

COMPLIANCE SURVEY

		Y	N	N/A	N/AU	or Comment #
155	Corrective actions taken and documented when I-131 effluent concentration reaches 1×10^{-10} uCi/ml (50%) during a sample period. ALARA procedures performed and documented when year-to-date reaches 40%. MODERATE [NRC]					155
156	Iodine glove box airflow measured at intervals not to exceed 3 months and meets license specifications. Properly documented on RS-56. MINIMAL [NRC]					156
157	Fume hood airflow measured at intervals not to exceed 6 months and meets license specifications. Properly documented on RS-56. MODERATE [NRC]					157
158	Dispensing errors resulting in patient misadministrations reported to Q&R and documented on Radiopharmaceutical Event Report. MODERATE [PNP]					158
159	Vehicle accidents involving RAM reported to Q&R within 24 hours of occurrence. MODERATE [PNP]					159
160	Tests results available on all DOT type 7A shipping containers that are used. MINIMAL [DOT]					160
161	Customer license file current, complete, and possession limits match MRSPL and MRSLO. MODERATE [NRC]					161
161a	Prescriptions and radioactive materials dispensed only to licensed users. SEVERE [NRC]					161a
162	Hepatitis B vaccination verification or HBV Waiver on file for each potentially exposed individual. MODERATE [PNP]					162
163	Bloodborne pathogen annual training record (NSP-1) available for all potentially exposed individuals. MODERATE [OSHA]					163
164	Training on fire safety, use of fire extinguisher, and emergency evacuation procedures is conducted and documented (NSP-3) for every employee. Emergency evacuation procedures are posted in prominent area. MODERATE [OSHA]					164
165	Documentation of personnel training on license conditions, 10 CFR 19.12, and NRC Regulatory Guide 8.13 (pregnancy information) on RS-60. MINIMAL [NRC]					165
166	Annual training on DOT requirements, emergency procedures and of the ALARA concept. Proper documentation on RS-59. MODERATE [NRC/DOT]					166
167	Technician duties clearly defined, documented, and followed in compliance with State Pharmacy Laws, and in compliance with Syncor policy. SEVERE [BOP/PNP]					167

COMPLIANCE SURVEY

		Y	N	N/A	N/Au or Comment #
168	Dispensers trained and tested in Moly/alumina breakthrough testing. Training documented on RS-61a and proficiency documented on RS-61b. MODERATE [NRC]				168
169	Initial employment training conducted and documented. MODERATE [NRC]				169
170	Periodic retraining programs conducted and documented on RS-59. MINIMAL [NRC]				170
171	Personnel trained in iodine compounding. Training documentation available. MODERATE [NRC]				171
172	Personnel trained in the Bioassay procedure. Training documentation available (I-131 or I-123, where applicable). MODERATE [NRC]				172
173	Personnel trained in Air Monitoring procedures. Training documentation available (I-131 or I-123, where applicable). MINIMAL [NRC]				173
174	Personnel trained in needle-less WBC procedure. Training documentation available, CRITICAL [PNP]				174
175	Personnel trained in surveys and contamination wipe tests. Training documentation available. MINIMAL [NRC]				175
176	Approved WBC work sheet properly completed, and copies on file. MINIMAL [PNP]				176
177	Clear identification of patient's blood (patient name, color code, etc.) for blood element labeling procedures. SEVERE [PNP]				177
178	Visitors' log properly completed. MINIMAL [NRC/PNP]				178
179	Restricted area cleaning staff escorted or trained (if applicable). MINIMAL [NRC]				179
180	Pharmacy in compliance with incident reporting requirements. MODERATE [PNP]				180
181	Request to the State Board of Pharmacy and other applicable agencies for advance approval of any remodeling, if appropriate. MODERATE [BOP]				181
182	Advised the State Board of Pharmacy of any changes of Pharmacist In Charge. MODERATE [BOP]				182
183	Annual letter to fire and police distributed and filed, if applicable. MINIMAL [NRC]				183

COMPLIANCE SURVEY

Y N N/A N/Au or Comment #

200 RESTRICTED AREA

201	All entrances to restricted and other areas posted as Radiation Area and Radioactive Materials. MODERATE [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	201
202	Shielding in all areas compliant with ALARA program. MODERATE [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	202
203	Buttoned lab coats worn in restricted area. MINIMAL [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	203
204	Gloves worn when handling radioactive or other potentially hazardous materials. MODERATE [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	204
205	Gloves monitored and/or changed to minimize contamination. MINIMAL [PNP]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	205
206	Personal dosimetry devices are worn by all employees when in restricted area and when handling and/or transporting radioactive material. MODERATE [NRC/PNP]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	206
207	One ring badge on each hand worn facing dispensers' palms. At least one ring badge worn by each handler. MODERATE [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	207
208	Fetal badges properly worn by "declared pregnant employees". MODERATE [NRC/PNP]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	208
209	Work areas where contamination is likely is covered with absorbent paper. Paper monitored and/or changed to minimize contamination. MINIMAL [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	209
210	Current RAM spill emergency procedures posted in restricted area. MINIMAL [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	210
211	Current Xe-133 emergency procedures and emergency procedures for personnel exposed to I-131 posted adjacent to the volatile substance room/area. MINIMAL [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	211
212	Smoking and open flames are prohibited in all areas used for flammable or combustible liquid storage. MODERATE [OSHA]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	212
213	No placing of objects in the mouth in the restricted area. MINIMAL [NRC/PNP]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	213
214	Hands and shoes adequately monitored for contamination immediately before exiting restricted area; monitor set at proper sensitivity. SEVERE [NRC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	214

COMPLIANCE SURVEY

Y N N/A N/Au or Comment #

215	Vial shields used at all times with radioactive materials. Tungsten shields used for kit preparation. PET dispensing system used when dispensing positron emitting radionuclides. MODERATE [NRC]					215
216	Vial shields labeled in accordance with all federal and state requirements. proper reference to kit prep sheet. MODERATE [NRC/BOP]					216
217	Syringe shields used during compounding and dispensing radioactive materials. Syringe shield stand properly used. MODERATE [NRC]					217
218	Syringe and vial shields maintained in good condition. MINIMAL [PNP]					218
219	Tongs/forceps used during assaying, compounding and dispensing radioactive materials. SEVERE [PNP]					219
220	Absorbent materials used in all outgoing packages and pigs containing liquid RAM. MINIMAL [DOT]					220
221	DOT 7A Type A shipping containers always used, in same configuration as tested. MINIMAL [DOT]					221
222	Delivery cases and packages containing radioactive materials properly surveyed, wiped, labeled, and sealed. MODERATE [NRC/DOT]					222
223	All containers containing radioactive materials are properly labeled. MODERATE [NRC]					223
224	Shipping papers filled out properly, and copy maintained for one year. MINIMAL [DOT]					224
225	Return delivery cases labeled according to medical waste regulations. MINIMAL [OSHA]					225
226	Limited quantity shipment return policy followed. MINIMAL [DOT]					226
227	Any reusable container must be decontaminated immediately upon discovery of visible biohazard contamination or segregated upon discovery of radioactive contamination. MINIMAL [OSHA]					227
228	Medical waste is stored in clearly marked, limited access areas. MODERATE [OSHA/PNP]					228
229	The following sign prominently posted in the medical waste processing area: "Caution Biological Hazard. Authorized Personnel Only." MODERATE [PNP]					229

COMPLIANCE SURVEY

Y N N/A N/Au or Comment #

- | 230 | The following signs prominently posted in the medical waste processing area:

"Never pick up needles with your hands",
"Always use tongs or forceps to handle needles",
"Never overfill medical waste containers." MINIMAL [PNP] | | | | 230 |
|-----|--|--|--|--|-----|
| 231 | Prior to transport for disposal, the outermost surface of each package of medical waste is marked with a water resistant identification tag or label which contains the following information:

The name "SYNCOR", the state permit or ID No. or location address if the state does not issue a permit or ID No., the transporter's name (BFI, etc.), the transporter's state permit or ID No., the date of the shipment, and identification of contents as medical waste. MINIMAL [DOT] | | | | 231 |
| 232 | International biohazard warning label is placed on the following items:

Biological safety cabinet (only if used for blood manipulation), centrifuge, and blood transport cases. MINIMAL [OSHA] | | | | 232 |
| 233 | Each container holding medical waste must have a water resistant label affixed to or printed on the outside of the container. The label must include the words "Biohazardous, Medical, or Infectious Waste" and display the international biohazard symbol. MINIMAL [OSHA] | | | | 233 |
| 234 | System in place to segregate radioactive waste by half-life. MINIMAL [NRC] | | | | 234 |
| 235 | Needle-less procedure for blood labeling strictly followed. CRITICAL [PNP] | | | | 235 |
| 236 | All sharps are immediately discarded into puncture-resistant containers. MODERATE [OSHA] | | | | 236 |
| 237 | Blood waste generated from cell labeling is segregated from all other waste, per state biohazardous waste regulations. MODERATE [PNP/STATE] | | | | 237 |
| 238 | Proper disinfection materials (example: 70% isopropyl alcohol or virucide) available and biohazard area disinfected after use. Other areas disinfected as appropriate. MINIMAL [OSHA/PNP] | | | | 238 |

COMPLIANCE SURVEY

		Y	N	N/A	N/Au	or Comment #
239	Refrigerator which contains radioactive material adequately shielded and posted. No food or drink stored in this refrigerator. MINIMAL [NRC]					239
240	Laminar and biohazard hoods used. Certified at intervals not to exceed 1 year. MODERATE [BOP/PNP]					240
241	High range survey meter on-site; back-up available. MINIMAL [NRC]					241
242	Dedicated check source attached to survey meters with external probes. MINIMAL [NRC]					242
243	Manufacturer's labeling on original chemical containers is not removed or defaced. MINIMAL [OSHA]					243
244	All chemicals removed from the original manufacturer's containers are labeled, tagged or marked so that they are easily identifiable. MINIMAL [OSHA]					244
245	First aid kits are adequately marked, prominently displayed, wall-mounted, and portable. A Syncor-approved first aid kit is provided and maintained fully stocked for each building and each floor. ThryoBlock tablets are available. MINIMAL [PNP]					245
246	Check-in procedures followed for incoming packages containing radioiodides. MODERATE [NRC]					246
247	Radioiodine (capsules and solutions) stored in sealed containers and xenon gas stored in fume hood. MODERATE [NRC]					247
248	Fume hood continuously operational. MODERATE [NRC]					248
249	Radioiodide vial vented with activated charcoal-filled syringe per procedure. MODERATE [NRC]					249
250	Radioiodine compounding procedures followed. MODERATE [NRC]					250
251	Radioiodine contamination and airborne radioactivity control procedures used. MODERATE [NRC]					251
252	Items potentially contaminated with radioiodide stored in sealed containers. MODERATE [NRC]					252
253	Radioiodide waste stored in sealed containers and stored separate from other waste. MODERATE [NRC]					253

COMPLIANCE SURVEY

		Y	N	N/A	N/Au	or Comment #
254	Glove box in proper working order. MODERATE [NRC]					254
255	Air monitors continuously operational and located in the proper areas. MODERATE [NRC]					255
256	I-131 air sampling system calibrated with mass flow calibrator (MFC) at intervals not to exceed 1 year. MINIMAL [NRC]					256
257	At least one portable fire extinguisher having a UL classification 2-A:10B:C (5.5 lb. ABC) is located: Within 10 feet of the outside of each door opening into any room used for storage of flammable or combustible liquids, between 10 and 25 feet from any flammable liquid storage area located outside of a storage room but inside a building, within 10 feet of the outside of each door opening into any storage room. MODERATE [OSHA]					257
258	All fire extinguishers are properly charged and operable, conspicuously located, readily accessible, located along normal paths of travel and appropriately mounted. Each fire extinguisher tagged with annual maintenance or recharge date. MODERATE [OSHA]					258
259	DELETED.					
260	DELETED.					
261	Combustible materials are stored at least 3 feet away in any direction from ignition sources (e.g. circuit breakers, water heaters, air conditioning equipment). MINIMAL [UFC]					261
262	Combustible materials shall not be stored in exits or exit enclosures. MINIMAL [UFC]					262
263	Flammable containers greater than 1 liter shall be stored in approved flammable liquid storage cabinets marked in conspicuous lettering "FLAMMABLE - KEEP FIRE AWAY." MINIMAL [NFPA]					263
264	No corrosive materials stored in flammable storage cabinet. Corrosives are stored in accordance with chemical compatibility requirements per Material Safety Data Sheet information. MINIMAL [NFPA]					264
265	SECURE™ Safety Inserts used properly. SEVERE [PNP]					265

COMPLIANCE SURVEY

Y N N/A N/Au or Comment #

300 CONTROLLED AREA

301	Current "Notice to Employees" sign posted in a location visible to all employees. MINIMAL [NRC]					301
302	Radioactive Material License(s) posted or sign posted saying where it is located. MINIMAL [NRC]					302
303	Copy of notice of violation and response posted when applicable. MINIMAL [NRC]					303
304	Current pharmacy permit displayed or timely renewal filed if pharmacy license will expire soon. MODERATE [BOP]					304
305	Current pharmacist, intern and technician licenses/permits/registration posted and/or available in accordance with State Board of Pharmacy law, and trained according to Syncor policy. MODERATE [BOP]					305
306	DELETED.					
307	Miscellaneous permits displayed or timely renewal filed (e.g., DEA permit, business licenses). MODERATE [PNP/Agencies]					307
308	DOT shipping labels and markings removed and properly disposed or obliterated prior to placing in clean trash. MINIMAL [NRC]					308
309	Flexible power cords do not run through holes in walls, ceilings, floors, door-ways or windows. Extension coras are used only for temporary (<90 days) installations. Flexible power cords are not attached to building surfaces (eg., taped, stapled, tied cords). MINIMAL [OSHA]					309
310	There is a radius of at least three feet of clear space in front of electrical circuit breaker panels. MINIMAL [NFPA]					310
311	Ceiling panels, doors, and other required fire resistive constructions are maintained and properly repaired, restored or replaced when damaged, altered, breached, penetrated, removed, or improperly installed. MINIMAL [UFC]					311
312	Flammable liquids (e.g., solvents, gasoline) are kept in sealed containers when not in use. MINIMAL [OSHA]					312
313	All exits are marked by readily visible signs which have plainly legible letters no less than 6 inches high with the major stroke of the letter no less than 0.75 inch wide. MINIMAL [OSHA]					313

COMPLIANCE SURVEY

		Y	N	N/A	N/Au	Or	Comment #
314	All exit doors have no locks requiring a key from inside or any other fastening devices that would prevent free escape from the building. SEVERE [OSHA]						314
315	All exits are clear and unobstructed at all times. MODERATE [OSHA]						315
316	All restricted areas safeguarded from unauthorized entry, and all radioactive materials and prescription items continuously secured. SEVERE [NRC/BOP]						316
317	Personnel dosimeters stored properly in a low background area when not in use. MINIMAL [NRC]						317
318	Prescription orders taken only by pharmacist, pharmacist intern, or other individual in accordance with state law. SEVERE [BOP/PNP]						318
319	Drug therapy orders taken only by pharmacist. CRITICAL [PNP]						319
320	Syncor's Biosafety Manual, Radiation Safety Manual, and P4M are readily available on-site. MINIMAL [PNP]						320
321	Current copies of State/NRC/DOT/Pharmacy regulations available. MINIMAL [NRC/DOT/BOP]						321
322	A current copy of the local medical waste regulations is on-site. MINIMAL [PNP]						322

COMPLIANCE SURVEY

400 TRANSPORTATION

Y N N/A N/Au or Comment #

401	Shipping papers carried on front passenger's seat within reach of the driver and accurately reflect inventory of labeled packages. MODERATE [DOT]					401
402	Shipping papers are properly returned. MODERATE [PNP]					402
403	Authorized location for delivery specified for each customer and documented in a drivers' manual. MINIMAL [NRC]					403
404	Packages delivered according to customer-specified procedures. MODERATE [NRC]					404
405	Adequate bracing used properly (restrict movement during normal transportation), in all vehicles. MODERATE [DOT]					405
406	Current emergency notification signs on all vehicles. Syncor emergency procedures from RAM license application, and current DOT Emergency Response Information available as per DOT regulations. MINIMAL [DOT/NRC]					406
407	Yellow III packages transported by Syncor in accordance with DOT Regulations and Syncor policy. SEVERE [DOT/PNP]					407
408	Security provided during loading of vehicles. Vehicles containing RAM or biohazardous material locked when unattended. SEVERE [NRC]					408

COMPLIANCE SURVEY

Y N N/A N/Au or Comment #

500 INTERVIEWS

501 Intra-company transfers are limited to unopened containers with manufacturer's instructions or in accordance with FDA and pharmacy law. MODERATE [BOP/FDA]

				501
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502 DELETED.

503 Used generators are not distributed to customers for human use unless approved by RAM license. SEVERE [NRC]

				503
--	--	--	--	-----

504 Knowledge of staff members of license conditions, 10 CFR 19.12, and NRC Regulatory Guide 8.13 (pregnancy information). MODERATE [NRC]

				504
--	--	--	--	-----

505 Knowledge of DOT requirements, emergency procedures and of the ALARA concept. MODERATE [NRC/DOT]

				505
--	--	--	--	-----

COMPLIANCE SURVEY

600	PHARMACY QUALITY ASSURANCE	Y	N	N/A	N/Au	or Comment #
601	Hoods cleaned prior to use, and cleaning documented. MINIMAL [BOP/PNP]					601
602	As needed, cleaning of LAF room or area (external/top/supports of LAFs; counter fronts/sides/tops; floor; supply racks/bins; LAF plenums) performed and documented. Room/area is cleaned to minimize dust. MINIMAL [BOP/PNP]					602
603	DELETED					603
604	Supplies appropriately stored in racks/bins, drawers or cupboards (syringes in sealed pouches, tubes in plastic bags, no corrugated cardboard storage). MINIMAL [BOP/PNP]					604
605	No particulate shedding materials used within LAF with exception of appropriate absorbent materials. MINIMAL [BOP/PNP]					605
606	LAFs free of unnecessary equipment and supplies when not in use. Sash or curtain closed when not running (no centrifuges within LAFs). MINIMAL [BOP/PNP]					606
607	Room or area maintained appropriately. Only appropriate equipment and furniture in area. LAF located in low traffic area. Traffic restrictions in place, when necessary, when hood in use. MINIMAL [BOP/PNP]					607
608	Plenum (area below work surface) clean and dust-free. MINIMAL [BOP/PNP]					608
609	Personnel trained in cleaning, maintenance and aseptic technique. Documentation of training available. Personnel technique validated every four months. MODERATE [BOP/PNP]					609
610	DELETED.					
611	Aseptic technique used (procedures performed toward center of hood, care taken not to interrupt vertical air flow over open containers). MODERATE [BOP/PNP]					611

COMPLIANCE SURVEY

COMMENTS:

(List all comments by section number)

COMPLIANCE SURVEY

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 pharmacy representative after review
of audit results.

Date

**FACILITY AND EQUIPMENT
SOUTHFIELD, MI**

Site Description

1. This Syncor facility is located in a commercially zoned area at: Syncor International Corporation, 21681 Melrose Avenue, Southfield, MI, 48075. This building is constructed of steel and concrete.

Adjacent tenants are located on the east and west sides of the facility. Wall monitors will be placed on the common walls.

This facility has its own heating and cooling system. Additionally, the restricted area has its own heating and cooling system.

2. Please see the attached site plan.

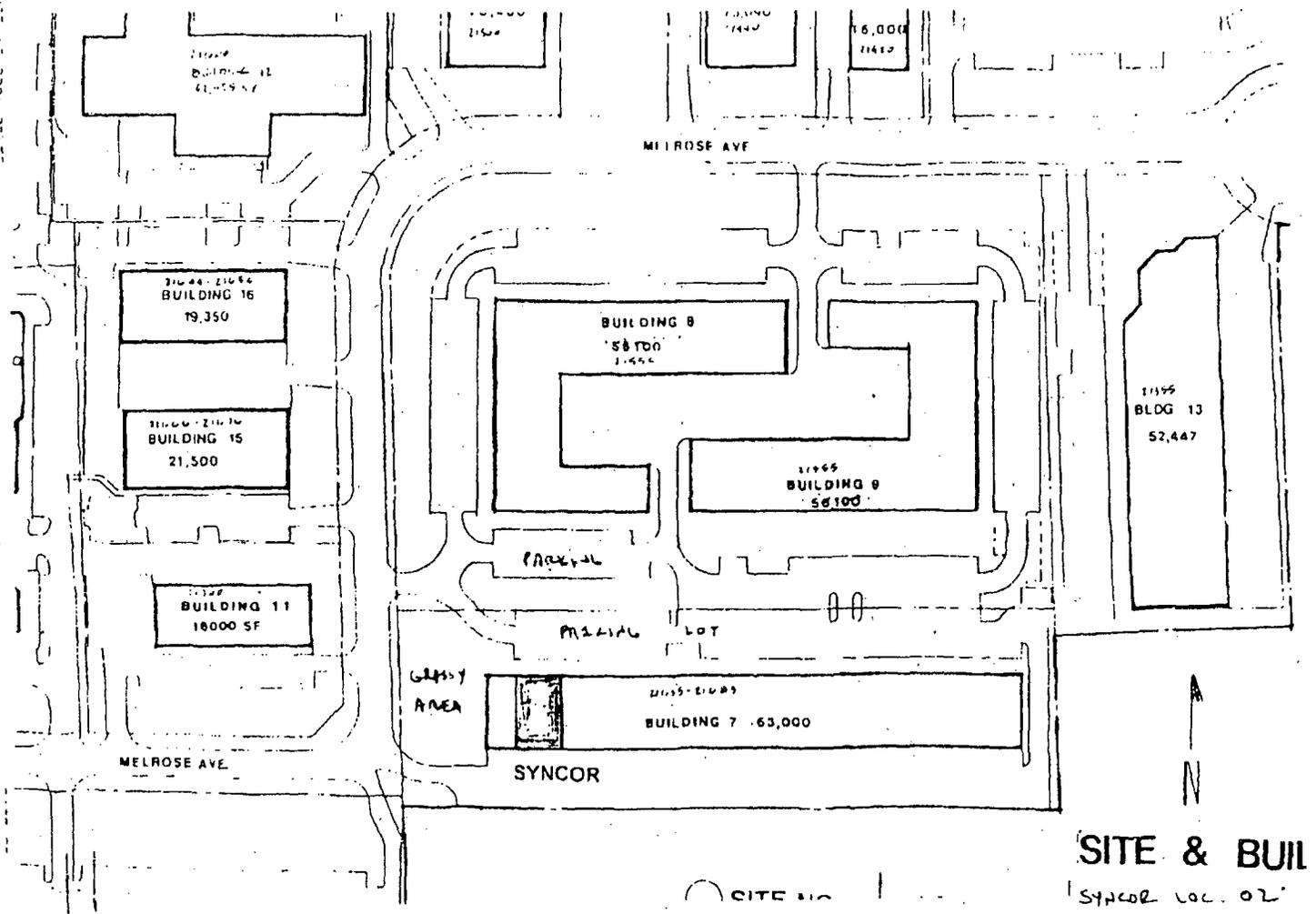


Figure 1 Site Plan

Syncor International Corporation

SOUTHFIELD, MI
 Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 6,400 square feet of space for use as a radiopharmacy. Approximately, 1,620 feet of this space is currently subleased to an adjacent tenant.

Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA

Elution Room - approximately 80 square feet

This area will be used for the 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. This area is labeled ELUTION on the floor plan.

Volatile Substance Room - approximately 90 square feet

This room will also 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 vents are 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. 3/8", 1/2", or 3/4" thick lead barrels will also be used in this room for storing iodine-131 waste in sealed containers, i.e., "ziplock" type plastic bags. This area is labeled THERAPY on the floor plan.

Labeling Room- approximately 120 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area is labeled LABELING on the floor plan.

Radiopharmaceutical Dispensing Area - approximately 992 square feet

This area is used for preparing and dispensing radiopharmaceuticals. A drawing station will be located as shown on the attached sketch. The drawing station 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.

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 that require refrigeration. This area is labeled DISPENSING on the floor plan.

Radioactive Waste Storage Area - approximately 288 square feet

This waste storage room is used for the storage and decay of waste materials. Waste will be stored in lead barrels of approximately 18.5 x 18.5 x 32 x 3/8", 1/2", or 3/4" thick lead. Ample lead bricks (2" x 4" x 8") are provided for additional shielding, as necessary. This area is labeled RAM WASTE STORAGE on the floor plan.

Container Processing Area- approximately 135 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled CASE RETURN on the floor plan.

Supply Storage Area- approximately 288 square feet

This area will be used for the storage of supplies. This area is labeled SUPPLY STORAGE on the floor plan.

UNRESTRICTED AREA

See attached floor plan.

NOTE: The room designated as the vestibule in the unrestricted area will be used for receipt of radioactive packages during off-duty hours. This will prevent the common carrier from having access to the nuclear pharmacy area proper.

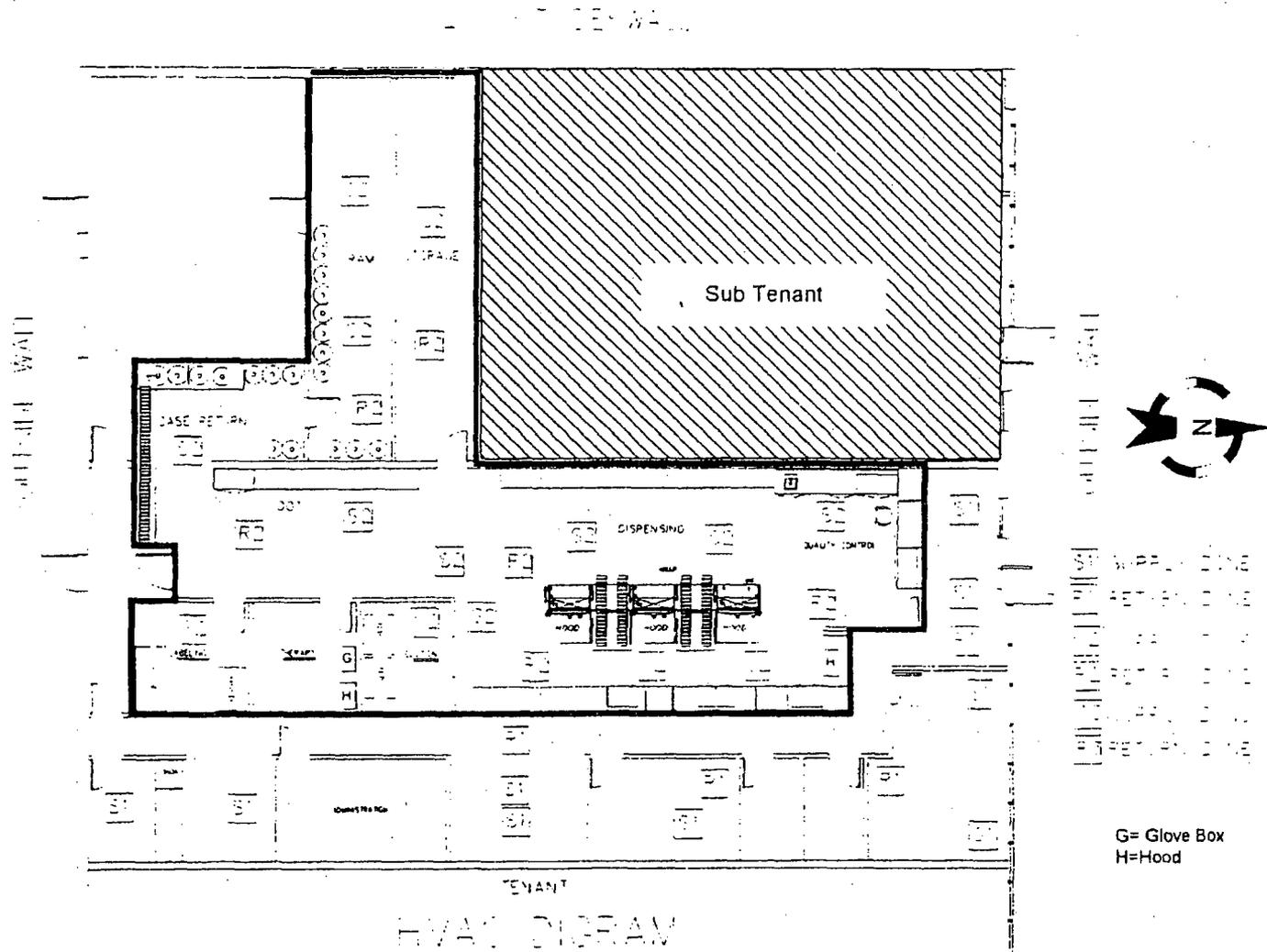


Figure 2 Facility Floor Plan The restricted area is outlined in black.

Syncor International Corporation

SOUTHFIELD, MI
Date: 4/26/2001

**FACILITY AND EQUIPMENT
RICHMOND, VA**

Site Description

1. This Syncor facility is located in a commercially zoned area at: Syncor International Corporation, 1500 Tomlyn Street, Richmond, VA 23230. This is a free standing building constructed of brick and concrete block. The heating and cooling is a multiple zone system.
2. Please see the attached site plan.
3. The fume hood stack extends five (5) feet above the roof, and is over 30 feet from the nearest point of access to the building or any unrestricted area.

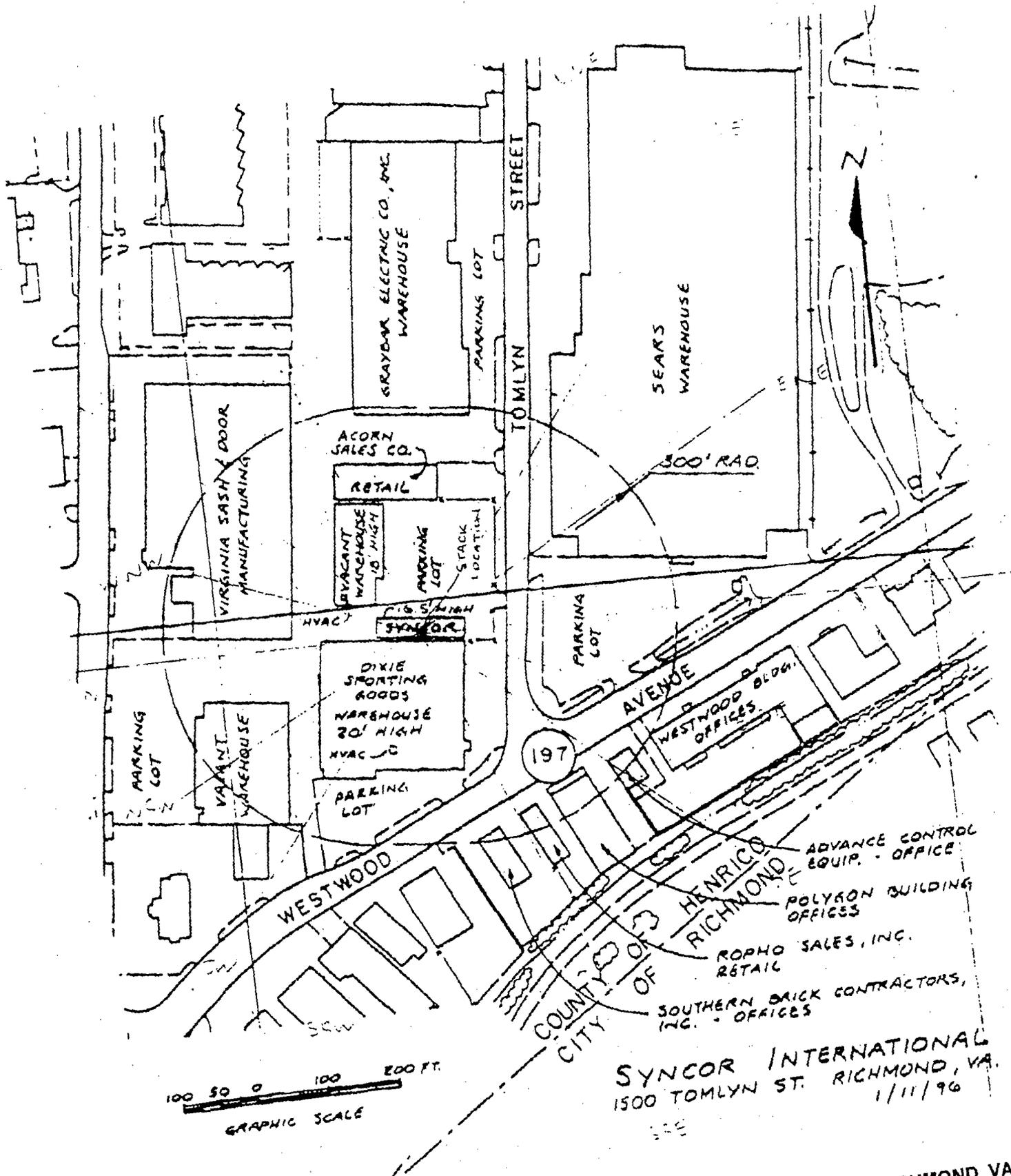


Figure 1 Site Plan

Syncor International Corporation

RICHMOND, VA
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 3,570 square feet of space for use as a radiopharmacy.

Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA – approximately 1,100 square feet

Elution Room - approximately 83 square feet

This area will be used for the 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. Sealed sources are also stored in this room, appropriately shielded. This area is labeled *ELUTION* on the floor plan.

Volatile Substance Room – approximately 105 square feet

This room will also 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 vents are 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. 3/8", 1/2", or 3/4" thick lead barrels will also be used in this room for storing iodine-131 waste in sealed containers, i.e., "ziplock" type plastic bags. This area is labeled *THERAPY* on the floor plan.

Labeling Room- approximately 105 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area is labeled *LABELING* on the floor plan.

Radiopharmaceutical Dispensing Area – approximately 530 square feet

This area is used for preparing and dispensing radiopharmaceuticals. A drawing station will be located as shown on the attached sketch. The drawing station 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.

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 that require refrigeration. This area is labeled *DISPENSING* on the floor plan.

Radioactive Waste Storage Area - approximately 66 square feet

This waste storage room is used for the storage and decay of waste materials. Waste will be stored in lead barrels of approximately 18.5 x 18.5 x 32 x 3/8", 1/2", or 3/4" thick lead. Ample lead bricks (2" x 4" x 8") are provided for additional shielding, as necessary. This area is labeled *DECAY* on the floor plan.

Container Processing Area- approximately 140 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CARE RETURN* on the floor plan.

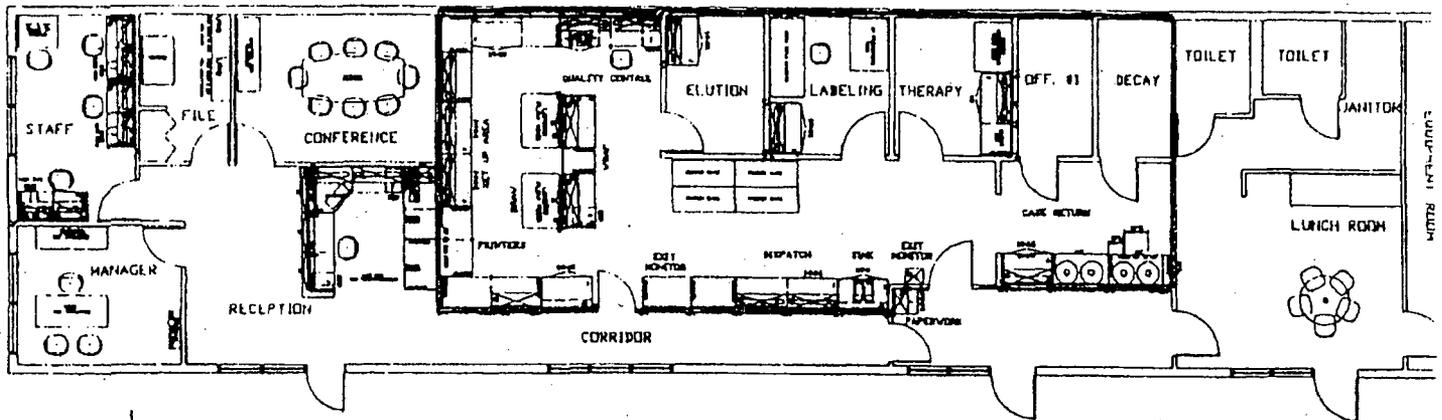
Storage Area- approximately 66 square feet

This area will be used for the storage of supplies and waste which has been decayed to low levels i.e. less than 2 mR/hr, to final decay and transfer to the medical waste hauler. This area is labeled *STORAGE* on the floor plan.

UNRESTRICTED AREA

See attached floor plan.

NOTE: The room designated as the vestibule (labeled *VESTIBULE* in the floor plan) in the unrestricted area will be used for receipt of radioactive packages during off-duty hours. Common carriers will be instructed to lock the outside door on completion of the delivery. The common carrier will not have access to the restricted area.



SCALE IN FEET
 1" = 10'

SYNCOR INTERNATIONAL
 RICHMOND, VA

FINAL 2/21/96 - REVISION ONE 4/25/96

Figure 2 Facility Floor Plan The restricted area is outlined in black

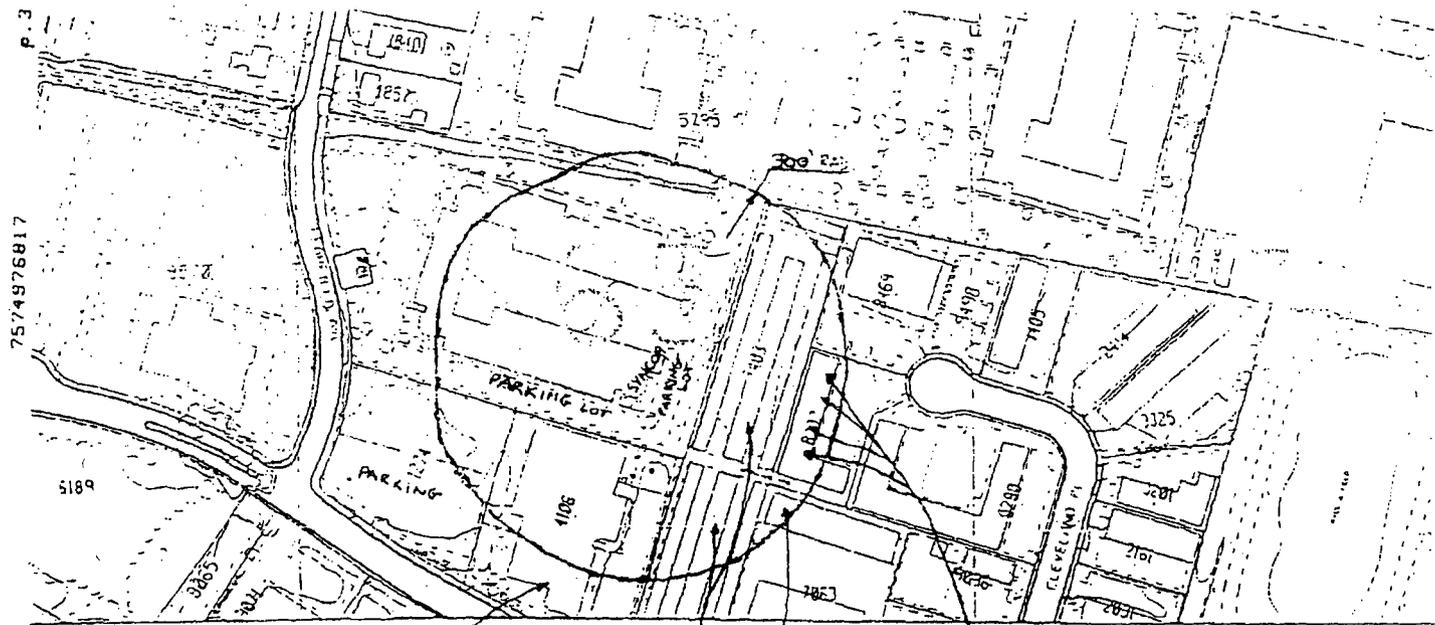
Syncor International Corporation

RICHMOND, VA
 Date: 4/26/2001

**FACILITY INFORMATION
VIRGINIA BEACH, VA**

Site Description

1. This Syncor facility will be located in a commercially zoned area at: 230 Clearfield Ave, Suite 125 Virginia Beach, VA 23462. This single story building utilizes concrete and steel frame construction. One common wall on the west side of the facility is shared with an adjacent tenant. A wall monitor will be placed on this wall. The common wall is a fire wall which extends to the roof of the building. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

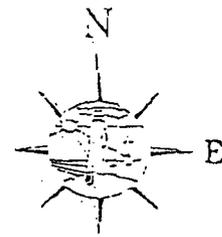


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COX COMMUNICATIONS

SEWER CONTROLS
WITCHDUCK SELF STORAGE

POWER SATellite SERVICES
VANDEBORN WRECKALL TIRE
FUTRE MASTERS
MTE INC. CHEMICAL DIVISION



09	19	29	39	49	59	69	79	89
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03	13	23	33	43	53	63	73	83
02	12	22	32	42	52	62	72	82
01	11	21	31	41	51	61	71	81

Figure 1 Site Plan

Syncor International Corporation

VIRGINIA BEACH, VA
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 3650 square feet of space for use as a radiopharmacy.

Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1488 square feet

Generator Room (Elution) - 100 square feet

This area is used for the 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. This room is labeled ELUTION on the floor plan.

Volatile Substance Room (Therapy) - 100 square feet

This room houses 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. 3/4" thick lead barrels will also be used in this room for storing Iodine 131 waste in sealed containers, i.e., zip-lock plastic bags. This room is labeled THERAPY on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - 840 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Drawing stations are 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 that require refrigeration. This area is labeled DISPENSING on the floor plan.

Radioactive Waste Storage and Break Down Area - 180 square feet

The waste storage room is used for the storage and decay of waste materials. Waste is stored in lead barrels of approximately 16" x 16" x 32 x 3/8", 1/2", or 3/4" thick lead. 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. This area is labeled BREAKDOWN on the floor plan.

Storage - 168 square feet

This area is used for storage of supplies and waste that has decayed to low levels i.e. less than 2 mR/hr prior to final decay and transfer to the medical waste hauler. This area is labeled STORAGE on the floor plan.

