MATERIALS LICENSE

Amendment No. 4

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	
1. **Syncor de Puerto Rico, Inc.**	**In accordance with the letter dated September 28, 1996** 3. License Number 52-16345-02MD **is amended in its entirety to read as follows:**
2. P.O. Box 4408 Carolina, Puerto Rico 00984	4. Expiration Date **April 30, 2005 (extended)**
	5. Docket or Reference No. 030-19134

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State requirements	A. Any form initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State requirements	A. Molybdenum 99 - 1.85 terabecquerels (TBq) (50 curies) ; Technetium 99m - 1.85 TBq (50 curies); **Iodine 131 - 33.3 gigabecquerels (GBq) (900 millicuries);** All others combined, 18.5 GBq (500 millicuries)
B. Any byproduct material authorized under 10 CFR, 35.57(a).	B. Any sealed source listed in paragraph 10 CFR 35.57(a) of 10 CFR Part 35 that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	B. **555 megabecquerels (MBq) (15 millicuries) total**
C. Any byproduct material identified in 10 CFR, Part 31.11(a)	C. Prepackaged units for <u>in vitro</u> diagnostic tests	C. 1.85 GBq (50 millicuries)
D. Uranium (depleted in the isotope uranium 235)	D. Metal enclosed in stainless steel	D. 180 kilograms

ML 21

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 52-16345-02MD

Docket or Reference Number: 030-19134

Amendment No. 4

9. Authorized Use:

A. Preparation and distribution of radioactive drugs (includes Mo99/Tc99m generators) to authorized recipients.

B. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 10 CFR 35.57(a) of 10 CFR Part 35 or under equivalent licenses of Agreement States.

C. Redistribution to specific licensees or general licensees pursuant to 31.11 of 10 CFR Part 31 provided the packaging and labelling remain unchanged.

D. Shielding for molybdenum 99/technetium 99m generators.

Pursuant to Sections 32.72 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through C. of this license to persons licensed pursuant to Sections 35.100, 35.200, and 35.300 of 10 CFR Part 35, or under equivalent Agreement State licenses.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at WA 15 Los Angeles, Carolina, Puerto Rico.

11. A. Licensed material shall be used by, or under the supervision of:

(1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 32.72(b)(2) and 32.72(b)(3) of 10 CFR Part 32, or

(2) authorized on Byproduct Materials License 04-26507-01MD;

(3) Alicia Albert, R.Ph.

B. The Radiation Safety Officer for this license is Jay R. Simon, R.Ph., and in his absence, Alicia Albert, R.Ph.

12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 52-16345-02MD

Docket or Reference Number: 030-19134

Amendment No. 4

CONDITIONS

Continued -

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

E. Sealed sources 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.

F. 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 II, ATTN: Chief, Materials Licensing/Inspection Branch, 101 Marietta St. NW, Atlanta, Georgia 30323-0199. The report shall specify the source involved, the test results, and corrective action taken.

G. 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.

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

14. The licensee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under this license.

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

16. Radioactive waste (e.g., syringes, vials) that contains or is contaminated with radioactive materials that the licensee originally supplied to its customers may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in the application dated December 7, 1988.

17. 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 52-16345-02MD

Docket or Reference Number: 030-19134

Amendment No. 4

CONDITIONS

Continued -

17. 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.

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

18. In addition to the possession limits in condition 8, the licensee shall further restrict the possession of licensed material so that at no time is a quantity of radioactive material possessed in excess of a quantity that requires decommissioning funding in accordance with 10 CFR 30.35(d), 10 CFR 40.36(b) or 10 CFR 70.25(d).

19. The licensee shall maintain records of information related to decommissioning at the licensee's facilities located at WA 15 Los Angeles, Carolina, Puerto Rico as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

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

A. Application dated December 7, 1988

B. Letters dated:

1. April 20, 1989 [alternate RSO qualifications]
2. March 2, 1994 [renewal application]
3. April 5, 1995 [survey instruments, calibration of dose calibrator, safe use procedures]
4. **July 19, 1996 [transfer of assets to Syncor de P.R. (IAW IN 89-25 Rev. 1); changes to facility; increase I-131 authorization; I-131 handling procedures; dose container and labels; bioassay procedures]**
5. **September 28, 1996 [approval of transfer by both Dr. Caamaño and Syncor de P.R., Inc.]**
6. **October 24, 1996 (fax) [qualifications of Alicia Albert]**

C. Reference NRC Letter dated March 1, 1996, extension of expiration date per 10 CFR 30.36(a)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

DATE OCT 25 1996 BY David J. Collins

10/25/96

N:\MLICENSE\52-16345.A04

Region II, Division of Nuclear Materials Safety
101 Marietta Street, N.W., Suite 2900
Atlanta, Georgia 30323-0199

October 25, 1996

Syncor de Puerto Rico, Inc
ATTN: Jay R. Simon, R.Ph.
Radiation safety Officer
P.O. Box 4408
Carolina, Puerto Rico 00984

SUBJECT: TRANSMITTAL AND EXPLANATION OF MATERIALS LICENSE
(REFERENCE: MAIL CONTROL NO. 257008; DOCKET NO. 030-19134)

Dear Mr. Simon:

Enclosed is Amendment 4 to Byproduct Materials License Number 52-16345-02MD, issued in response to the letter request dated September 28, 1996 as supplemented. Please read the license carefully, ensure that you understand it and the commitments made to support the amendment. If you have any questions, please contact me at (404) 331-5624 (voice) or (404) 331-7437 (fax).

Changes made in the license have been emphasized in **BOLD** type. Specifically, we have changed the licensee name to reflect the change in operation and control to Syncor de Puerto Rico, Inc., which we understand to be a wholly owned subsidiary of Syncor Overseas, Ltd. We have named you as the Radiation Safety Officer (RSO) and Ms. Alicia Albert as alternate RSO in your absence. We have listed Ms. Albert as an Authorized Nuclear Pharmacist (ANP) on this license. In my review of your preceptorship certification, I note that the certification does not indicate the license upon which your name appears, although I have noted that you are named as an Authorized User on License No. 34-16654-01MD, amendment 120, dated November 28, 1995, thus qualifying to be designated an ANP as allowed by 10 CFR 32.74(b)(4). You should obtain documentation of this qualification for use as proof of preceptor qualification. I have also approved the increased use of iodine 131 at the facility in accordance with the statements made in the July 19, 1996 letter. Those statements include the use of specific equipment. Iodine 131 use is only permitted when the specified equipment and procedures are installed and used.

The transfer of licensed activities has been determined to comply with NRC's acceptable guidance for transfer of licensed materials as required by 10 CFR 30.41. We have copied Mr. Monty Fu, President of Syncor Overseas, Ltd. We have enclosed additional materials which you may find useful.

Sincerely,

David J. Collins, Health Physicist
Materials Licensing/Inspection Branch 2
Division of Nuclear Materials Safety

Enclosure:
1. Amendment 4, License No. 52-16345-02MD

cc:
Syncor Overseas, Ltd.
ATTN: Mr. Monty Fu
President
20001 Prairie Street
Chatsworth, California 91311

Public
Commonwealth of Puerto Rico

OFFICE	RII:DNMS	RII:DNMS				
SIGNATURE	DJCollins	JPPotter				
NAME	DJCollins	JPPotter				
DATE	10 / 25 / 96	10 / 26 / 96	10 / / 96	10 / / 96	10 / / 96	10 / / 96
COPY?	YES (NO)	YES NO	YES NO	YES NO	YES NO	YES NO

OFFICIAL RECORD COPY DOCUMENT NAME: G:\DNMS\MLIB2\LICLTR\257008.DJC

Syncor
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Syncor Overseas Ltd.

24 October 1996

by facsimile (404) 331-7437 & courier

Mr David J Collins
Health Physicist
Materials Licensing/Inspection Branch 2
United States Nuclear Regulatory Commission
101 Marietta Street
Atlanta, GA 30323

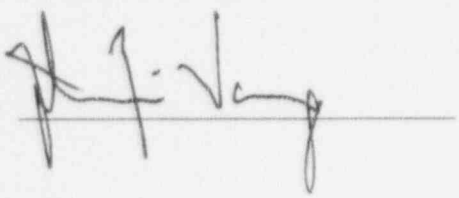
Re: Supporting Documentation for Alicia Albert
Materials License
Syncor de Puerto Rico, Inc.
WA 15 Marginal
Urbanization Los Angeles
Carolina 00979 Puerto Rico

Dear Mr Collins

In connection with our written request dated 18 October 1996, please find enclosed the complete set of supporting documentation concerning Alicia Albert, for instatement as Assistant RSO at Syncor de Puerto Rico's Carolina pharmacy.

Thank you again for the attention you have given to this matter. If you have any questions or concerns, please call me at (818) 717-4579.

Sincerely yours
SYNCOR OVERSEAS LTD.



cc: Jay Simon
Haig Bagedjian

18429-1

Syncor

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Syncor International Corporation

Syncor International Corporation

certifies that

ALICIA ALBERT

successfully completed the

Authorized Users Training Program

on

October 17, 1996

Chairman of the Board

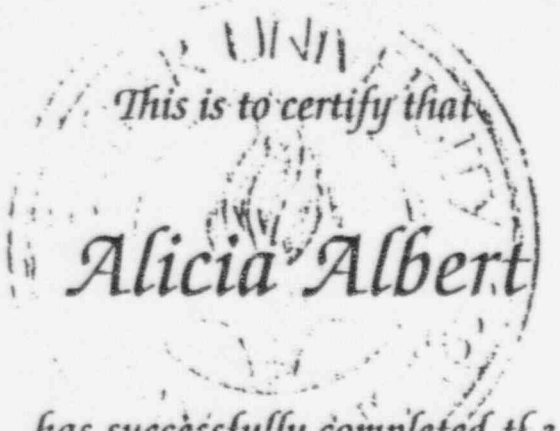
Director, Regulatory

President and Chief Executive Officer

Program Manager, Educational Resources

Butler University

College of Pharmacy and Health Sciences



This is to certify that

Alicia Albert

has successfully completed the

Nuclear Pharmacy Authorized Users Program

October 17, 1996

Program Director

Dean

FIGURE 9 – 1

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Alicia Albert, R.Ph.

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, CHATSWORTH, CA	8/12/96 thru 8/30/96 AND 9/30/96 thru 10/17/96	SYNCOR AUTHORIZED USERS 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

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Syncor International Corporation

RADIOISOTOPE HANDLING EXPERIENCE

Name: Alicia Albert Date: 10/23/96

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	4 Ci	1,6,7	5/6/96 thru 8/10/96 equals 544 hours 9/3/96 thru 9/28/96 equals 120 hours Total: 664 hours	Syncor de Puerto Rico Carolina, PR
Tc-99m	4 Ci	1,3,4,5,6,7		
I-131	10 mCi	1,3,4,6		
Ga-67	150 mCi	1,3,4,5,6		
Tl-201	150 mCi	1,3,4,5,6		
Co-57	4 mCi	1,2,6		
Cs-137	300 uCi	2,6		

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

1. 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

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ANP Certification

DOCUMENTATION OF AUTHORIZED NUCLEAR PHARMACIST TRAINING

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

Pharmacist Name (print) Alicia Albert.

Pharmacist Signature Alicia Albert Date 10/24/96.

Preceptor Name (print) JAY R SIMANI

Preceptor Signature _____ Date 10/21/96

Board of Pharmacy of Puerto Rico

ESTADO LIBRE ASOCIADO DE PUERTO RICO
DEPARTAMENTO DE SALUD
JUNTA EXAMINADORA

TARJETA DE CERTIFICACION Y REGISTRO

ALBERT RODRIGUEZ-ALICIA
Profesion FARMACEUTICA
Num Licencia 002321
Num Registro 95-646917
Fecha Expiracion 30/SEP/76

DEPARTAMENTO DE SALUD

This is to Certify that Alicia Albert Rodriguez

of San Juan, P.R. *who has complied with the law governing the practice of Pharmacy, has been duly registered as a Registered Pharmacist and hereby granted this* **License to practice Pharmacy** *in Puerto Rico, in accordance with a law "Providing for the creation of a Board of Pharmacy".*

In Witness Whereof, We, the officers of the said Board of Pharmacy of Puerto Rico have hereunto set our hands and affixed the Seal of the Board this 19th *day of February, 1976.*

TRADUCCION

Certificamos que Alicia Albert Rodriguez de San Juan, P.R. ha cumplido con lo que establece la ley de farmacia se le ha autorizado para practicar dicha profesion concediendole una LICENCIA PARA PRACTICAR LA CARRERA DE FARMACIA EN PUERTO RICO de acuerdo con la ley PROVEYENDO LO NECESARIO PARA LA CREACION DE UNA JUNTA DE FARMACIA"

ESTADO LIBRE ASOCIADO DE P.R.
JUNTA DE FARMACIA

2321 10, 115

10CFR35.980 Training for Nuclear Pharmacist

The licensee shall require the Authorized Nuclear Pharmacist to be a

☒ Pharmacist (proof required) who: P.R. board lic. no. 002321 Reg. no. 95-C48917

a. [] Has current board certification as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties, or

b.1. ~~[]~~ ☒ Has completed 700 hrs in a structured educational program consisting of both :

b.1.i. [] Didactic training in the following areas:

a. Radiation Physics and instrumentation: 92
b. Radiation Protection; 50
c. Mathematics pertaining to the use and measurement of radioactivity; 24
d. Chemistry of byproduct material for medical use; and, 25
e. Radiation biology; AND 36

227 total ~~454~~ hrs

+ 664 hrs total

b.1.ii. [] Supervised experience in a nuclear pharmacy involving the following:

a. Shipping, receiving, and performing related radiation surveys;
b. Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
c. Calculating, assaying and safely preparing dosages for patients or human research subjects;
d. Using administrative controls to avoid mistakes in the administration of byproduct material;
e. Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

b.2. [] Has obtained a written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

891 hrs

Recentness of Training

§35.972 training has been within 7 years prior to today — 1996

§35.981 pharmacist who has completed a structured educational program as above prior to 12/2/94 and who is working a s an ANP would qualify ans an ANP. Experienced ANP does not need to comply the the preceptor statement and recentness of training to qualify as an ANP

meets qualifications name to license DJC

Preceptor by Jay Simon, R. Ph. 10/21/96

Licensee: Syncor de Puerto Rico License No. 52-16345-02MD

Name: Alicia Albert Docket No. 30-19134

Reviewer: DJCollins 64 Date: 10/25/96 ~~n:\chklist\qual-anp.980~~

Syncor
The Service Difference

Syncor Overseas Ltd.

18 October 1996

by facsimile (404) 331-7437 & US mail

Mr David J Collins
Health Physicist
Materials Licensing/Inspection Branch 2
United States Nuclear Regulatory Commission
101 Marietta Street
Atlanta, GA 30323

Re: Materials License
Syncor de Puerto Rico, Inc.
WA 15 Marginal
Urbanization Los Angeles
Carolina 00979 Puerto Rico

Dear Mr Collins

We enjoyed speaking with you today. To confirm our conversations, Syncor Overseas Ltd. requests the following for our Puerto Rico license:

1. Jay Simon, RSO; and

2. Alicia Albert, Assistant RSO.

Alicia is scheduled to fly back to Puerto Rico today, and will resume her duties at the Carolina facility this coming Monday October 21, 1996. We greatly appreciate the attention you have given to this matter. If you have any questions or concerns, please call me at (818) 717-4579.

Sincerely yours
SYNCOR OVERSEAS LTD.

cc: Jay Simon
Haig Bagedjian

18391-2

From: David Collins
To: JPP, DMC, BSM1, HXB1
Date: 10/18/96 2:31pm
Subject: SYNCOR de PUERTO RICO

I talked with Jay Simon Friday afetrnoon (10/18) about the am,ended license. The ANP they will name as ass't completes her classes today. SYNCOR will send the amendment modification papers with her qualifications to us next week. I will hold the amendment until then.

David

CONVERSATION RECORD

TIME 1500 | DATE 10/3/96

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE (X FAX) ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.

ROUTING	
NAME/SYMBOL	INT

SUBJECT: Diagnostic Pluton - Lyeon

SUMMARY

(1) I faxed a draft copy of the renamed license to Jay Simon and Haig Bagedjian for review.

tel

(2) In conversation with Jay Simon at his Arizona home I discovered he intended to spend less than half time in P.R. and was intending to name a newly trained RSO in a few weeks.

(3) Based upon the above, and since Dr. Caamaño is functioning as consultant RSO, I have left Dr. Caamaño as RSO and named Jay Simon as absence alternate.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
David Collins	David J. Collins	10/9/96

ACTION TAKEN

SIGNATURE	TITLE	DATE

MATERIALS LICENSE

Amendment No. 4

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.

DRAFT

Licensee	In accordance with letter dated September 28, 1996
1. Syncor de Puerto Rico, Inc.	3. License Number 52-16345-02MD
	is amended in its entirety to read as follows:
2. P.O. Box 4408 Carolina, Puerto Rico 00984	4. Expiration Date April 30, 2000
	5. Docket or Reference No. 030-19134

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State requirements	A. Any form initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State requirements	A. Molybdenum 99 - 1.85 terabecquerels (TBq) (50 curies) ; Technetium 99m - 1.85 TBq (50 curies); Iodine 131 - 33.3 gigabecquerels (GBq) (900 millicuries); All others combined, 18.5 GBq (500 millicuries)
B. Any byproduct material authorized under 10 CFR, 35.57(a).	B. Any sealed source listed in paragraph 10 CFR 35.57(a) of 10 CFR Part 35 that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	B. 555 megabecquerels (MBq) (15 millicuries) total
C. Any byproduct material identified in 10 CFR, Part 31.11(a)	C. Prepackaged units for <u>in vitro</u> diagnostic tests	C. 1.85 GBq (50 millicuries)
D. Uranium (depleted in the isotope uranium 235)	D. Metal enclosed in stainless steel	D. 180 kilograms

DRAFT

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 52-16345-02MD

Docket or Reference Number 030-19134

Amendment No. 3

9. Authorized Use:

A. Preparation and distribution of radioactive drugs (includes Mo99/Tc99m generators) to authorized recipients.

B. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 10 CFR 35.57(a) of 10 CFR Part 35 or under equivalent licenses of Agreement States.

C. Redistribution to specific licensees or general licensees pursuant to 31.11 of 10 CFR Part 31 provided the packaging and labelling remain unchanged.

D. Shielding for molybdenum 99/technetium 99m generators.

Pursuant to Sections 32.72 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through C. of this license to persons licensed pursuant to Sections 35.100, 35.200, and 35.300 of 10 CFR Part 35, or under equivalent Agreement State licenses.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at WA 15 Los Angeles, Carolina, Puerto Rico.

11. A. **Licensed material shall be used by, or under the supervision of:**

(1) **a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 32.72(b)(2) and 32.72(b)(3) of 10 CFR Part 32, or**

(2) **authorized on Byproduct Materials License 04-26507-01MD;**

B. **The Radiation Safety Officer for this license is Jay R. Simon, R.Ph.**

fix this

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

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

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

Replace leak testing

License Number 52-16345-02MD

Docket or Reference Number 030-19134

Amendment No. 3

MATERIALS LICENSE SUPPLEMENTARY SHEET

CONDITIONS

Continued -

12. 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 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. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed 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 II, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 101 Marietta Street, N.W., Suite 2900, Atlanta, Georgia 30323. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

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

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

14. The licensee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under this license.

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

16. Radioactive waste (e.g., syringes, vials) that contains or is contaminated with radioactive materials that the licensee originally supplied to its customers may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in the application dated December 7, 1988.

17. 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.

DRAFT

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 52-16345-02MD

Docket or Reference Number 030-19134

Amendment No. 3

Continued -

CONDITIONS

17. 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.

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

18. In addition to the possession limits in condition 8, the licensee shall further restrict the possession of licensed material so that at no time is a quantity of radioactive material possessed in excess of a quantity that requires decommissioning funding in accordance with 10 CFR 30.35(d), 10 CFR 40.36(b) or 10 CFR 70.25(d).

19. The licensee shall maintain records of information related to decommissioning at the licensee's facilities located at WA 15 Los Angeles, Carolina, Puerto Rico as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

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

A. Application dated December 7, 1988

B. Letters dated:

1. April 20, 1989 [alternate RSO qualifications]
2. March 2, 1994 [renewal application]
3. April 5, 1995 [survey instruments, calibration of dose calibrator, safe use procedures]
4. July 19, 1996 [transfer of assets to Syncor de P.R. (IAW IN 89-25 Rev. 1); changes to facility; increase I-131 authorization; I-131 handling procedures; dose container and labels; bioassay procedures]
5. September 28, 1996 [approval of transfer by both Dr. Caamaño and Syncor de P.R., Inc.]

C. Reference NRC Letter dated March 1, 196 extension of expiration date per 10 CFR 30.36(a)

Syncor
The Service Difference
Syncor International Corporation

September 28, 1996

Bruce S. Mallett, Director
United States Nuclear Regulatory Commission
Region II
101 Marietta Street, NW, Suite 2900
Atlanta, Georgia 30323-0199

RE: Transfer of Diagnostic Photon Corporation Materials License Number 52-16345-02MD to Syncor de Puerto Rico, Inc., (the "NRC License").

Dear Mr. Mallett:

This letter is to ask for your permission to transfer NRC License issued to Diagnostic Photon Corporation ("DPC") to Syncor de Puerto Rico, Inc. ("SPRI"), a wholly owned subsidiary of Syncor Overseas, Ltd., ("SOL"). This being the forth letter concerning NRC License it may be helpful to summarize the sequence of previous events.

On March 25, 1996, in the letter to NRC from DPC, DPC asked certain amendments to be made to NRC License. On May 15, 1996, NRC requested addition information before granting such an amendment. In June, 1996 an unsigned letter from DPC provided NRC requested information. On July 19, 1996 SOL requested transfer of NRC License. In September, 1996, SOL applied for a new license for the same premises.

In making your determination to grant the transfer requested in this letter, please disregard all previous requests with exception of the July 19, 1996 request from SOL. The following changes should be made to the July 19, 1996 letter to more accurately represent the current situation : (1) Item 5 should be deleted; (2) the last sentence of Item 6 should be replaced with the following - "The organization will be changed to Syncor de Puerto Rico, Inc." and (3) the last sentence of Item 14 should be deleted.

If you have any questions, feel free to contact Mr. Gonzalez Geigel at (809) 753-6090 or Mr. Bagerdjian at (818)717-4549. Thank you.