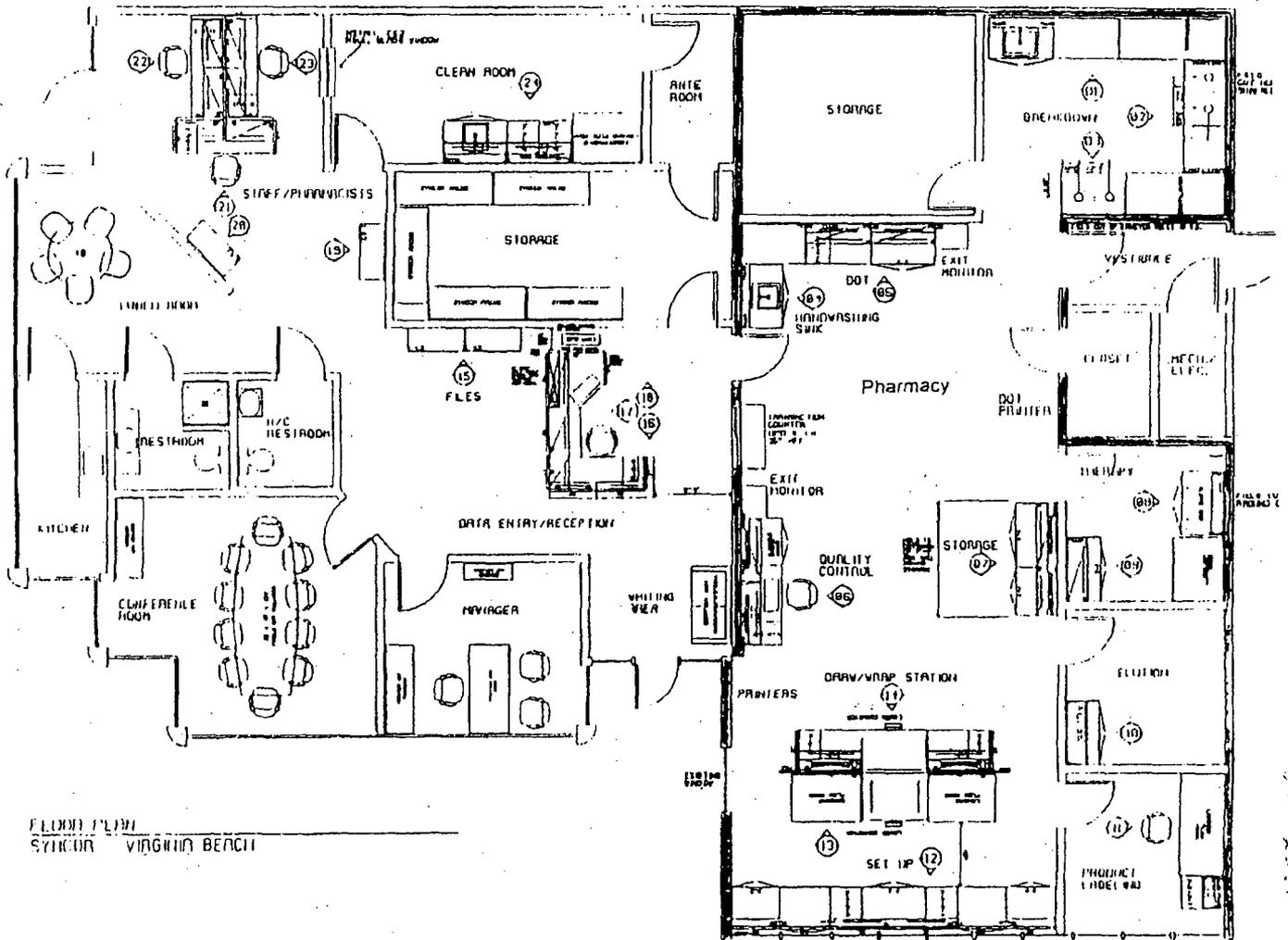
Labeling (WBC Tagging Area) - 100 square feet

This area houses the biohazard hoods and is used for blood cell component tagging. This area is labeled PRODUCT LABELING on the floor plan.

UNRESTRICTED AREA

Please see the attached floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled VESTIBULE. 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.



FLOOR PLAN
 SYNCOR VIRGINIA BEACH

Figure 2 Facility Floor Plan The restricted area is outlined in black

Syncor International Corporation

VIRGINIA BEACH, VA
 Date: 04/26/2001

**FACILITY AND EQUIPMENT
INDIANAPOLIS, IN**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 7920 West 79th Street, Suite 100, Indianapolis, IN 46268. This single story building utilizes brick and steel frame construction. A common wall on the south side of the facility is shared with an adjacent tenant. Unrestricted controlled areas share this tenant common wall, allowing evaluation of radiation levels in the tenant space to be performed in the Syncor facility. The common wall is a fire wall which extends to the roof of the building. 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.

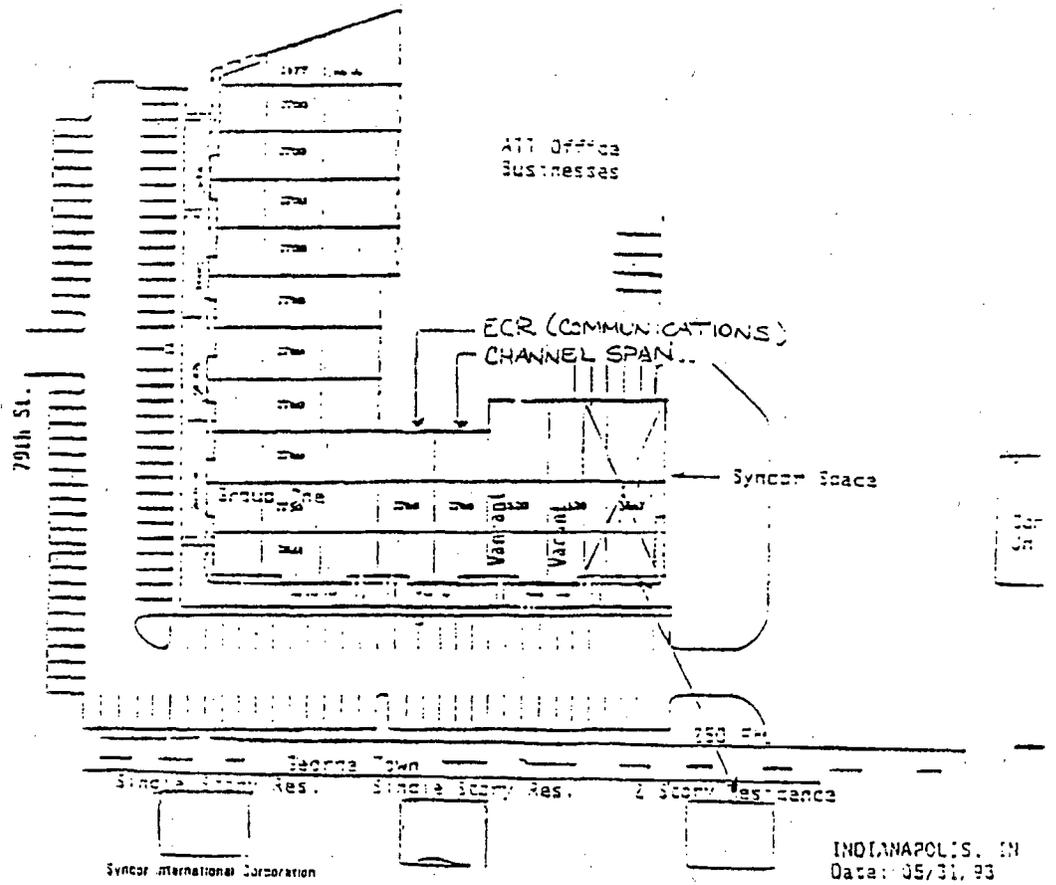


Figure 1 Site Plan

Syncor International Corporation

INDIANAPOLIS, IN
 Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 4900 square feet of space for use as a radiopharmacy.

Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1408 square feet

Generator Room (Elution) - 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. This room is labeled ELUTION on the floor plan.

Volatile Substance Room (Therapy) - 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 875 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. This area is labeled PHARMACY on the floor plan.

Radioactive Waste Storage and Break Down Area - 192 square feet

This room is 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. This area is labeled BREAKDOWN on the floor plan.

Storage - 80 square feet

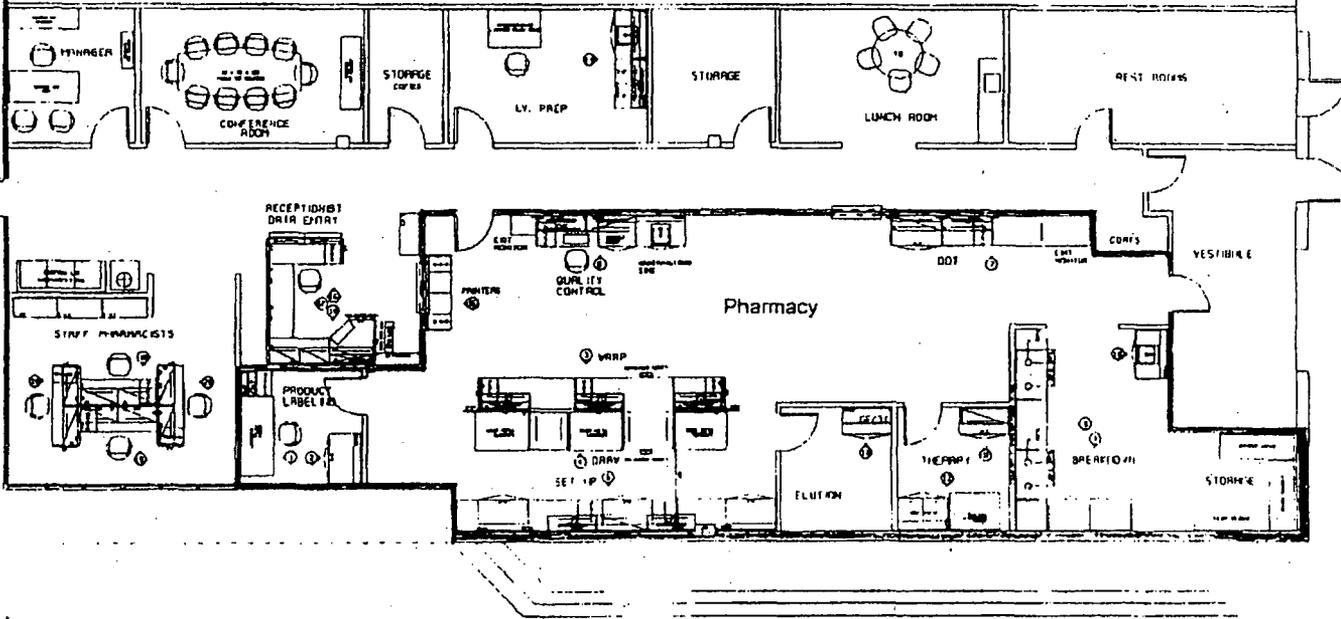
This area is used for storage of supplies and waste which have decayed to low levels (i.e. less than 2 mR/hr) prior to final decay and transfer to the medical waste hauler. This area is labeled STORAGE on the floor plan.

Labeling (WBC Tagging Area) - 81 square feet

This area houses the biohazards hoods and is used for blood cell component tagging. This room is labeled PRODUCT LABELING on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled 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.

02-01-93



SYNOR - INDIANAPOLIS

THIS DRAWING IS THE PROPERTY OF SYNOR INC. AND IS NOT TO BE REPRODUCED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS, ELECTRONIC OR MECHANICAL, INCLUDING PHOTOCOPYING, RECORDING, OR BY ANY INFORMATION STORAGE AND RETRIEVAL SYSTEM.

Figure 2 Facility Floor Plan The restricted area is outlined in black

Synor International Corporation

INDIANAPOLIS, IN
Date: 04/26/2001

**FACILITY AND EQUIPMENT
Grand Rapids, MI**

1. This facility is located in a commercial/industrial type area at:

Syncor International Corporation
1864 Pine Ridge Drive #A
Jenison, MI 49428

2. This facility is in a single-story, multi-tenant building and utilizes concrete tilt-up construction. The west wall of the facility is adjacent to an empty space as shown in Figure 1. A wall badge will be placed on the common wall. The heating and cooling system is exclusive for the restricted area.

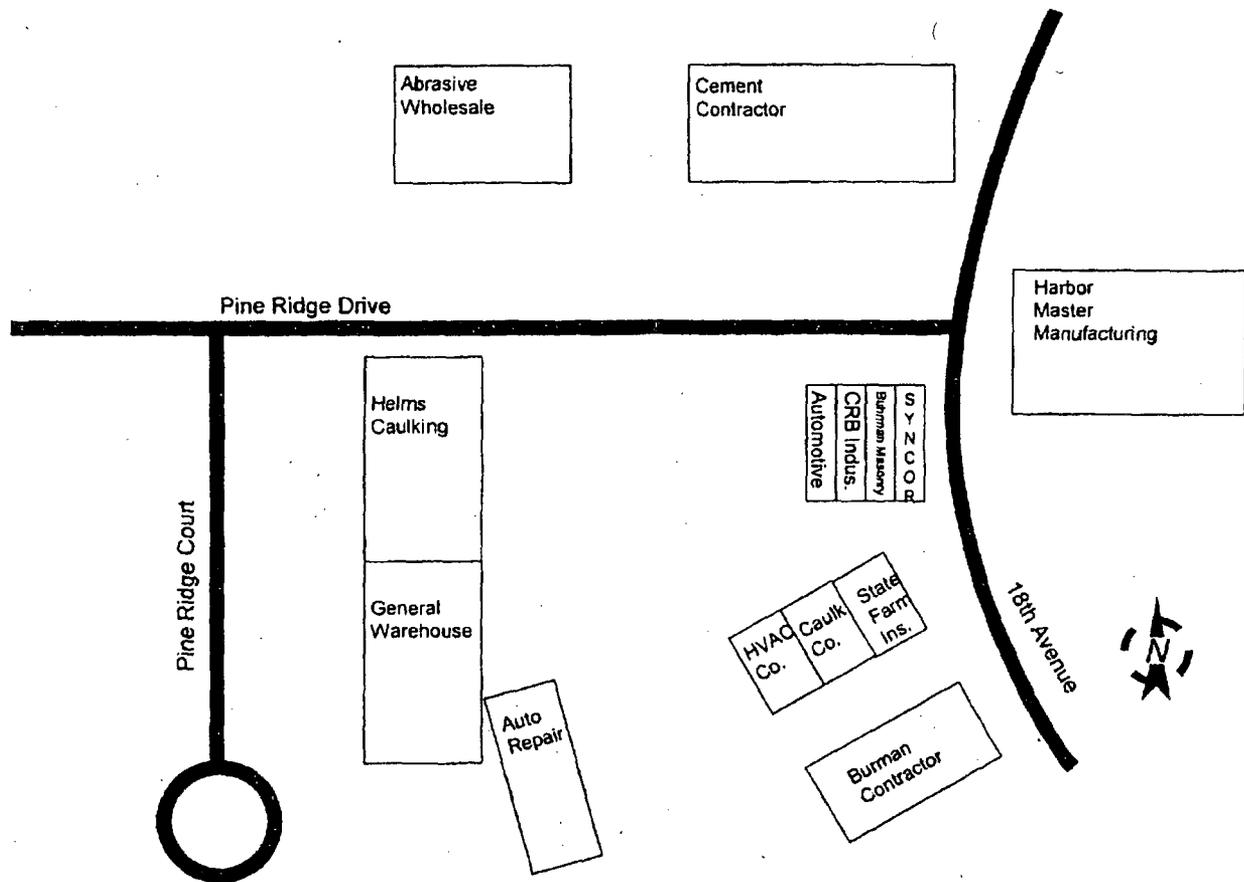


Figure 1 Site Plan

Syncor International Corporation

GRAND RAPIDS, MI
Date:04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 3760 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1350 square feet

Elution Area – approximately 90 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled ELUTION on the diagram.

Volatile Substance Room (Therapy) – approximately 100 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled IODINE on the diagram.

Labeling Room – approximately 120 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled LABELING on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) – approximately 625 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps.

Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled DISPENSING on the diagram.

Container Processing Area – approximately 55 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled CASE RETURN on the diagram.

Waste Storage Room – approximately 130 square feet

This area will also be used for the storage and decay of waste. This area is labeled WASTE on the diagram.

UNRESTRICTED AREA

Vestibule Area – approximately 150 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled VESTIBULE on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

**FACILITY INFORMATION
GLASTONBURY, CT**

Site Description

1. This Syncor facility will be located in a free standing building in a commercially zoned area at: 628 Hebron Ave. Building D, Glastonbury, CT 06033. This single story building utilizes brick and steel frame construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

General Description of Facility

Syncor International Corporation has leased approximately 5200 square feet of space for use as a radiopharmacy in a single story, free standing building located in a commercially zoned area. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1700 square feet

Generator Room (Elution) - 88 square feet

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

Volatile Substance Room (Therapy) - 96 square feet

This room houses the fume hood and glove box type fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent is 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 803 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 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. This area is labeled PHARMACY on the floor plan.

Radioactive Waste Storage and Break Down Area - 192 square feet

This room is used for the storage and decay of waste materials. Waste is stored in lead barrels of approximately 16" x 16" x 32 x 3/8", and 1/2" thick lead. 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. This area is labeled BREAKDOWN on the floor plan.

Storage -140 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 mR/hr) prior to final decay and transfer to the medical waste hauler. This area is labeled STORAGE on the floor plan.

Labeling (WBC Tagging Area) - 95 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This area is labeled PRODUCT LABELING on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled Vest. 2. 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.

UNRESTRICTED AREA

See attached floor plan.

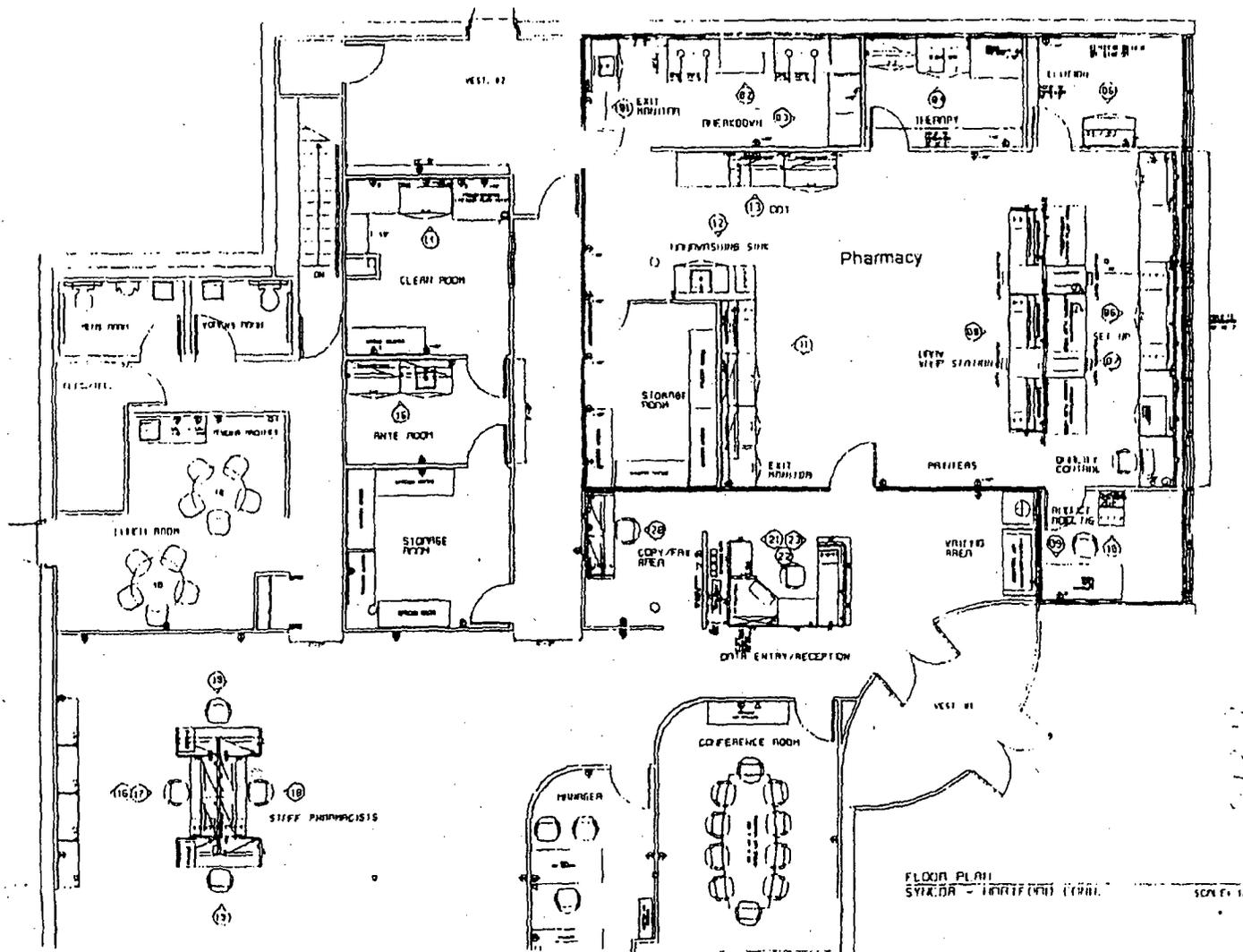


Figure 2 Facility Floor Plan The restricted area is outlined in black

Syncor International Corporation

GLASTONBURY, CT
Date: 04/26/2001

**FACILITY AND EQUIPMENT
GRIFFITH, IN**

Site Description

1. This facility is located at 200 Ivanhoe Court, Griffith, IN 46319. This single story, multi-tenant building utilizes concrete tilt-up construction. The west wall of this facility is shared with an adjacent tenant. The heating and cooling system is exclusive for this facility.
2. Please see the attached site plan.

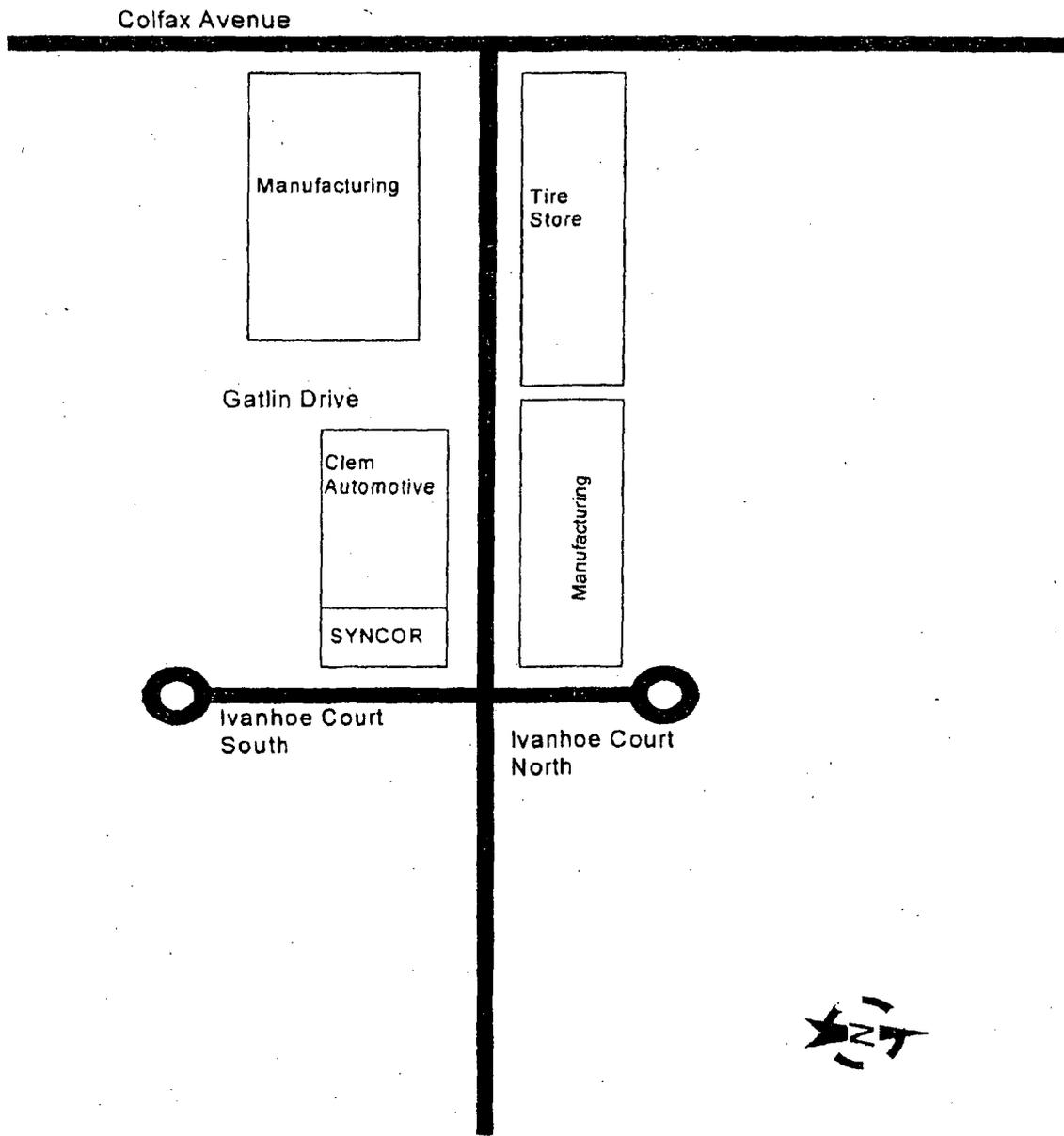


Figure 1 Site Plan

Syncor International Corporation

GRIFFITH, IN
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 5175 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1650 square feet

Generator Room (Elution) - 105 square feet

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

Volatile Substance Room (Therapy) - 105 square feet

This room houses the fume hood and glove box type fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent is 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. This room is labeled IODINE on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 735 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 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. This area is labeled DISPENSING on the floor plan.

Radioactive Waste Storage and Break Down Area - 156 square feet

This room is used for the storage and decay of waste materials. Waste is stored in lead barrels of approximately 16" x 16" x 32 x 3/8", and 1/2" thick lead. 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. This area is labeled WASTE on the floor plan.

Supply Room - 125 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 mR/hr) prior to final decay and transfer to the medical waste hauler. This area is labeled STORAGE on the floor plan.

Labeling (WBC Tagging Area) - 95 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This area is labeled LABELING on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled VESTIBULE. 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.

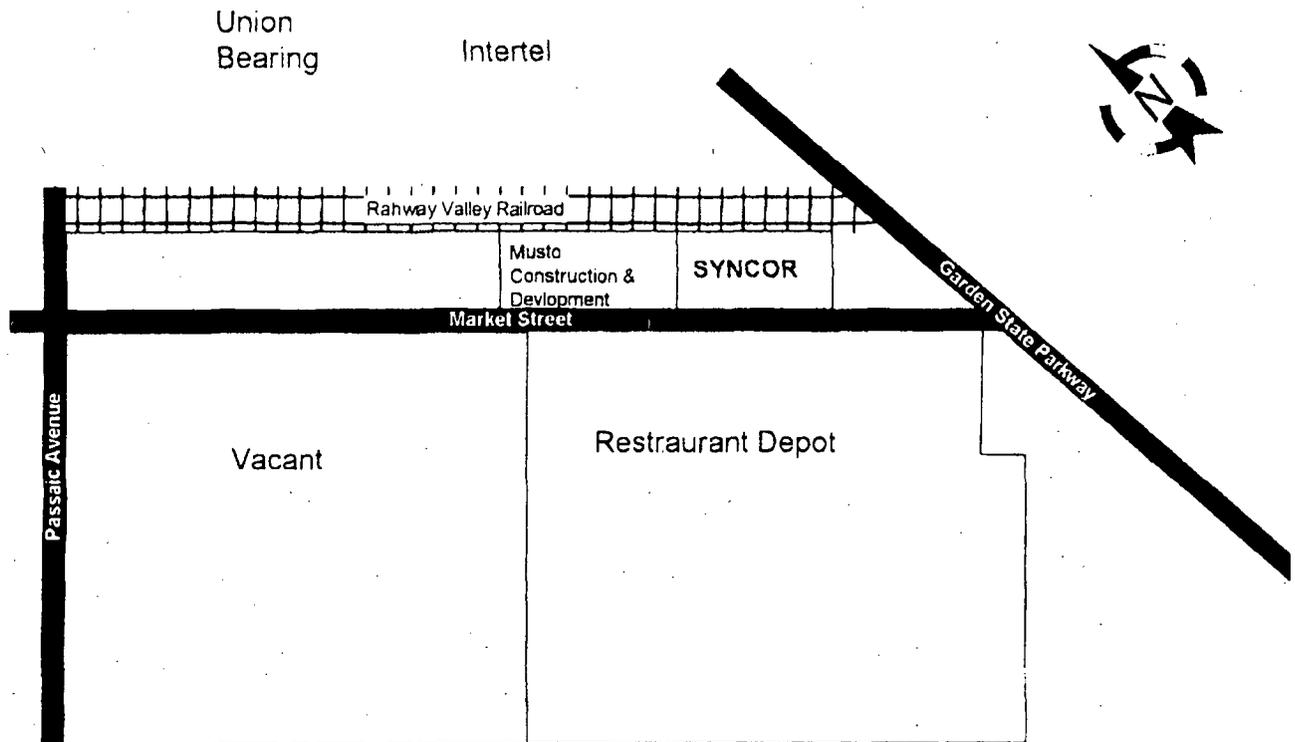
UNRESTRICTED AREA

See attached floor plan.

**FACILITY AND EQUIPMENT
KENILWOTH, NJ (CURRENT LOCATION)**

Site Description

1. This facility is located at 130 Market Street, Kenilworth, NJ 07033. This single story, freestanding building utilizes concrete block construction. The west wall of this facility is shared with an adjacent tenant. The heating and cooling system is exclusive for this facility.
2. Please see the attached site plan.



Residential Area

Figure 1 Site Plan

Syncor International Corporation

KENILWORTH, NJ
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 7200 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1738 square feet

Generator Room (Elution) - 105 square feet

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

Volatile Substance Room (Therapy) - 140 square feet

This room houses the fume hood and glove box type fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent is 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 1008 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 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. This area is labeled DISPENSING on the floor plan.

Container Processing Room - 170 square feet

This room is used for the storage and decay of waste materials. Waste is stored in lead barrels 18.5" in diameter, 24" high and 1/4"-3/4" thick. This area is used for receipt and handling of radiopharmaceutical deliveries. This area is labeled CASE RETURN on the floor plan.

Storage Room - 125 square feet

This room is also used for the storage and decay of radioactive waste materials. Waste is stored in lead barrels 18.5" in diameter, 24" high and 1/4"-3/4" thick. This area is labeled STORAGE on the floor plan.

Labeling (WBC Tagging Area) - 95 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This area is labeled LABELING on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled VESTIBULE. 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.

UNRESTRICTED AREA

See attached floor plan.

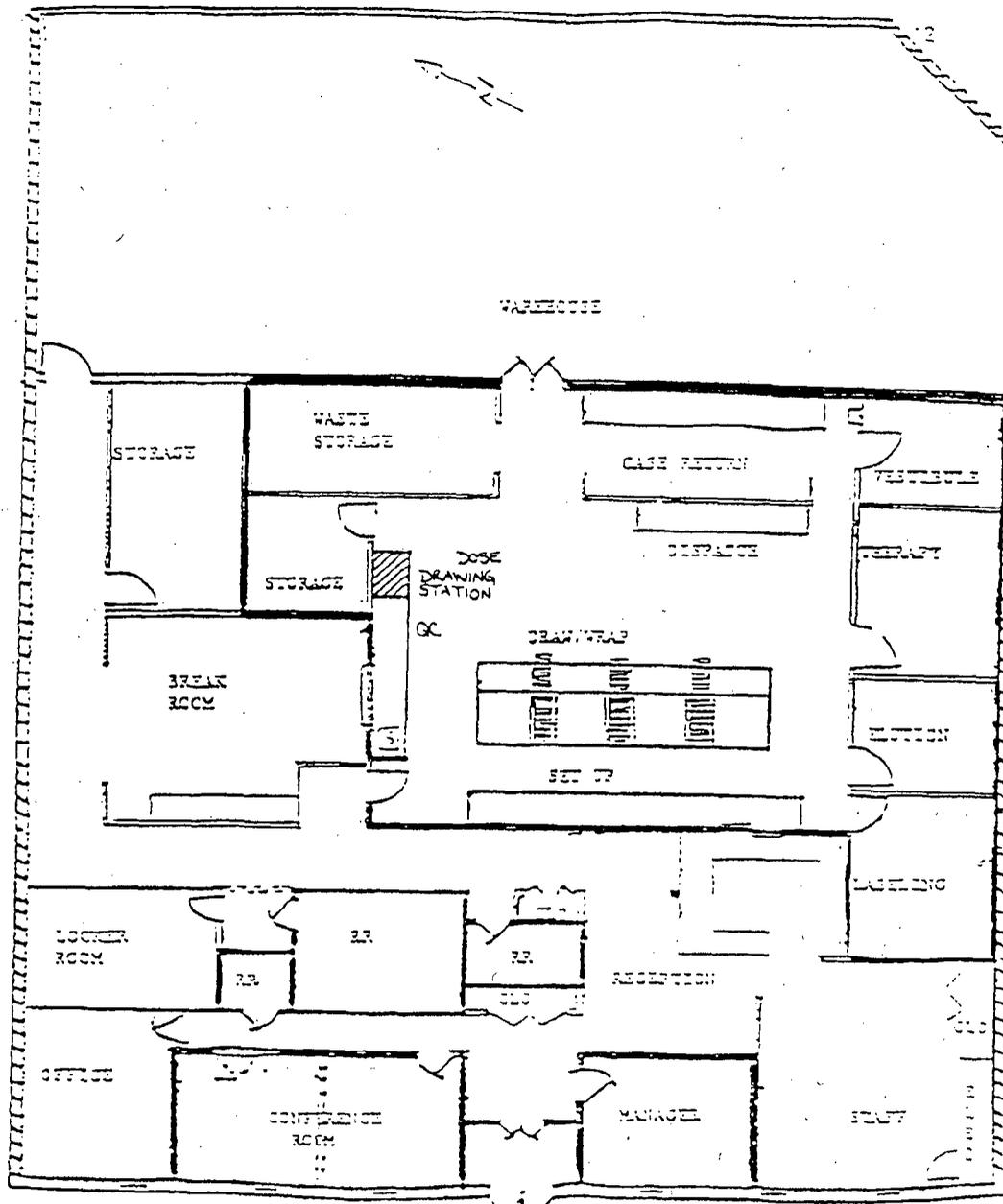


Figure 2 Facility Floor Plan The restricted area is outlined in black.

Syncor International Corporation

KENILWORTH, NJ
Date: 04/26/2001

**FACILITIES AND EQUIPMENT
MOUNTAINSIDE, NJ
(PROPOSED LOCATION FOR FACILITY CURRENTLY LOCATED IN
KENILWORTH, NJ)**

Site Description

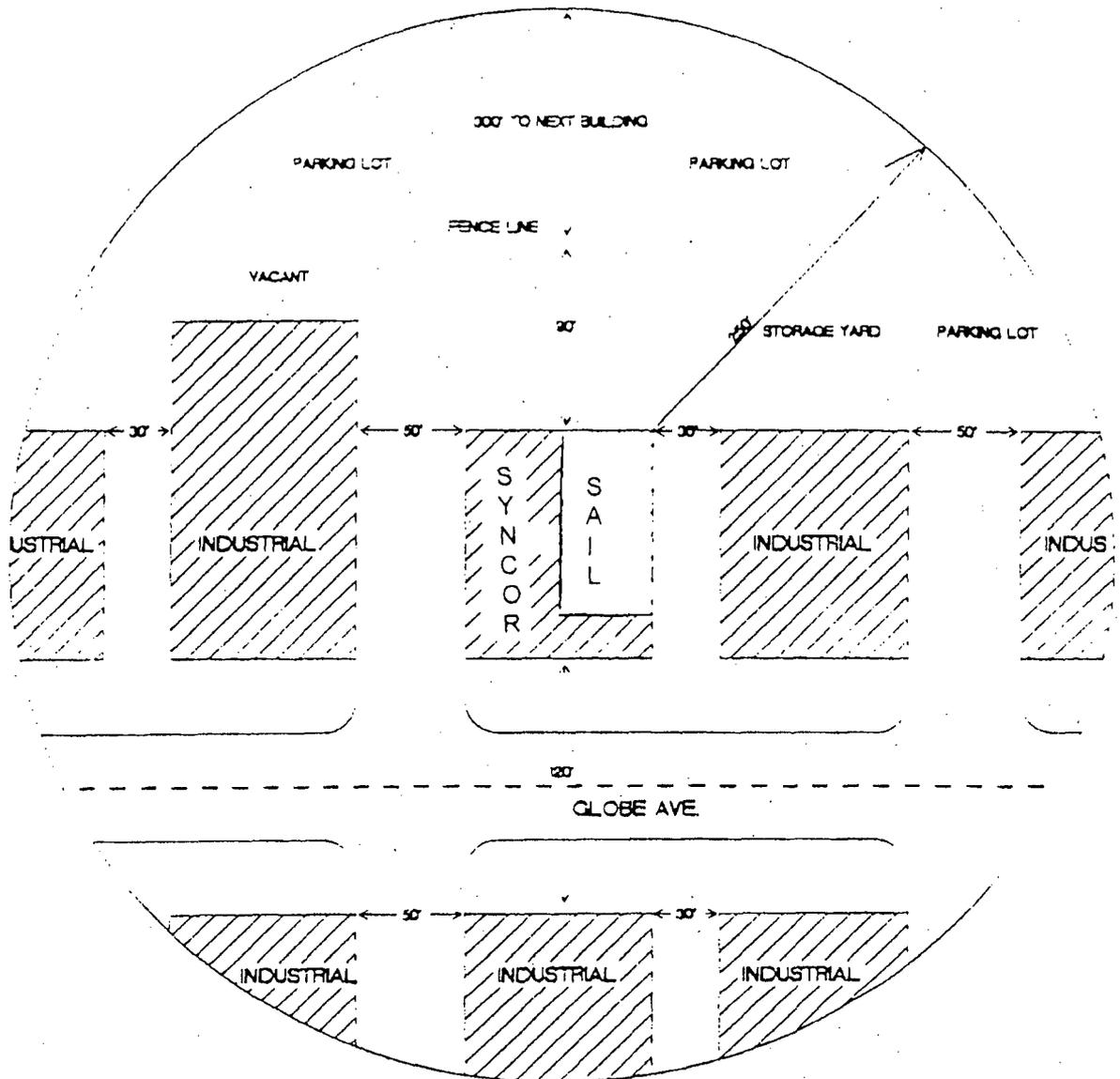
1. This facility is located in a commercial/industrial type area at:

Syncor International Corporation
1094 Globe Avenue
Mountainside, NJ 07092

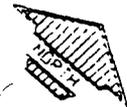
This single-story, multi-tenant building utilizes concrete block construction. One common wall on the northeast side of our facility is shared with Syncor Advanced Isotopes, LLC (SAIL). SAIL is a subsidiary of Syncor International Corporation whose operations are independent of those of the pharmacy. A wall monitor will be placed on the common wall. The heating and cooling system is exclusive for this facility.

2. Please see the site plan shown in Figure 1.

SITE PLAN



NEWARK, LOC #19
1094 GLOBE AVE.
MOUNTAINSIDE, N.J.
LOT 8P, BLOCK 23C



SCALE 1" = 70'-0"

Figure 1 Site Plan

Syncor International Corporation

MOUNTAINSIDE, NJ
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 6300 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 2700 square feet

Elution Room - approximately 115 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled ELUTION on the diagram.

Therapy Room - approximately 110 square feet

This area also houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled THERAPY on the diagram.

Sterile Prep Area - approximately 120 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled STERILE PREP AREA on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 1350 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps.

Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled DISPENSING on the diagram.

Radioactive Waste Storage Area - approximately 96 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled WASTE STORAGE on the diagram.

Container Processing Area - approximately 225 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled CASE RETURN on the diagram.

The other portions of the Restricted Area are used for supply storage (area labeled SUPPLY) and for storage of non-radioactive medical waste (area labeled MED STORAGE).

UNRESTRICTED AREA

Vestibule Area - approximately 423 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *DROP OFF* on the diagram.

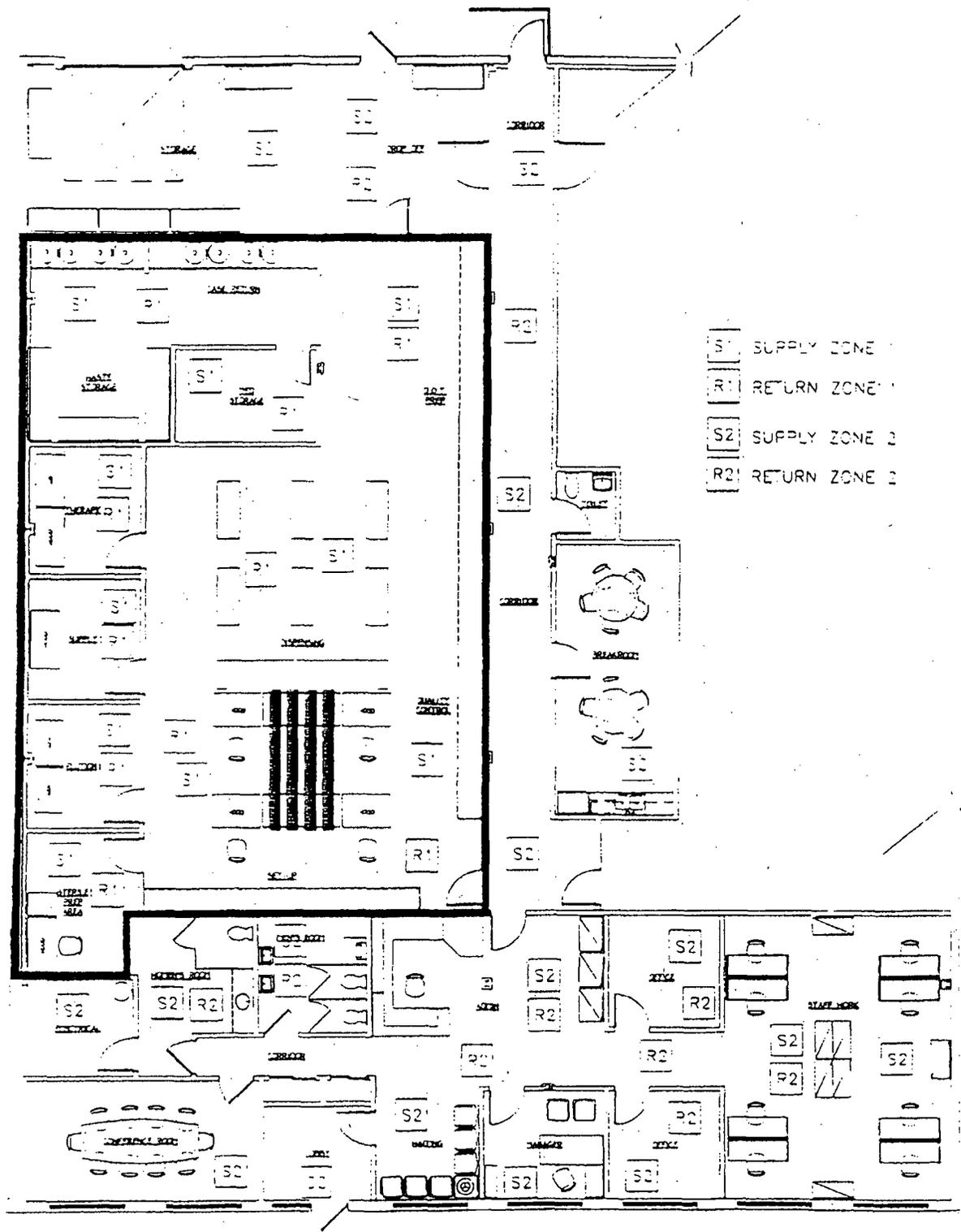


Figure 2 Facility Floor Plan. The restricted area is outlined in black.

Syncor International Corporation

MOUNTAINSIDE, NJ
 Date: 04/26/2001

**FACILITIES AND EQUIPMENT
BETHLEHEM, PA**

1. This facility is located in a commercial/industrial type area at:

Syncor International Corporation
2444 Brodhead Road, Suite F
Bethlehem, PA 18017

2. This facility is in a single-story, multi-tenant building and utilizes cinder block construction with a concrete slab floor. The east wall of the facility is shared with an adjacent tenant as shown in Figure 1. A wall monitor will be placed on the common wall. The heating and cooling system is exclusive for the restricted area.

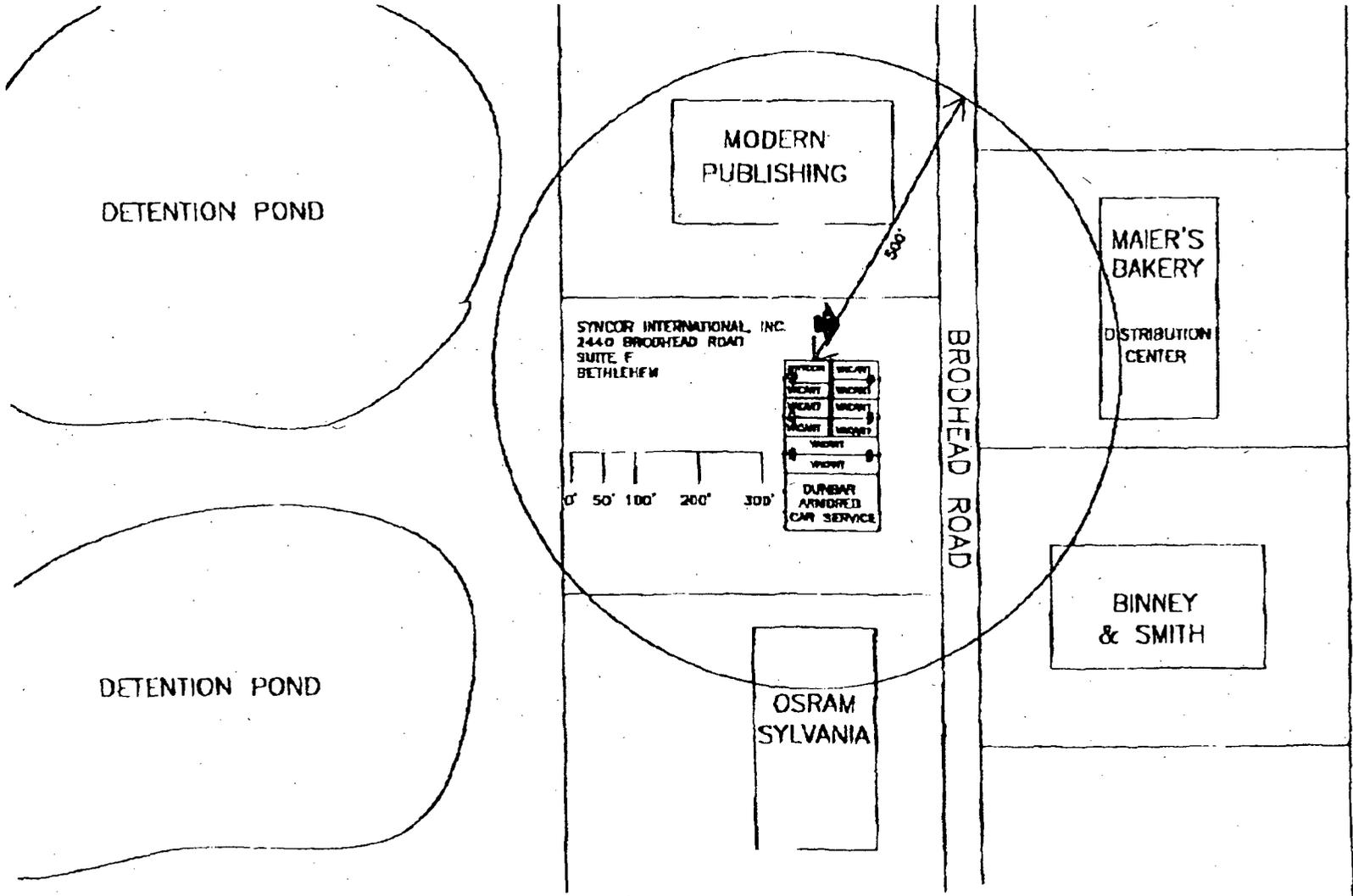


Figure 1 Site Plan

BETHLEHEM, PA
Date: 04/26/2001

Sincor International Corporation

General Description of Facility

Syncor International Corporation has leased approximately 2660 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1300 square feet

Elution Area – approximately 70 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled GENERATOR ROOM on the diagram.

Volatile Substance Room (Therapy) – approximately 100 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled THERAPY on the diagram.

Labeling Room – approximately 70 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area is labeled LABELING on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) – approximately 620 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps.

Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled DISPENSING on the diagram.

Container Processing Area – approximately 105 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled BREAKDOWN on the diagram.

Waste Storage Room – approximately 160 square feet

This area will also be used for the storage and decay of waste. This area is labeled RAM STORAGE on the diagram.

UNRESTRICTED AREA

Vestibule Area – approximately 90 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled VESTIBULE on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

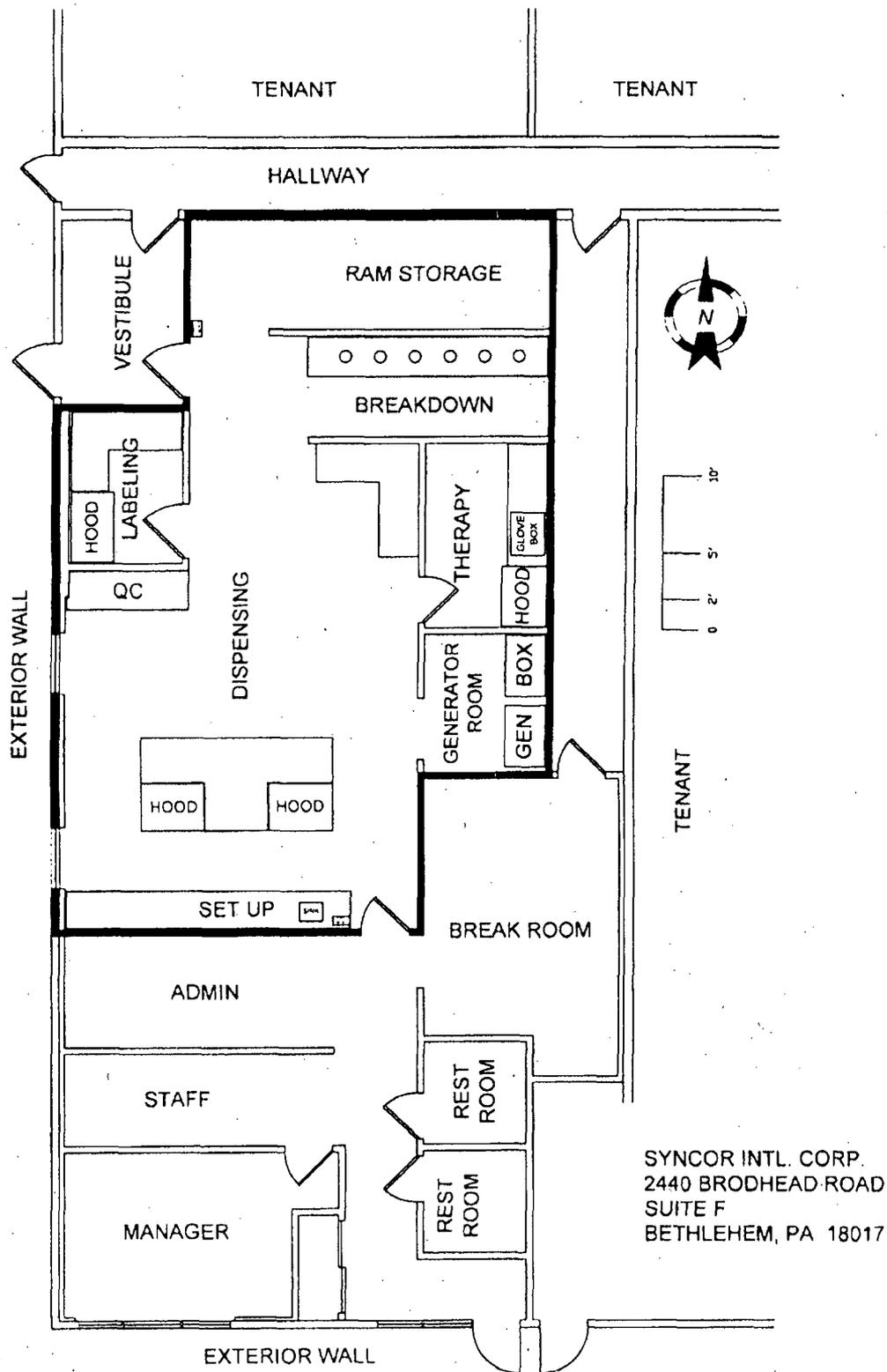


Figure 2 Facility floor plan. The restricted area is outlined in black.

**FACILITIES AND EQUIPMENT
SWARTZ CREEK, MI**

Site Description

1. This Syncor facility is located in a commercially zoned area at 5370 Miller Road, Suite #25, Swartz Creek, Michigan, 48473. The building is constructed of steel, concrete, and brick. The south wall of this facility is shared with an adjacent tenant. The shared wall is a fire wall, which extends to the roof of the building. The heating and cooling system is exclusive for Syncor's facility, with no air being recirculated to the adjacent tenants' offices.
2. Please see the attached area diagram.

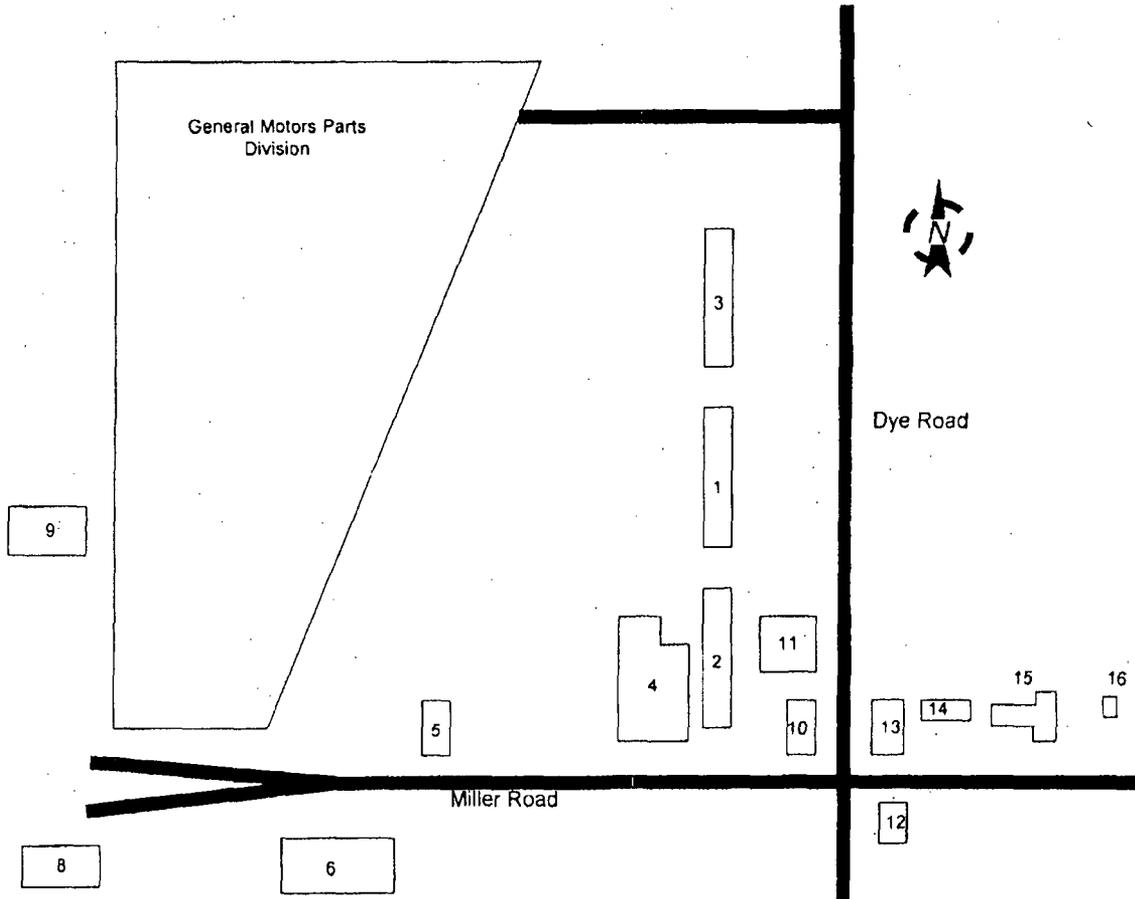


Figure 1 Site Plan

Syncor International Corporation

SWARTZ CREEK, MI
Date: 04/26/2001

Key For Location Map

1. 5370 Miller Road, Building B Suites 21, 22, 23, 24, 25, 26
Suites 21 & 22 - Midwest Wireless
Suites 23, 24, 25 & 26 - Syncor International Corporation
2. 5370 Miller Road, Building A Suites 11, 12, & 13
Suite 12 - The Mallory Group Realtors
Suites 11 & 13 - Flint Surveying and Engineering
3. 5370 Miller Road, Building C Suites 31, 32, 33, 34, 35 & 36
Suites 31 & 32 - DHL Worldwide Express
Suite 33 - Neuro Behavior Diagnostic and Treatment
Suite 34 - Michigan Safety
Suite 35 - Healthcare Technologies
Suite 36 - AFLAC
4. Hager Fox
5. Bunt Shop
6. Genesec Valley Golf Club
7. O'Tooles Restaurant
8. Strip Mall
9. Closest Farm (3 miles from release point, Syncor Int. Corp)
10. Private Residence
11. Ford's Party Rental
12. Pesto's Restaurant
13. Randy's Party Store
14. Speedway Gas Station
15. Old Kent Bank
16. The Surgery Center
17. Sunco Gas Station
18. G.M. Parts Division

General Description of Facility

Syncor International Corporation has leased approximately 2960 square feet for use as a radiopharmacy in a single story building located in a commercially zoned area.

Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA

Radiopharmaceutical Dispensing Lab - approximately 528 square feet

This area is used for preparing and dispensing radiopharmaceuticals. Each drawing station consists of a lead L-block shield with leaded glass, a dose calibrator, and a set of forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers. The refrigerator is utilized for storage of both radiopharmaceuticals (in appropriate shielding) and cold kits needing refrigerated storage. Quality control, as well as shipping and packaging are done in this area. This area is labeled PHARMACY on the floor plan.

Generator Room – approximately 64 square feet

This area is used for storage of ongoing, used radiopharmaceuticals, including Mo99/Tc99m generators. Benches are provided for generator storage and elution. All actively used generators are housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the perimeter of the storage bench. Other materials are stored in their original shipping containers behind auxiliary lead shielding. This room is labeled ELUTION on the floor plan.

Therapy Room – approximately 77 square feet

This room houses the fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility due to the exhaust of the continuously operating fume hood. No return vents are located in this room, thereby ensuring that no air from this room is circulated to any other area of the facility. This room is labeled THERAPY on the floor plan.

Indium WBC Room – approximately 88 square feet

This area houses the biohazard hood for use in tagging cellular blood components. This room is labeled LABELING/IVP on the floor plan.

Waste Storage Area - approximately 102 square feet

Syncor International Corporation

SWARTZ CREEK, MI
Date: 04/26/2001

This area is used for the storage and decay of waste. This area is labeled DECAY on the floor plan.

Container Processing Area- approximately 140 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled CASE RETURN on the floor plan.

UNRESTRICTED AREA

Vestibule -

This area is designated for deliveries of radioactive material during off duty hours. Common carriers will have keyed access to the vestibule but will not have access to the restricted area. This area is labeled VESTIBULE on the floor plan.

FLINT # 25

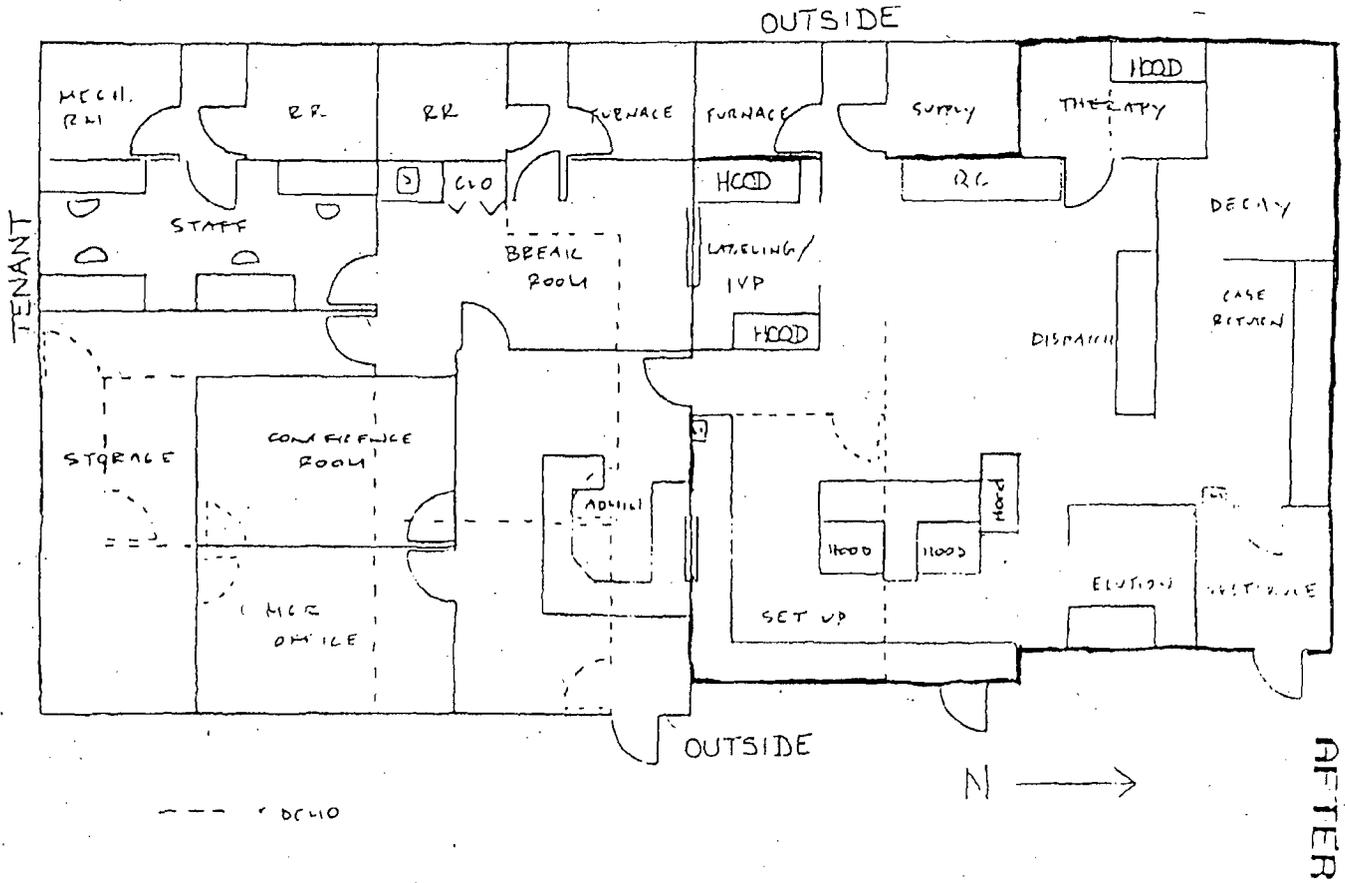


Figure 2 Facility Floor Plan The restricted area is outlined in black

Syncor International Corporation

SWARTZ CREEK, MI
Date: 04/26/2001

**FACILITY AND EQUIPMENT
KANSAS CITY, MO**

Site Description

1. This Syncor facility will be located in a commercially zoned area at Bannister Square Business Park, 9668-9670 Marion Park Drive, Kansas City, MO 64137. This single story building utilizes brick and steel frame construction. The east wall of this facility is shared with an adjacent tenant, however, the adjacent space is unoccupied at this time. The common wall is a fire wall which extends to the roof of the building. 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.



DANNISTER SQUARE BUSINESS PARK - BUILDING SITES FOR SALE

LOCATED SOUTH EAST CORNER OF DANFORTH AND E-35, KANSAS CITY, MISSOURI
AT THE DANFORTH INDUSTRIAL AND LABOR CENTER
OFFICE ACCESS ROUTE 35A FROM I-435 AND THE FUTURE DANFORTH INDUSTRIAL
TRUCK RAIL STATION IS TRAILS SYCAMORE, AND INDUSTRIAL
TRAIL PARKS SOUTH A DISTRICT

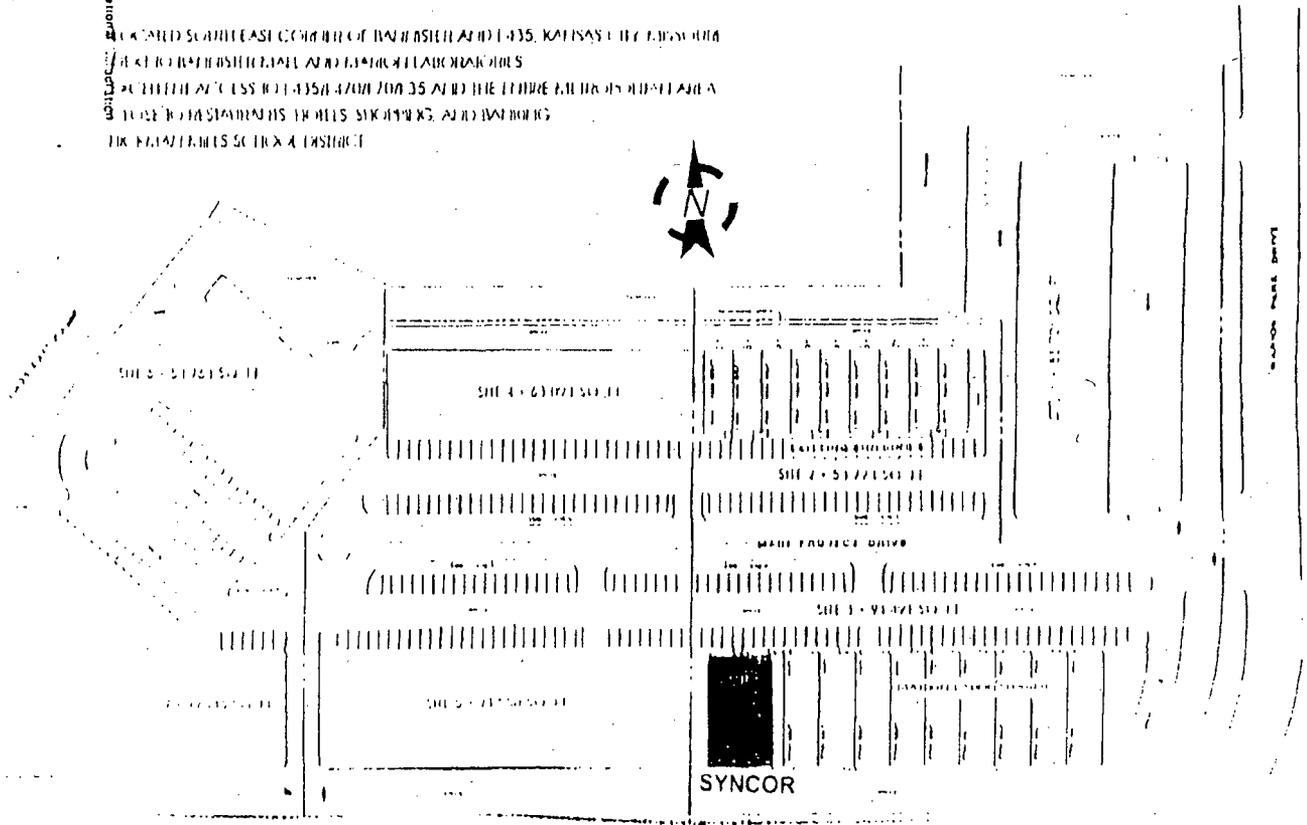


Figure 1 Site Plan

Syncor International Corporation

KANSAS CITY, MO
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 5000 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA - 1000 square feet

Generator Room (Elution) - 100 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. This room is labeled ELUTION on the floor plan.

Volatile Substance Room (Therapy) - 100 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 252 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. This room is labeled PHARMACY on the floor plan.

Radioactive Waste Storage and Break Down Area - 168 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 1/4"-3/4" 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. This room is labeled BREAKDOWN on the floor plan

Storage - 100 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 mR/hr) prior to final decay and transfer to the medical waste hauler. This room is labeled STORAGE on the floor plan.

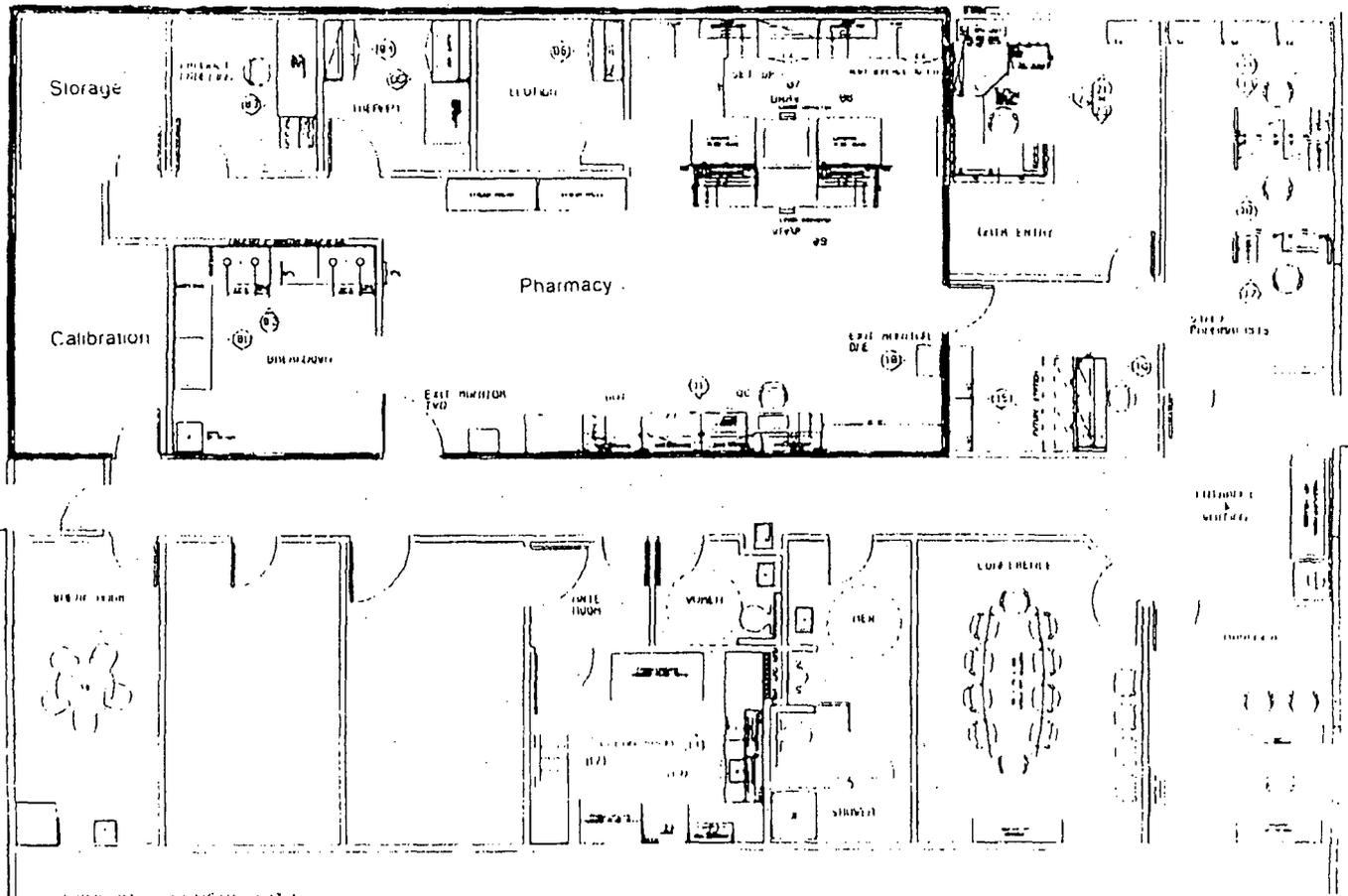
Labeling (WBC Tagging Area) - 100 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This room is labeled PRODUCT LABELING on the floor plan.

Calibration Room - 150 square feet

This area will be used for calibration of survey meters and monitoring equipment. See Appendix A. This room is labeled CALIBRATION on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled VESTIBULE. 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.



STORON KANSAS CITY
FLOOR PLAN (11)

Figure 2 Facility Floor Plan The restricted area is outlined in black.

Syncor International Corporation

KANSAS CITY, MO
Date: 04/26/2001

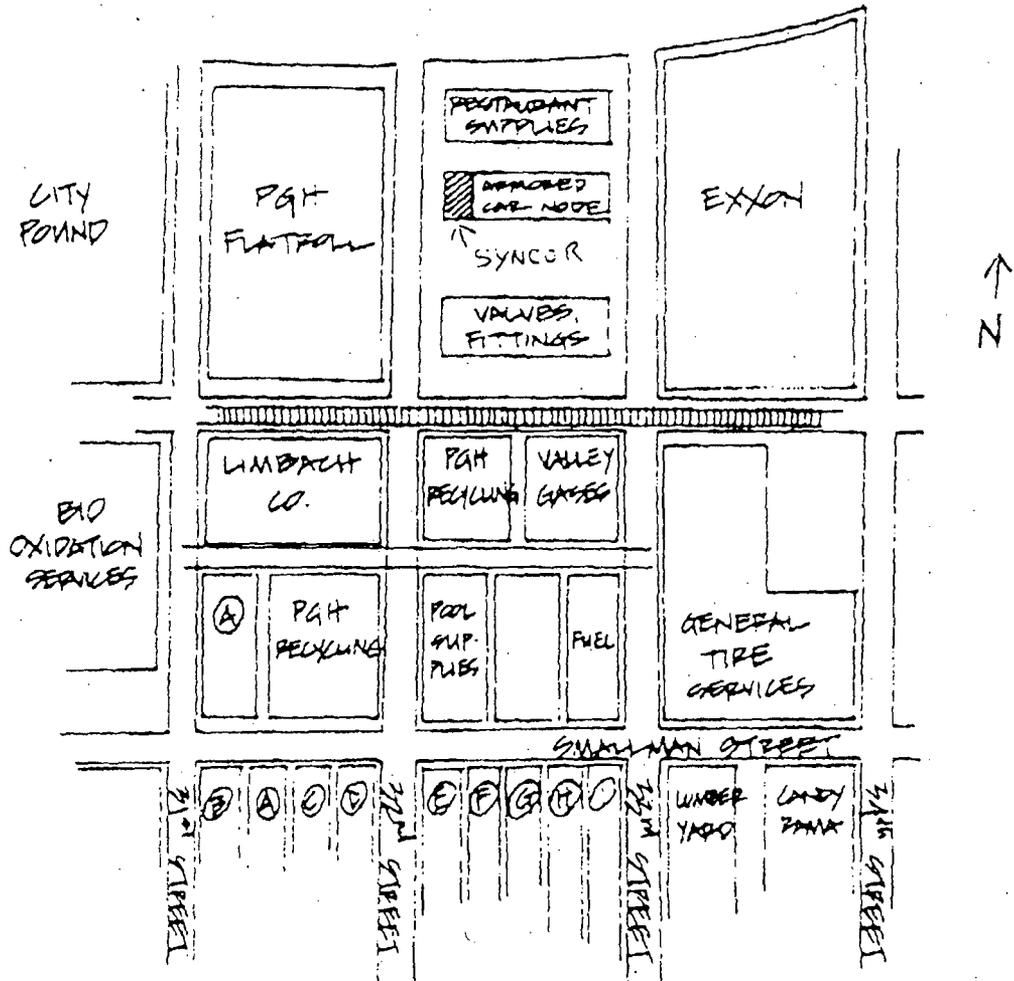
FACILITY AND EQUIPMENT
Pittsburgh, PA

1. This facility is located in a commercial/industrial type area at:

Syncor International Corporation
70 33rd Street, Suite A
Pittsburgh, PA 15201

2. This facility is in a single-story, multi-tenant building and utilizes cinder block construction with a concrete slab floor. The east wall of the facility is shared with an adjacent tenant as shown in Figure 1. A wall monitor will be placed on the common wall. The heating and cooling system is exclusive for the restricted area.

A L L E G H E N Y R I V E R



Syncor International Corporation
 70 33rd Street, Suite A
 Pittsburgh, PA 15201

- A - SHEET METAL
- B - ITALIAN RESTAURANT
- C - TRUCK PARTS
- D - GEMCO SALES
- E - VALVES
- F - AUTO REPAIR
- G - ELECTRICAL PARTS
- H - VACANT
- I - SPICE/CONDENSING CASING

Figure 1 Site Plan

PITTSBURGH, PA
 Date: 04/26/2001

Syncor International Corporation

General Description of Facility

Syncor International Corporation has leased approximately 5000 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 2315 square feet

Elution Area – approximately 120 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled ELUTION on the diagram.

Volatile Substance Room (Therapy) – approximately 130 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled IODINE on the diagram.

Labeling Room – approximately 100 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area is labeled LABELING on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) – approximately 650 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps.

Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled DISPENSING on the diagram.

Container Processing Area – approximately 140 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled CASE RETURN on the diagram.

Waste Storage Room – approximately 140 square feet

This area will also be used for the storage and decay of waste. This area is labeled RAM WASTE on the diagram.

UNRESTRICTED AREA

Vestibule Area – approximately 50 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled VESTIBULE on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

Syncor International Corporation
70 33rd Street, Suite A
Pittsburgh, PA 15201

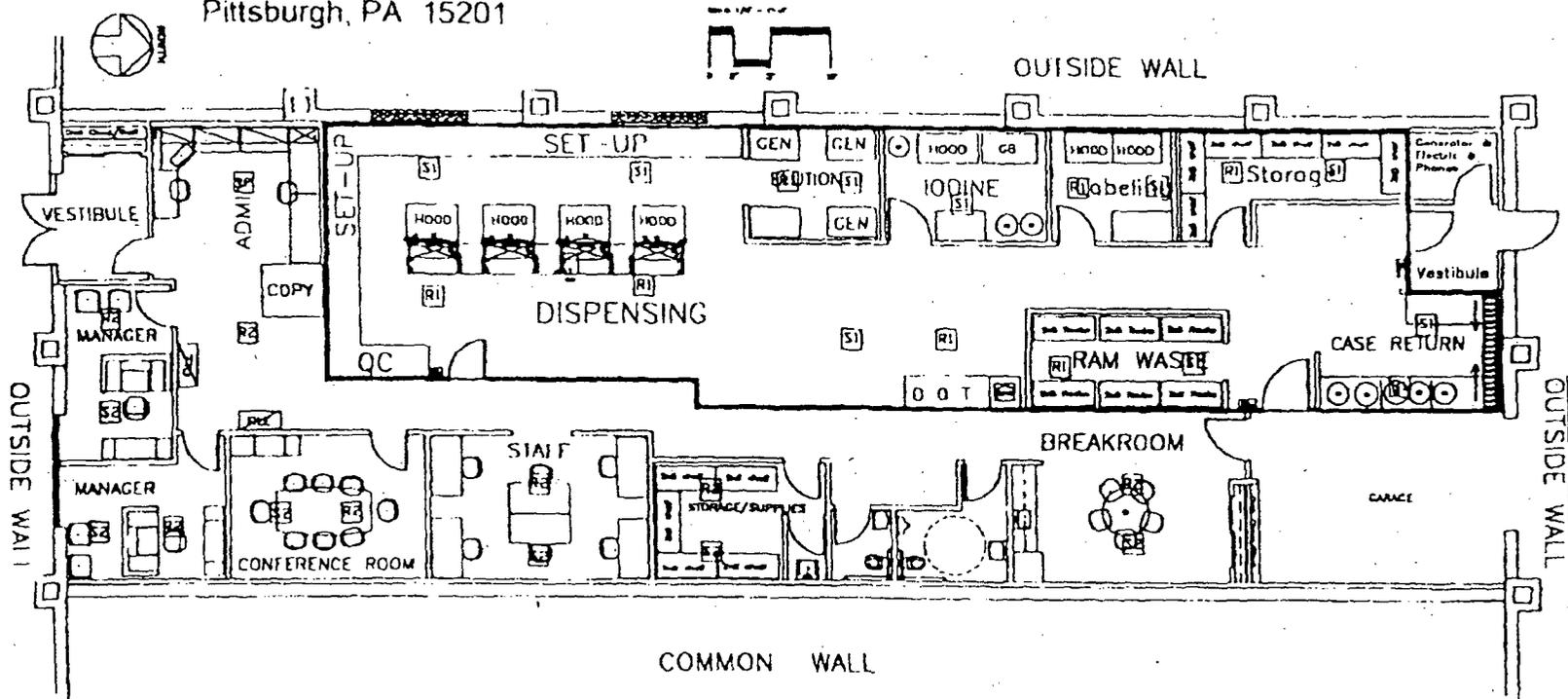


Figure 2 Facility Floor Plan. The restricted area is outlined in black.

PITTSBURGH, PA
Date: 04/26/2001

Syncor International Corporation

**FACILITY INFORMATION
ST. LOUIS (OVERLAND), MO**

Site Description

1. This Syncor facility will be located in a commercially zoned area at: 1901 Beltway Drive, St. Louis, Missouri, 63114

This multi-tenant building is constructed of steel frame, glass and metal steel and concrete. The walls on the north and southeast sides of the facility are shared with adjacent tenants.

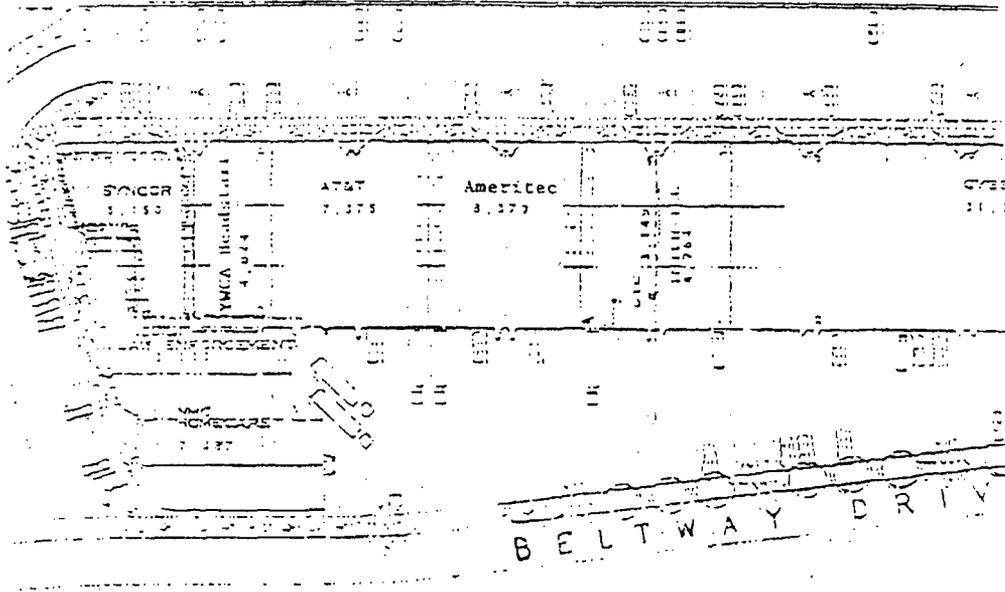
This office space has its own heating and cooling system, and the walls between the pharmacy and adjacent tenants are one hour fire walls which extend to the roof of the building.

The pharmacy space HVAC system is a dedicated roof top unit

2. Please see the attached site plan.

EXHIBIT D
DESIGNATED PARKING SPACE LOCATIONS

These spaces shall remain the sole property of the City of St. Louis, Missouri, and shall be used for the parking of vehicles of the Syncor International Corporation, its employees and its visitors in a non-exclusive and undesignated area. Five (5) of these spaces, as designated on the plan below, shall be designated for Syncor's exclusive, reserved use.



SYNCOR INTERNATIONAL CORPORATION
LOCATION 30, OVERLAND, MO.

I-170 CENTER

NORTH →

Figure 1 Site Plan

Syncor International Corporation

ST. LOUIS (OVERLAND), MO
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 5,150 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA

See attached sketch.

Generator Room - 64 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. This room is labeled GENERATOR ROOM on the floor plan.

Volatile Substance Room - 64 square feet

This room will also 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. This room is labeled THERAPY ROOM on the floor plan.

Radiopharmaceutical Dispensing Area - 700 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. A drawing station will be located as shown on the attached sketch. The drawing station 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. This area houses the biohazard hood for use in tagging cellular blood components. This area is labeled LAB AREA on the floor plan.

Radioactive Waste Storage and Break Down Area - 192 square feet

This waste storage room will be used for the storage and decay of waste materials. Waste will be stored in lead barrels of approximately 18.5 x 18.5 x 32 x 3/8" thick lead. The room will have seven of these. Ample lead bricks 2" x 4" x 8" are provided for additional shielding, as necessary. This area is labeled BREAKDOWN AREA on the floor plan.

UNRESTRICTED AREA

See attached floor plan.

NOTE: The room designated as "After Hours Delivery" in the unrestricted area will be used for receipt of radioactive packages during off-duty hours. This will prevent the common carrier from having access to the nuclear pharmacy area proper.