Sincerely,

Dr. Justo M. Calmaño
President, Diagnostic Photon Corporation

Haig S. Bagedjian

WA 15 Marginal • WRB Los Angeles • Carolina, Puerto Rico • 00979 • 809-727-1313

July 29, 1996

CAL No. 2-96-011

Syncor Overseas Ltd.
ATTN: Mr. Monty Fu
President
20001 Prairie Street
Chatsworth, CA 91311

Dear Mr. Fu:

SUBJECT: CONFIRMATORY ACTION LETTER (CAL NO. 2-96-011)

This refers to your use of radioactive materials under the NRC license (No. 52-16345-02MD) issued to Diagnostic Photon Corporation. Your July 19, 1996, letter to NRC, Region II, requests a transfer of the Diagnostic Photon license to Syncor. The management agreement submitted with your letter, however, contains statements that would suggest that Syncor has already taken over control of licensed activities at Diagnostic Photon without authorization from the NRC. Results of a July 26, 1996 NRC inspection of licensed activities at the Diagnostic Photon site in Puerto Rico, indicate that you have taken actions that hinder licensee management's oversight of activities authorized by the Diagnostic Photon license. For example, the Radiation Safety Officer has not been permitted unfettered access to the facility and may not be able to carry out the duties authorized and required by the Diagnostic Photon license.

There is no NRC license currently issued to Syncor for use of radioactive materials at the Diagnostic Photon site in Puerto Rico. Therefore, your use of radioactive materials under NRC License Number 52-16345-02MD, must be under the control and supervision of Diagnostic Photon and in accordance with procedures authorized by the license. Pursuant to a July 26, 1996 telephone conversation between you, me, Mr. Haig Bagerdjian, and other Syncor staff, and with Carolyn Evans and other staff of this office, it is our understanding that you have taken or will take the following actions until you receive an NRC license or Diagnostic Photon requests and receives NRC authorization to transfer its license to Syncor:

1. You will use radioactive materials at the Diagnostic Photon site in accordance with the terms, conditions, and procedures in the Diagnostic Photon license, NRC License Number 52-16345-02MD.

2. You will cease any actions that hinder the management of Diagnostic Photon in exercising its control over the use of radioactive materials under the license issued to Diagnostic Photon.

3. You will afford the Diagnostic Photon Radiation Safety Officer unfettered access to the facility for purposes of carrying out responsibilities to supervise and control activities authorized under the Diagnostic Photon license.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, and 10 CFR 2.204, you are required to:

1. Notify me immediately if your understanding differs from that set forth above,

2. Notify me if for any reason you cannot complete the actions within the specified sequence and advise me in writing of your modified sequence in advance of the change, and;

3. Notify me in writing when you have completed the actions referenced and addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee. Nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter will be placed in the NRC Public Document Room.

Sincerely,

/S/

Bruce S. Mallett, Director
Division of Nuclear Materials Safety

cc: Dr. Justo Caamaño, President
Diagnostic Photon Corporation
P. O. Box 4408
Carolina, Puerto Rico 00984

Commonwealth of Puerto Rico

Distribution:
H. Thompson, EDO
J. Lieberman, OE
C. Paperiello, NMSS
D. Cool, NMSS
L. Camper, NMSS
S. Ebneter, RII

Distribution cont'd: (See page 3)

July 19, 1996

U.S. Nuclear Regulatory Commission, Reg II
Material Radiation Protection Section
101 Marietta Street, Suite 2900
Atlanta, GA 30323

RE: Transfer of Diagnostic Photon Corporation Materials License Number 52-16245-02MD to Syncor de Puerto Rico, Inc., a wholly owned subsidiary of Syncor Overseas Ltd.

Attention Materials Licensing:

Syncor de Puerto Rico, Inc., a wholly owned subsidiary of Syncor Overseas Ltd., has entered into an agreement with Diagnostic Photon Corporation. Per the agreement with Diagnostic Photon Corporation, we wish to transfer Diagnostic Photon Corporation's Material License to Syncor de Puerto Rico, Inc. Because we wish to transfer this license to Syncor de Puerto Rico, Inc., which has a different management and ownership structure than Syncor International Corporation, we do not wish to add this pharmacy to Syncor International Corporation's NRC Consolidated License at this time.

We have reviewed NRC Information Notice 89-25, Revision 1 (IN 89-25), dated December 7, 1994. The information requested in Attachment 1 to IN 89-25 to transfer control of a license is as follows:

1. The new name of the licensed organization will be Syncor de Puerto Rico, Inc., a wholly owned subsidiary of Syncor Overseas Ltd.

2. The new licensee contact is Jay R. Simon, R.Ph. Mr. Simon's phone numbers are:

   (809) 727-1313
   (800) 678-6779, extension 2142

3. We request to change the RSO to Jay R. Simon, R.Ph. Mr. Simon is listed as an Authorized Nuclear Pharmacist on Syncor International Corporation's NRC Materials License Number 04-26507-01MD.

We wish to list as Authorized Nuclear Pharmacists all Authorized Nuclear Pharmacists listed on Syncor International Corporation's Materials License Number 04-26507-01MD. We commit to maintaining on hand a copy of Syncor International Corporation's Materials License, all amendments, and Syncor International Corporation's list of Authorized Nuclear Pharmacists.

4. The transferor (Diagnostic Photon Corporation - Dr. Justo Caa[illegible]no) wishes to retain his option to open a diagnostic imaging center (a non-licensed business without the Materials License) at a later date.

5. ~~Please see the enclosed excerpt from the Agreement by and between Nuclear Pharmacy, Inc., Diagnostic Photon Corporation, and Syncor International Corporation. Also, please see the enclosed assignment between Syncor International Corporation and Syncor Overseas Ltd.~~ delete 9/28/96

6. There will be no changes in location or procedures at this time. We are proposing to remodel the facility (see item 7 below). We are also proposing to install new equipment to allow iodine-131 solution and capsule compounding (please see item 8 below). The organization will change to ~~the extent that the facility will be managed by Syncor Overseas Ltd.~~ (be) Syncor de Puerto Rico, Inc. delete letter 9/28/96

7. Please see the enclosed floor plans for the changes we wish to make in terms of location and storage of licensed material. These changes are necessary to add an I-131 handling room and increase our waste handling areas.

8. ✓ A. Please increase our possession limit for I-131 to 990 millicuries under license Item 8.A.

   ✓ B. Please increase our possession limit to 15 millicuries under license item 8.B.

   C. Please see item 7 above for our request to change the physical layout of the pharmacy. Sketches of the present physical layout and the proposed layout are enclosed for item 7 above.

   D. We wish to begin using a new unit dose container and container labels. Please see the enclosed new unit dose container description and container labels.

   E. We wish to compound I-131 capsules and solution. Please see the enclosed sections entitled Special Equipment for Handling Millicurie Quantities of Liquid Radioiodine, and Precautionary Measures for Handling Millicurie Quantities of Liquid Radioiodine.

9. All surveillance items and records will be current at the time of transfer and are

believed to be so at this time.

10. All records concerning the safe and effective decommissioning of the facility have been transferred to Syncor de Puerto Rico.

11. No contamination is present and Syncor de Puerto Rico agrees to full liability for decontamination.

12. Financial assurance is not required for this license under 10 CFR 30.35.

13. Syncor de Puerto Rico agrees to abide by all commitments and representations previously made to the NRC by Diagnostic Photon Corporation.

    Syncor de Puerto Rico agrees to assume full liability for the decontamination of the facilities, and financial assurance is not required pursuant to 10 CFR 30.35.

    Syncor de Puerto Rico is not aware of any open inspection items.

14. Syncor de Puerto Rico agrees to the change in ownership and control of the licensed material and the activities, and the conditions of transfer. Please see the enclosed excerpt from the Agreement by and between Nuclear Pharmacy, Inc., Diagnostic Photon Corporation, and Syncor International Corporation indicating Diagnostic Photon Corporation's approval.

~~Syncor de Puerto Rico is not aware of any open inspection items.~~ deleted 4/28/96

15. We agree to abide by all constraints, conditions, requirements, conditions, requirements, representations, and commitments identified in the existing Diagnostic Photon Corporation license.

During this transitional period, please direct correspondence to me at:

Syncor Overseas Ltd.
20001 Prairie Street
Chatsworth, CA 91311

Sincerely,

Monty Fu
President, Syncor Overseas Ltd.

cc: Jay Simon, R.Ph., Radiation Safety Officer
Freddie Pena
License File

ITEM 5

ASSIGNMENT

THIS ASSIGNMENT is executed this July 16th, 1996, made by Syncor International Corporation, a Delaware USA corporation with its principal office located at 20001 Prairie Street, Chatsworth, California 91311 ("**Assignor**"), in favor of Syncor Overseas Ltd., a company organized in the British Virgin Islands, with registered office and agent at Citco Building, Wickhams Cay, P.O. Box 662, Road Town, Tortola ("**Assignee**").

RECITALS

WHEREAS on or about the 6th of February 1996, Assignor entered into Management Agreement with Nuclear Pharmacy, Inc. ("**NPI**") and Diagnostic Photon Corporation ("**DPC**"), both Puerto Rican corporations;

WHEREAS on or about the 6th of February 1996, Assignor entered into a Commercial Lease with Dr. Justo M. Caamaño, a citizen of the Commonwealth of Puerto Rico and the principle stockholder of NPI and DPC;

WHEREAS on or about the 6th of February 1996, Assignor entered into a Consulting Agreement and a Non-Competition and Non-Disclosure Agreement with Dr. Justo M. Caamaño;

WHEREAS on or about the 6th of February 1996, Assignor entered into an Employment Agreement and a Non-Competition and Non-Disclosure Agreement with Norman T. Oldham, formerly associated with NPI and DPC;

AND WHEREAS for the purposes of this Assignment, the contracts referred to in the recitals herein will collectively be known as the "**Agreements**";

NOW THEREFORE, for valuable consideration, the receipt and sufficiency of which Assignor and Assignee acknowledge, the parties agree as follows:

AGREEMENT

1. Assignor assigns, transfers and conveys to Assignee all of Assignor's right, title and interest in and to the Agreements and delegates to Assignee all of Assignor's right, title and interest in and to the Agreements and delegates to Assignee of all of Assignor's duties and obligations under the Agreements.

2. Assignee accepts the assignment to it by Assignor of all of Assignor's right, title and interest in and to the Agreements, and the delegation to it by Assignor of all of Assignor's duties and obligations under the Agreements.

3. This Assignment is effective the date first written above.

IN WITNESS WHEREOF, the parties hereto have caused this Assignment to be executed and delivered by their respective duly authorized officers as of the effective date.

"Assignor"
SYNCOR INTERNATIONAL CORPORATION
a Delaware USA corporation

By: _____
Haig S. Bagerdjian
Vice President

"Assignee"
SYNCOR OVERSEAS LTD.
a British Virgin Islands company

By: _____
Monty Fu
President

MANAGEMENT AGREEMENT

THIS MANAGEMENT AGREEMENT (this **"Agreement"**) is executed as of the 6th day of February 1996, by and between Nuclear Pharmacy, Inc., Diagnostic Photon Corporation, both Puerto Rico Corporations, with their principal offices at 18 A Marginal, Baldorioty de Castro Carolina, Puerto Rico 00984 (collectively called **"NPI"**) and Syncor International Corporation, a Delaware USA corporation, with its principal offices at 20001 Prairie Street, Chatsworth, California 91311, USA (**"Syncor"**).