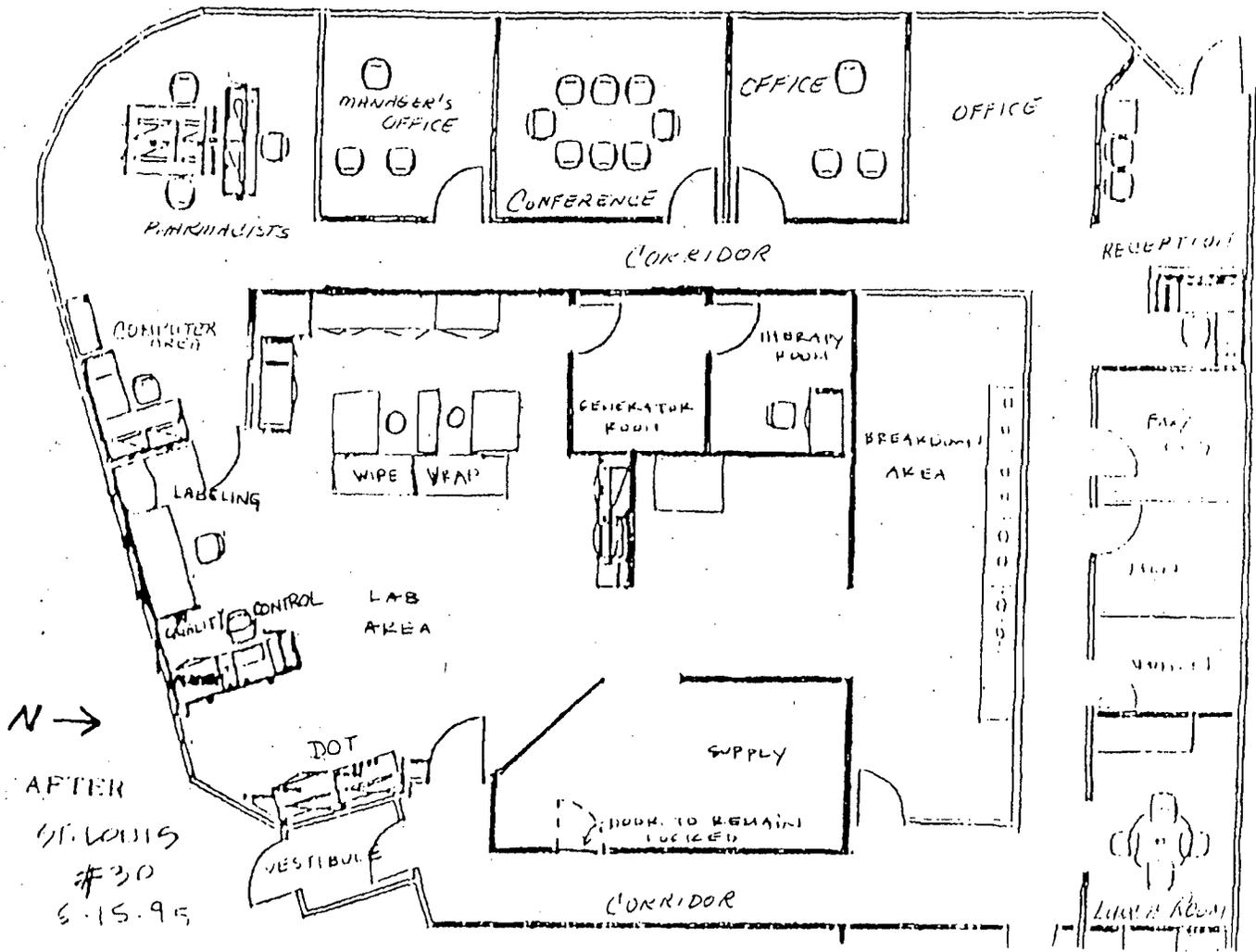


Figure 2 Facility Floor Plan The restricted area is outlined in black

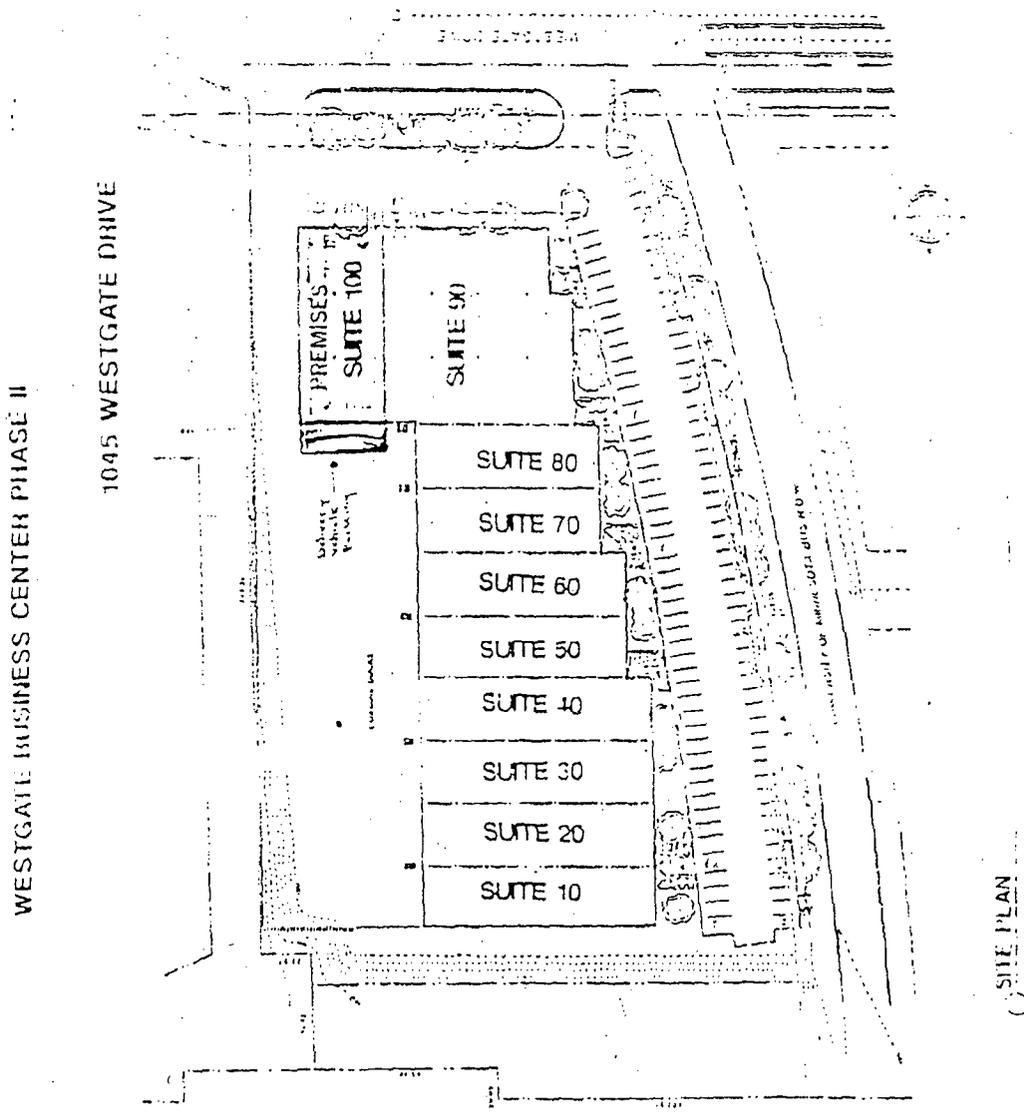
Syncor International Corporation

ST. LOUIS (OVERLAND), MO
 Date: 04/26/2001

**FACILITY AND EQUIPMENT
ST. PAUL, MN**

Site Description

1. This Syncor facility is located in a commercially zoned area at 1045 Westgate Drive, Suite 100, St Paul, MN 55114. This multitenant building is constructed of concrete block walls, concrete floor, and a flat roof. The south wall of this facility is shared with an adjacent tenant. The adjacent space is currently unoccupied. The common wall is a fire wall which extends to the roof of the building. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.



Syncor International Corporation - Suite 100
 Consortium Books - Suites 90, 30, 70, 60
 Northwestern Foods - Suites 50, 40, 30, 20, 10

Figure 1 Site Plan

Syncor International Corporation

ST PAUL, MN
 Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 6466 square feet of space for use as a radiopharmacy in a single story, multi-tenant building located in a commercially zoned area. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA

Generator Room (Elution) - 90 square feet

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

Volatile Substance Room (Therapy) - 100 square feet

This room will also house the fume hood and glove box type fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent is 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 132 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 are a minimum of 1" thick lead with leaded glass viewing windows.

Radiopharmaceutical Dispensing Area (continued)

Technetium and technetium products are 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, is done in this area. A refrigerator is also located in this area for storing radiopharmaceuticals and cold kits which require refrigeration. This area is labeled PHARMACY on the floor plan.

Radioactive Waste Storage and Break Down Area - 170 square feet

This room is used for the storage and decay of waste materials. Waste is stored in lead barrels of approximately 18.5 x 18.5 x 32 x 3/8" thick lead. 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. This room is labeled BREAKDOWN on the floor plan.

Storage -120 square feet

This area is used for storage of supplies and waste which has been decayed to low levels (i.e. less than 2 mR/hr) prior to final decay and transfer to the medical waste hauler. This room is labeled STORAGE on the floor plan.

Sterile (WBC Tagging Area) - 109 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This area is labeled BLOOD LABELING ROOM on the floor plan.

NOTE: After hours deliveries are made to the rear door in the room labelled warehouse. 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.

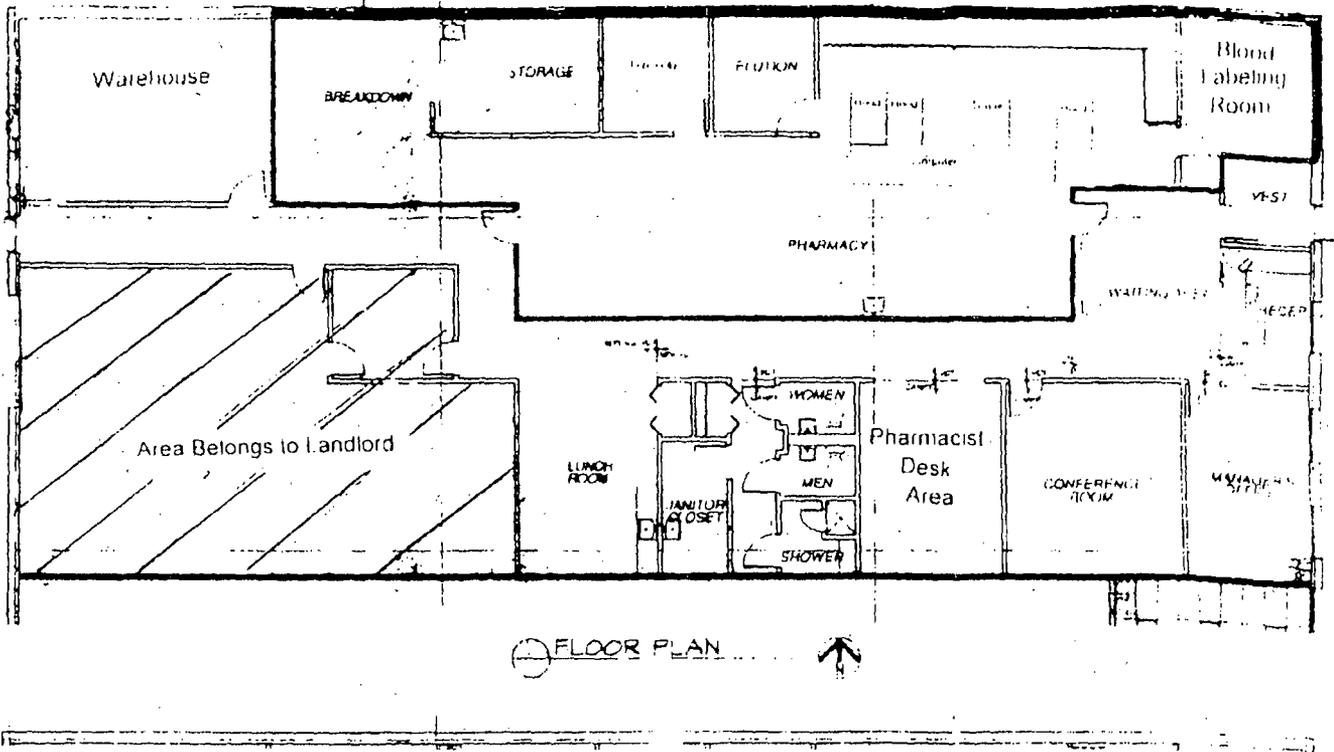


Figure 2 Facility Floor Plan The restricted area is outlined in black.

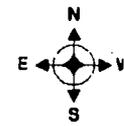
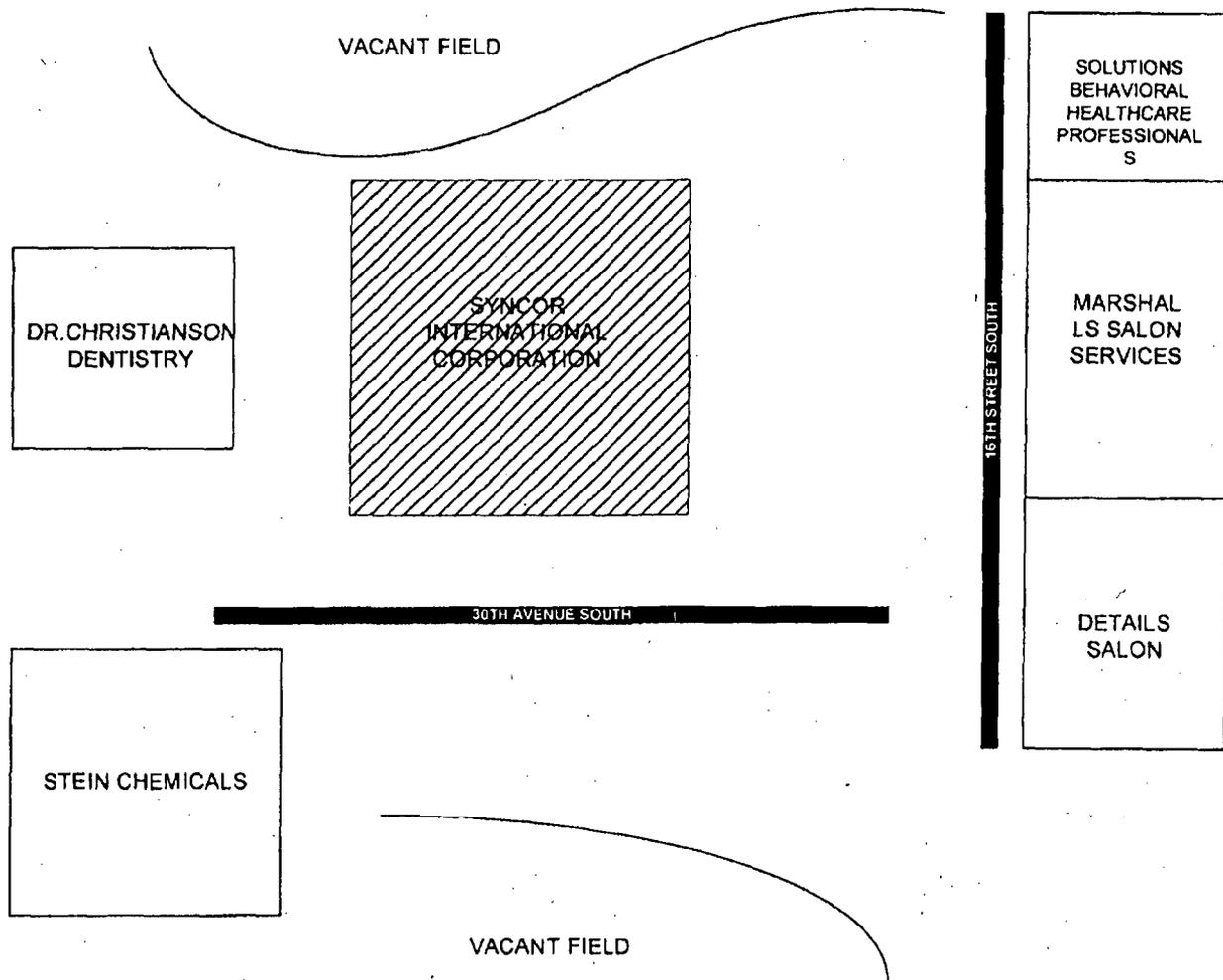
Syncor International Corporation

ST PAUL, MN
Date: 04/26/2001

FACILITY AND EQUIPMENT
Moorhead, MN

Site Description

1. This Syncor facility will be located in a commercially zoned area at 1610 30th Avenue, Moorhead, Minnesota 56560. This single story building utilizes concrete block construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.



Loc 39 Site
Moorhead,

Figure 1. Facility Site Plan
Syncor International Corporation

Moorhead, MN
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 2400 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 880 square feet

Elution Room - approximately 92 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *ELUTION* on the diagram.

Volatile Substance Room - approximately 92 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 111 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 460 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPATCH* on the diagram.

Radioactive Waste Storage - approximately 72 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *STORAGE* on the diagram.

Container Processing Area - approximately 53 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN* on the diagram.

Unrestricted Area - See Floor Diagram

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

Syncor International Corporation

**Moorhead, MN
Date: 4/26/2001**

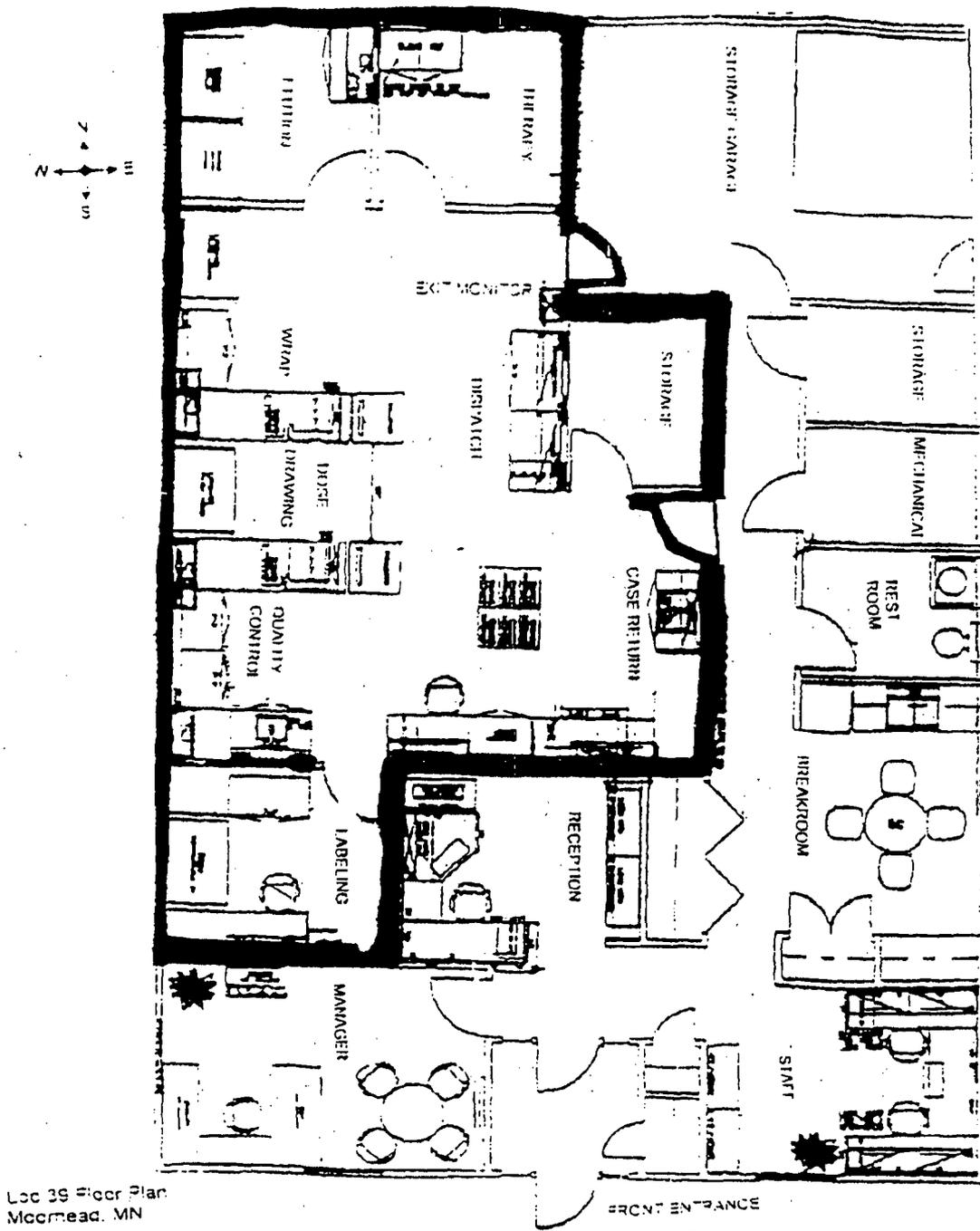


Figure 2. Facility Floor Plan

Syncor International Corporation

Moorhead, MN
Date: 4/26/2001

**FACILITY AND EQUIPMENT
Wauwatosa, WI**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 11829 W. Ripley Avenue, Wauwatosa, Wisconsin 53226. This one story building utilizes concrete brick construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

**FACILITY INFORMATION
GLASTONBURY, CT**

Site Description

1. This Syncor facility will be located in a free standing building in a commercially zoned area at: 628 Hebron Ave. Building D, Glastonbury, CT 06033. This single story building utilizes brick and steel frame construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

General Description of Facility

Syncor International Corporation has leased approximately 5200 square feet of space for use as a radiopharmacy in a single story, free standing building located in a commercially zoned area. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1700 square feet

Generator Room (Elution) - 88 square feet

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

Volatile Substance Room (Therapy) - 96 square feet

This room houses the fume hood and glove box type fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent is 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 803 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 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. This area is labeled PHARMACY on the floor plan.

Radioactive Waste Storage and Break Down Area - 192 square feet

This room is used for the storage and decay of waste materials. Waste is stored in lead barrels of approximately 16" x 16" x 32 x 3/8", and 1/2" thick lead. 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. This area is labeled BREAKDOWN on the floor plan.

Storage -140 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 mR/hr) prior to final decay and transfer to the medical waste hauler. This area is labeled STORAGE on the floor plan.

Labeling (WBC Tagging Area) - 95 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This area is labeled PRODUCT LABELING on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled Vest. 2. 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.

UNRESTRICTED AREA

See attached floor plan.

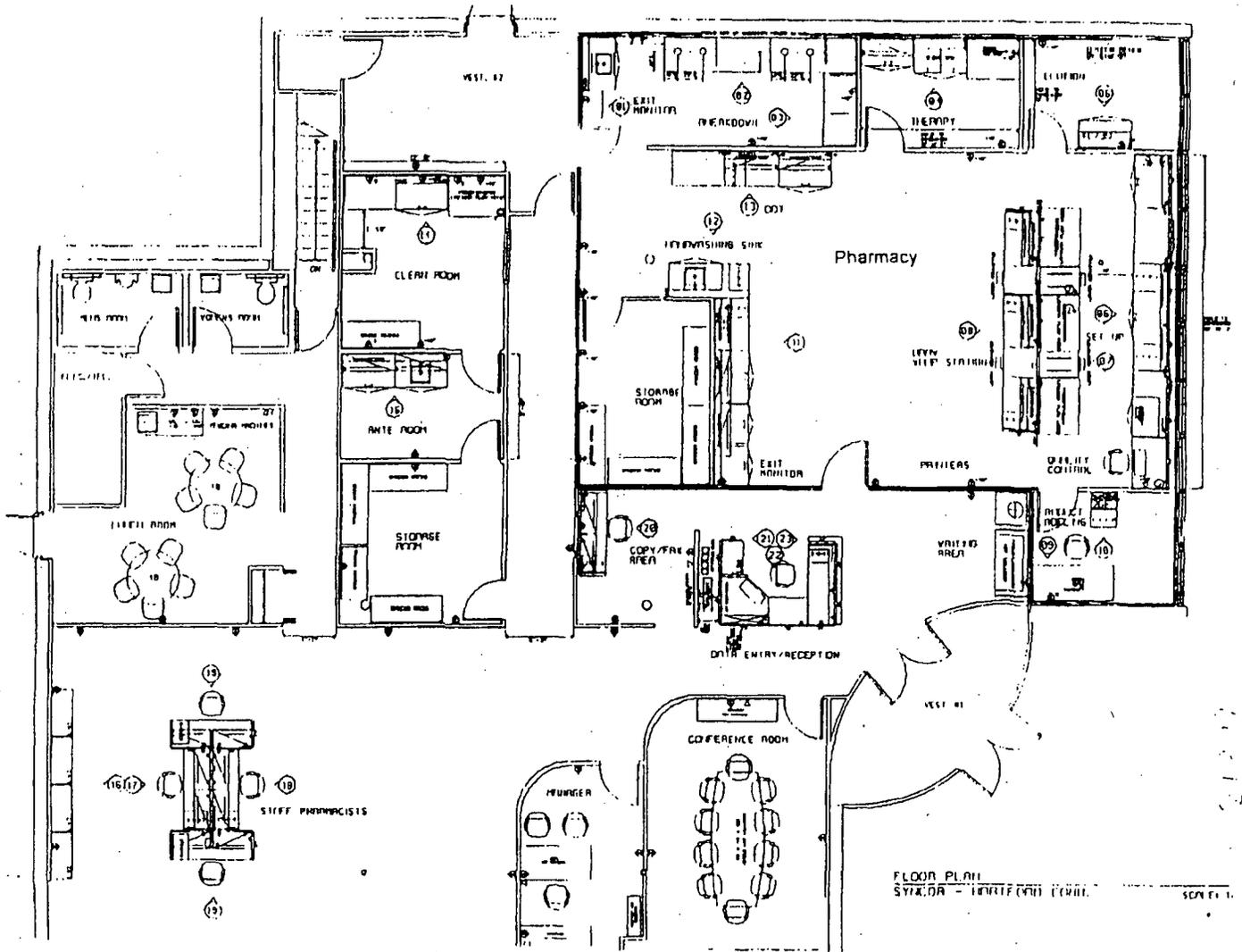


Figure 2 Facility Floor Plan The restricted area is outlined in black

Syncor International Corporation

GLASTONBURY, CT
Date: 04/26/2001

**FACILITY AND EQUIPMENT
GRIFFITH, IN**

Site Description

1. This facility is located at 200 Ivanhoe Court, Griffith, IN 46319. This single story, multi-tenant building utilizes concrete tilt-up construction. The west wall of this facility is shared with an adjacent tenant. The heating and cooling system is exclusive for this facility.
2. Please see the attached site plan.

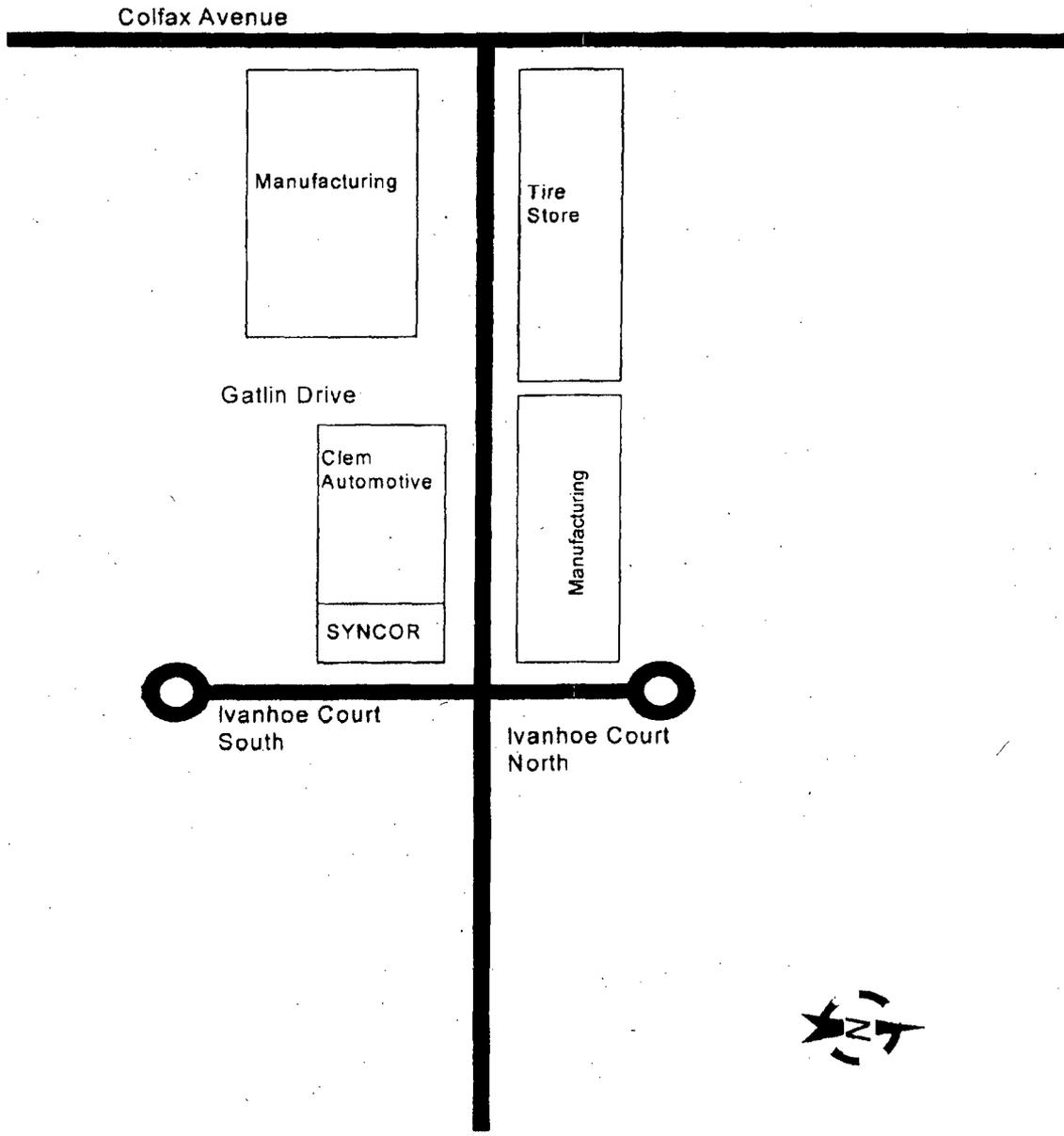


Figure 1 Site Plan

Syncor International Corporation

GRIFFITH, IN
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 5175 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1650 square feet

Generator Room (Elution) - 105 square feet

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

Volatile Substance Room (Therapy) - 105 square feet

This room houses the fume hood and glove box type fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent is 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. This room is labeled IODINE on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 735 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 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. This area is labeled DISPENSING on the floor plan.

Radioactive Waste Storage and Break Down Area - 156 square feet

This room is used for the storage and decay of waste materials. Waste is stored in lead barrels of approximately 16" x 16" x 32 x 3/8", and 1/2" thick lead. 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. This area is labeled WASTE on the floor plan.

Supply Room - 125 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 mR/hr) prior to final decay and transfer to the medical waste hauler. This area is labeled STORAGE on the floor plan.

Labeling (WBC Tagging Area) - 95 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This area is labeled LABELING on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled VESTIBULE. 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.

UNRESTRICTED AREA

See attached floor plan.

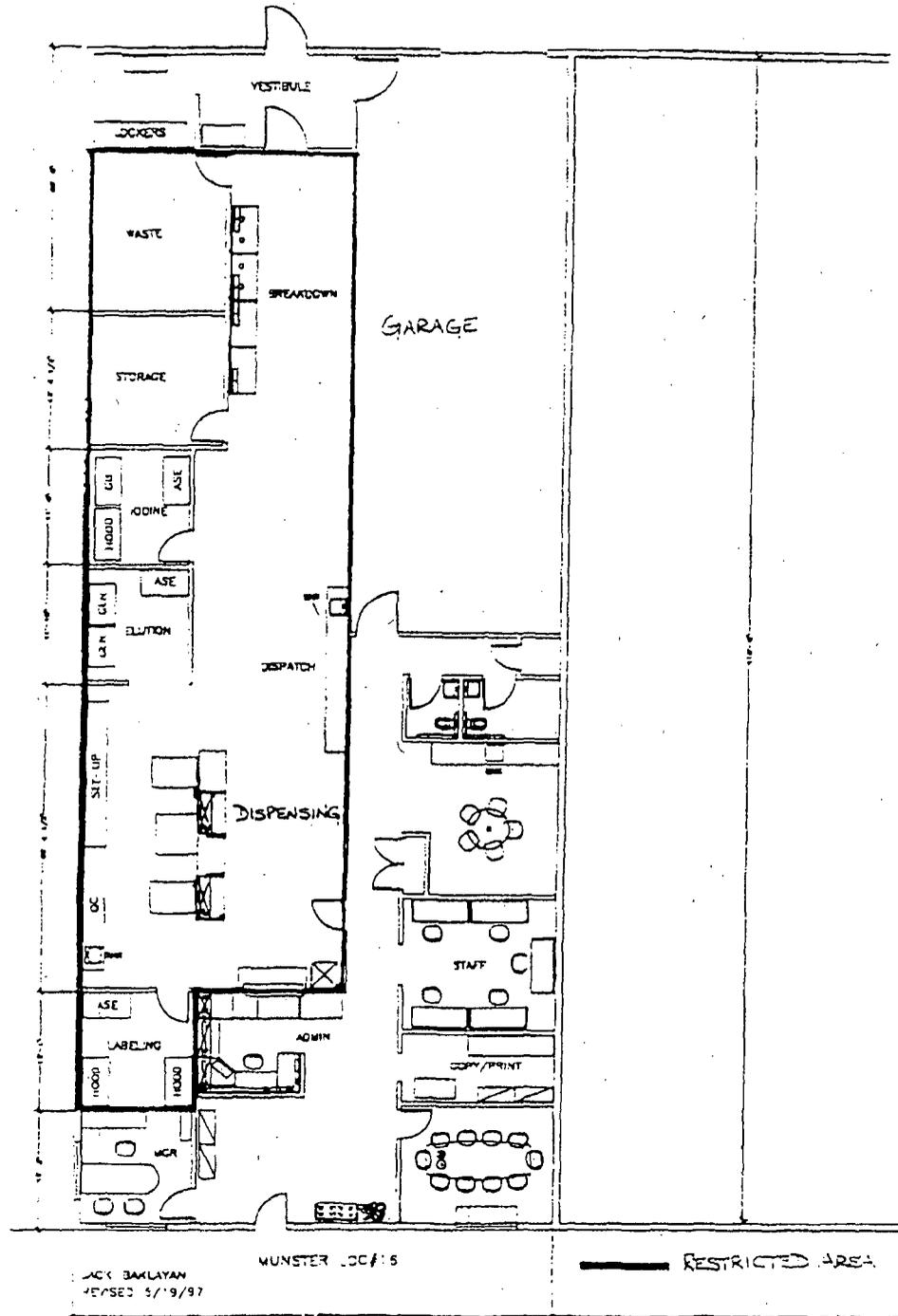


Figure 2 Facility Floor Plan The restricted area is outlined in black

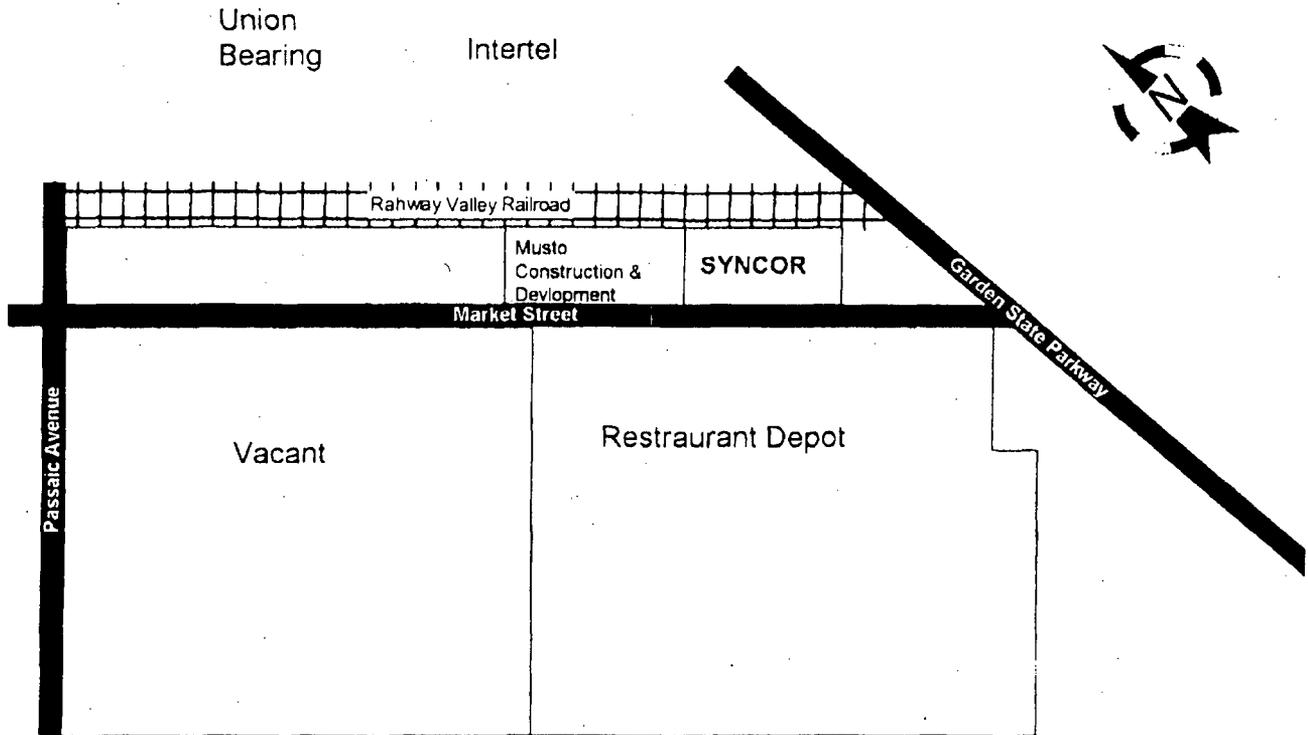
Syncor International Corporation

GRIFFITH, IN
 Date: 04/26/2001

**FACILITY AND EQUIPMENT
KENILWOTH, NJ (CURRENT LOCATION)**

Site Description

1. This facility is located at 130 Market Street, Kenilworth, NJ 07033. This single story, freestanding building utilizes concrete block construction. The west wall of this facility is shared with an adjacent tenant. The heating and cooling system is exclusive for this facility.
2. Please see the attached site plan.



Residential Area

Figure 1 Site Plan

Syncor International Corporation

KENILWORTH, NJ
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 7200 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1738 square feet

Generator Room (Elution) - 105 square feet

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

Volatile Substance Room (Therapy) - 140 square feet

This room houses the fume hood and glove box type fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent is 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 1008 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 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. This area is labeled DISPENSING on the floor plan.

Container Processing Room - 170 square feet

This room is used for the storage and decay of waste materials. Waste is stored in lead barrels 18.5" in diameter, 24" high and 1/4"-3/4" thick. This area is used for receipt and handling of radiopharmaceutical deliveries. This area is labeled CASE RETURN on the floor plan.

Storage Room -125 square feet

This room is also used for the storage and decay of radioactive waste materials. Waste is stored in lead barrels 18.5" in diameter, 24" high and 1/4"-3/4" thick. This area is labeled STORAGE on the floor plan.

Labeling (WBC Tagging Area) - 95 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This area is labeled LABELING on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled VESTIBULE. 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.

UNRESTRICTED AREA

See attached floor plan.

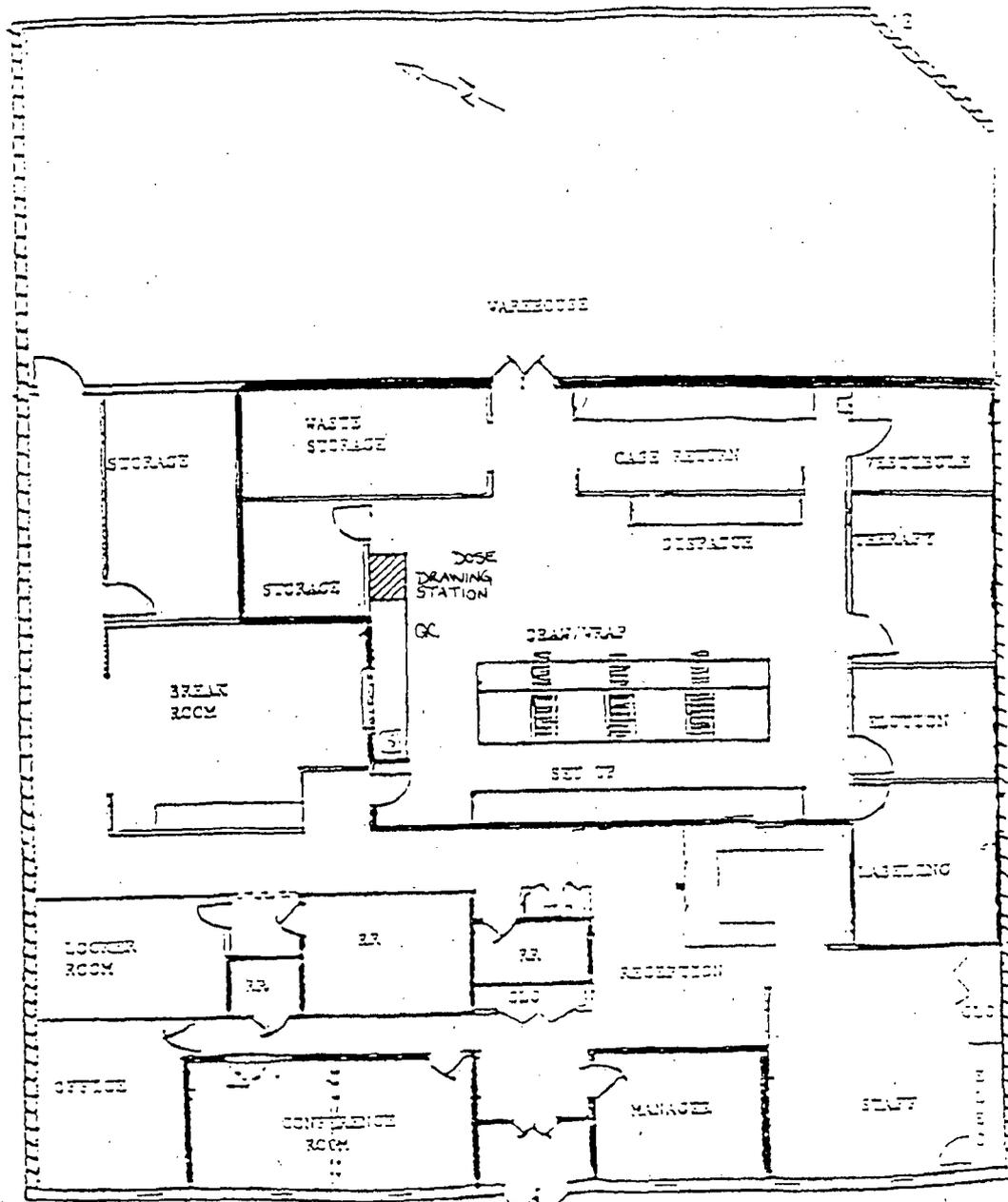


Figure 2 Facility Floor Plan The restricted area is outlined in black.