RECITALS

A. WHEREAS NPI founded the first centralized radiopharmacy in the Commonwealth of Puerto Rico with the intention of providing an exemplary service in radiopharmaceuticals and related products to the medical community;

B. WHEREAS NPI currently owns and operates a centralized radiopharmacy located at 18 A Marginal, Baldorioty de Castor, Carolina, Puerto Rico 00984 (the **"NPI Radiopharmacy"**);

C. WHEREAS Dr. Justo Caamaño is the founder and the principal stockholder of NPI;

D. WHEREAS NPI does not intend to manage the day-to-day operation of the NPI Radiopharmacy;

E. WHEREAS Syncor is the leading radiopharmaceutical supplier with over twenty (20) years of experience in managing centralized radiopharmacy businesses and presently owns and operates over one hundred twenty five (125) centralized radiopharmacies worldwide;

F. AND WHEREAS NPI desires to have Syncor, as the agent for NPI, to fully manage and operate the NPI Radiopharmacy and Syncor is willing to perform such services for the account of NPI on the terms and conditions set forth herein;

G. NOW, THEREFORE, in consideration of the premises and the mutual covenants herein contained, the parties hereto agree as follows:

AGREEMENT

1. APPOINTMENT OF SYNCOR

1.1 Appointment

Effective March 1, 1996, ("**Effective Date**"), NPI hereby appoints and employs Syncor as NPI's exclusive agent to supervise, direct, control and carry out the management and operation of the NPI Radiopharmacy for the Term. Syncor accepts said appointment and agrees to manage the NPI Radiopharmacy during the Term in accordance with the terms and conditions hereinafter set forth.

1.2 Delegation of Authority

The NPI Radiopharmacy operations shall be under the exclusive supervision and control of Syncor which, except as otherwise specifically provided in this Agreement, shall be responsible for the proper and efficient operation of the NPI Radiopharmacy. Syncor shall have discretion and control, free from interference, interruption or disturbance, in all matters relating to management and operation of the NPI Radiopharmacy, including, without limitation, credit and collection policies, employment policies, receipt, holding disbursement of funds, maintenance of bank accounts, procurement of inventories, supplies and services, promotion and publicity and, generally, all activities necessary for operation of the NPI Radiopharmacy.

1.3 No Covenants or Restrictions

NPI warrants that there will be on the Effective Date no covenants or restrictions which would prohibit or limit Syncor from operating the NPI Radiopharmacy. NPI agrees, upon request by Syncor, to sign promptly and without charge applications for any and all licenses, permits or other instruments, including to permit access to any working bank accounts of NPI, necessary for the day-to-day operation of the NPI Radiopharmacy.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the day and year first written above.

"NPI"
Nuclear Pharmacy, Inc.
a Puerto Rico corporation

By: _____
Dr. Justo Caamaño
President

Witnessed:

By: _____
Norma T. Oldham

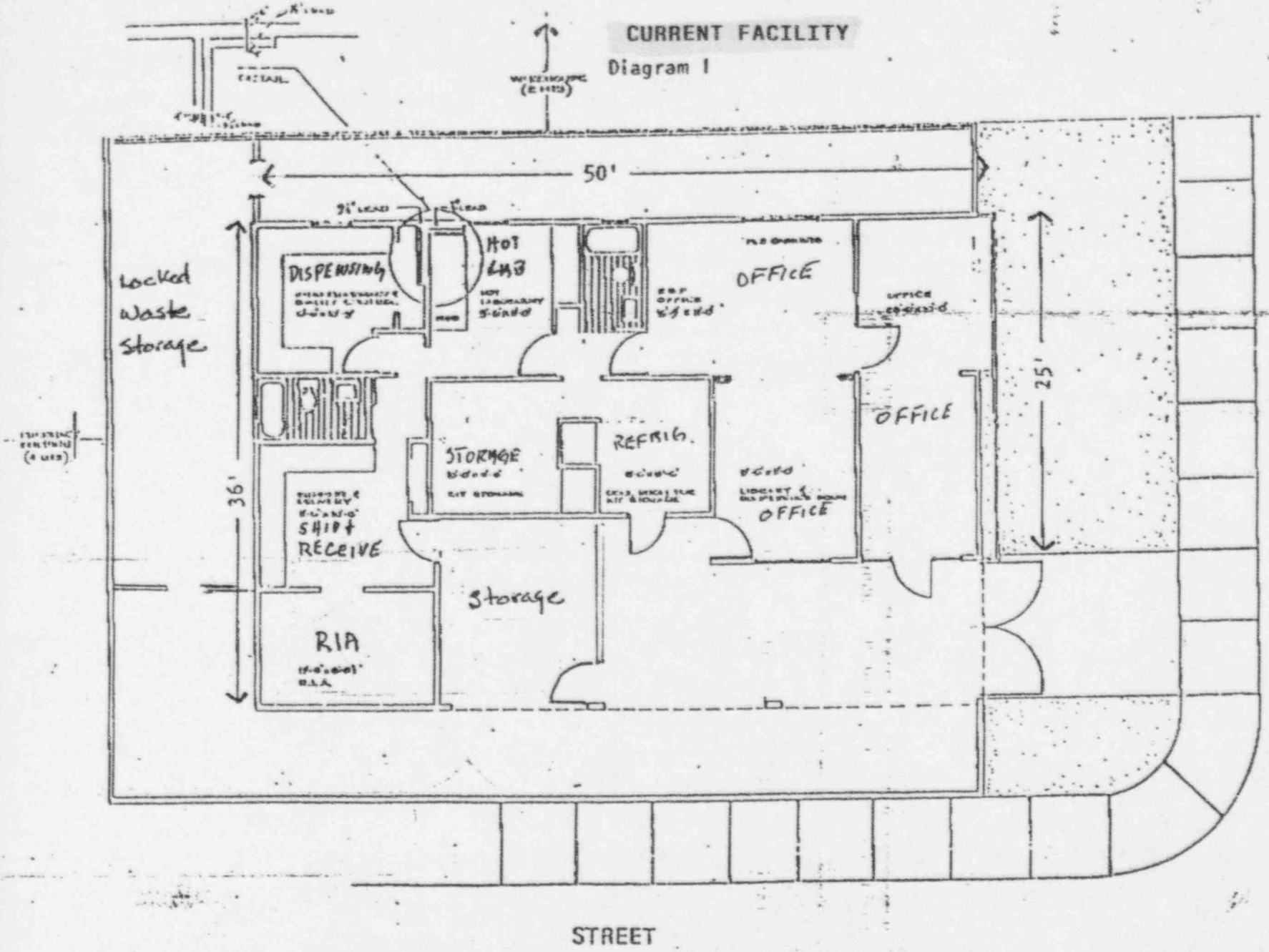
"Syncor"
Syncor International Corporation
a Delaware USA corporation

By: _____
Monty Fu
Chairman of the Board

ITEM 7

CURRENT FACILITY

Diagram I



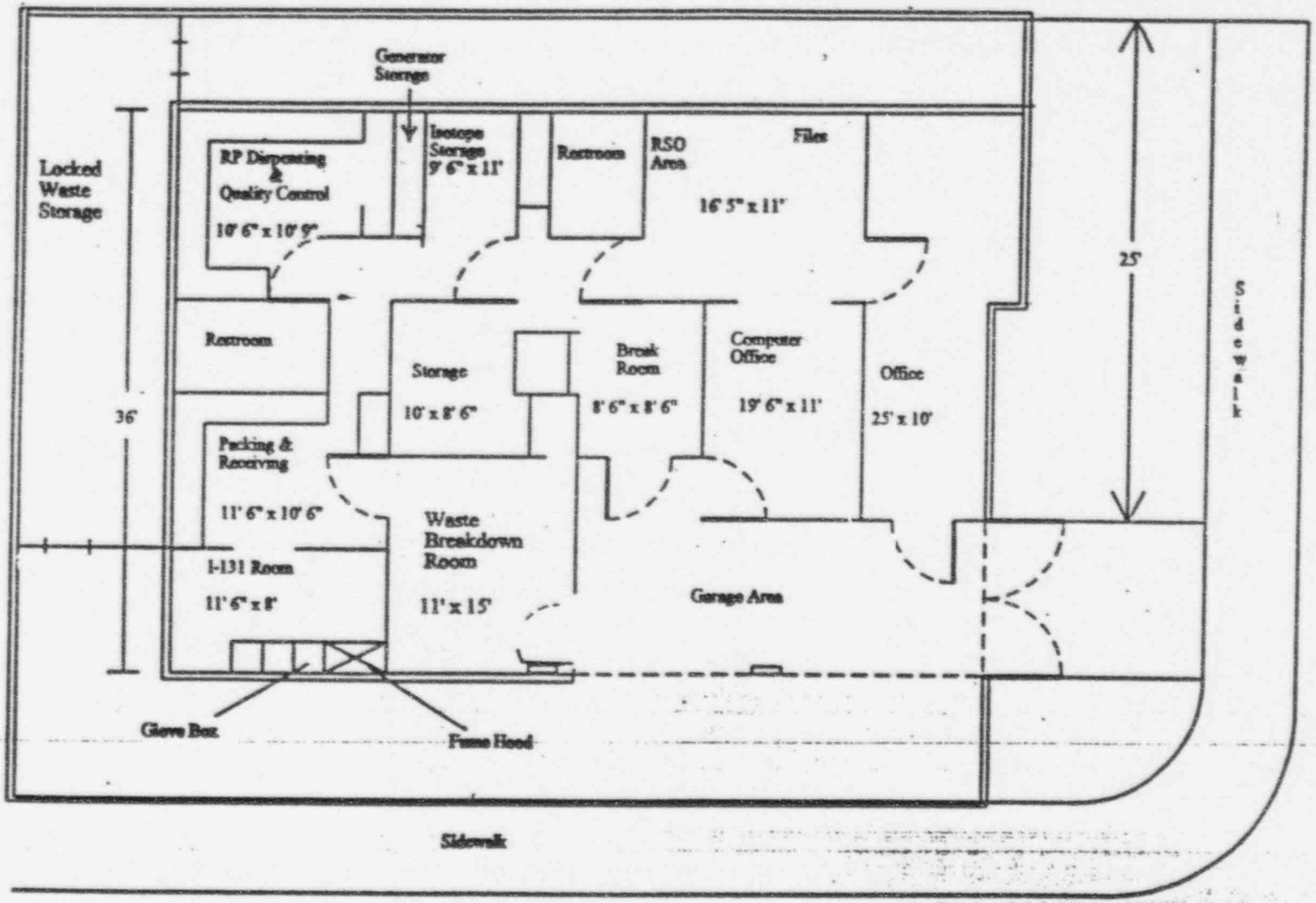
STREET

The building is constructed of 12 inch concrete block reinforced with 3/8" steel rods at each corner. Steel bars are at each window. An iron wrought and cement block fence provide perimeter security (see dotted line).

PROPOSED FACILITY

Outside wall Constructed of 12 inch concrete block with 3/8 inch steel rod reinforcement at each corner.

A wrought iron and cement block fence provide perimeter security (see dotted line).