Syncor International Corporation

KENILWORTH, NJ
Date: 04/26/2001

**FACILITIES AND EQUIPMENT
MOUNTAINSIDE, NJ
(PROPOSED LOCATION FOR FACILITY CURRENTLY LOCATED IN
KENILWORTH, NJ)**

Site Description

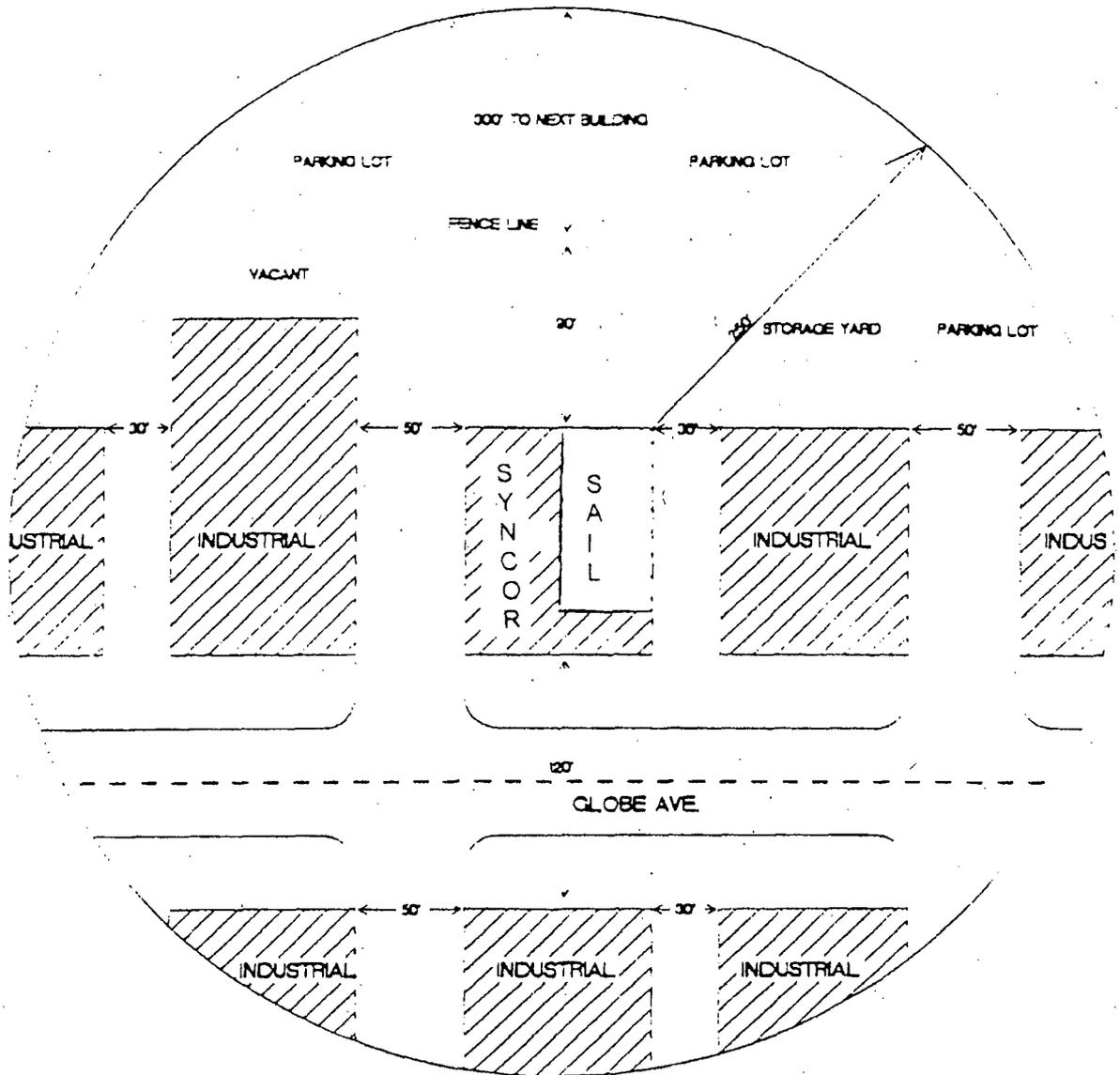
1. This facility is located in a commercial/industrial type area at:

Syncor International Corporation
1094 Globe Avenue
Mountainside, NJ 07092

This single-story, multi-tenant building utilizes concrete block construction. One common wall on the northeast side of our facility is shared with Syncor Advanced Isotopes, LLC (SAIL). SAIL is a subsidiary of Syncor International Corporation whose operations are independent of those of the pharmacy. A wall monitor will be placed on the common wall. The heating and cooling system is exclusive for this facility.

2. Please see the site plan shown in Figure 1.

SITE PLAN



NEWARK, LOC #19
1094 GLOBE AVE.
MOUNTAINSIDE, N.J.
LOT 8P, BLOCK 23C



SCALE 1" = 70'-0"

Figure 1 Site Plan

Syncor International Corporation

MOUNTAINSIDE, NJ
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 6300 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 2700 square feet

Elution Room - approximately 115 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled ELUTION on the diagram.

Therapy Room - approximately 110 square feet

This area also houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled THERAPY on the diagram.

Sterile Prep Area - approximately 120 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled STERILE PREP AREA on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 1350 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps.

Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled DISPENSING on the diagram.

Radioactive Waste Storage Area - approximately 96 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled WASTE STORAGE on the diagram.

Container Processing Area - approximately 225 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled CASE RETURN on the diagram.

The other portions of the Restricted Area are used for supply storage (area labeled SUPPLY) and for storage of non-radioactive medical waste (area labeled MED STORAGE).

UNRESTRICTED AREA

Vestibule Area - approximately 423 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled DROP OFF on the diagram.

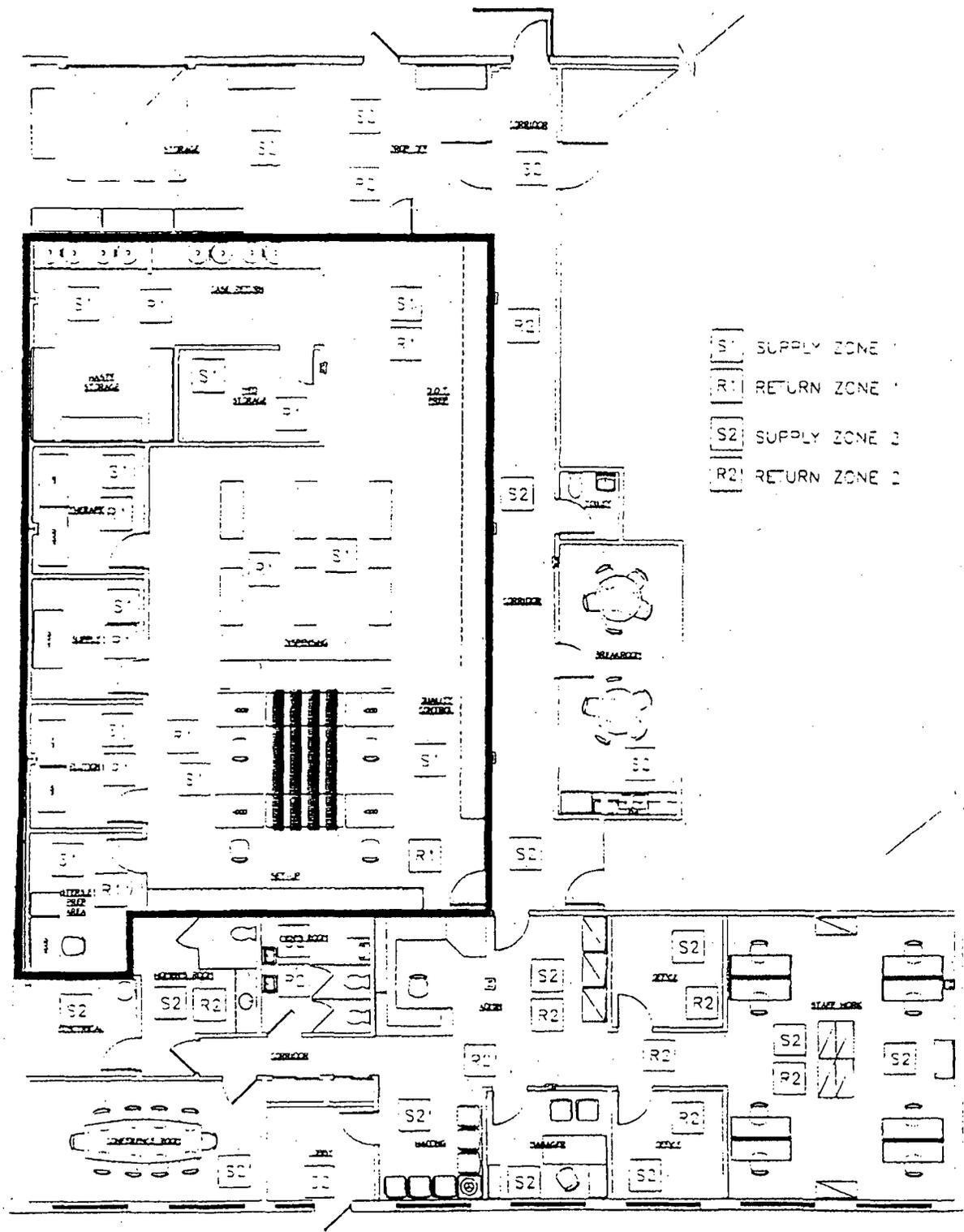
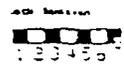


Figure 2 Facility Floor Plan. The restricted area is outlined in black.

Syncor International Corporation

MOUNTAINSIDE, NJ
 Date: 04/26/2001



**FACILITIES AND EQUIPMENT
BETHLEHEM, PA**

1. This facility is located in a commercial/industrial type area at:

Syncor International Corporation
2444 Brodhead Road, Suite F
Bethlehem, PA 18017

2. This facility is in a single-story, multi-tenant building and utilizes cinder block construction with a concrete slab floor. The east wall of the facility is shared with an adjacent tenant as shown in Figure 1. A wall monitor will be placed on the common wall. The heating and cooling system is exclusive for the restricted area.

General Description of Facility

Syncor International Corporation has leased approximately 2660 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1300 square feet

Elution Area – approximately 70 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled GENERATOR ROOM on the diagram.

Volatile Substance Room (Therapy) – approximately 100 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled THERAPY on the diagram.

Labeling Room – approximately 70 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area is labeled LABELING on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) – approximately 620 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps.

Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled DISPENSING on the diagram.

Container Processing Area – approximately 105 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled BREAKDOWN on the diagram.

Waste Storage Room – approximately 160 square feet

This area will also be used for the storage and decay of waste. This area is labeled RAM STORAGE on the diagram.

UNRESTRICTED AREA

Vestibule Area – approximately 90 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled VESTIBULE on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

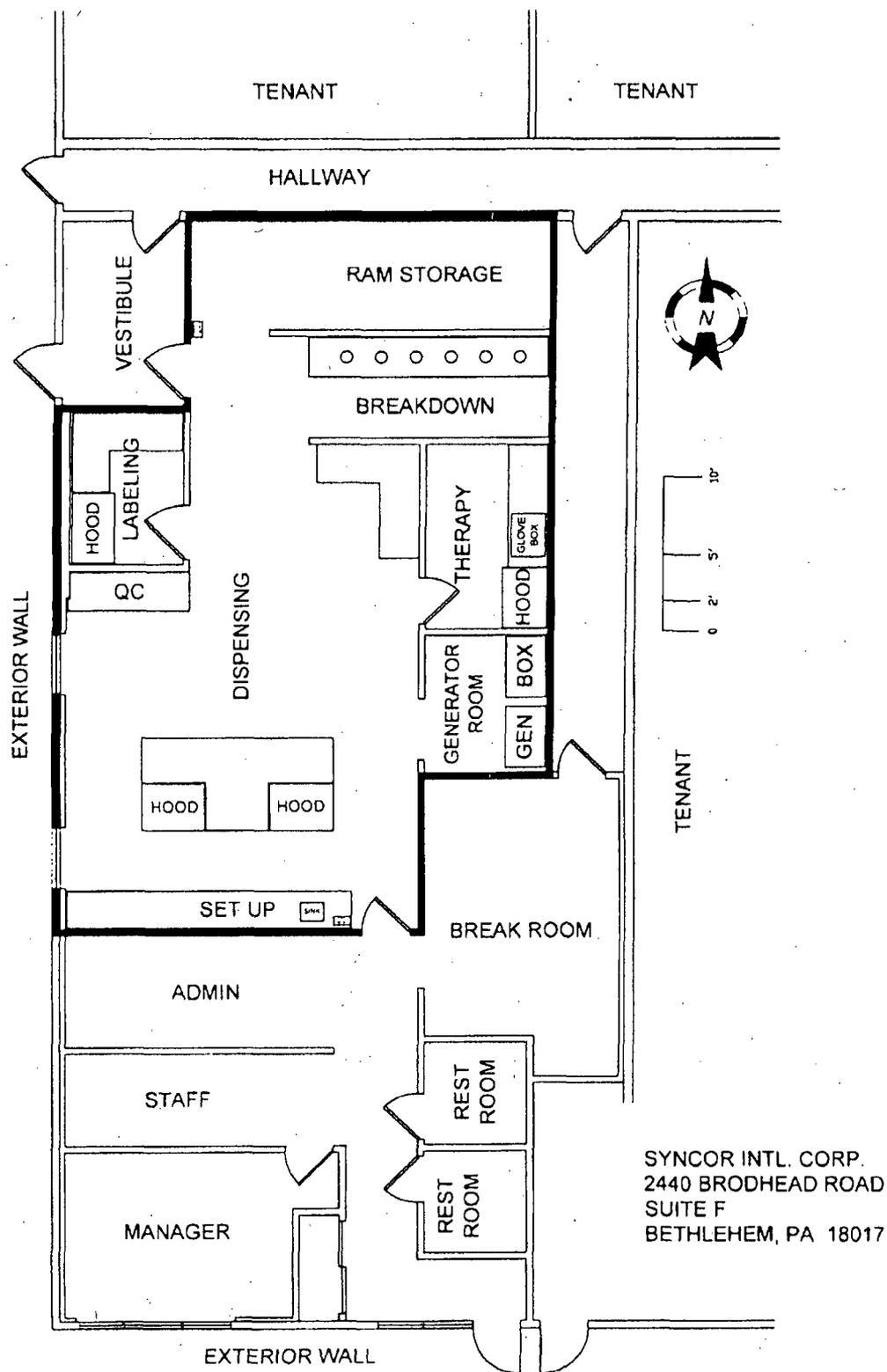


Figure 2 Facility floor plan. The restricted area is outlined in black.

**FACILITIES AND EQUIPMENT
SWARTZ CREEK, MI**

Site Description

1. This Syncor facility is located in a commercially zoned area at 5370 Miller Road, Suite #25, Swartz Creek, Michigan, 48473. The building is constructed of steel, concrete, and brick. The south wall of this facility is shared with an adjacent tenant. The shared wall is a fire wall, which extends to the roof of the building. The heating and cooling system is exclusive for Syncor's facility, with no air being recirculated to the adjacent tenants' offices.
2. Please see the attached area diagram.

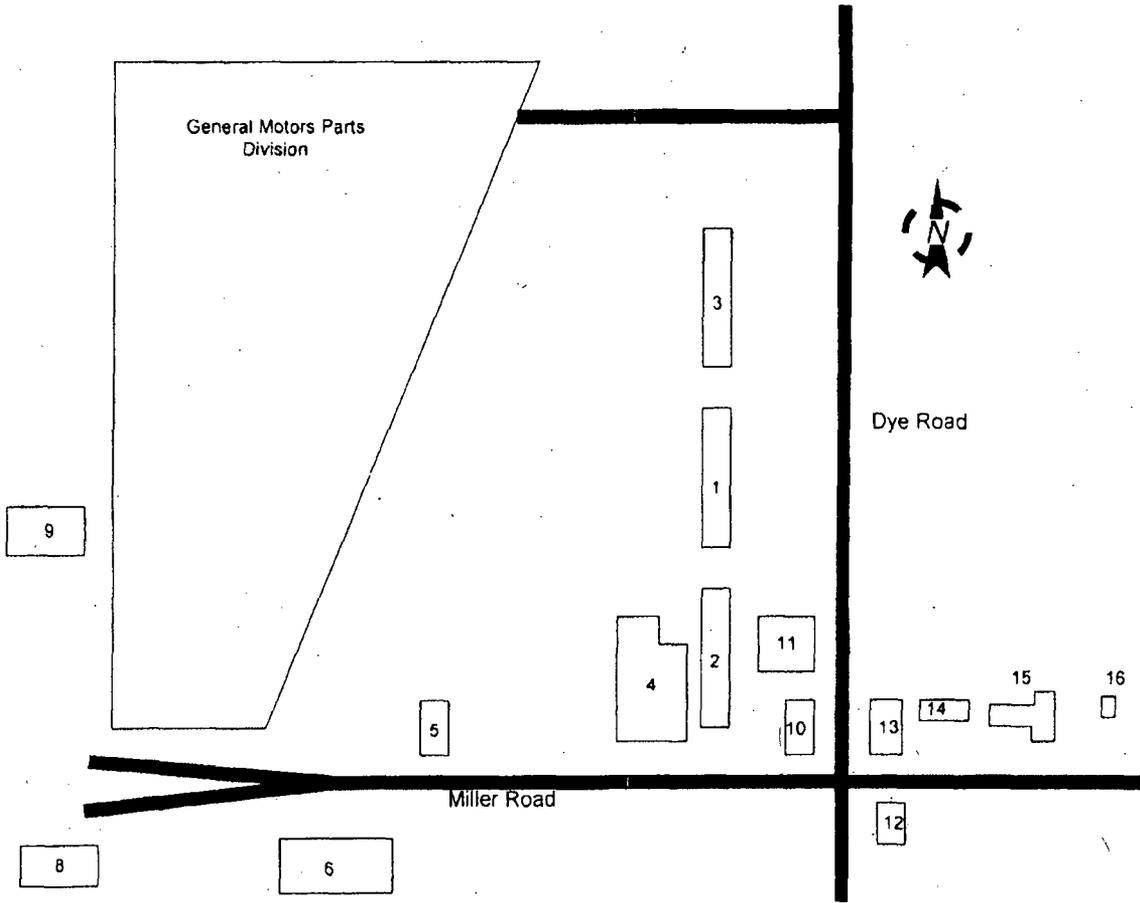


Figure 1 Site Plan

Syncor International Corporation

SWARTZ CREEK, MI
Date: 04/26/2001

Key For Location Map

1. 5370 Miller Road, Building B Suites 21, 22, 23, 24, 25, 26
Suites 21 & 22 - Midwest Wireless
Suites 23, 24, 25 & 26 - Syncor International Corporation
2. 5370 Miller Road, Building A Suites 11, 12, & 13
Suite 12 - The Mallory Group Realtors
Suites 11 & 13 - Flint Surveying and Engineering
3. 5370 Miller Road, Building C Suites 31, 32, 33, 34, 35 & 36
Suites 31 & 32 - DTL Worldwide Express
Suite 33 - Neuro Behavior Diagnostic and Treatment
Suite 34 - Michigan Safety
Suite 35 - Healthcare Technologies
Suite 36 - AFLAC
4. Hager Fox
5. Bunt Shop
6. Genesec Valley Golf Club
7. O'Tooles Restaurant
8. Strip Mail
9. Closest Farm (3 miles from release point, Syncor Int. Corp)
10. Private Residence
11. Ford's Party Rental
12. Pesto's Restaurant
13. Randy's Party Store
14. Speedway Gas Station
15. Old Kent Bank
16. The Surgery Center
17. Sunco Gas Station
18. G.M. Parts Division

General Description of Facility

Syncor International Corporation has leased approximately 2960 square feet for use as a radiopharmacy in a single story building located in a commercially zoned area.

Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA

Radiopharmaceutical Dispensing Lab - approximately 528 square feet

This area is used for preparing and dispensing radiopharmaceuticals. Each drawing station consists of a lead L-block shield with leaded glass, a dose calibrator, and a set of forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers. The refrigerator is utilized for storage of both radiopharmaceuticals (in appropriate shielding) and cold kits needing refrigerated storage. Quality control, as well as shipping and packaging are done in this area. This area is labeled PHARMACY on the floor plan.

Generator Room - approximately 64 square feet

This area is used for storage of ongoing, used radiopharmaceuticals, including Mo99/Tc99m generators. Benches are provided for generator storage and elution. All actively used generators are housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the perimeter of the storage bench. Other materials are stored in their original shipping containers behind auxiliary lead shielding. This room is labeled ELUTION on the floor plan.

Therapy Room - approximately 77 square feet

This room houses the fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility due to the exhaust of the continuously operating fume hood. No return vents are located in this room, thereby ensuring that no air from this room is circulated to any other area of the facility. This room is labeled THERAPY on the floor plan.

Indium WBC Room - approximately 88 square feet

This area houses the biohazard hood for use in tagging cellular blood components. This room is labeled LABELING/IVP on the floor plan.

Waste Storage Area - approximately 102 square feet

Syncor International Corporation

SWARTZ CREEK, MI

Date: 04/26/2001

This area is used for the storage and decay of waste. This area is labeled DECAY on the floor plan.

Container Processing Area- approximately 140 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled CASE RETURN on the floor plan.

UNRESTRICTED AREA

Vestibule -

This area is designated for deliveries of radioactive material during off duty hours. Common carriers will have keyed access to the vestibule but will not have access to the restricted area. This area is labeled VESTIBULE on the floor plan.

FLINT # 25

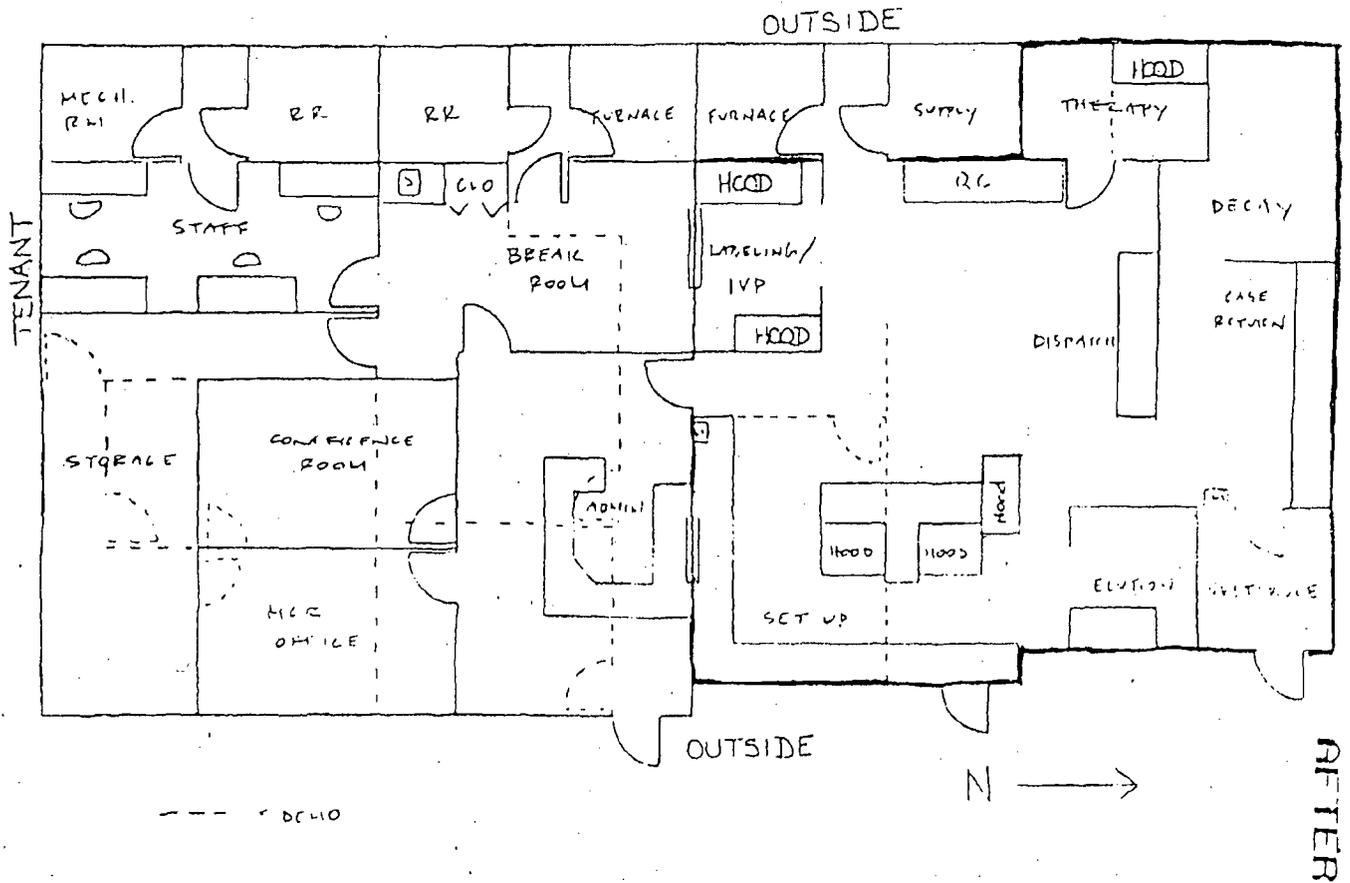


Figure 2 Facility Floor Plan The restricted area is outlined in black

Syncor International Corporation

SWARTZ CREEK, MI
Date: 04/26/2001

**FACILITY AND EQUIPMENT
KANSAS CITY, MO**

Site Description

1. This Syncor facility will be located in a commercially zoned area at Bannister Square Business Park, 9668-9670 Marion Park Drive, Kansas City, MO 64137. This single story building utilizes brick and steel frame construction. The east wall of this facility is shared with an adjacent tenant, however, the adjacent space is unoccupied at this time. The common wall is a fire wall which extends to the roof of the building. 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.



DANNISTER SQUARE BUSINESS PARK - BUILDING SITES FOR SALE

LOCATED SOUTHEAST CORNER OF BARNHILL AND 135, KANSAS CITY, MISSOURI
ADJACENT TO BARNHILL PARK AND PARKWAY LABORATORIES
ADJACENT ACCESS ROUTE 135 FROM 200.35 AND THE FUTURE KANSAS ROUTE 64
CLOSE TO ESTABLISHED TRAILS, SEVENWKS, AND WALKWAYS
FOR FUTURE TRAILS SCENIC ENTRANCE

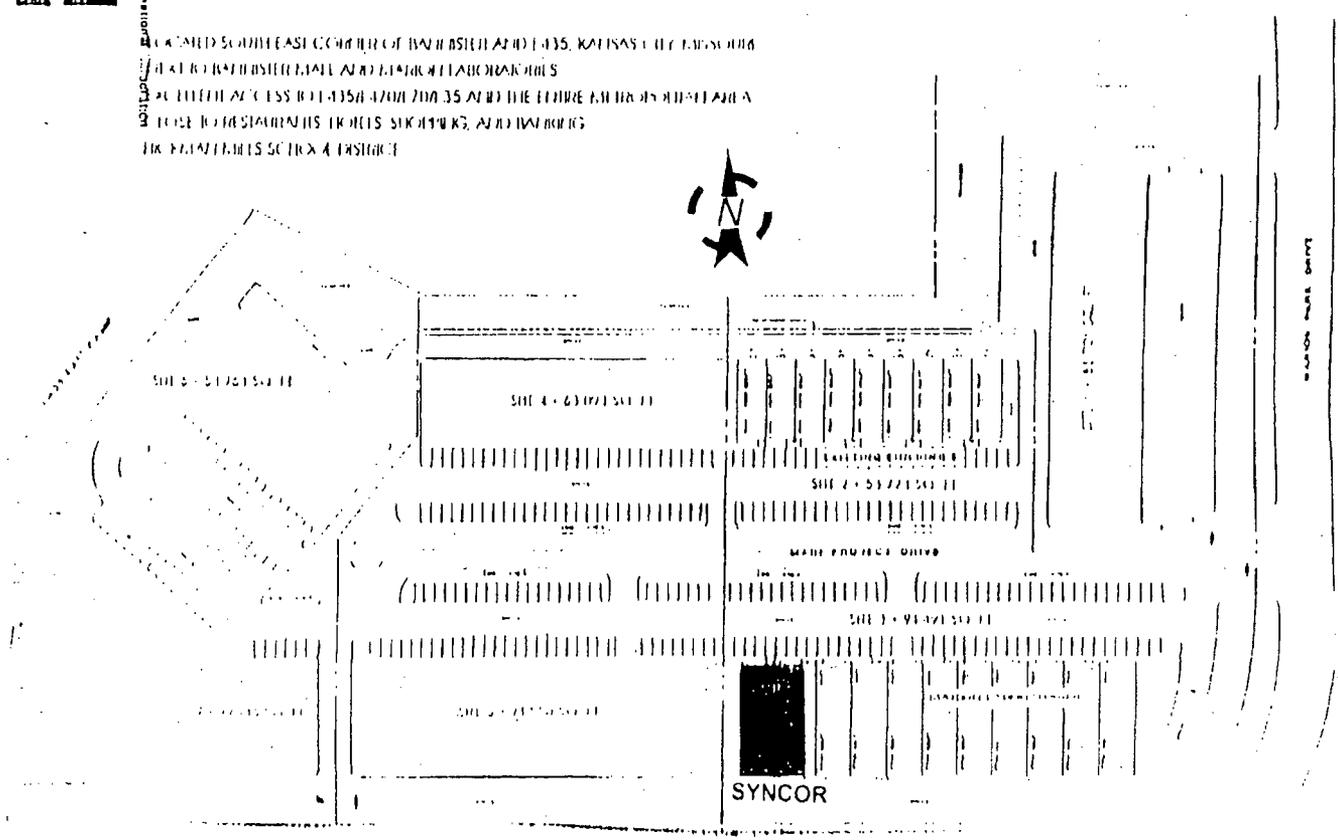


Figure 1 Site Plan

Syncor International Corporation

KANSAS CITY, MO

Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 5000 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA -1000 square feet

Generator Room (Elution) - 100 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. This room is labeled ELUTION on the floor plan.

Volatile Substance Room (Therapy) - 100 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 252 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. This room is labeled PHARMACY on the floor plan.

Radioactive Waste Storage and Break Down Area - 168 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 1/4"-3/4" 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. This room is labeled BREAKDOWN on the floor plan

Storage - 100 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 mR/hr) prior to final decay and transfer to the medical waste hauler. This room is labeled STORAGE on the floor plan.

Labeling (WBC Tagging Area) - 100 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This room is labeled PRODUCT LABELING on the floor plan.

Calibration Room - 150 square feet

This area will be used for calibration of survey meters and monitoring equipment. See Appendix A. This room is labeled CALIBRATION on the floor plan.

NOTE: After hours delivery will be made to the rear door in the room labeled VESTIBULE. 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.

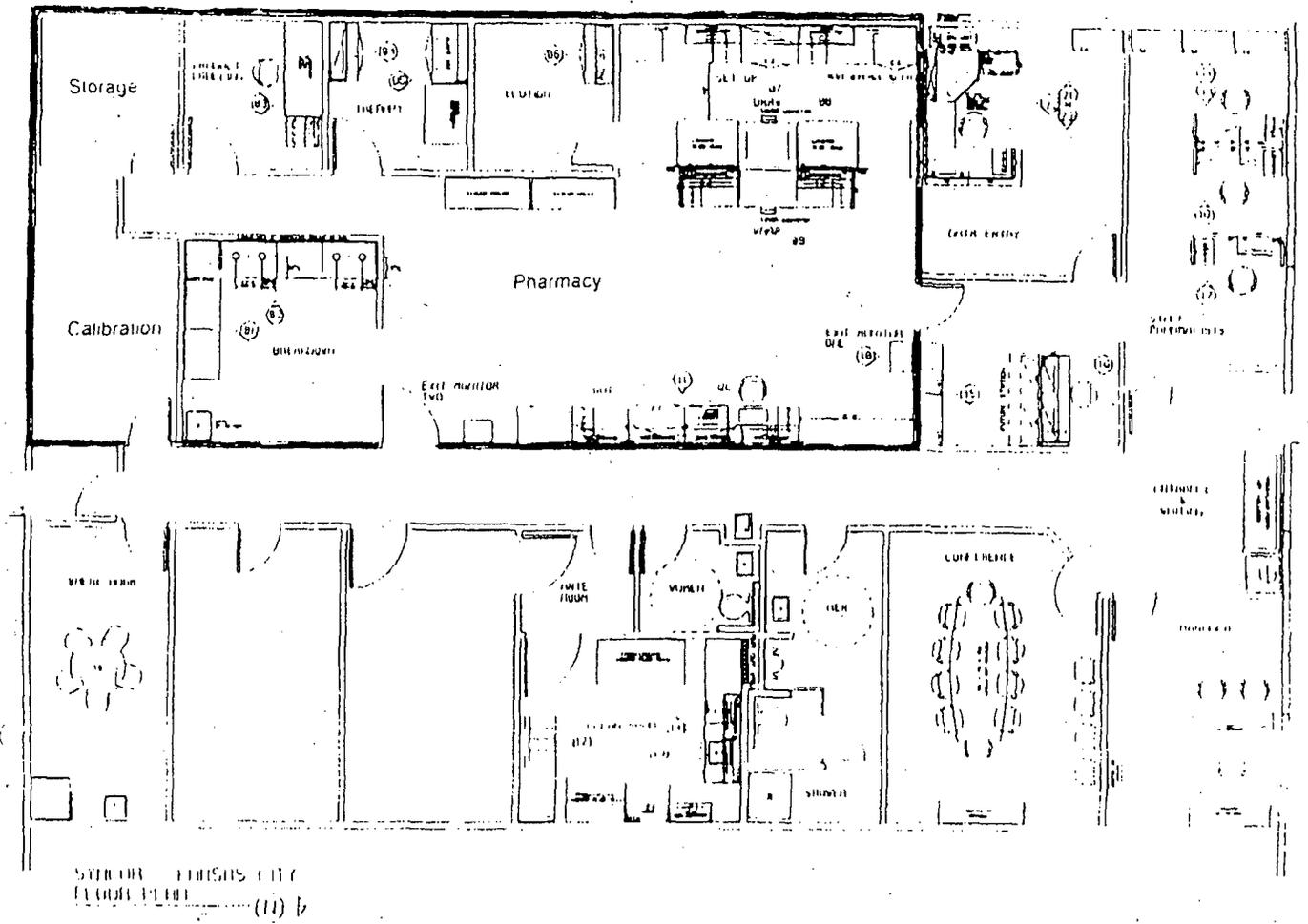


Figure 2 Facility Floor Plan The restricted area is outlined in black.

Syncor International Corporation

KANSAS CITY, MO
Date: 04/26/2001

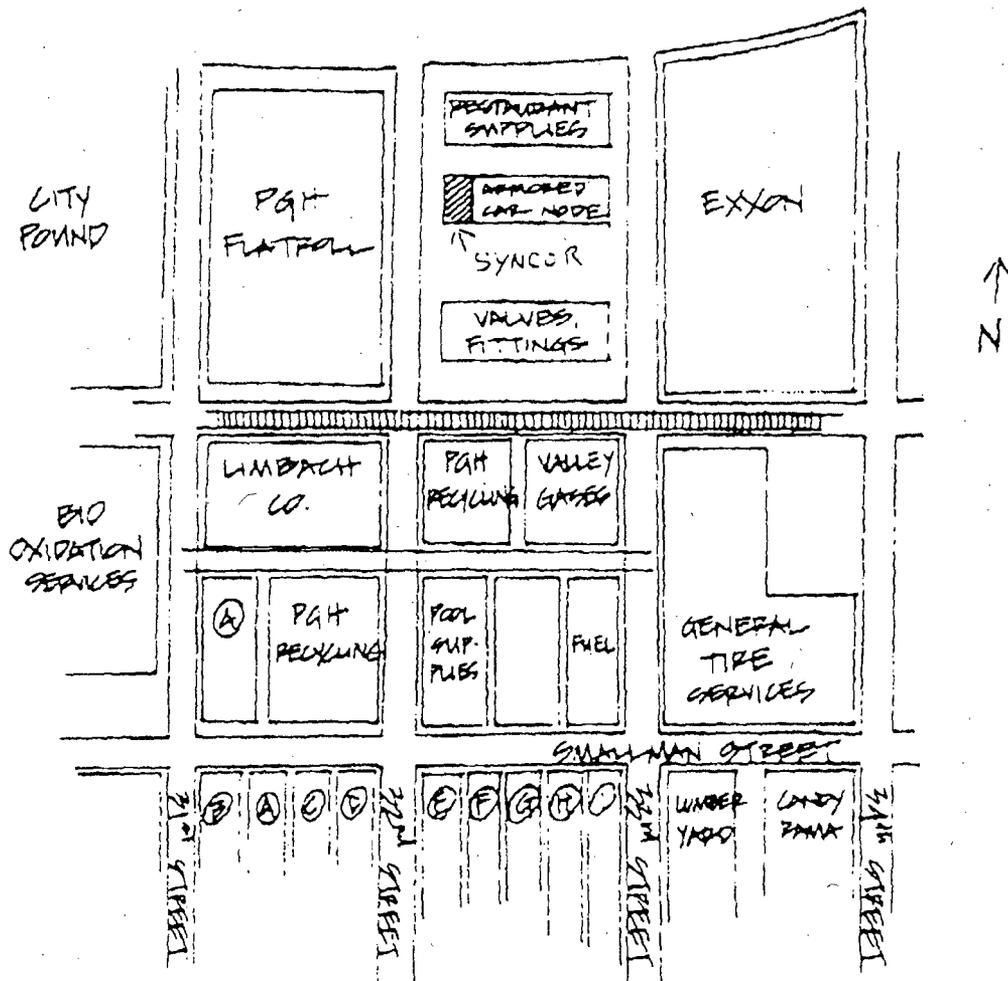
**FACILITY AND EQUIPMENT
Pittsburgh, PA**

1. This facility is located in a commercial/industrial type area at:

Syncor International Corporation
70 33rd Street, Suite A
Pittsburgh, PA 15201

2. This facility is in a single-story, multi-tenant building and utilizes cinder block construction with a concrete slab floor. The east wall of the facility is shared with an adjacent tenant as shown in Figure 1. A wall monitor will be placed on the common wall. The heating and cooling system is exclusive for the restricted area.

A L L E G H E N Y R I V E R



Syncor International Corporation
 70 33rd Street, Suite A
 Pittsburgh, PA 15201

- A. SHEET METAL
- B. ITALIAN RESTAURANT
- C. TRUCK PARTS
- D. GEMCO SALES
- E. VALVES
- F. AUTO REPAIR
- G. ELECTRICAL PARTS
- H. VACANT
- I. GRICE/CONCRETE CASING

Figure 1 Site Plan

PITTSBURGH, PA
 Date: 04/26/2001

Syncor International Corporation

General Description of Facility

Syncor International Corporation has leased approximately 5000 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 2315 square feet

Elution Area – approximately 120 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled ELUTION on the diagram.

Volatile Substance Room (Therapy) – approximately 130 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled IODINE on the diagram.

Labeling Room – approximately 100 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area is labeled LABELING on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) – approximately 650 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps.

Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled DISPENSING on the diagram.

Container Processing Area – approximately 140 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled CASE RETURN on the diagram.

Waste Storage Room – approximately 140 square feet

This area will also be used for the storage and decay of waste. This area is labeled RAM WASTE on the diagram.

UNRESTRICTED AREA

Vestibule Area – approximately 50 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled VESTIBULE on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

Syncor International Corporation
70 33rd Street, Suite A
Pittsburgh, PA 15201

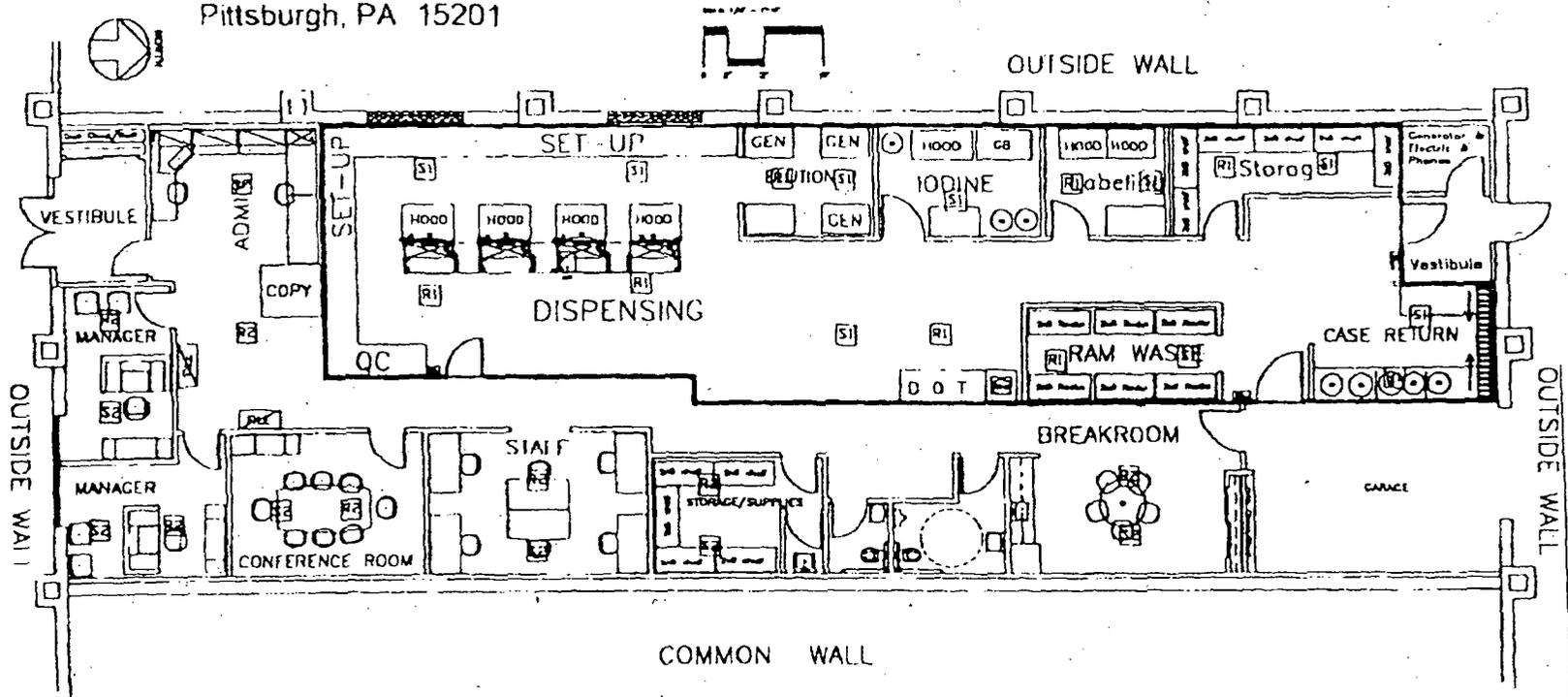


Figure 2 Facility Floor Plan. The restricted area is outlined in black.

PITTSBURGH, PA
Date: 04/26/2001

Syncor International Corporation

**FACILITY INFORMATION
ST. LOUIS (OVERLAND), MO**

Site Description

1. This Syncor facility will be located in a commercially zoned area at: 1901 Beltway Drive, St. Louis, Missouri, 63114

This multi-tenant building is constructed of steel frame, glass and metal steel and concrete. The walls on the north and southeast sides of the facility are shared with adjacent tenants.

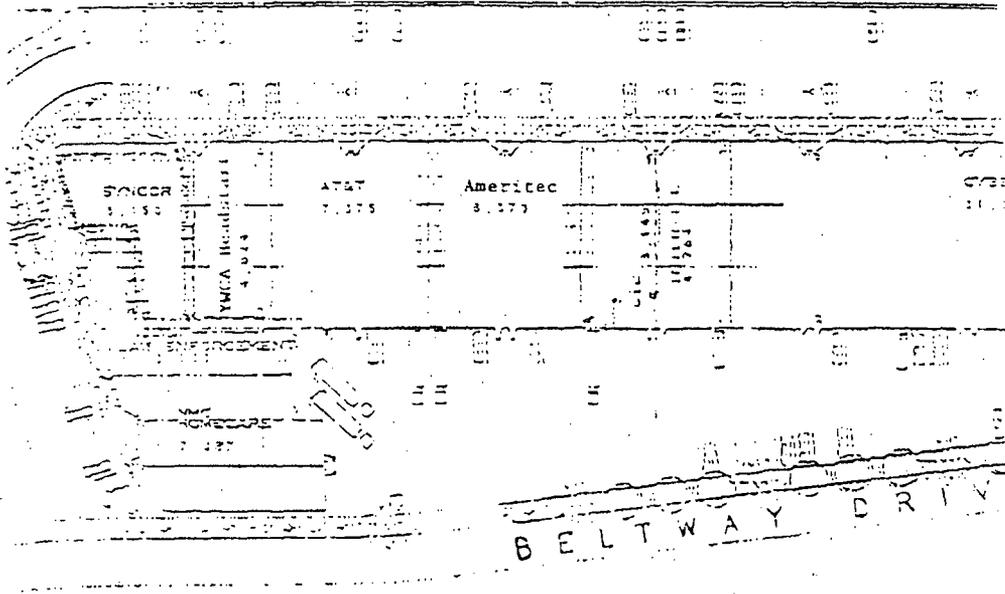
This office space has its own heating and cooling system, and the walls between the pharmacy and adjacent tenants are one hour fire walls which extend to the roof of the building.

The pharmacy space HVAC system is a dedicated roof top unit

2. Please see the attached site plan.

EXHIBIT D
DESIGNATED PARKING SPACE LOCATIONS

Tenant shall hereby, for each term have the right to use the parking spaces reserved in the parking lot adjacent to the leased Premises for use by employees and its vehicles on a non-exclusive and undesignated basis. Five (5) of these spaces, as designated in site plan below, shall be designated for Tenant's exclusive, reserved use.



SYNCOR INTERNATIONAL CORPORATION
LOCATION 30, OVERLAND, MO.

I-170 CENTER

NORTH →

Figure 1 Site Plan

Syncor International Corporation

ST. LOUIS (OVERLAND), MO
Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 5,150 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA

See attached sketch.

Generator Room - 64 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. This room is labeled GENERATOR ROOM on the floor plan.

Volatile Substance Room - 64 square feet

This room will also 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. This room is labeled THERAPY ROOM on the floor plan.

Radiopharmaceutical Dispensing Area - 700 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. A drawing station will be located as shown on the attached sketch. The drawing station 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. This area houses the biohazard hood for use in tagging cellular blood components. This area is labeled LAB AREA on the floor plan.

Radioactive Waste Storage and Break Down Area - 192 square feet

This waste storage room will be used for the storage and decay of waste materials. Waste will be stored in lead barrels of approximately 18.5 x 18.5 x 32 x 3/8" thick lead. The room will have seven of these. Ample lead bricks 2" x 4" x 8" are provided for additional shielding, as necessary. This area is labeled BREAKDOWN AREA on the floor plan.

UNRESTRICTED AREA

See attached floor plan.

NOTE: The room designated as "After Hours Delivery" in the unrestricted area will be used for receipt of radioactive packages during off-duty hours. This will prevent the common carrier from having access to the nuclear pharmacy area proper.

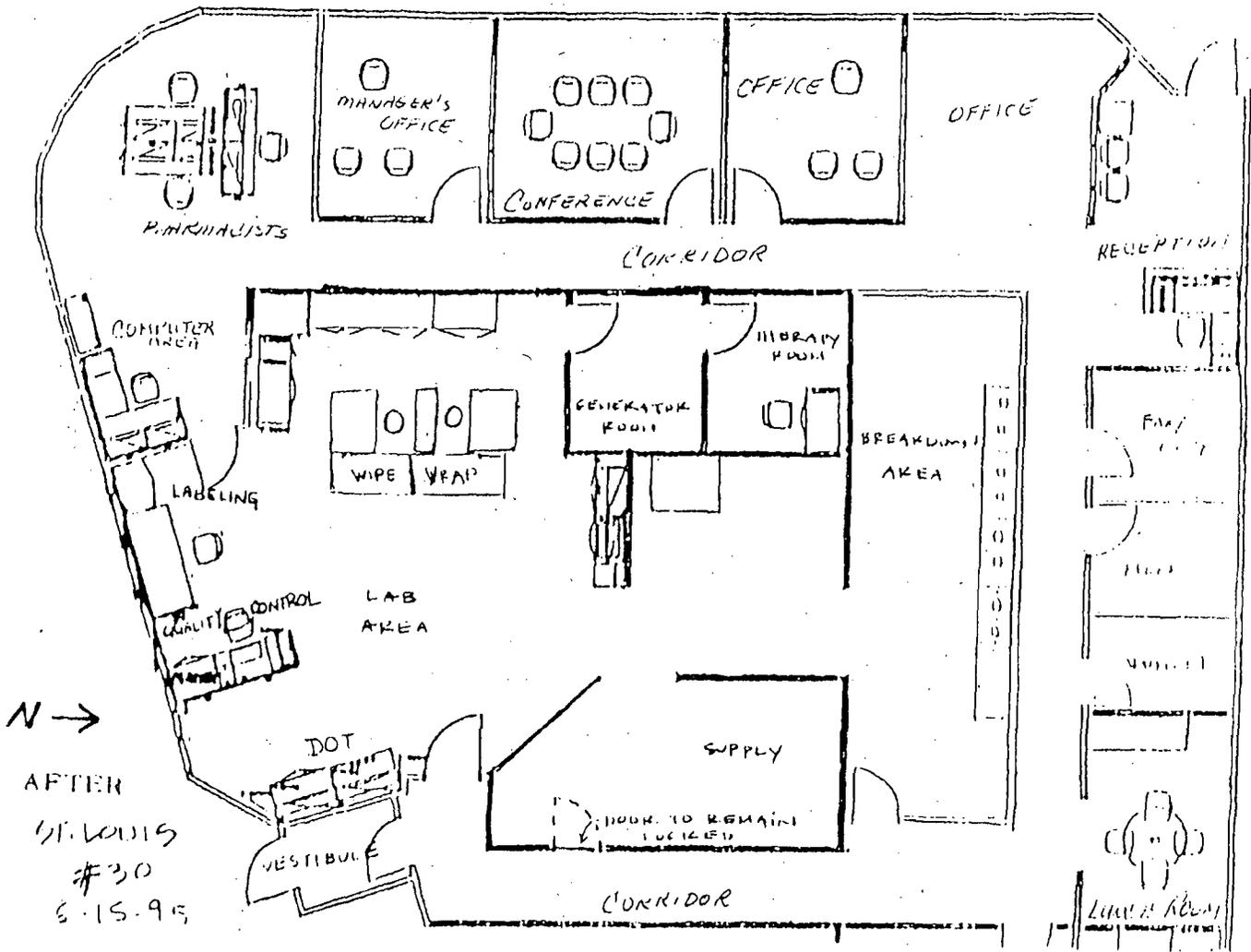


Figure 2 Facility Floor Plan The restricted area is outlined in black

Syncor International Corporation

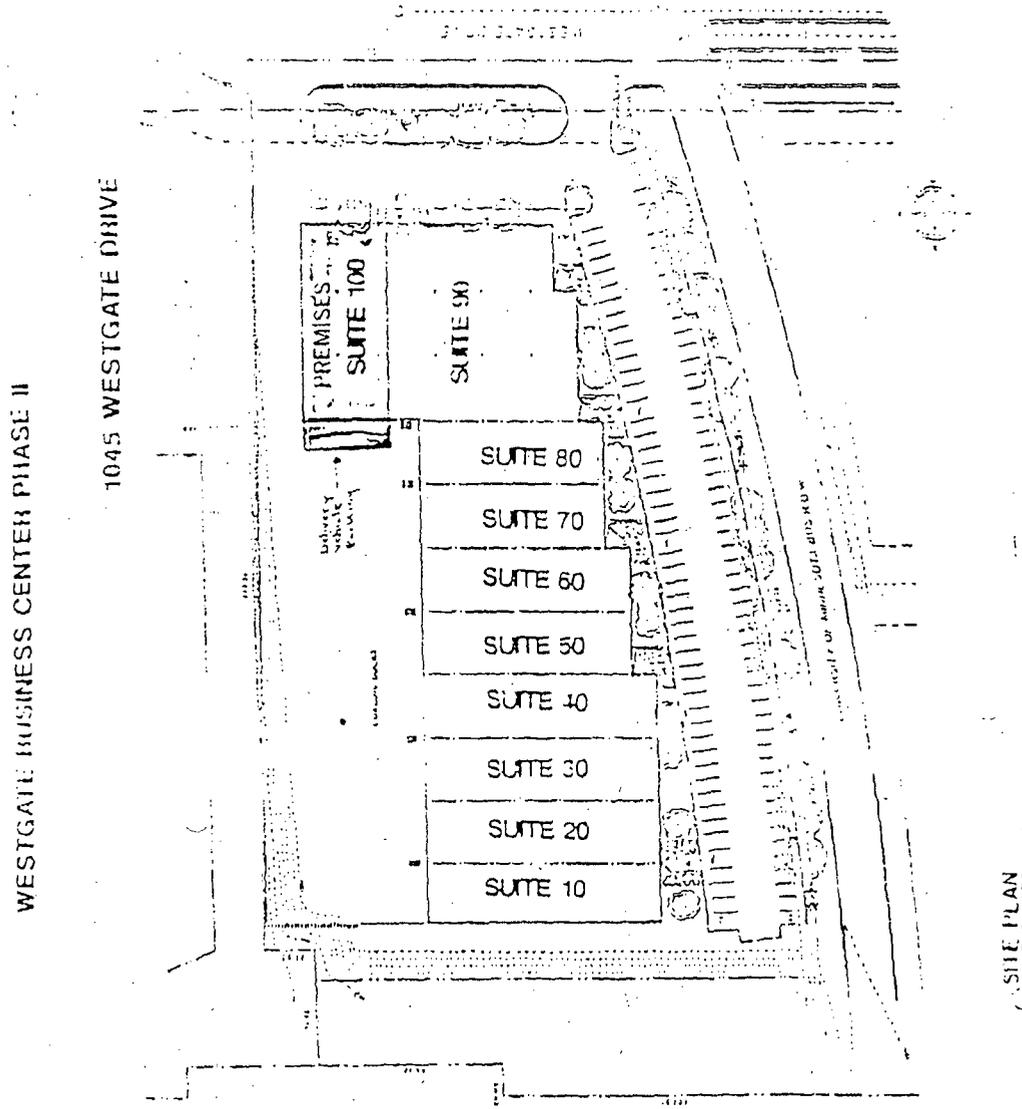
ST. LOUIS (OVERLAND), MO

Date: 04/26/2001

**FACILITY AND EQUIPMENT
ST. PAUL, MN**

Site Description

1. This Syncor facility is located in a commercially zoned area at 1045 Westgate Drive, Suite 100, St Paul, MN 55114. This multitenant building is constructed of concrete block walls, concrete floor, and a flat roof. The south wall of this facility is shared with an adjacent tenant. The adjacent space is currently unoccupied. The common wall is a fire wall which extends to the roof of the building. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.



Syncor International Corporation - Suite 100
 Consortium Books - Suites 90, 30, 70, 60
 Northwestern Foods - Suites 50, 40, 30, 20, 10

Figure 1 Site Plan

Syncor International Corporation

ST PAUL, MN
 Date: 04/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 6466 square feet of space for use as a radiopharmacy in a single story, multi-tenant building located in a commercially zoned area. Sketches of the floor plan and equipment placement are attached to this written description.

RESTRICTED AREA

Generator Room (Elution) - 90 square feet

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

Volatile Substance Room (Therapy) - 100 square feet

This room will also house the fume hood and glove box type fume hood. All volatile substances are stored and handled in this area. A negative pressure is maintained in this area relative to the rest of the facility, due to the exhaust of the continuously operating fume hood. No return vent is 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. This room is labeled THERAPY on the floor plan.

Radiopharmaceutical Dispensing Area (Pharmacy) - 132 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 are a minimum of 1" thick lead with leaded glass viewing windows.

Radiopharmaceutical Dispensing Area (continued)

Technetium and technetium products are 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, is done in this area. A refrigerator is also located in this area for storing radiopharmaceuticals and cold kits which require refrigeration. This area is labeled PHARMACY on the floor plan.

Radioactive Waste Storage and Break Down Area - 170 square feet

This room is used for the storage and decay of waste materials. Waste is stored in lead barrels of approximately 18.5 x 18.5 x 32 x 3/8" thick lead. 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. This room is labeled BREAKDOWN on the floor plan.

Storage - 120 square feet

This area is used for storage of supplies and waste which has been decayed to low levels (i.e. less than 2 mR/hr) prior to final decay and transfer to the medical waste hauler. This room is labeled STORAGE on the floor plan.

Sterile (WBC Tagging Area) - 109 square feet

This area will house the biohazards hoods and be used for blood cell component tagging. This area is labeled BLOOD LABELING ROOM on the floor plan.

NOTE: After hours deliveries are made to the rear door in the room labelled warehouse. 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.

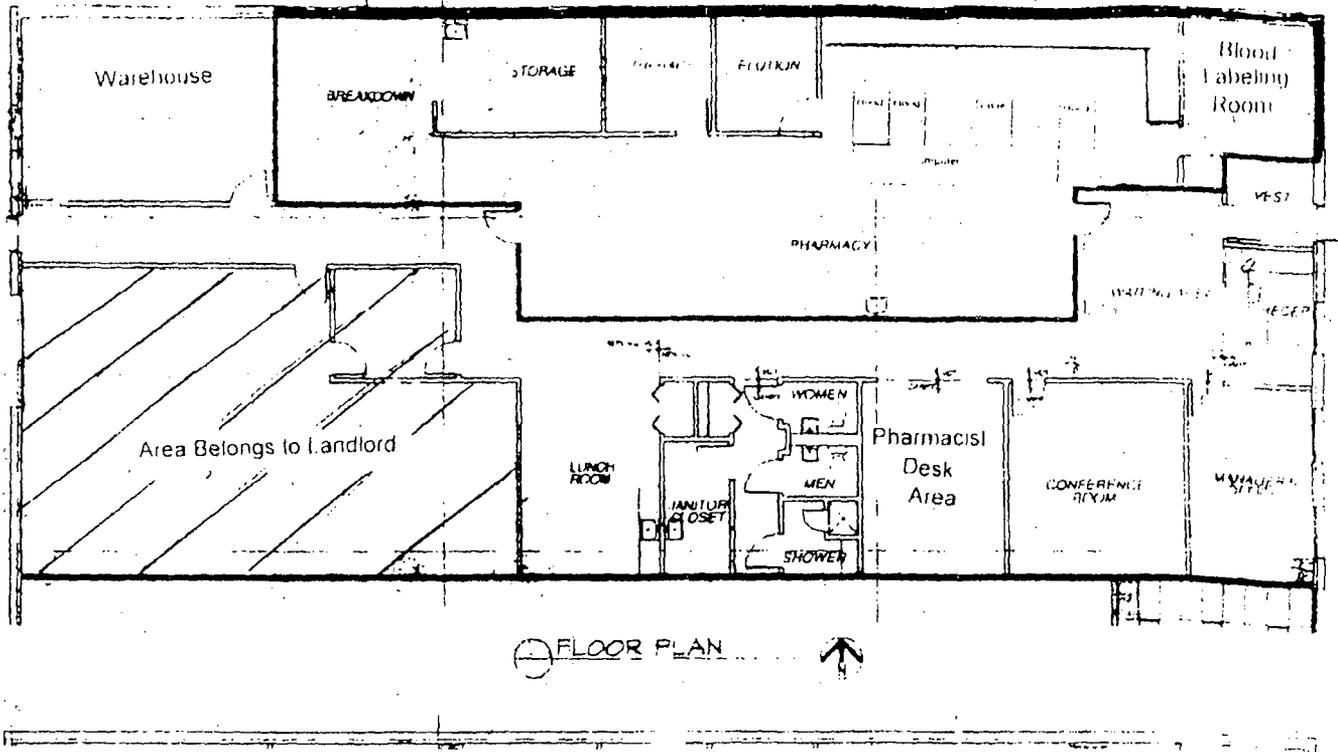


Figure 2 Facility Floor Plan The restricted area is outlined in black.

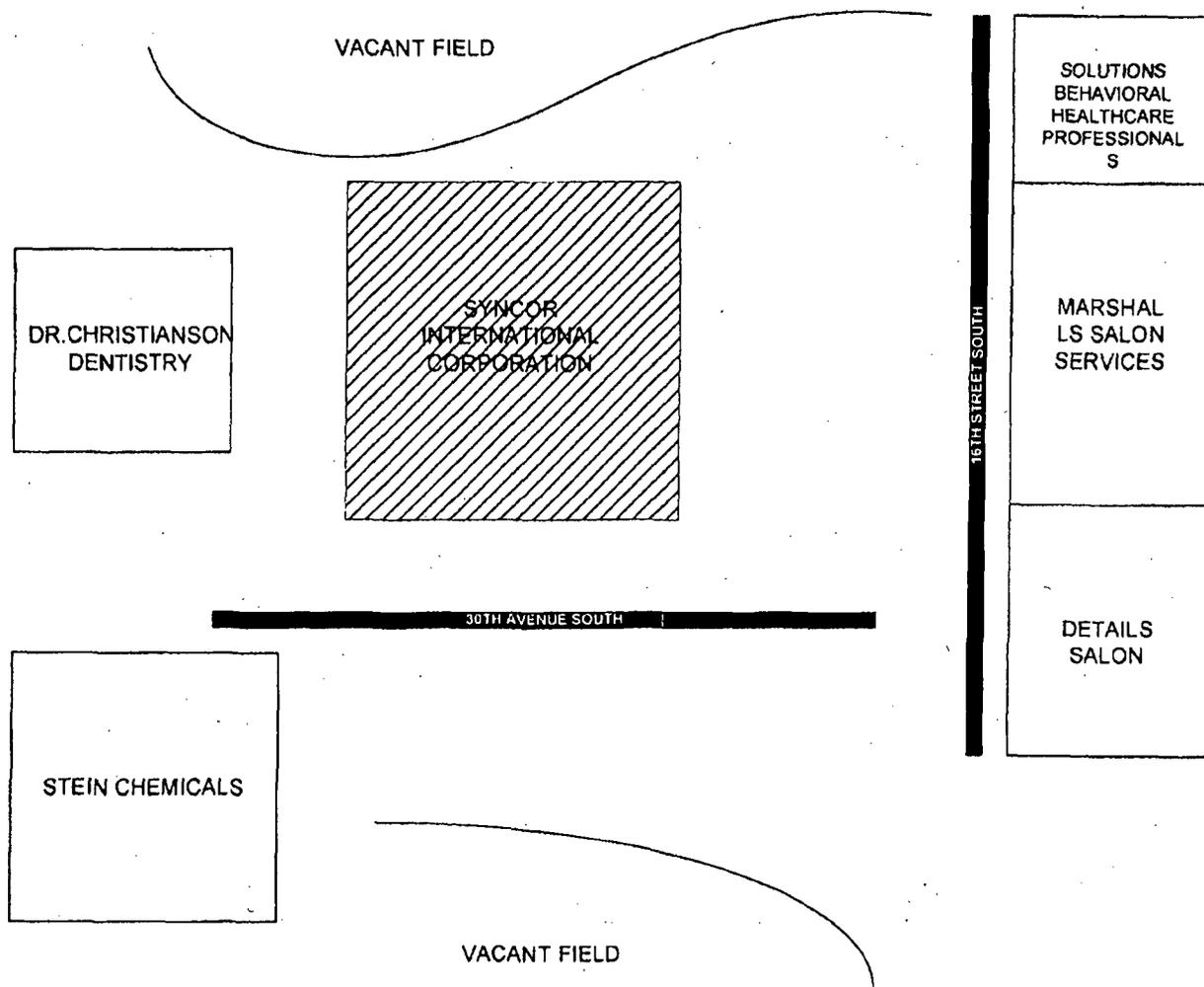
Syncor International Corporation

ST PAUL, MN
Date: 04/26/2001

**FACILITY AND EQUIPMENT
Moorhead, MN**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 1610 30th Avenue, Moorhead, Minnesota 56560. This single story building utilizes concrete block construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.



N
 E W S
 Loc 39 Site
 Moorhead,

Figure 1. Facility Site Plan
Syncor International Corporation

Moorhead, MN
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 2400 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 880 square feet

Elution Room - approximately 92 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *ELUTION* on the diagram.

Volatile Substance Room - approximately 92 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 111 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 460 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPATCH* on the diagram.

Radioactive Waste Storage - approximately 72 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *STORAGE* on the diagram.

Container Processing Area - approximately 53 square feet

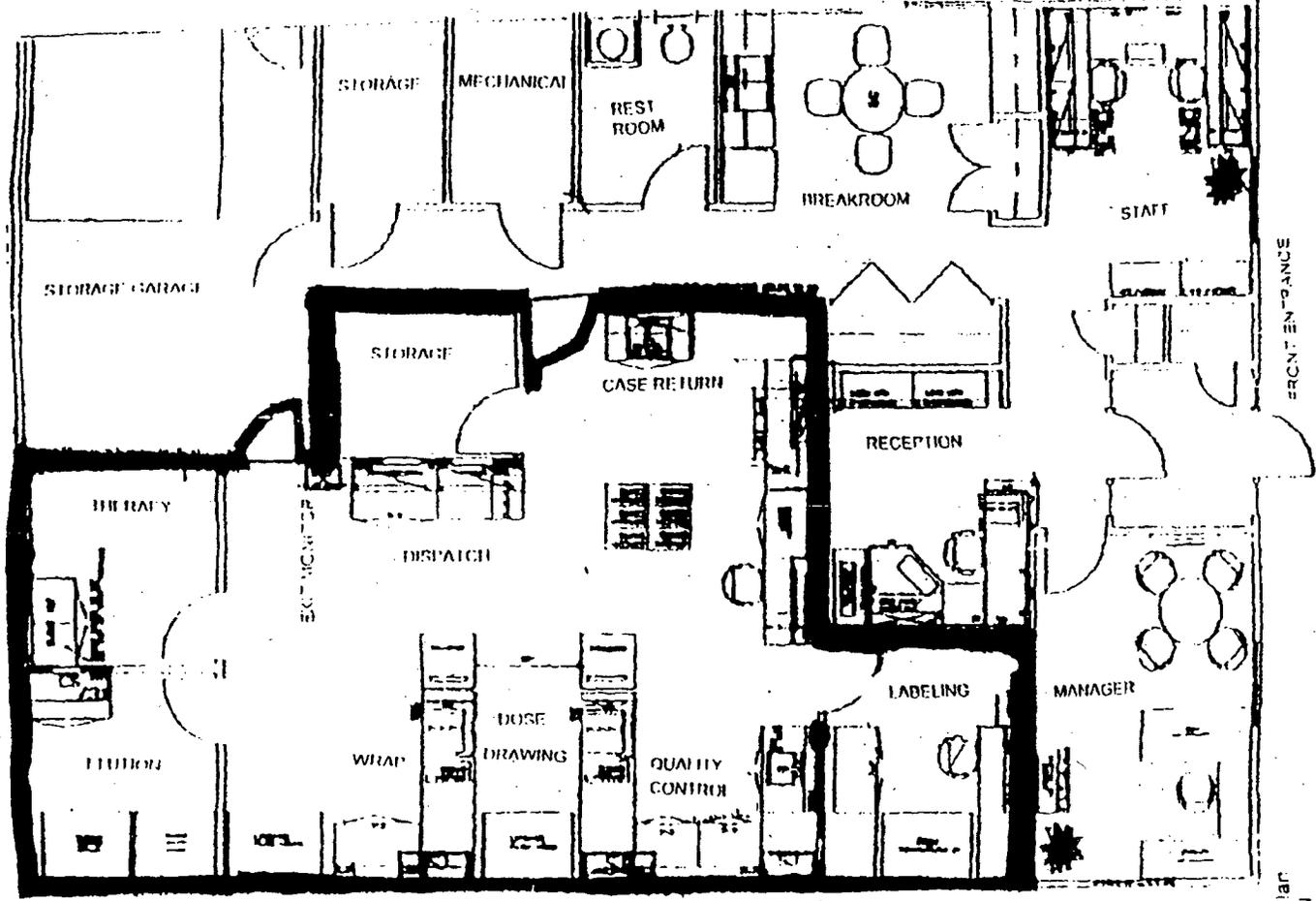
This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN* on the diagram.

Unrestricted Area - See Floor Diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

Syncor International Corporation

**Moorhead, MN
Date: 4/26/2001**



LSC 35 Floor Plan
 Moorhead, MN

Figure 2. Facility Floor Plan

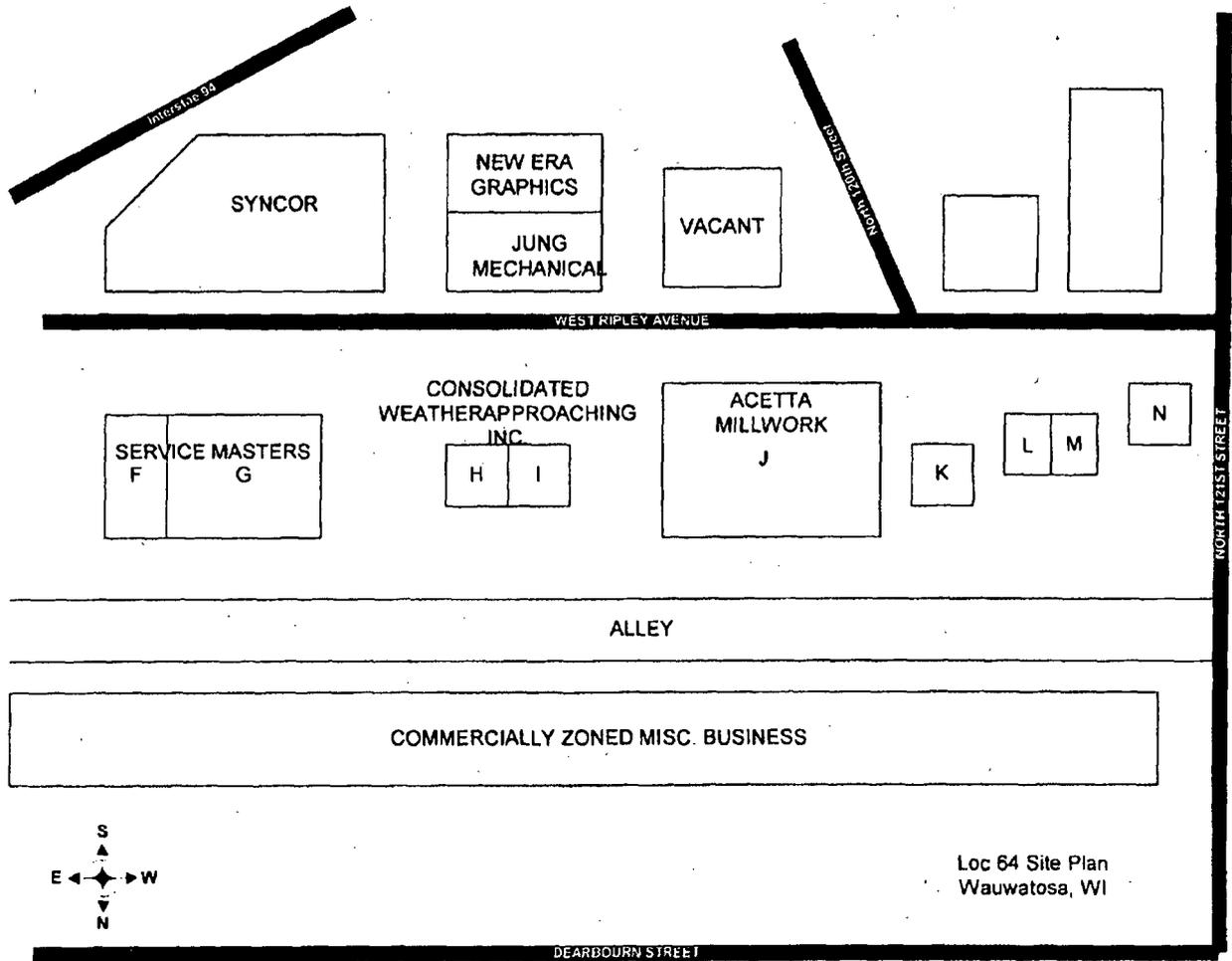
Syncor International Corporation

Moorhead, MN
 Date: 4/26/2001

**FACILITY AND EQUIPMENT
Wauwatosa, WI**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 11829 W. Ripley Avenue, Wauwatosa, Wisconsin 53226. This one story building utilizes concrete brick construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.



**Figure 1. Facility Site Plan
Syncor International Corporation**

**Wauwatosa, WI
Date: 4/26/2001**

General Description of Facility

Syncor International Corporation has leased approximately 5500 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1400 square feet

Elution Room - approximately 120 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *Tc99 GENERATOR ROOM* on the diagram.

Volatile Substance Room - approximately 215 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *I-131 ROOM* on the diagram.

Labeling Room - approximately 90 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *CLEAN ROOM* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 655 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Radioactive Waste Storage - approximately 70 square feet

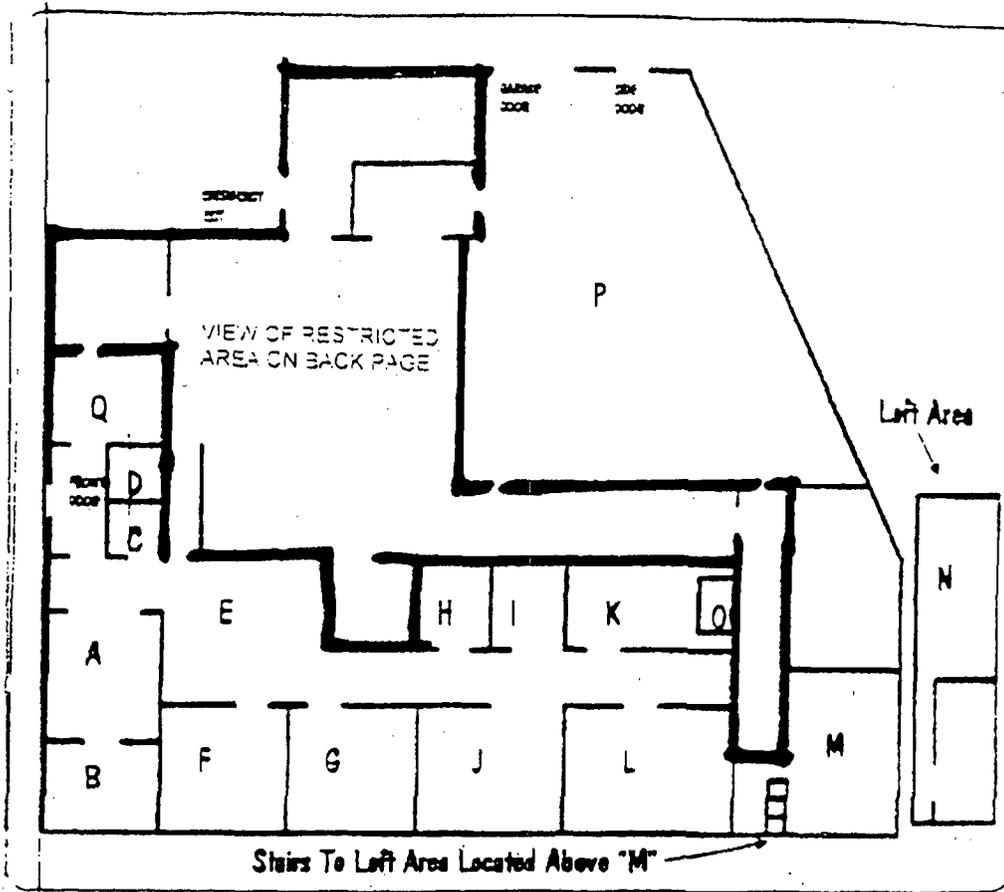
This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *BOXED BIOHAZARDOUS WASTE* on the diagram.

UNRESTRICTED AREA

Vestibule Area - approximately 82 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *VESTIBULE* on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.



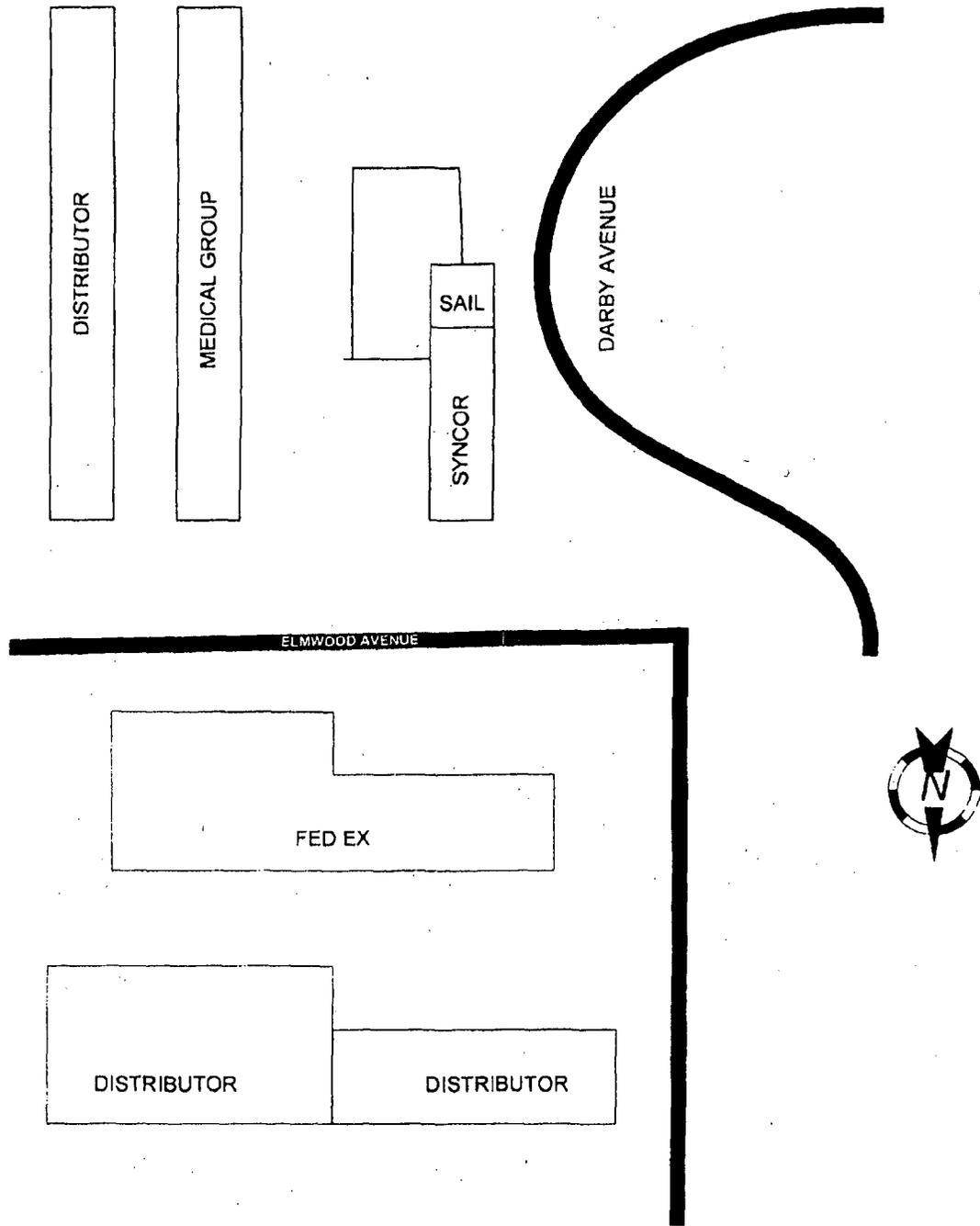
AREA LETTER	DESCRIPTION OF AREA	AREA LETTER	DESCRIPTION OF AREA
A	Reception Area	J	Employee Breakroom
B	Office Supply Room	K	Pharmacist Offices
C	Restroom # 1	L	Conference Room
D	Restroom # 2	M	Storage # 1
E	Computer Room	N	Records Storage
F	Manager's Office	O	Closet
G	RSO / Sales Office	P	Garage Area
H	Restroom # 3	Q	Vestibule
I	Kitchen Area		

Figure 2. Facility Floor Plan

FACILITY AND EQUIPMENT
Sharon Hill, PA

Site Description

1. This Syncor facility will be located in a commercially zoned area at 650 Elmwood Ave, Sharon Hill, Pennsylvania, 19079. This building utilizes concrete block construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.



Loc 72 Site Plan
 Sharon Hill, PA

Figure 1. Facility Site Plan
 Syncor International Corporation

Sharon Hill, PA
 Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 5000 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 2200 square feet

Elution Room - approximately 100 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *ELUTION* on the diagram.

Volatile Substance Room - approximately 140 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 200 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 1260 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Radioactive Waste Storage - approximately 210 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *STORAGE* on the diagram.

Container Processing Area - approximately 290 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *BREAKDOWN* on the diagram.

UNRESTRICTED AREA

Vestibule Area - approximately 130 square feet

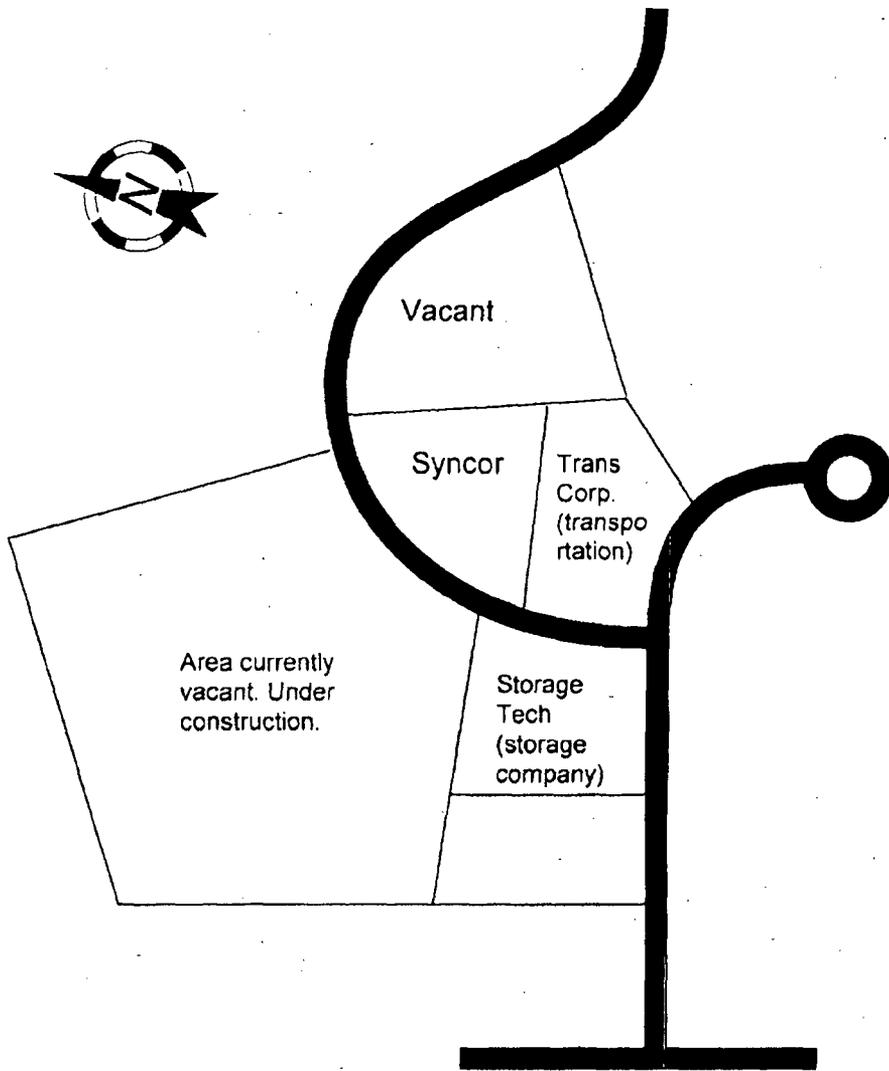
This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *VESTIBULE* on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

**FACILITY AND EQUIPMENT
Hummelstown, PA**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 8181 Presidents Drive, Hummelstown, Pennsylvania 17036. This single-story, freestanding structure is constructed of steel and brick. The heating and cooling system is exclusive for Syncor's facility and the restricted area has its own HVAC system.
2. Please see the attached site plan.



Loc 73 Site Plan
Hummelstown, PA

Figure 1. Facility Site Plan
Syncor International Corporation

Hummelstown, PA
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 4500 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1800 square feet

Elution Room - approximately 90 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *ELUTION* on the diagram.

Volatile Substance Room - approximately 90 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 84 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *PRODUCT LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 1200 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Radioactive Waste Storage - approximately 120 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *STORAGE #6* on the diagram.

Container Processing Area - approximately 220 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *BREAKDOWN* on the diagram.