ITEM 8

NEW UNIT DOSE CONTAINER

NEW UNIT DOSE CONTAINER DESCRIPTION

This new unit dose container is a variation on the design of previous containers that we have used. The variation is that the new unit dose container has inside of it a plastic sharps container for use in the transportation of medical waste. When shipping the dose to the customer, the lower sleeve of the sharps container is inserted into the lower half of the leaded shield, and then the top half of the leaded shield is screwed on. The top of the sharps container is transported separately from the unit dose shield. After injection of the dose, the customer returns the used syringe to the unit dose shield, and locks down the top half of the sharps container. The top piece of the unit dose shield is then screwed on, and the entire unit is returned to the pharmacy.

At the pharmacy, the unit dose shield is identified (by label/prescription), opened, and the sharps container is dumped into the appropriate bin *in its entirety* without opening the sharps container. Please see the attached procedures for handling waste at the nuclear pharmacy using this new system.

PRODUCT SHIELDING

The following information regards the radionuclide, chemical and physical form, packaging (including maximum activity per package) and shielding provided by the packaging of the byproduct material that is appropriate for safe handling and storage of radiopharmaceuticals of group licensees:

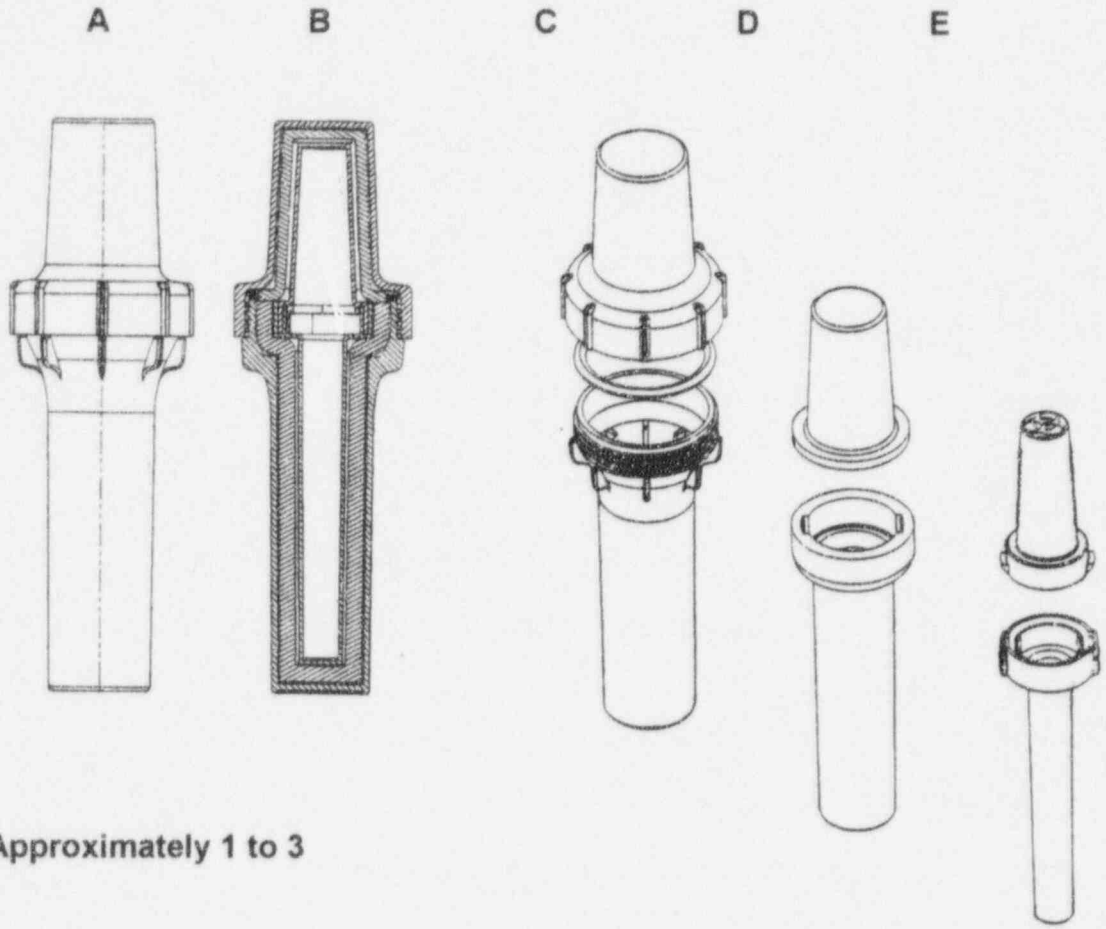
Isotope	Chemical/Physical Form	Maximum Activity per Syringe	Maximum Exposure Rate at 1 cm From the Surface of the Shield (mR/hr)	Maximum Exposure Rate at 1 m From the Surface of the Shield (mR/hr)
Tc-99m	sodium pertechnetate, tagged drug solution	634 mCi	0.67	0.0
Cr-51	sodium chromate solution	203 uCi	0.33	0.0
I-123	sodium iodide capsule	3.48 mCi	8.70	0.01

Isotope	Chemical/Physical Form	Maximum Activity per Syringe	Maximum Exposure Rate at 1 cm From the Surface of the Shield (mR/hr)	Maximum Exposure Rate at 1 m From the Surface of the Shield (mR/hr)
I-131	sodium iodide capsule, solution	1.33 mCi	66.9	0.1
Ga-67	gallium citrate solution	12.17 mCi	65.6	0.09
Tl-201	thallous chloride solution	10.5 mCi	4.01	0.05
In-111	indium chloride, DTPA, or oxine solution	12.05 mCi	37.5	0.05

NOTE: The above values were taken with a Victoreen Model 470-A Ion Chamber. Values reflect correcting for distance using the inverse square law from 8.15 cm (distance from the virtual center of the ion chamber to the center of the container), to 3.15 cm (distance from 1 cm from the surface of the container to the center of the container).

	TOP PIECE	BOTTOM PIECE	TOTAL
Thickness of Lead	sides: 3.9 mm top: 3.6 mm	6.4 mm	---
Length	16.3 cm	8.4 cm	22.2 cm (some overlap)

SECURE™ SAFETY INSERT SYSTEM



SCALE: Approximately 1 to 3

A Unit Dose Shield

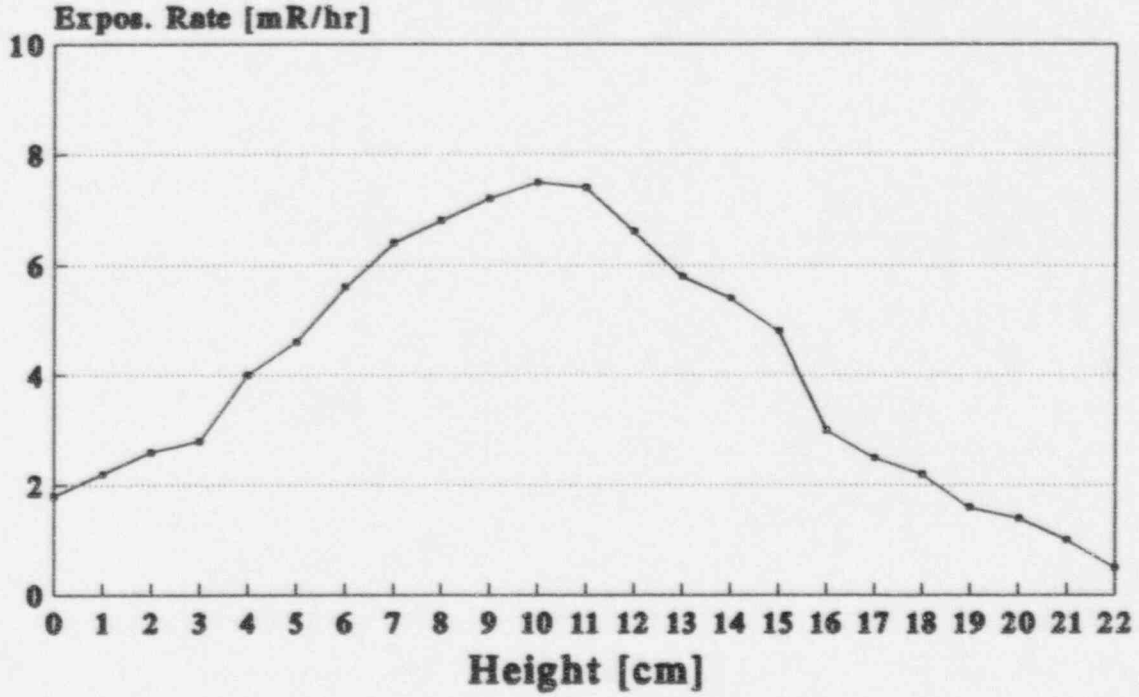
B Cross Section of Unit Dose Shield with Disposable Insert

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

Isoresponse Curve
At 6 cm using 9.6 mCi of Ga-67



0 cm = bottom; 22 cm = top

PRODUCT LABELS

PRESCRIPTION FORM AND CONTAINER LABELS

EXAMPLE

PRESCRIPTION FORM

Rt. Run

Doctor	#
R	
Procedure	Date
Lot No.	Expires
Qty. Ordered	
Assay	As Of
Volume	Dispensed By / Checked
Qty. Dispensed	

Caution: To be used under the direct supervision of a physician.

Pt.

LABEL A

CAUTION RADIOACTIVE MATERIAL #

DRUG ID

LABEL B

Dr.

#

Lot Expires

Qty. Ordered

Assay As Of

Volume

Qty. Dispensed

Qty. Admin. By

Pt.

CUSTOMER COPY

LABEL C

CAUTION RADIOACTIVE MATERIAL

Dr.

#

Lot Expires

Qty. Ordered

Assay As Of

Volume Dispensed By

Qty. Dispensed

Caution: To be used under the direct supervision of a physician.

Pt.

CONTAINER LABEL

REQUIRED CONTAINER LABELING

1. VIALS:

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

2. SYRINGES:

   Syringes will be labeled with label A.

3. VIAL SHIELDS:

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

4. UNIT DOSE CONTAINER SHIELDS:

   Unit dose containers will be labeled with label C.

5. GENERATORS:

   Generators will be labeled with the manufacturer's original label.

In addition to the container, syringe, and vial labels, this new format supplies the customer with a prescription (PRESCRIPTION FORM) and label (LABEL B) for their records, which 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.

SPECIAL EQUIPMENT FOR HANDLING MILLICURIE QUANTITIES OF LIQUID RADIOIODINE

A radioiodine (glove box type) fume hood will be utilized for dispensing liquid I-131 sodium iodide and compounding iodine-131 therapy capsules. The effluent from this fume hood will be connected directly into the standard laboratory fume hood exhaust

Two charcoal filters will be used in the radioiodine fume hood. Each filter is one foot square and one inch thick. One filter will be stacked on top of the other so that the iodine-131 will be exhausted through two inches of charcoal. This ensures a trapping efficiency of at least 90%. Measurements with an anemometer of air flow at the arm ports for this iodine-131 fume hood show a linear air flow of 50 to 70 feet/min, or greater.