UNRESTRICTED AREA

Vestibule Area - approximately 110 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *VESTIBULE* on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

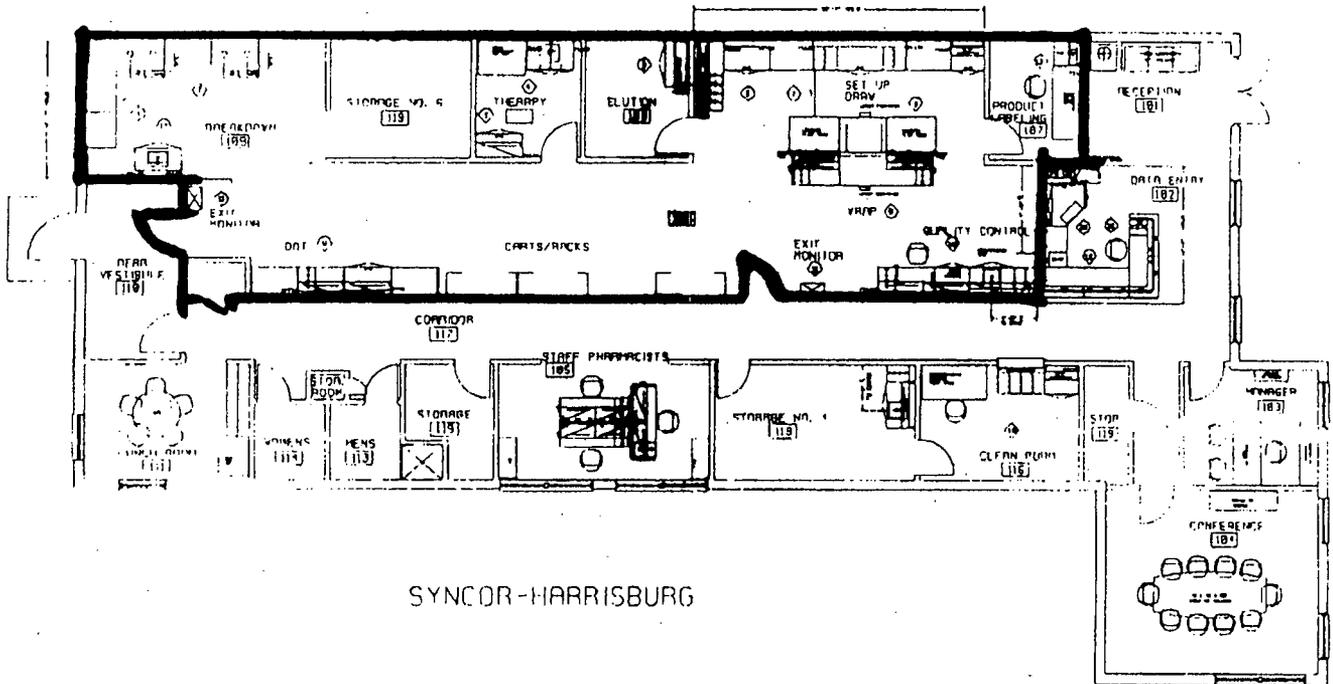


Figure 2. Facility Floor Plan

Syncor International Corporation

Hummelstown, PA
Date: 4/26/2001

**FACILITY AND EQUIPMENT
Stamford, CT**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 28 Omega Drive, Building 7, Stamford, Connecticut, 06907. This building utilizes concrete block construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

LOC 88 SITE PLAN
STAMFORD, CT

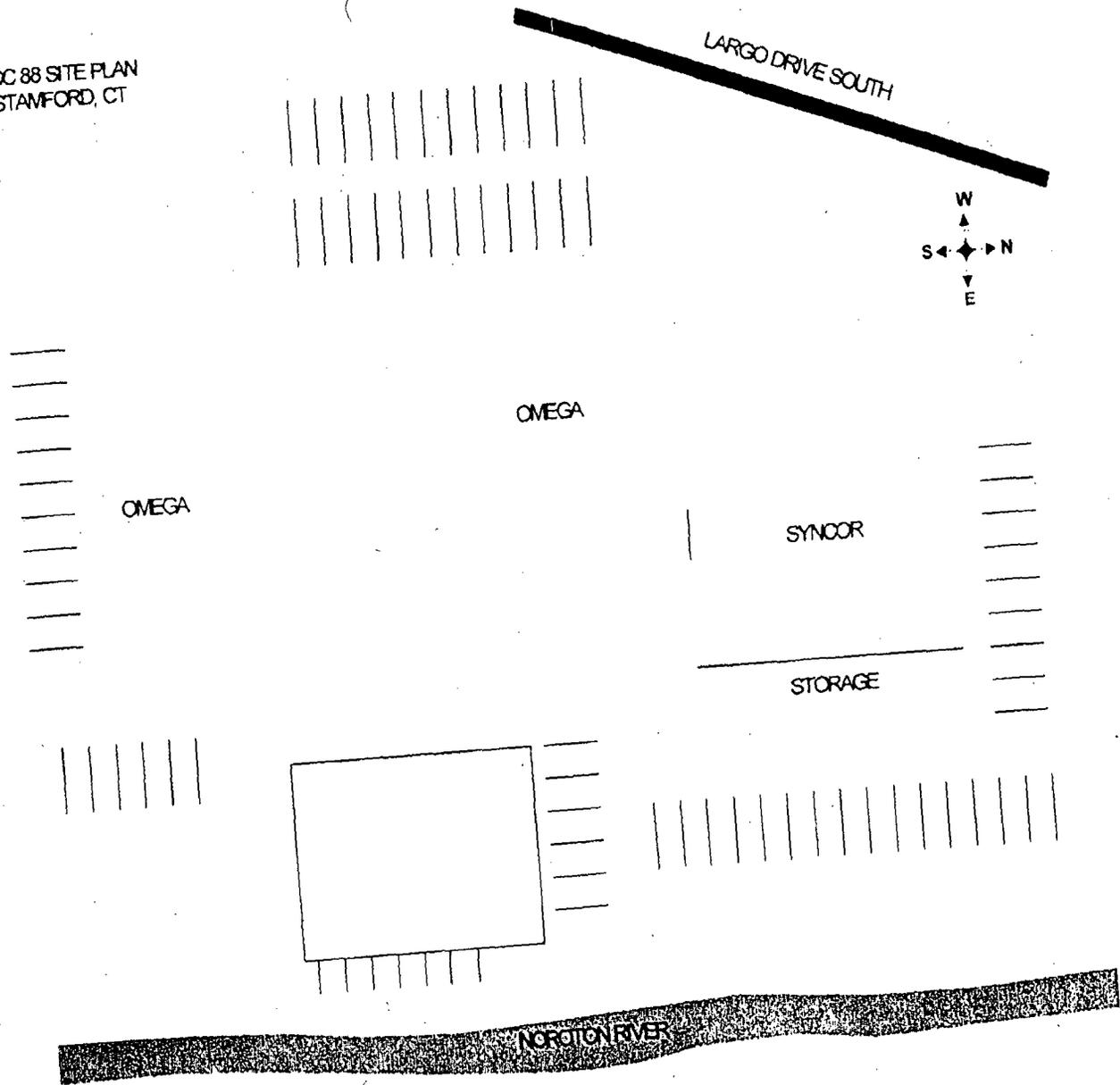


Figure 1. Facility Site Plan
Syncor International Corporation

Stamford, CT
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 5040 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1420 square feet

Elution Room - approximately 90 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *ELUTION* on the diagram.

Volatile Substance Room - approximately 90 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 170 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 710 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Radioactive Waste Storage - approximately 120 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *STORAGE* on the diagram.

Container Processing Area - approximately 240 square feet

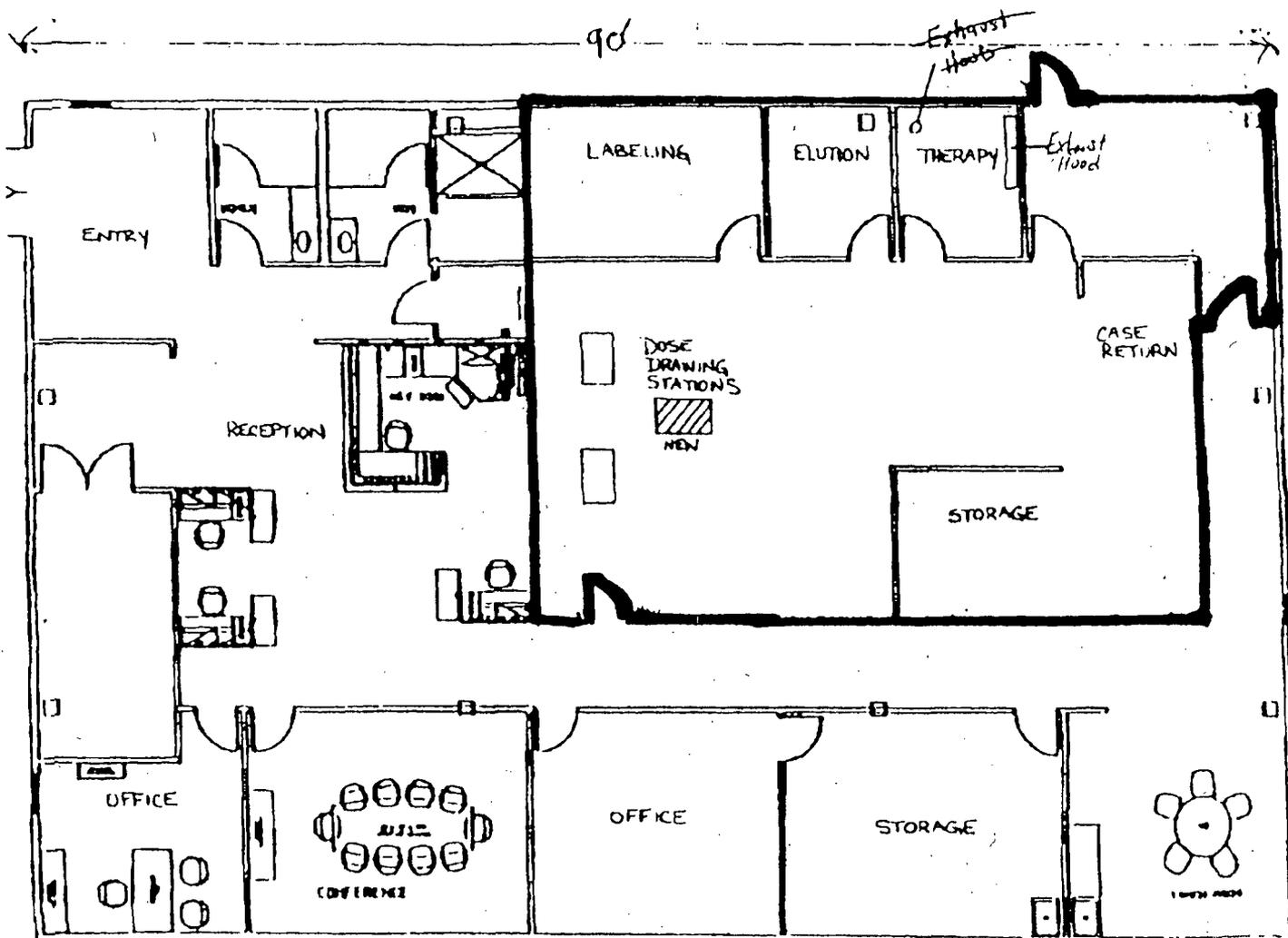
This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN* on the diagram.

UNRESTRICTED AREA

Vestibule Area - approximately 160 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *VESTIBULE* on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.



SYNCOR INTERNATIONAL CORPORATION
 28 OMEGA DRIVE, BUILDING 7
 STAMFORD, CT 06907



Figure 2. Facility Floor Plan

Syncor International Corporation

Stamford, CT
 Date: 4/26/2001

**FACILITY AND EQUIPMENT
Bristol, PA**

Site Description

1. This single-story, multi-tenant structure constructed of steel and concrete block is located at 200 Rittenhouse Circle Unit 9E, Bristol, Pennsylvania, 19057. There is one adjacent tenant. The common wall (North wall) is a fire wall and extends to the roof of the building. This facility has its own HVAC system.
2. Please see the attached site plan.

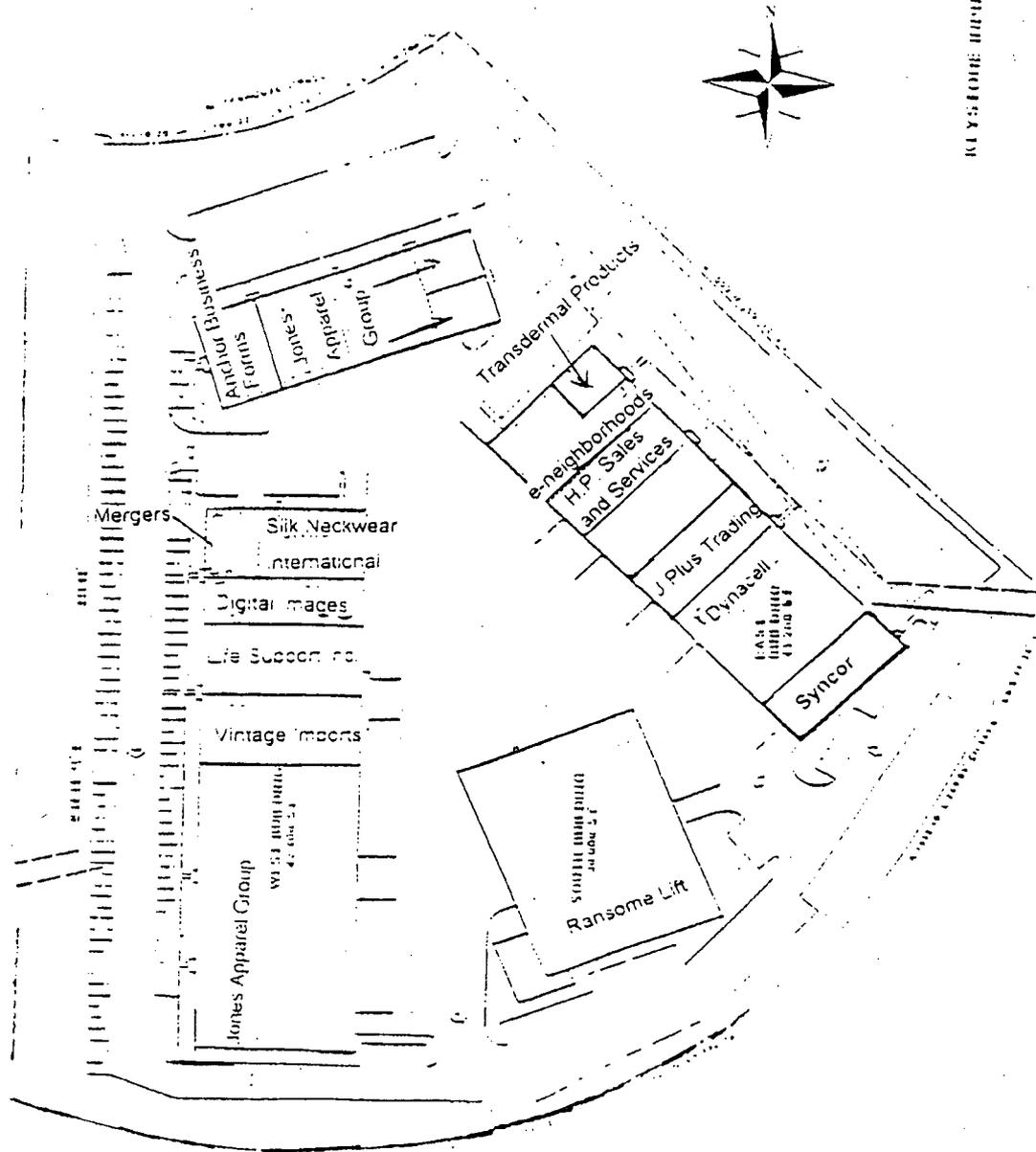


Figure 1. Facility Site Plan

Syncor International Corporation

Bristol, PA
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 4800 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1600 square feet

Elution Room - approximately 90 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *ELUTION* on the diagram.

Volatile Substance Room - approximately 90 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 90 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 110 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *PHARMACY* on the diagram.

Radioactive Waste Storage - approximately 90 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *WASTE ROOM* on the diagram.

Container Processing Area - approximately 120 square feet

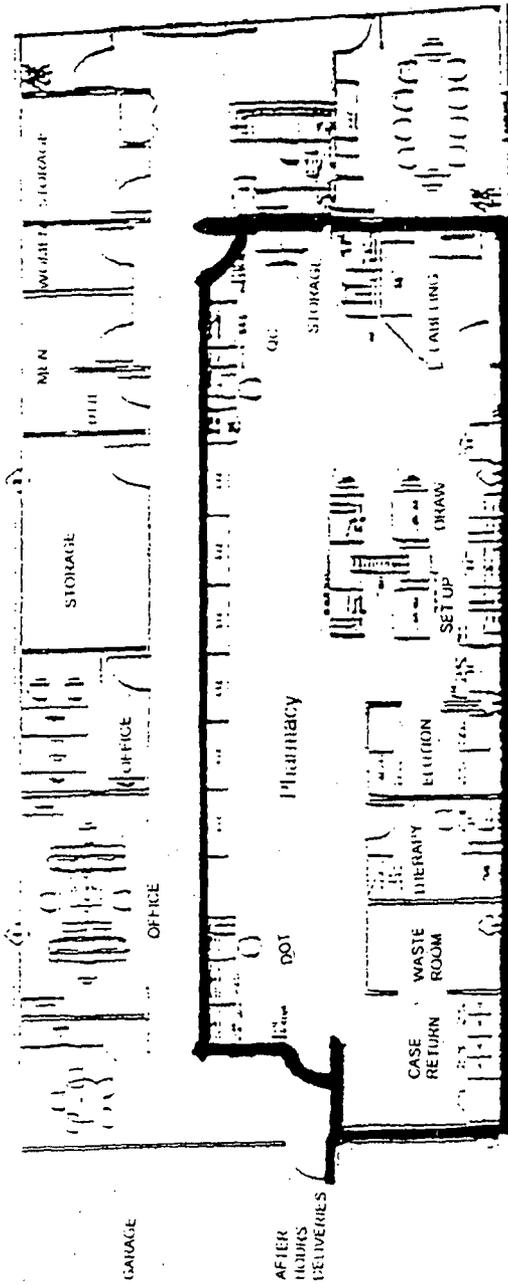
This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN* on the diagram.

Unrestricted Area - See Floor Diagram

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

Syncor International Corporation

**Bristol, PA
Date: 4/26/2001**



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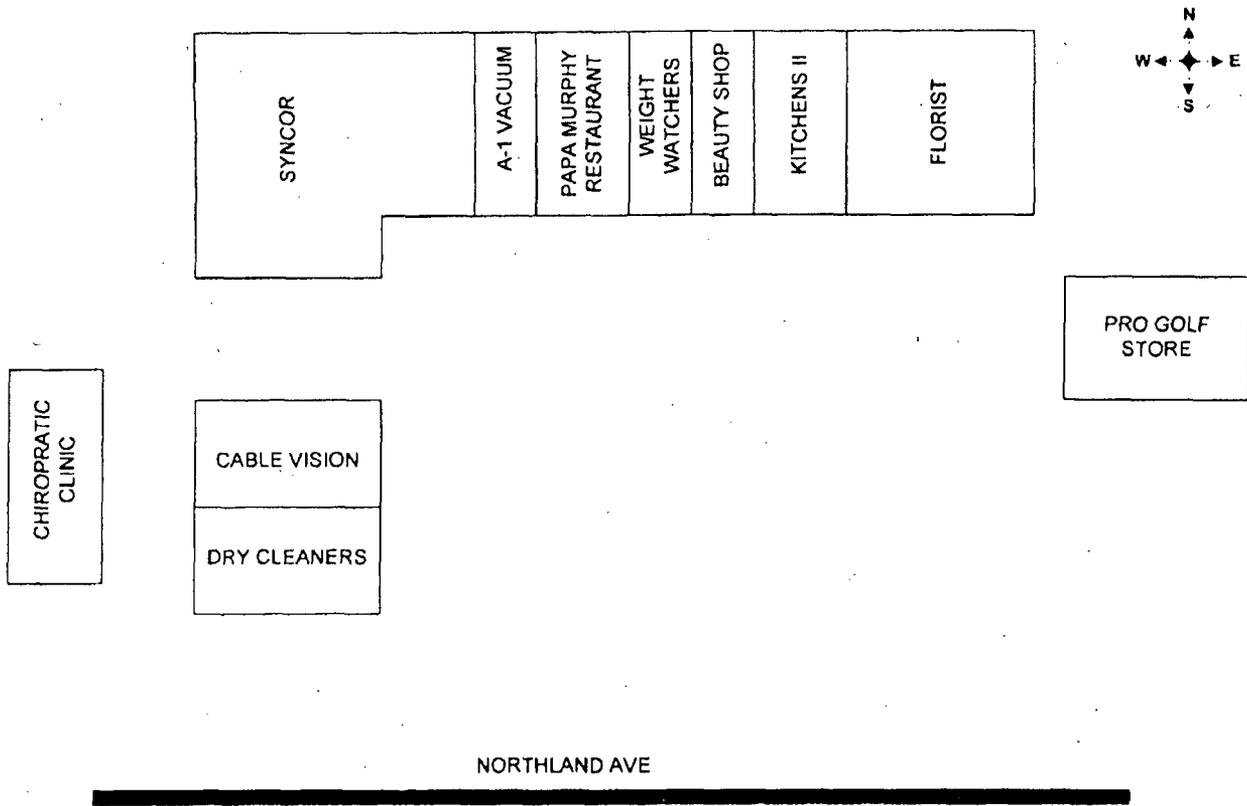
Figure 2. Facility Floor Plan
 Syncor International Corporation

Bristol, PA
 Date: 4/26/2001

**FACILITY AND EQUIPMENT
Appleton, WI**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 420 East Northland Avenue, Appleton, Wisconsin 54915. This single story building utilizes concrete block construction. One common wall is shared with an adjacent tenant. The tenant is adjacent to the east wall of the facility. The common wall is a fire wall which extends to the roof of the building. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.



Loc 106 Site Plan
Appleton, WI

Figure 1. Facility Site Plan

Syncor International Corporation

Appleton, WI
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 3860 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 740 square feet

Elution Room - approximately 90 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *GENERATOR ROOM* on the diagram.

Volatile Substance Room - approximately 90 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 130 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 250 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Radioactive Waste Storage - approximately 90 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *RAM STORAGE* on the diagram.

Container Processing Area - approximately 90 square feet

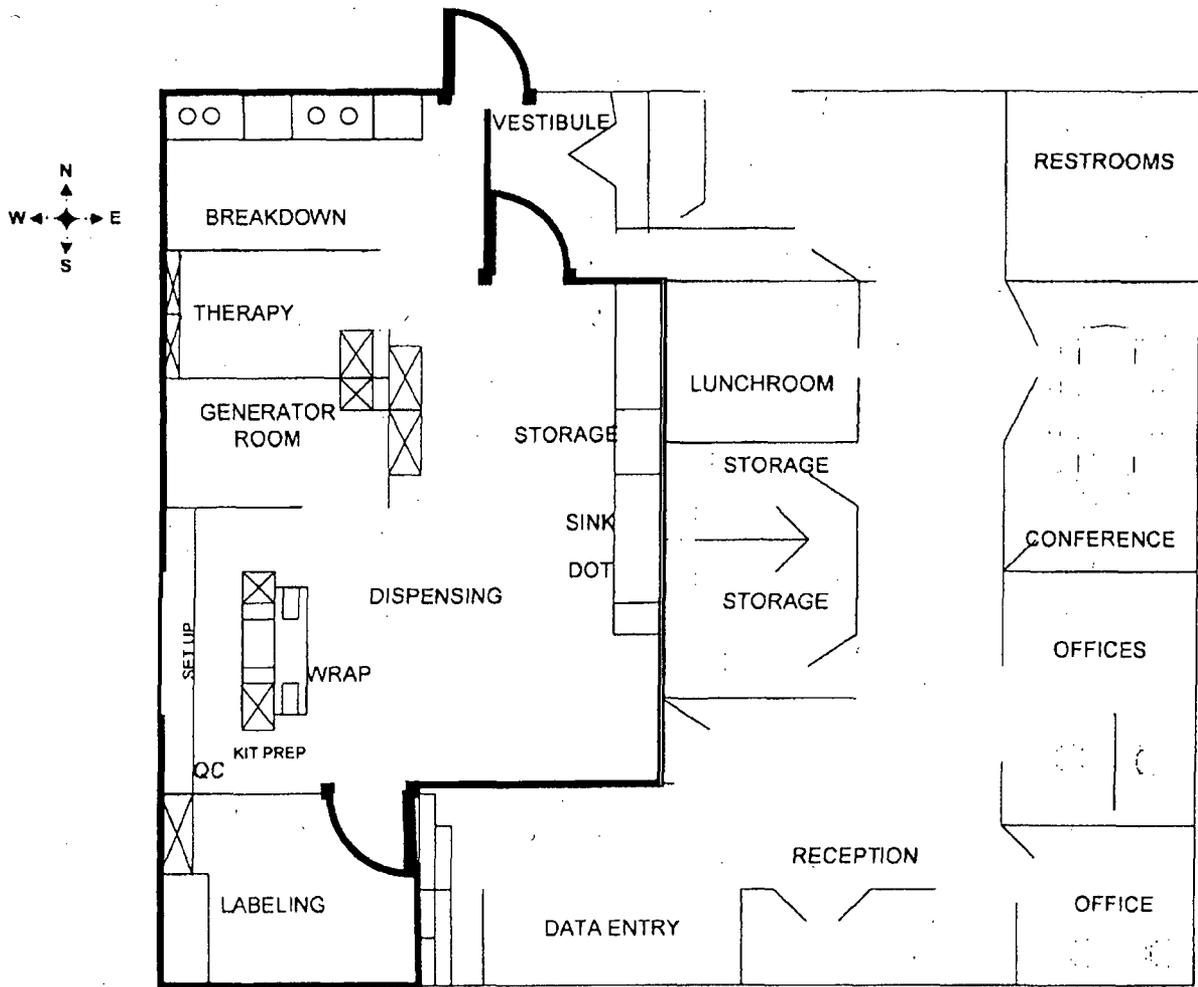
This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *BREAKDOWN* on the diagram.

UNRESTRICTED AREA

Vestibule Area - approximately 110 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *VESTIBULE* on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.



Loc 106 Floor Plan
Appleton, WI

Figure 2. Facility Floor Plan

Syncor International Corporation

Appleton, WI
Date: 4/26/2001

**FACILITY AND EQUIPMENT
Huntington, WV**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 1 Syncor Drive, Huntington, West Virginia, 25705. This one story building utilizes concrete block construction. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

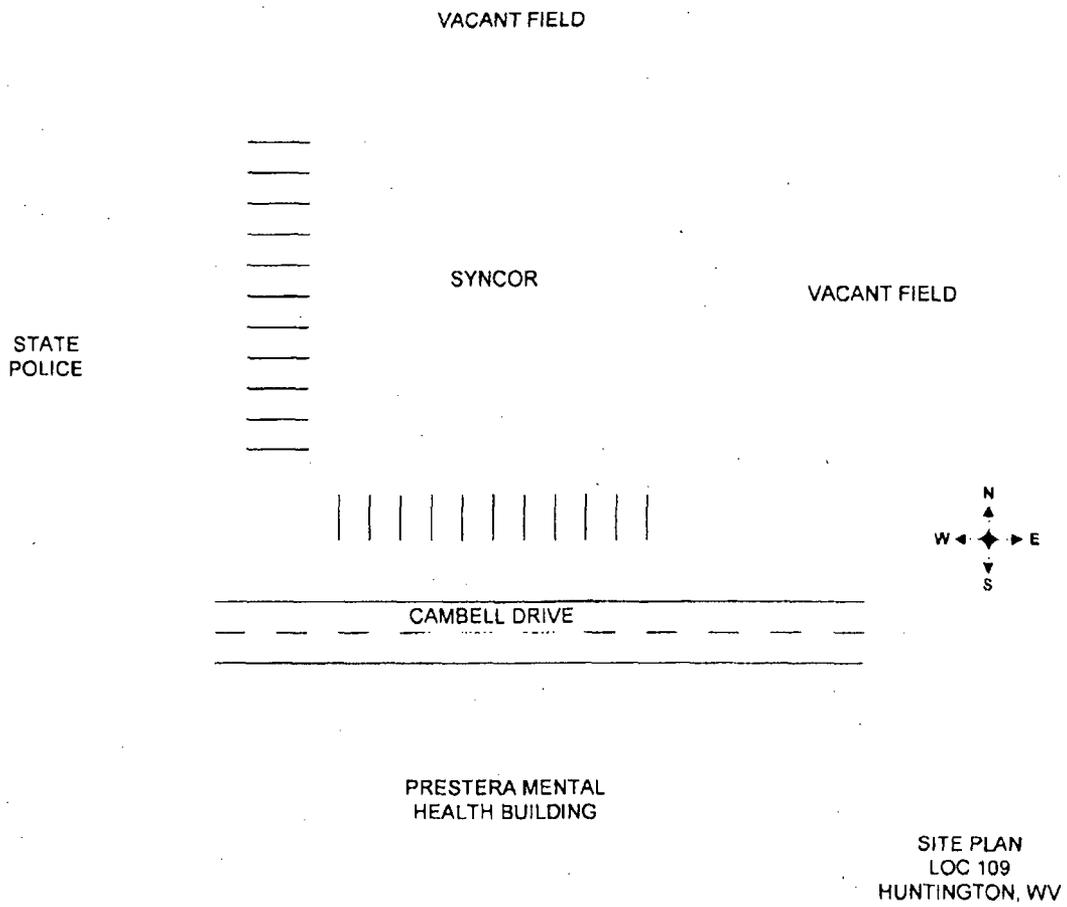


Figure 1. Facility Site Plan
Syncor International Corporation

Huntington, WV
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 4000 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1350 square feet

Elution Room - approximately 40 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *ELUTION* on the diagram.

Volatile Substance Room - approximately 90 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 125 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 940 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Container Processing Area - approximately 100 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN* on the diagram.

UNRESTRICTED AREA

Vestibule Area - approximately 160 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *VESTIBULE* on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

Syncor International Corporation

Huntington, WV
Date: 4/26/2001

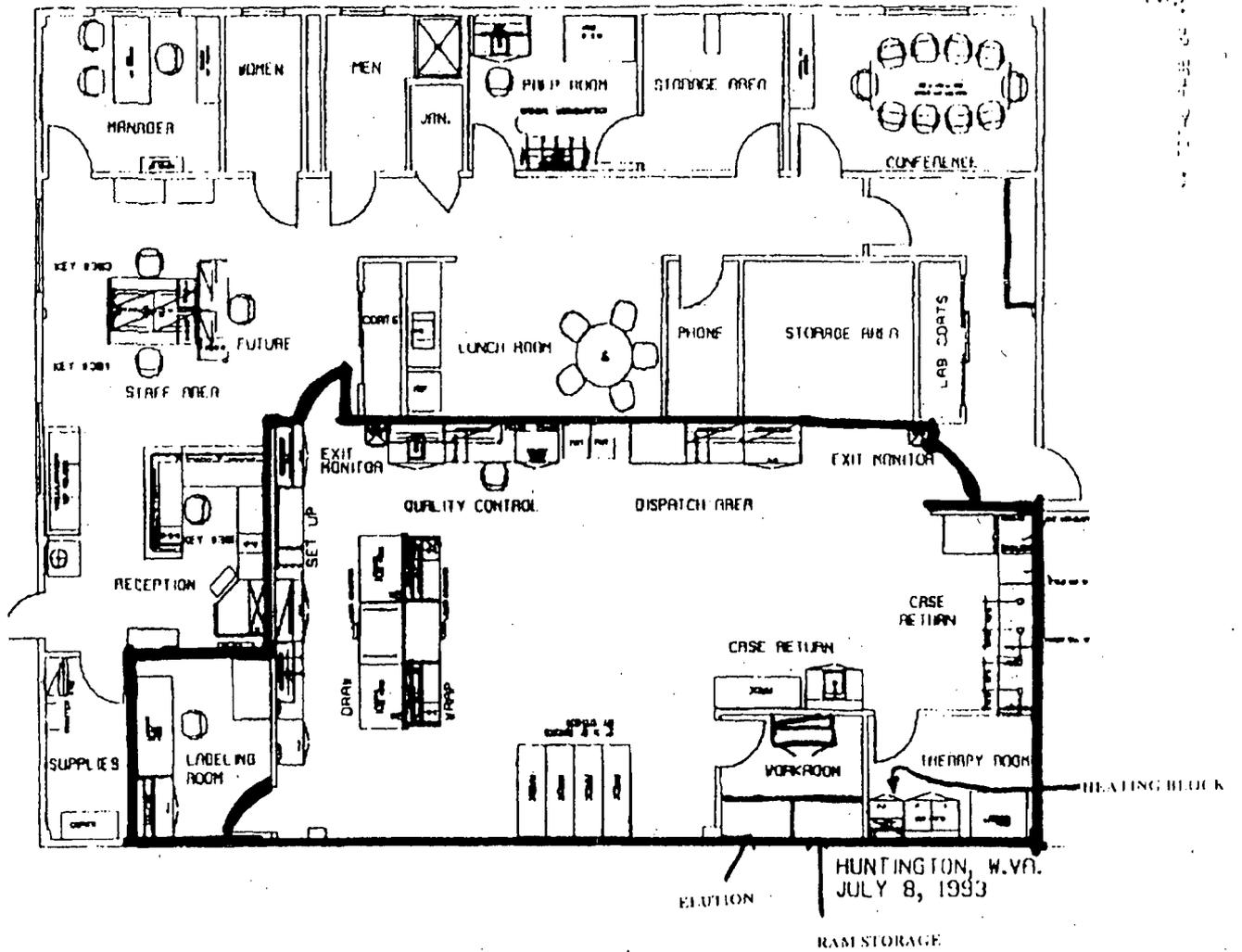


Figure 2. Facility Floor Plan

Syncor International Corporation

Huntington, WV
Date: 4/26/2001

**FACILITY AND EQUIPMENT
Duncansville, PA**

Site Description

1. This single story, multi-tenant building made of cement block construction is located at 3432 Route 764, Sugar Run Plaza, Building 1, Duncansville, Pennsylvania, 19973. There are adjacent tenants located on the north, east, and southeast walls. The common walls are fire walls that extend to the roof of the building. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

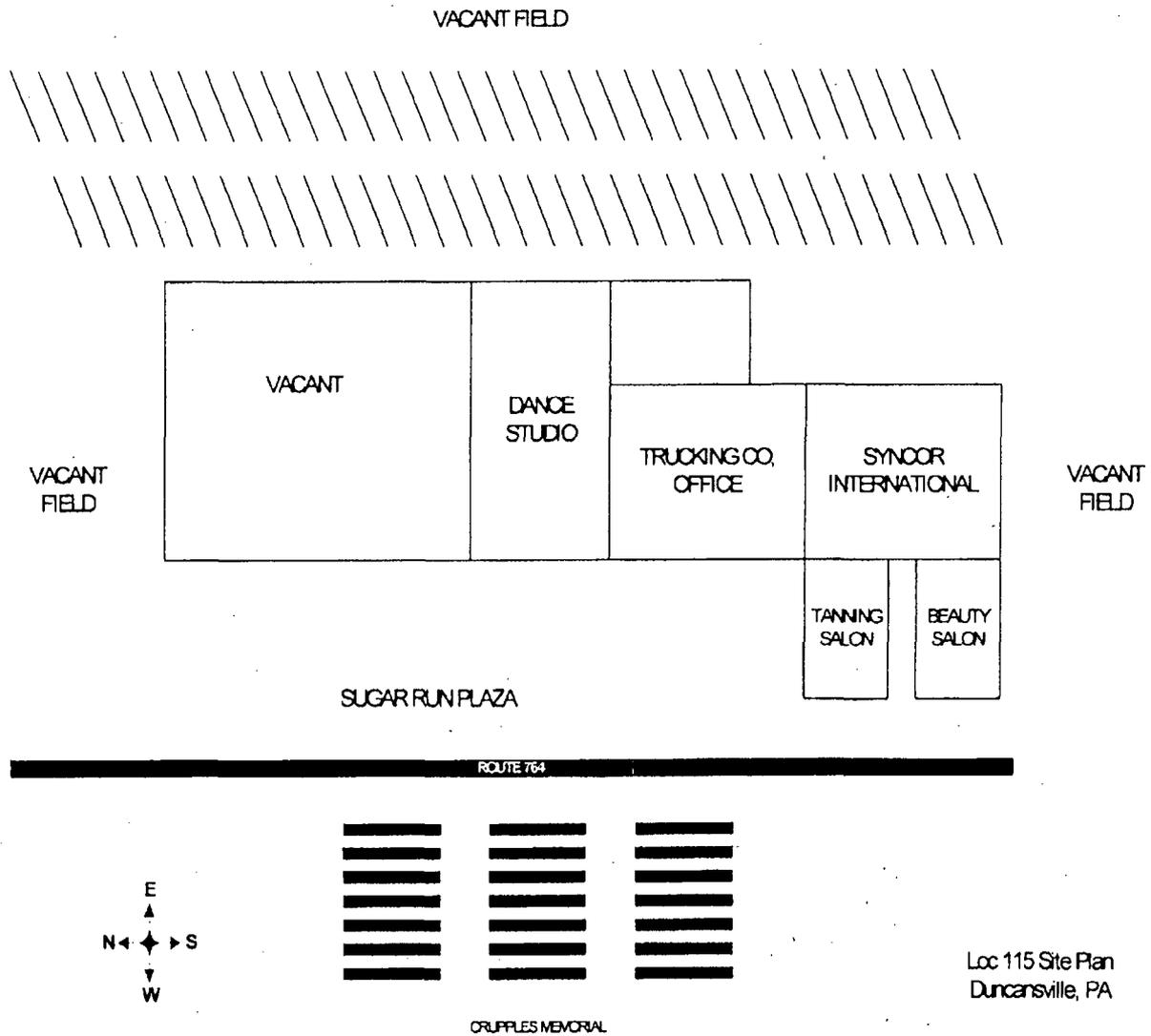


Figure 1. Facility Site Plan

Syncor International Corporation

Duncansville, PA
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 2250 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 713 square feet

Elution and Volatile Substance Room - approximately 144 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area also houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 81 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 380 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Radioactive Waste Storage and Breakdown Area - approximately 108 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN* on the diagram.

UNRESTRICTED AREA

Vestibule Area - approximately 190 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *VESTIBULE* on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

An amendment request has been submitted to the NRC pertaining to changes to the floor diagram. The current and proposed floor plans are attached.

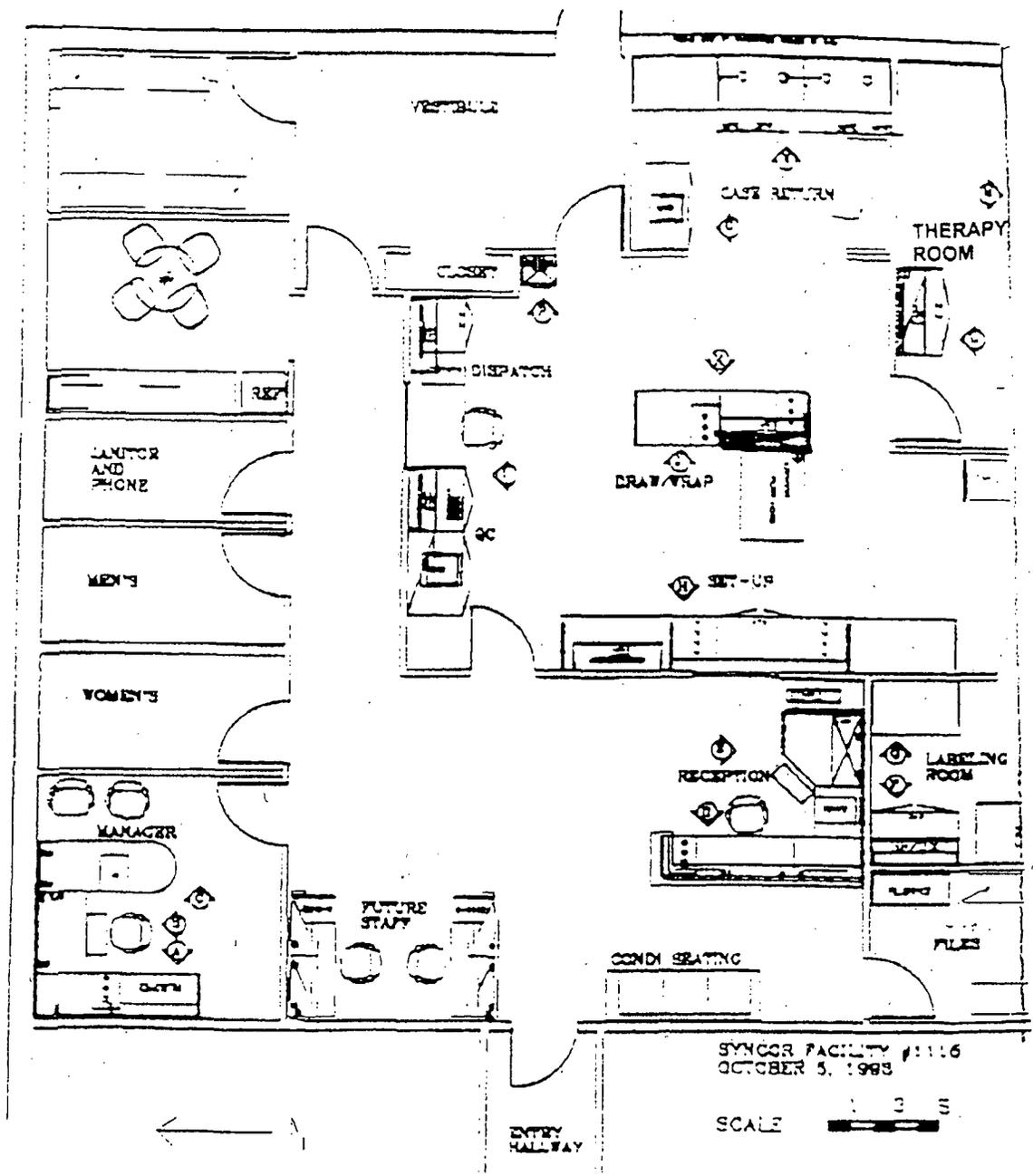


Figure 2. Current Facility Floor Plan

Syncor International Corporation

Duncansville, PA
 Date: 4/26/2001

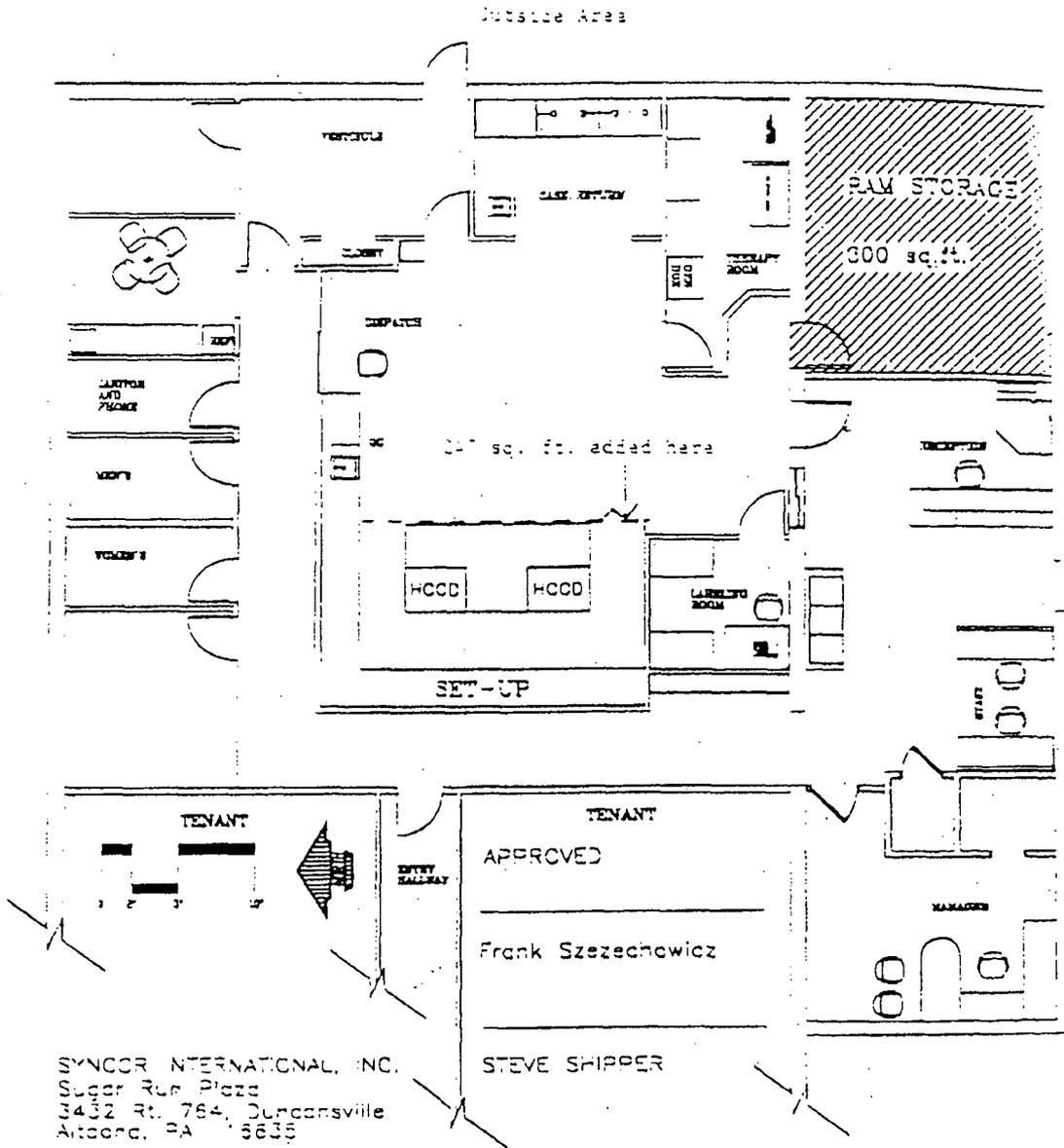


Figure 3. Proposed Facility Floor Plan

Syncor International Corporation

Duncansville, PA
Date: 4/26/2001

**FACILITY AND EQUIPMENT
Springfield, MO**

Site Description

1. This Syncor facility will be located in a commercially zoned area at 3040 East Elm Street, Springfield, Missouri 65802. The single story building utilizes concrete block construction. The east wall is shared with a neighboring tenant. At present time, the neighboring facility is vacant. One common wall is shared with an adjacent tenant. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

General Description of Facility

Syncor International Corporation has leased approximately 2212 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 830 square feet

Elution Room - approximately 60 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *ELUTION* on the diagram.

Volatile Substance Room – approximately 72 square feet

This area houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *IODINE* on the diagram.

Labeling Room - approximately 40 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 550 square feet

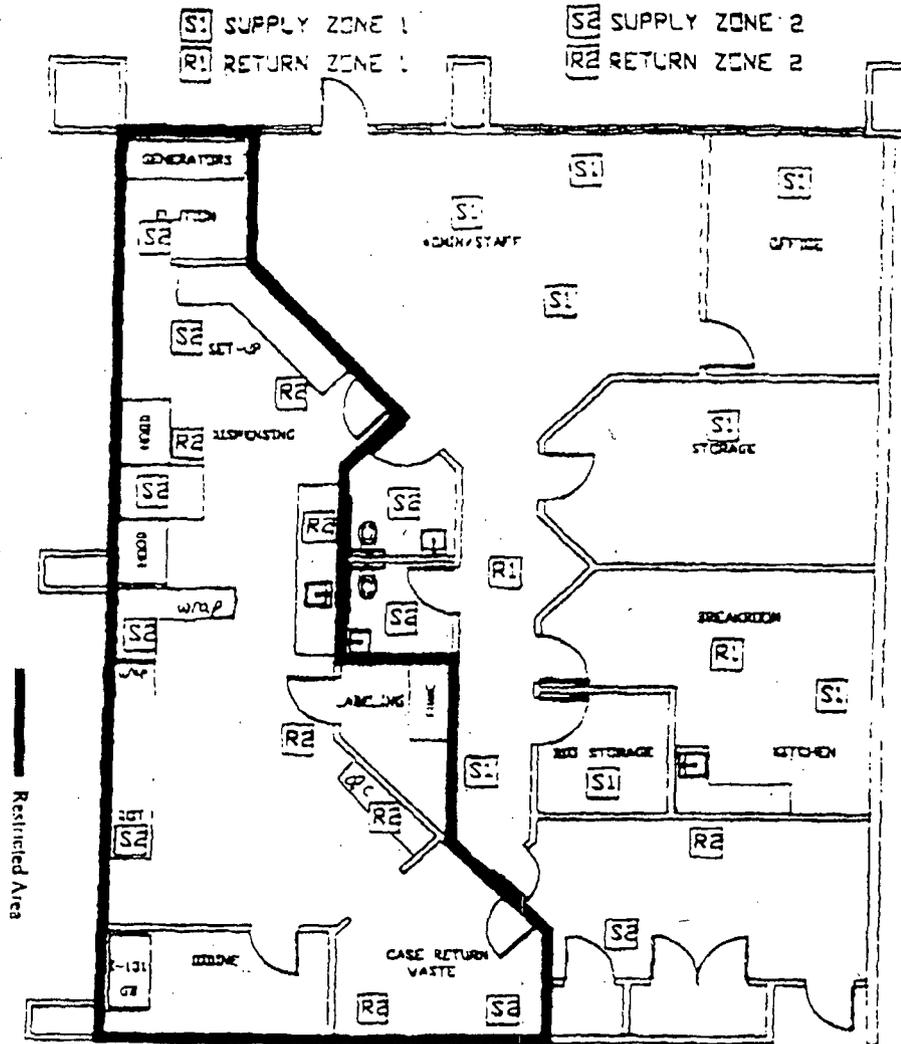
This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Radioactive Waste Storage - approximately 105 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN WASTE* on the diagram.

Unrestricted Area – See Floor Diagram

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.



MANAGER APPROVAL / DATE

SPRINGFIELD, LOC #120
 3040 E. ELM ST
 SPRINGFIELD MISSOURI
 65802

SCALE 1/8"=1'-0"
 3/24/98 JA
 1234567



Figure 2. Facility Floor Plan

Syncor International Corporation

Springfield, MO
 Date: 4/26/2001

FACILITY AND EQUIPMENT
Erie, PA

Site Description

1. This single story, multi-tenant building made of concrete and brick construction is located at 3800 West 12th Street, Erie, Pennsylvania, 16505. The southwest and southeast walls of this facility are outside walls. There is an adjacent tenant located on the northeast wall. The common wall is a fire wall that extends to the roof of the building. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.

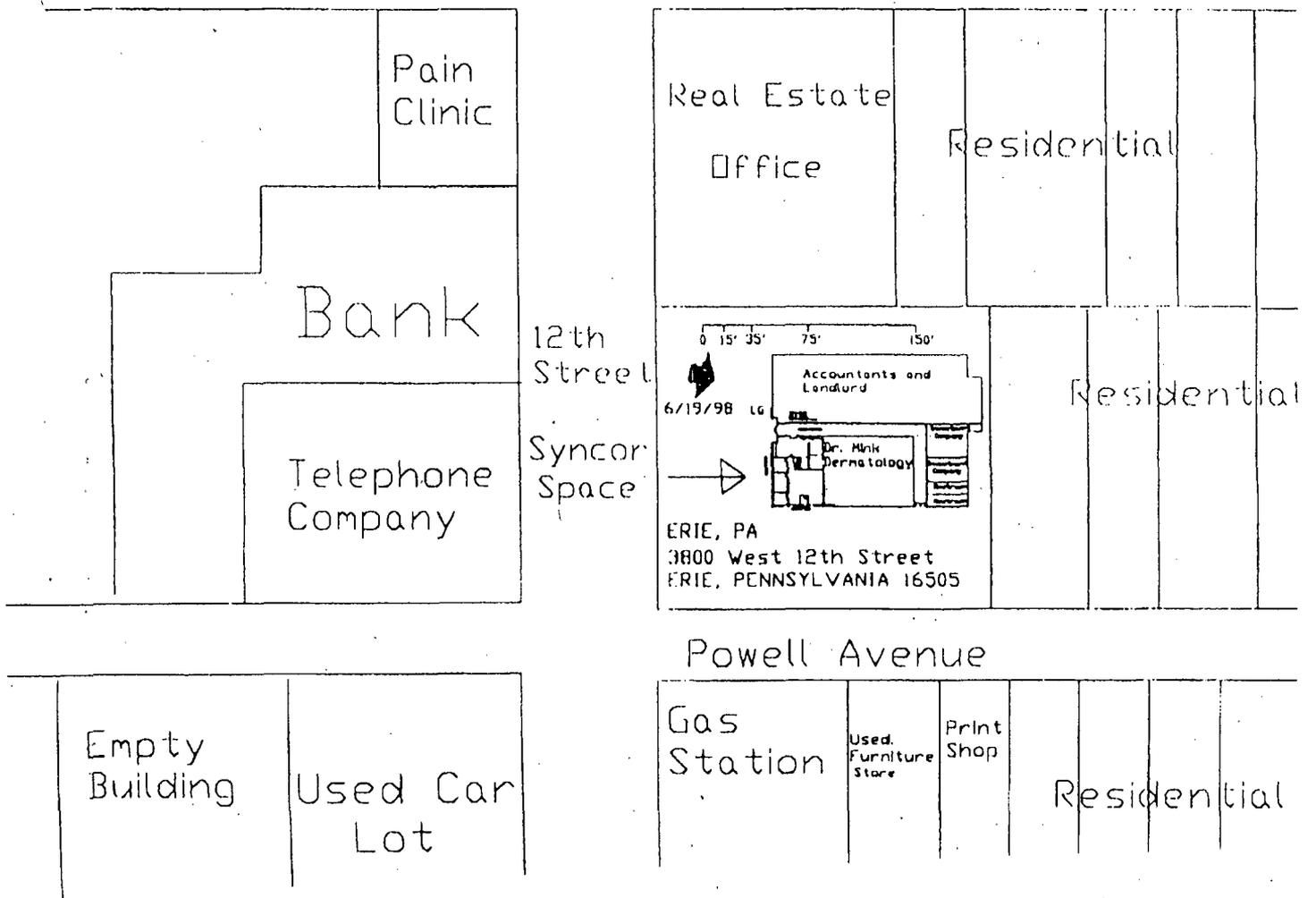


Figure 1. Facility Site Plan

Syncor International Corporation

Erie, PA
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 1548 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 984 square feet

Elution and Volatile Substance Room - approximately 140 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area also houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *IODINE AND ELUTION* on the diagram.

Labeling Room - approximately 100 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 600 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPENSING* on the diagram.

Radioactive Waste Storage Area - approximately 80 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *RAM* on the diagram.

Container Processing Area – approximately 64 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN* on the diagram.

Unrestricted Area – See Floor Diagram

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

Syncor International Corporation

Erie, PA
Date: 4/26/2001

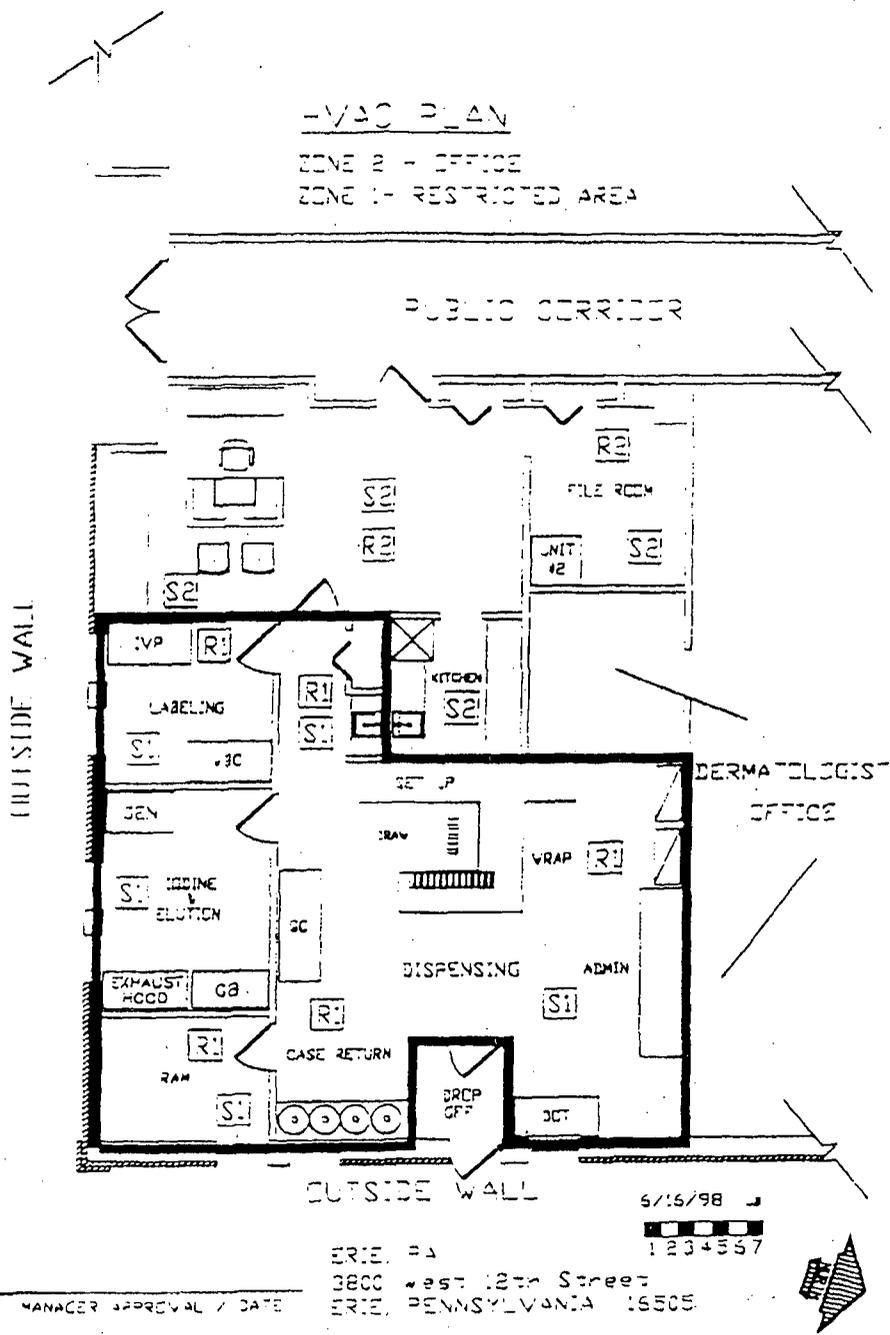


Figure 2. Facility Floor Plan

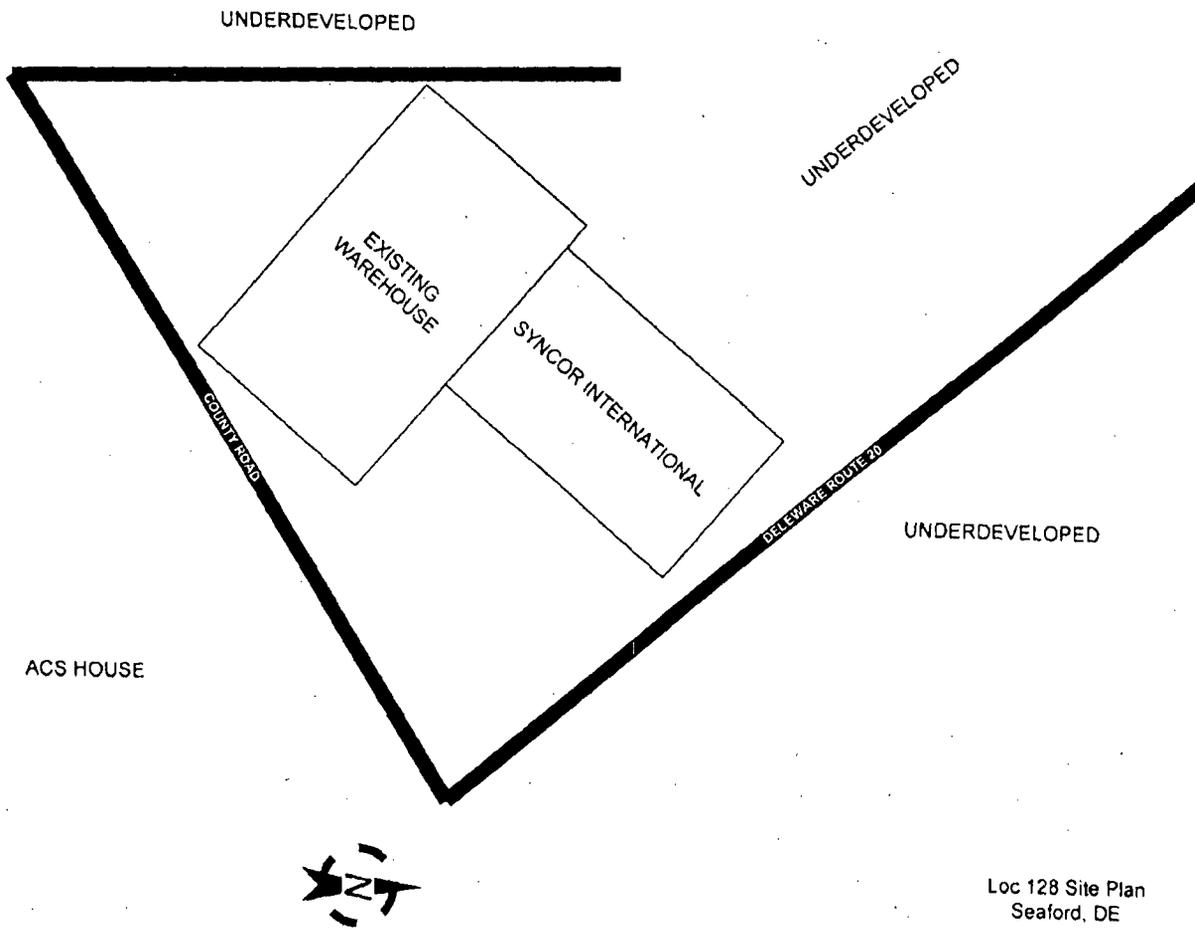
Syncor International Corporation

Erie, PA
Date: 4/26/2001

FACILITY AND EQUIPMENT
Seaford, DE

Site Description

1. This single story, multi-tenant building made of metal construction, with a metal roof and concrete flooring is located at Rd 3, Box 367, Route 20 West, Seaford, Delaware 19973. There is one adjacent tenant located on the south wall. The common wall is a fire wall that extends to the roof of the building. The heating and cooling system is exclusive for Syncor's facility and is a multiple zone system.
2. Please see the attached site plan.



Loc 128 Site Plan
Seaford, DE

Figure 1. Facility Site Plan
Syncor International Corporation

Seaford, DE
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 3200 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 560 square feet

Elution and Volatile Substance Room - approximately 104 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area also houses the standard laboratory fume hood and radioiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *THERAPY* on the diagram.

Labeling Room - approximately 88 square feet

This room houses the biohazard hood and is used for blood cell component tagging. This area also houses the vertical flow hood for use in I.V. preparation. This area is labeled *LABELING* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 220 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *DISPATCH* on the diagram.

Radioactive Waste Storage and Breakdown Area - approximately 120 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *CASE RETURN* on the diagram.

UNRESTRICTED AREA

Vestibule Area - approximately 130 square feet

This area is for the receipt of packages received during non-business hours. The carriers have keyed access to the vestibule only, with the remainder of the facility being secure from the delivery personnel. This area is labeled *VESTIBULE* on the diagram.

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

Syncor International Corporation

Seaford, DE
Date: 4/26/2001

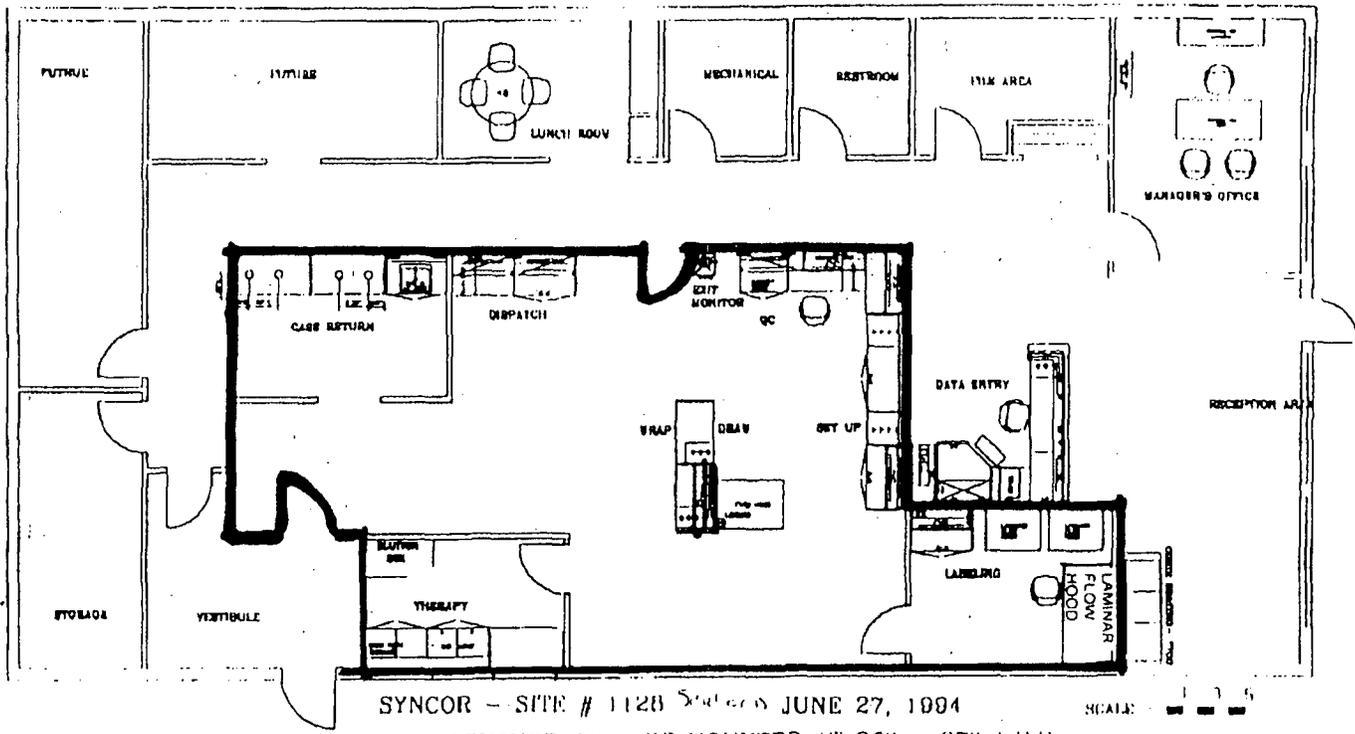


Figure 2. Facility Floor Plan

Syncor International Corporation

Seaford, DE
 Date: 4/26/2001

**FACILITY AND EQUIPMENT
Marshfield, WI**

Site Description

1. This single-story, free standing building constructed of concrete block is located at 201 West 6th Street, Marshfield, WI 54449. This facility has its own HVAC system.
2. Please see the attached site plan.

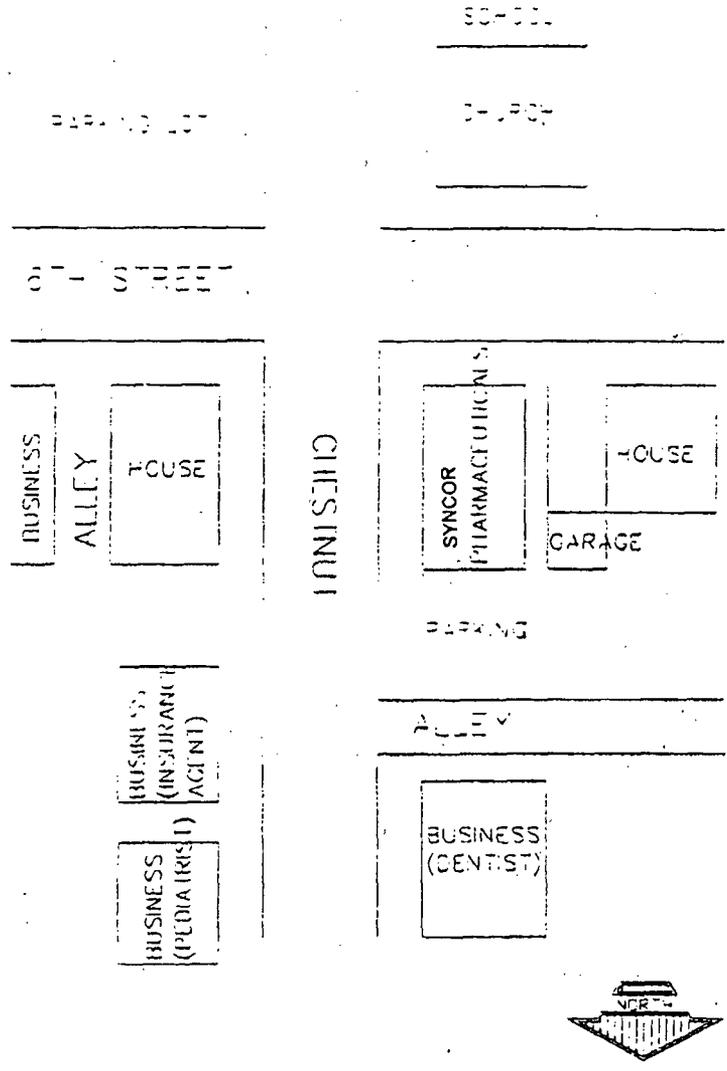


Figure 1. Facility Site Plan

Syncor International Corporation

Marshfield, WI
Date: 4/26/2001

General Description of Facility

Syncor International Corporation has leased approximately 2500 square feet of space for use as a radiopharmacy. Sketches of the floor plan and equipment placement are shown in Figure 2.

RESTRICTED AREA - approximately 1350 square feet

Elution Room - approximately 23 square feet

This area is used for storage of ongoing, used radiopharmaceuticals and sealed sources, including Mo99/Tc99m generators. All actively used generators will be housed in auxiliary shielding provided by the manufacturer with additional lead shielding located around the generators, as necessary. This area is labeled *GENERATOR ROOM* on the diagram.

Volatile Substance Room - approximately 61 square feet

This area houses the standard laboratory fume hood and radiiodine compounding fume hood. All volatile substances are stored and handled in this area (i.e. the storage of xenon-133 and the compounding of iodine-131.) 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 area to ensure that no air from this room may be circulated to other areas of the facility. This area is labeled *I-131* on the diagram.

Brachytherapy Room - approximately 95 square feet

This room is used for the storage of brachytherapy seeds. This area is labeled *BRACHYTHERAPY* on the diagram.

Radiopharmaceutical Dispensing Area (Pharmacy) - approximately 988 square feet

This area is used for preparation and dispensing of radiopharmaceuticals. Dose dispensing stations will be located as shown on the attached floor plan. The dose dispensing stations consist of a leaded glass L-block, a dose calibrator, and forceps. Technetium and technetium products are eluted, prepared, and stored in elution vial shields supplied by the various generator manufacturers or Syncor. Quality control and DOT procedures are also performed in this area. This area is labeled *PHARMACY* on the diagram.

Radioactive Waste Storage - approximately 106 square feet

This area is used for the processing of shipping containers returned from customers and for the storage and decay of waste. This area is labeled *WASTE ROOM* on the diagram.

Unrestricted Area - See Floor Diagram

NOTE: Manufacturer's shielding will be used in isotope and waste storage areas. Additional shielding will be provided as necessary.

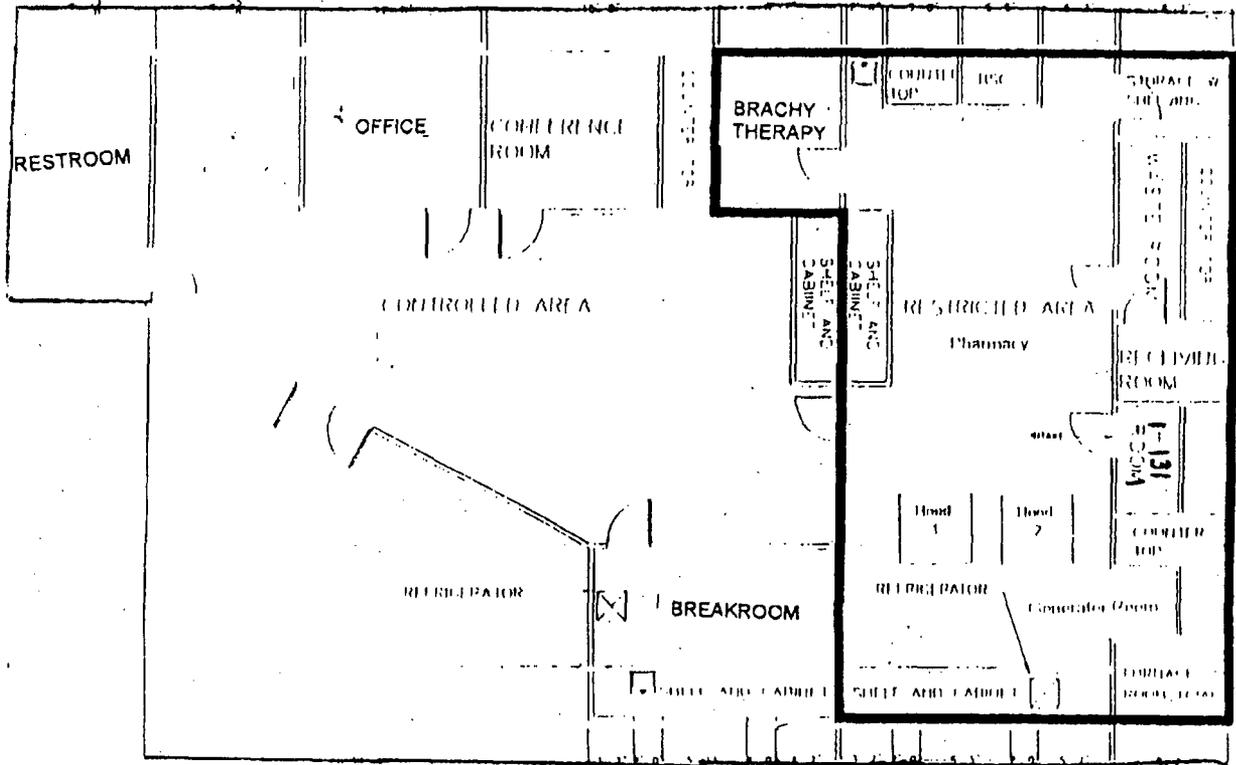


Figure 2. Facility Floor Plan

Syncor International Corporation

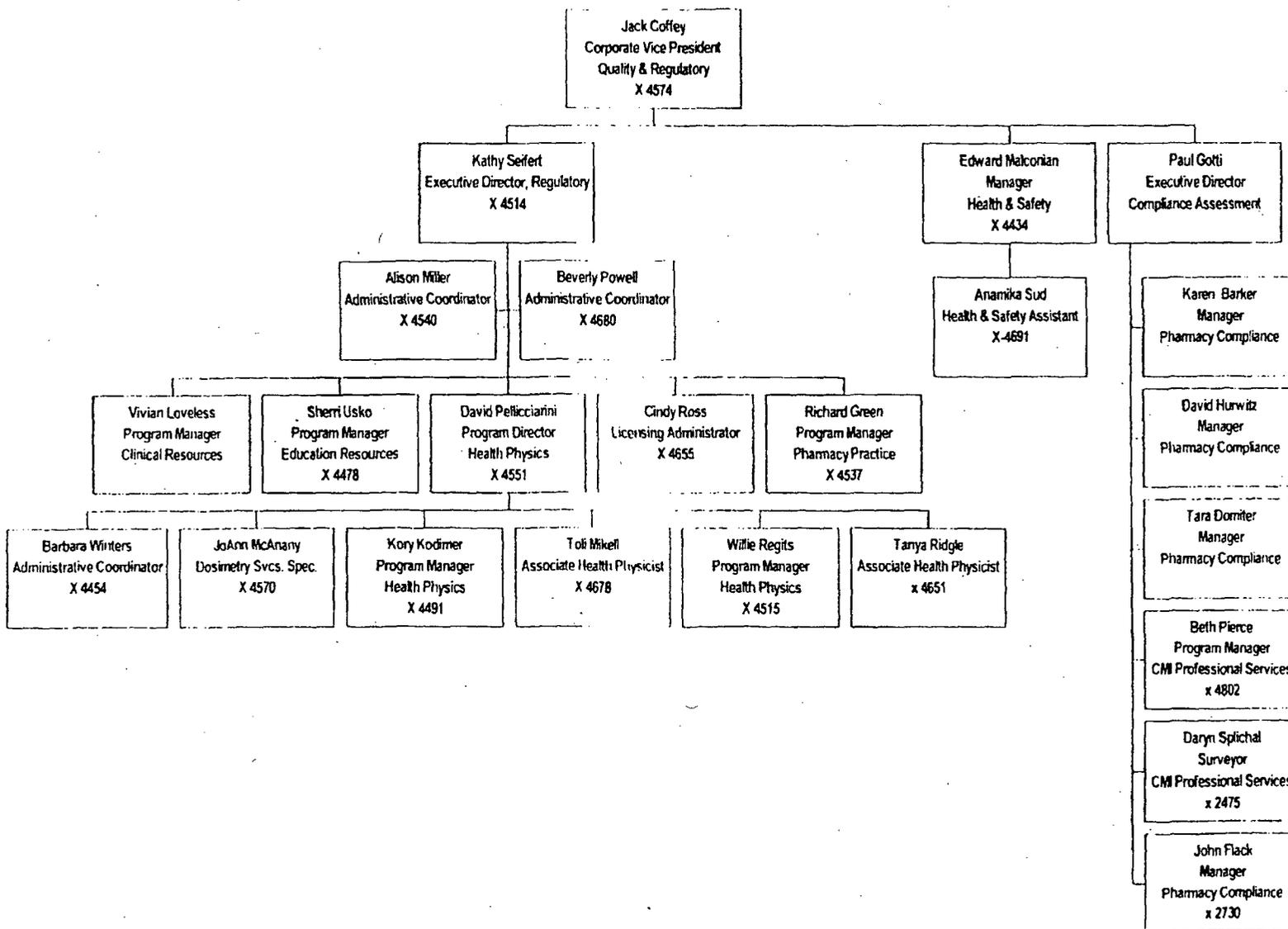
**Marshfield, WI
Date: 4/26/2001**

APPENDIX F
SYNCOR ORGANIZATIONAL CHARTS

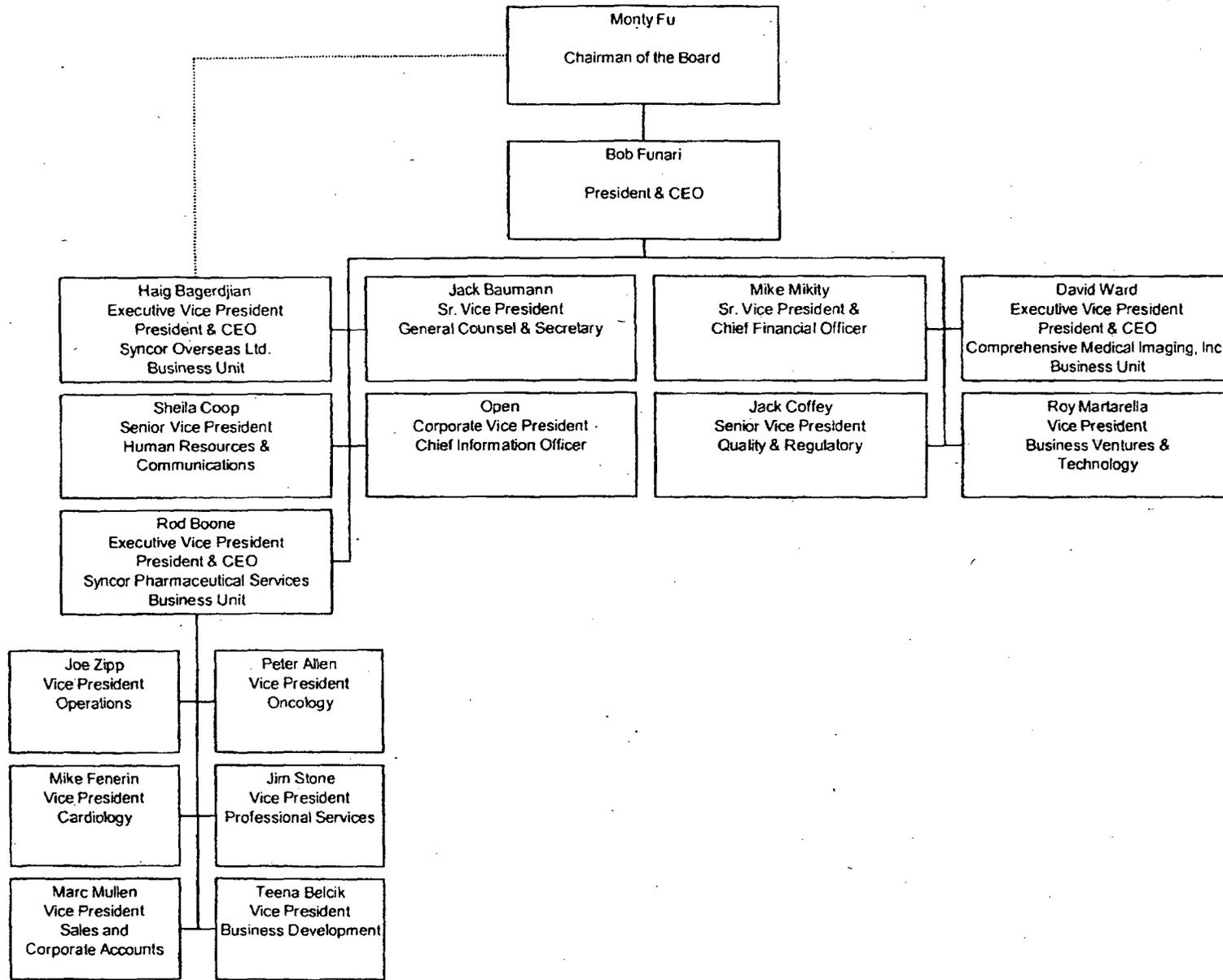
Syncor International Corporation

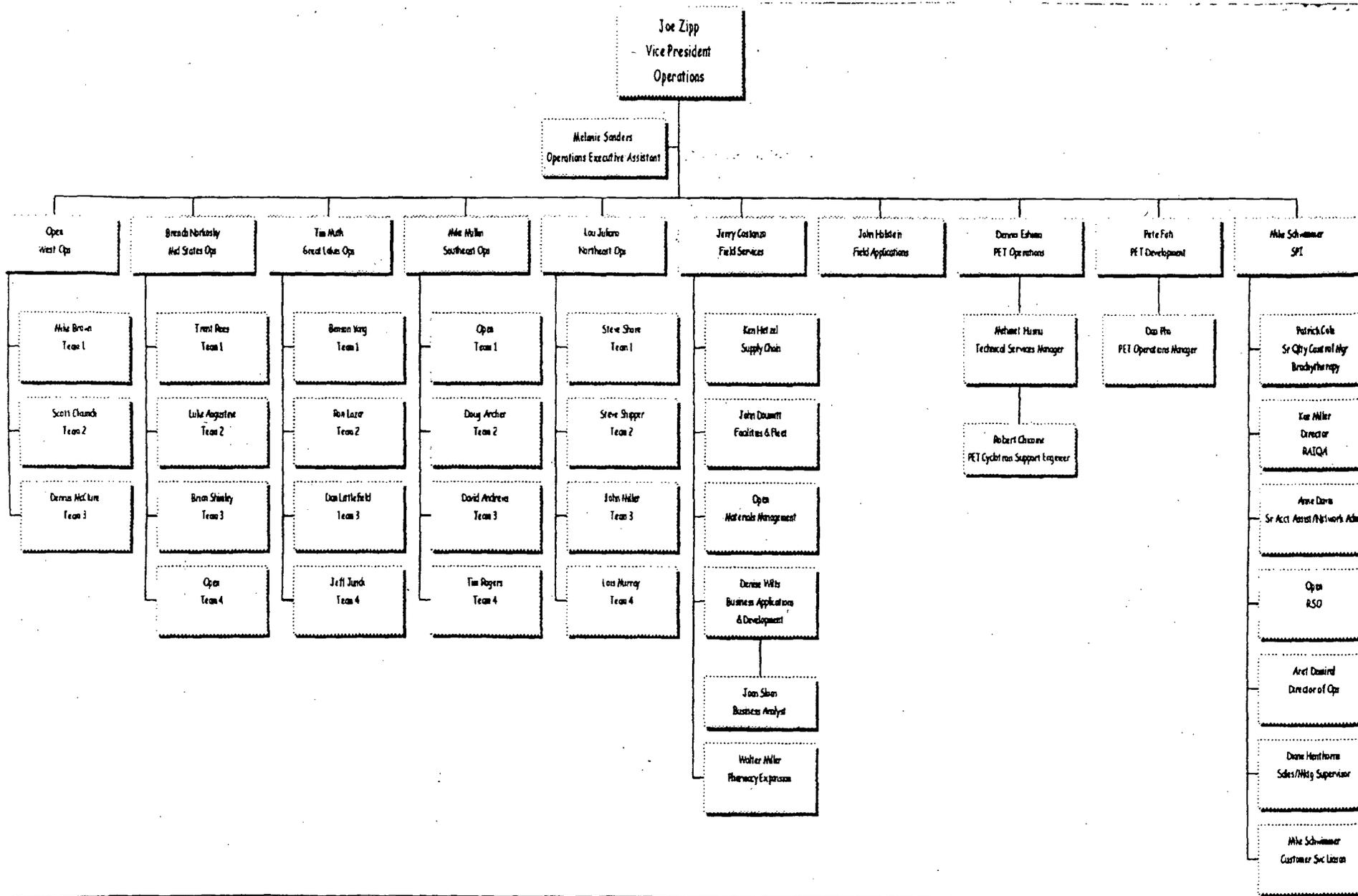
Organizational Chart - Quality & Regulatory Department

January 2001



Syncor International Corporation





Operations Organizational Chart