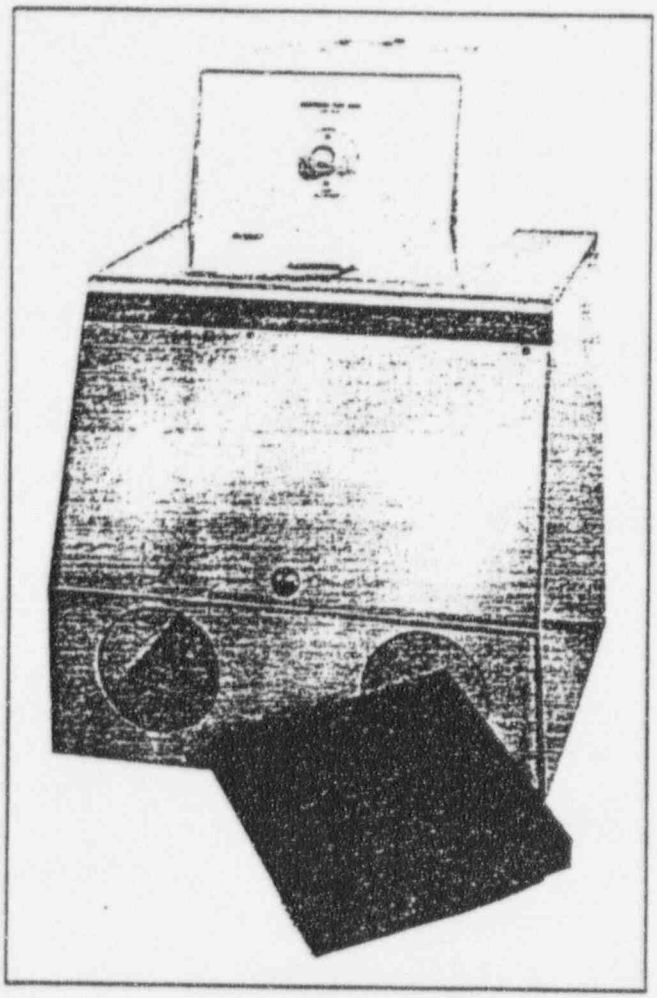
The efficiency of this trapping system is checked weekly. The filters are removed and the radiation level at their surfaces is measured with a pancake probe type survey meter or more sensitive device. When the measured level of the top filter is equal to or greater than 10% of the measured level of the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

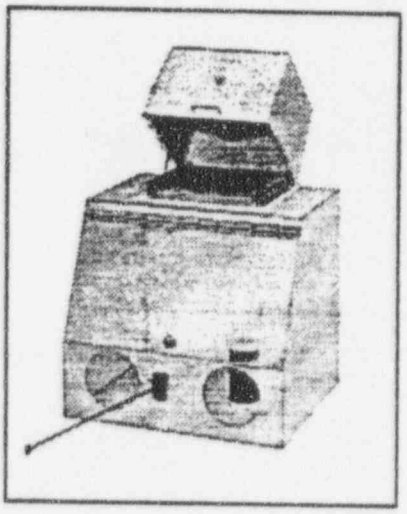
Air sampling for volatile I-131 will be performed in conjunction with the use of the radioiodine fume hood. Please see the following air sampling procedure.

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

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

Radioiodine Fume Hood





Constructed of 3/8" clear plexiglass, this rugged Radioiodine Fume Hood is designed to meet the problems associated with iodination procedures. The large internal work area and spacious arm ports allow maximum uninhibited manipulation of material within the unit. A 24" x 13" swing-away front door permits easy placement and retrieval of items. An air baffle assures an even flow speed of air out of the box. Negative air flow speed can be adjusted from 0 to a maximum of 80 CFM. The motor is a UL approved induction type. The disposable charcoal filter traps 90% of the radioiodine produced. Each unit can accommodate up to two filters. One 12" x 12" x 1" activated charcoal filter is supplied with the system.

SPECIFICATIONS:

Motor: 1/45" H.P., 61 Watts, 3/4 Amps, 110 VAC, 50/60 Hz

Glove Box: 24" x 20" base x 36" height (61 cm x 51 cm x 91.4 cm

Shipping Weight: 90 lbs. (41 kgs.)

EQUIPMENT AND STANDARDS

Item 1

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

Item 2

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

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

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

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

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

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

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

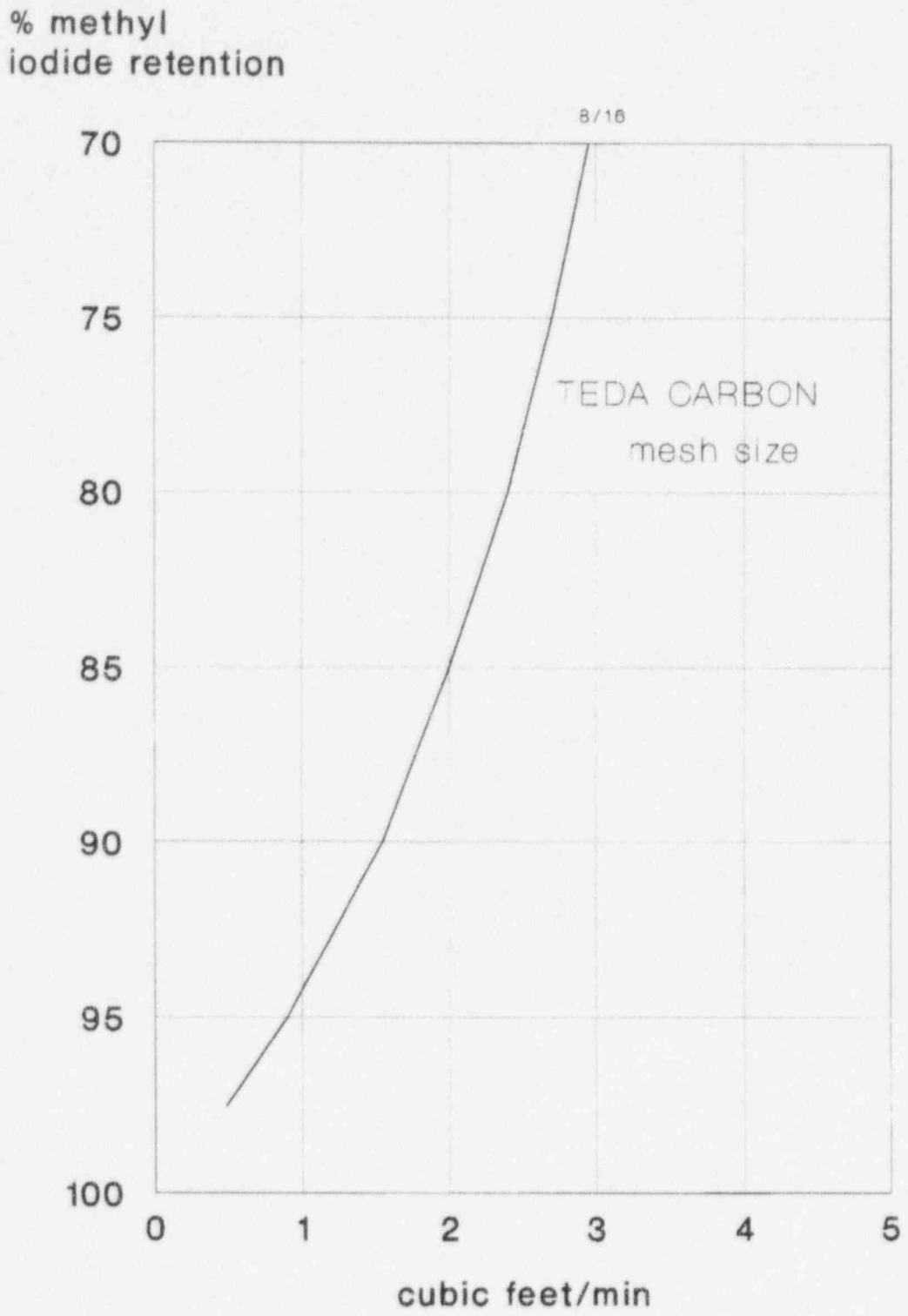
Isotope Products Laboratories (IPL)
1800 N. Keystone Street
Burbank, CA 91504
818/843-7000

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

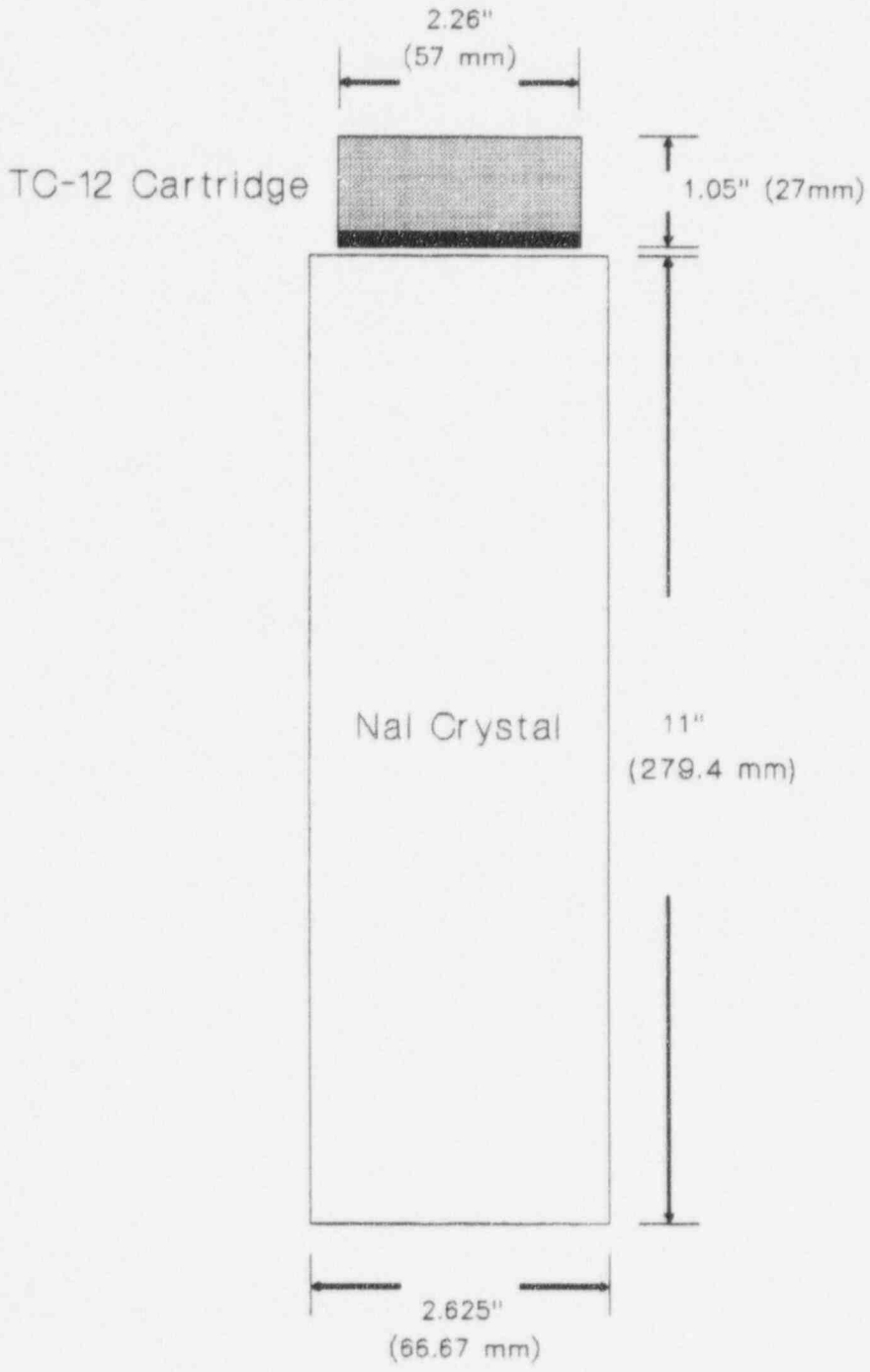
Item 3

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

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


% methyl
iodide retention
8/16
70
75
80
85
90
95
100
TEDA CARBON
mesh size
0
1
2
3
4
5
cubic feet/min

EXAMPLE



(not to scale)

Procedures for Completion of Iodine-131 Air Monitoring

The following pages give detailed instructions for performing iodine-131 air monitoring, including the operating procedures for cartridges. This is followed by the installation instructions.

Procedures for 131-Iodine Air Monitoring

A. Discussion

1. The handling of certain volatile radioactive materials may require that air sampling and/or calculations be performed to document that excessive concentrations of radioactive material in air do not exist in the restricted area or the Effluent Limits are not exceeded in unrestricted areas.

2. If calculations are submitted, it is necessary to document those specifications and measurements (such as fume hood flow in cfm, etc.) are checked periodically to ensure that the conclusions made from the calculations have not changed.

3. For volatile iodine-131, Syncor facilities are required to use air sampling data by the conditions of their licenses or license applications. The following procedure is provided and is to be used with Form RS-55, or an equivalent computer generated form.

B. Equipment

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

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

2. Appropriate teflon tubing

3. Charcoal Cartridge holder

4. TEDA impregnated charcoal cartridge

5. Scintillation counting assembly and barium-133 cartridge standard

C. Operating Procedure for Air Cartridges

1. Mount the air sampling apparatus in a manner which will ensure that effluent being released to both restricted and unrestricted areas will be sampled. Sampling must be done in the exhaust vent pipe on the down stream side of any additional air filtering system. Be sure that the standard laboratory fume hood sash opening is positioned to optimize the face velocity across the fume hood opening. This decreases the amount of volatile I-131 that will escape into the restricted area.

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

   NOTE: IN THE EVENT OF A SPILL THE CHARCOAL CARTRIDGE WILL BE COUNTED IMMEDIATELY.

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

   (a) Put on disposable gloves.

   (b) Calibrate the counting system, using iodine-131 to peak the instrument, and the barium-133 cartridge to obtain a calibration factor. Place iodine-131 in front of the probe. Set the analyzer transmission with the lower discriminator at 314 keV and the upper discriminator at 414 keV and peak the instrument by adjusting the high voltage potentiometer or gain control. Then set the analyzer transmission with the lower discriminator at 300 keV and the upper discriminator at 430 keV. 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 on RS-55 form or enter this data into the RS-55 computer program.

   (c) Place the cartridge on the scintillation probe in the same geometrical configuration as the barium-133 standard source; and,

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

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

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

5. Record uCi quantity of barium-133 standard.

D. Procedure for Calculating the Concentration of Volatile Iodine

The following calculations may be used to determine the concentration of volatile iodine in uCi/ml in the restricted and unrestricted areas. (See the attached worksheet).

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

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

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

t = 1/2 of the sampling period

CF = the efficiency for the Ba-133 standard in cpm/uCi.

$e^{\lambda t}$ is the correction factor for decay.

A simplifying assumption is to back-decay the activity for 1/2 of the sampling time to correct for sample decay.

3. Determine the air flow through the sampling pump in ml from pump flow data in ml/min x sampling time in minutes.

4. Calculate the iodine-131 concentration in uCi/ml using the formula below.

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

5. The regulatory limits for iodine-131 are:

   i. Effluent Concentration = 2×10^{-10} uCi/ml
   ii. Occupational DAC = 2×10^{-8} uCi/ml

E. Procedures for Installation

1. The restricted area air sampling cartridge holder should be mounted on the OUTSIDE of the iodine-131 hood above the area where an individual would be working, near the worker's face. This cartridge monitors the air in the RESTRICTED area (occupational concentration) at the level of the operators breathing zone.

2. The unrestricted area air sampling cartridge holder should be positioned with the sampling probe mounted in the vent stack. This cartridge monitors the air to the UNRESTRICTED area (effluent concentration), i.e., the air being vented to the environment.

WORK SHEET FOR IODINE-131 AIR MONITORING

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

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

2. Sample count (cartridge) = _____ cpm.

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

4. Ba-133 Standard Activity = _____ uCi.

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

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

B. Determine flow through sampling pump:

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

2. Pump-on Duration = _____ min.

3. Pump Flow _____ ml/min x Pump-on Duration _____ min = _____ ml

C. Determine concentration in uCi/ml:

I-131 Concentration in Air (uCi/ml) = $\frac{\text{I-131 uCi from A6 above}}{\text{Flow through pump (ml)}}$

= _____ uCi/ml

Instrument _____

Analyzer Setting _____ keV to _____ keV

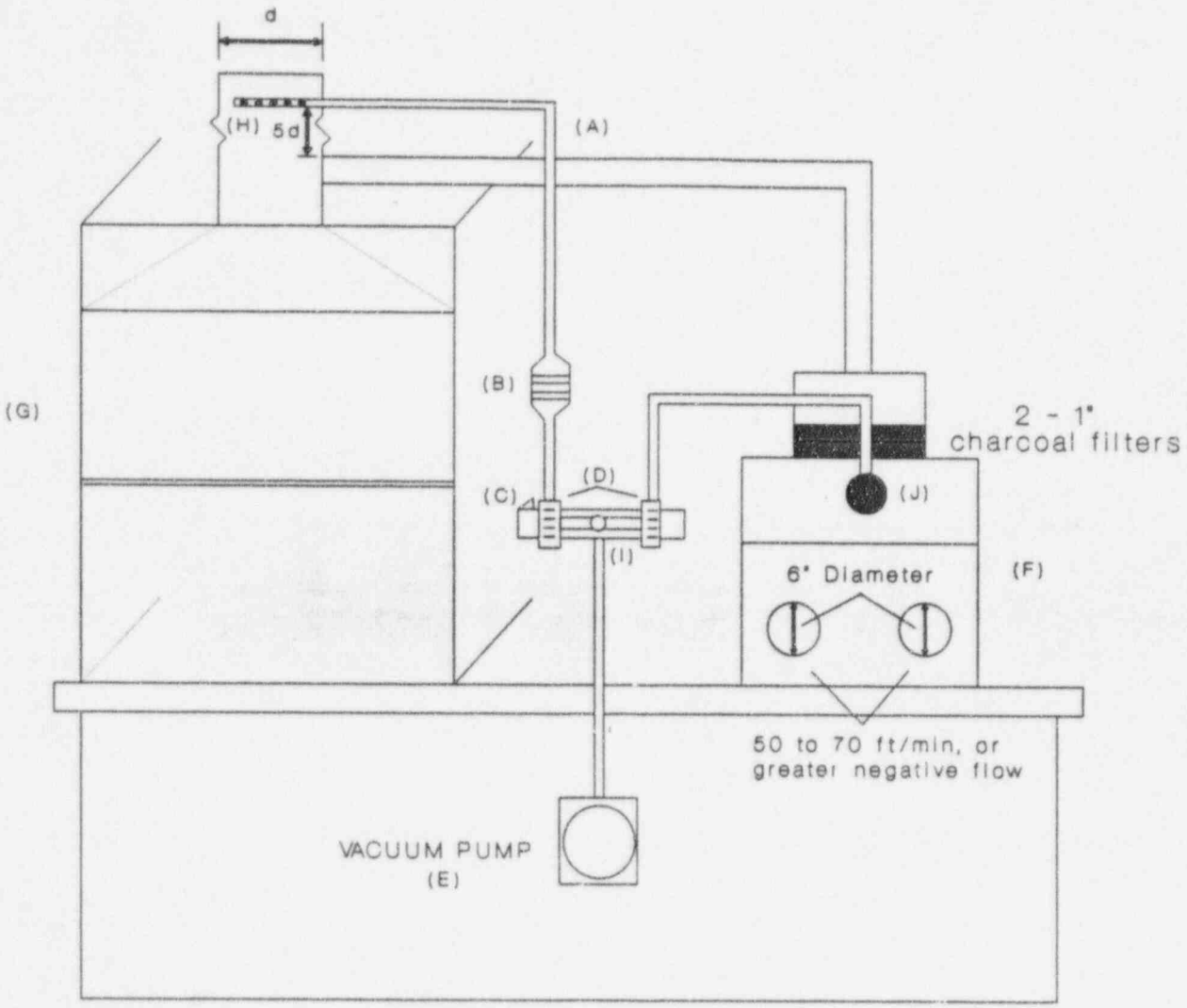
Signature _____ Date _____

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

** $e^{\lambda t}$ = decay correction where t = 1/2 the time between samples.

VOLATILE SUBSTANCE HANDLING AND SAMPLING SYSTEM

NOTE: FUME HOOD MOTOR IS LOCATED ON THE ROOF.



A. 1/2" TEFLON SEMI-RIGID TUBING
B. FILTER HOLDER (CONTAINS CHARCOAL CARTRIDGE)
C. L-BRACKET
D. ROTAMETER
E. VACUUM PUMP
F. GLOVE BOX I-131 HOOD
G. STANDARD LABORATORY FUME HOOD
H. SAMPLING PROBE
I. "T" CONNECTION
J. RESTRICTED AREA AIR SAMPLING CARTRIDGE

EXAMPLE of "I-131 AIR MONITORING RECORD" (RS-55)

RS55 (5.0) Syncor International Corporation 12/20/9

I-131 Air Monitoring Record

Location Id:

Beginning Date: Ending Date:

Sample Date: Sample Time: Test Performed By:
S/N: Make:
Model: Desc:

Background	Pump Flow	Cap/Source Used	Unrestricted Area	Restricted Area
CNT TME:	Prod/Lot :	Measure:	Sample Filter Count:	
Bkg:	Count :	Pump On:	Net Count:	
	Net Count:	Flow :	Corrected Net:	
	Activity :	Flow-Rate:	I131 Released (uCi):	
	Efficiency:	Ba-131 Factor:	'Air' Conc (uCi/ml):	
	LLD cpm:	MDA:		
			% Regulatory Limit :	

EXAMPLE of "I-131 RELEASED YTD" (RS-55A)

RS55A (5.0) Syncor International Corporation 12/20/9

Run Date 12/20/93 **I-131 Released (YTD)** Run Time 12:00

Location Id: Date:

Sampling Date/Time	I-131 Collected	Air Flow Sampled	Avg I-131 Concentration	Fume Hood Flow Rate

Totals:

Avg I131 Concentration (YTD) :
Avg Fume Hood Flow (YTD) :
Total ml Of Fume Hood Flow (YTD) :
Total I131 Released To Environment (YTD) :
% Effluent limit for Unrestricted Area (YTD) :

SODIUM PHOSPHATE CAPSULE PREPARATION

* * * MATERIALS NEEDED * * *

(1) Sodium phosphate di-basic anhydrous, powder

There are two commercially available products:

1. J.T. Baker 500 mg cat. # 3828-1
2. Mallinckrodt 500 mg cat. # 7917-1

Special note: The sodium phosphate must be acs reagent grade, according to the usp monograph.

The sodium phosphate should be stored "tightly sealed" to assure freshness. By leaving the jar uncapped for extended periods of time defeats the purpose of "being anhydrous".

(2) Gelatin capsules

Special note: Gelatin capsules should not be brittle. They should be pliable to the touch. The capsules will become brittle with age; and brittle if stored next to excessive heat.

(3) Latex gloves

Special note: By wearing latex gloves not only do you protect your skin from the sodium phosphate, the gloves protect the capsules from the moisture of your skin.

(4) Glass pill tile / spatula

Special note: If a glass pill tile or ointment slab is not available it is not necessary to purchase one. You can improvise by using a flat counter top with a sheet of waxed paper.

(5) Air-tight storage container

Special note: A capped 20 dram plastic rx vial fits nicely inside a 40 dram plastic Rx vial. This method of storage protects the capsules from moisture.

SODIUM PHOSPHATE CAPSULE PREPARATION

* * * FILLING PROCEDURE * * *

(1) On a clean glass pill tile place a small portion of sodium phosphate powder.

(2) Use a spatula (or piece of waxed paper) to pack down the powder. Be sure the sodium phosphate powder is packed tightly.

(3) Wearing latex gloves, fill the long end of the #1 capsule with as much sodium phosphate powder as possible. The piggy-back filling method often taught in pharmacy school is not the preferred method since it does not allow you to pack the capsules the fullest you possibly can. Instead, be sure to hold the capsule directly in your hand and punch until the capsule is full. Fill the shorter-half capsule approximately two-thirds full. Place the two ends firmly together and be sure the capsule feels very hard when pressed between your fingers.

(4) Make twenty (20) or more sodium phosphate capsules depending on your usage. Store in an air-tight container in the freezer.

Special note: When a liquid reacts with sodium phosphate anhydrous an "exothermic" reaction occurs, heat is released therefore by starting with a very cold sodium phosphate capsule you reduce the chance of melting the gelatin capsule upon injection of liquid sodium iodide.

Sodium Iodide I-131 Capsule Preparation

* * * Materials Needed * * *

(1) I-131 Tx solution

(2) Sodium phosphate size #I capsules

(3) 0.5 cc syringes

(4) Dispensing container

(5) Lead dispensing/shipping container

(6) Lead "capsule holder" (see diagram "a")

(7) 1 cc tuberculin syringe shield

(8) Tongs

(9) "Brower's" modified straw (used to pick up capsule shell)

(10) Latex gloves

(11) Shoulder length plastic gloves

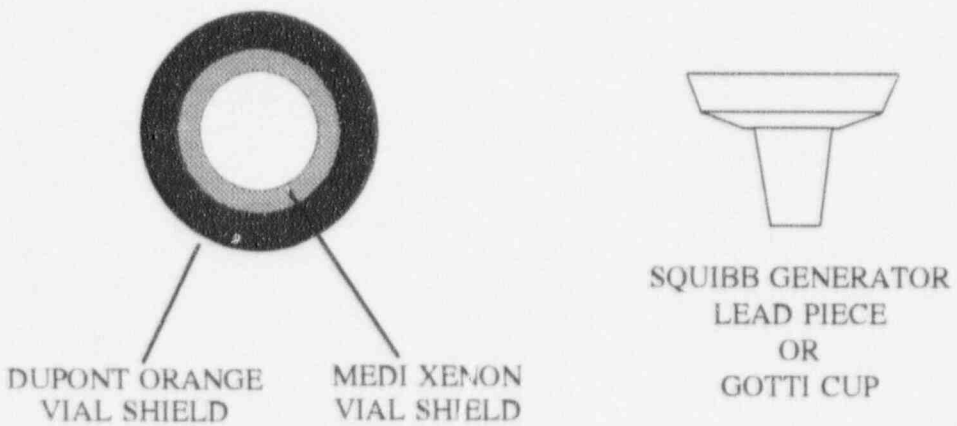
LEAD CAPSULE HOLDER

Materials needed: one orange Du Pont lead container
(dupont ga-67 lead container)

one medi-physics xenon lead container

one Squibb "generator lead piece" or Gotti Cup
(scavenged lead portion from the squibb generator's needle adaptor assembly)

Insert the Medi lead xenon container into the orange Du Pont lead container. Hammer the xenon lead container until it is all the way into the orange one. Place the Squibb "generator lead piece" on top of the orange lead container.



SODIUM IODIDE I-131 CAPSULE PREPARATION

* * * Compounding Procedure * * *

(1) Turn on the main fume hood and radioiodine fume hood if not already operating. Check to make sure the equipment is operating properly.

(2) Turn on the vacuum pump for air monitoring if not already operating. Check to make sure the gauges and vacuum pump are operating properly.

(3) Wear two (2) pair(s) of gloves. First, put on a pair of shoulder length plastic gloves. Next, put on a pair of latex gloves over the shoulder length gloves you are wearing.

(4) Perform an area survey of the radioiodine fume hood and work area to be sure that it is contamination free. If not, decontaminate the work area before you start. Always use ALARA principles!

(Special note) a survey meter equipped with a pancake probe is ideal for isolating I-131 contamination. This probe is extra sensitive to beta-radiation; more so than a GM sidewall probe.

(5) Calculate the amount of I-131 solution needed to fill the prescription. Remember to take into consideration "decay" if the therapy capsule is for the next day. Also, the residual volume left in the lo-dose syringe will be approximately 200-400 uCi. This must also be taken into consideration, especially when very low millicurie capsules are made.

(6) In the radioiodine fume hood vent the I-131 solution through a charcoal syringe. Next, draw up the activity needed in a shielded lo-dose syringe and assay.

(Special note) Do not exceed capsule volume capacity. If the prescribed dose exceeds this, a second capsule should be made. In addition, only fill the syringe with that amount of solution to be injected into a single capsule.

(7) Place the shielded I-131 lo-dose syringe and I-131 solution in the main fume hood so it is out of the way.

(8) Set up the orange Du Pont lead vial with the Squibb gen. lead piece on top. This set-up will be referred to as the "lead capsule holder".

(9) Take a small piece of saran wrap (approx. 3" X 3") and place on top of the lead capsule holder.

(10) Separate a size "0" gelatin capsule. Take the long end and push the plastic wrap into the lead capsule holder.

(11) Place a sodium phosphate capsule (from the freezer) into the shielded size "0" capsule.

(12) Take an empty lo-dose syringe and bore a pilot hole through the center top of the sodium phosphate capsule.

(Special note) This procedure will prevent coring which very often clogs the needle.

(13) Insert the needle of the shielded I-131 dose into the hole as far as it will go. Inject the capsule with a slow but constant injection.

(Special note) If your injection is made too slowly, you increase the chances that the sodium phosphate powder will harden prematurely before you are able to make the entire injection. If your injection is made too quickly, the sodium phosphate's ability to absorb the solution will be exceeded. This will be obvious by the distorted appearance of the finished capsule.

(14) Once the injection is complete, remove the needle from the capsule and cap. Place the empty I-131 syringe in its holder and store in the fume hood out of the way.

(15) Using a "Brower's" modified straw, pick up the other size "0" capsule half and place on the capsule in the lead capsule holder. Invert the straw and tap it down tightly.

(16) Remove the capsule by injecting the Squibb gen. lead piece onto a second orange lead container that has a "dispensing container" within. With an empty lo-dose syringe push the capsule through the Squibb gen. lead piece so it drops into the dispensing container.

(17) Remove the Squibb gen. lead piece and cap the dispensing container inside. Cover the orange lead container with its lead top.

(18) Assay the I-131 therapy capsule, account for decay, and assure that the finished capsule strength is not greater than 10% which was ordered.

(18A) Clear work area.

(19) Remove your latex gloves and replace with new ones. (Make this step a part of your normal routine)

(special note) If for any reason your outer gloves are contaminated it is important to change them now to assure that you don't contaminate the lead shipping container;

(20) Dispense the I-131 therapy capsule in a heavy lead container.

Special note: Perform a wet smear on the lead container to assure that there is no removable contamination.

(21) Remove the shielded I-131 syringe from the main fume hood and place in the radioiodine fume hood. Rinse the syringe into a shielded 10 cc or 20 cc saline "wash vial". Store the I-131 "wash vial" in the main fume hood for future use. Dispose of the I-131 syringe in the appropriate radioactive waste bin.

Special note: This rinse procedure will help contain the I-131 if it becomes volatile and therefore help reduce airborne I-131 contamination.

(22) Perform an area survey of the radioiodine fume hood and other immediate work areas to assure it is contamination free. Decontaminate if necessary!

(23) Follow the air monitoring procedure as outlined in your NRC or Agreement State license.

(24) Follow the thyroid bioassay procedure as outlined in your NRC or Agreement State license.

Discussion: I-131 solution is a very high concentration material, so if any contamination exists as a result of handling this material, the contamination can contribute to volatile iodine levels.

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

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

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

A. CHECK IN PROCEDURE

1. Follow routine procedures for receipt of radioactive material.

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

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

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

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

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

B. PREPARATION FOR USE

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

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

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

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

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

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

C. CONTAMINATION CONTROL

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

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

3. Liquid I-131 will be handled in a double charcoal filtered glove box, which is located outside of the standard laboratory fume hood. The effluent from this glove box will be piped to the lab fume hood, thereby, insuring that MPC levels are not exceeded and contamination is isolated to the glove box area.

D. RSO PROCEDURES FOR CONTAMINATED SOURCES

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

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

E. Use and Maintenance of I-131 Glove Box

NOTE: At installation and prior to use, the linear flow across the arm ports of the hood will be determined with a velometer under conditions of normal

operation, i.e., negative air flow speed adjusted to maximum with both charcoal filters in place, and the laboratory fume hood on. Quarterly measurements will be obtained and documented to insure that the unit continues to operate at this base line level determination, with respect to negative linear flow.

1. Procedures for Use

   a. Put on disposable gloves.

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

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

   d. Placed sealed stock solution of iodine-131 in hood behind the L-block shield on the absorbent pad.

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

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

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

   h. Prepare for shipping.

   i. Replace stock I-131 in storage.

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

   k. Clean up and change absorbent pad, if necessary (survey meter readings will indicate if the pad is contaminated).

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

NOTE: If initial survey, with a pancake probe, indicated radiation levels no greater than background or no contamination, it is unnecessary to survey after clean up. If contamination was present on initial survey and on the after clean up survey, perform wipe test and decontaminate Iodine Hood until removable contamination is less than 2200 dpm/100 cm^2.

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

2. Maintenance Procedures

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

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

b. To insure that the system is operating properly, a determination of linear flow at the arm ports will be taken quarterly using an anemometer. If flow decreases below 50 lfm, the filter(s) will be changed to insure proper operation.

3. Procedure for Survey and Change of Filter

a. Disconnect exhaust pipe connector to fume hood.

b. Lift filter housing lid.

c. Put on disposable gloves.

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

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

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

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

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

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

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

PRECAUTIONARY MEASURES FOR HANDLING MILLICURIE QUANTITIES OF LIQUID RADIOIODINE

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

In Vivo Thyroid Bioassay

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

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

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

   a. Obtain background of counting system

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

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

   d. Calculate thyroid activity from:

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

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

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

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

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

   b. Sample calculations: Minimum detectable activity

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

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

      R_b = the background counting rate

      T_b = time taken to count the background

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

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

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

$$MDA = 3.3 \times \frac{\sqrt{2 \times \frac{290\ counts\ per\ minute}{1\ min}}}{4000 cpm/uCi} = 0.018\ uCi$$

      which satisfies the requisite sensitivity.

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

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

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

4. For our bioassay programs, action levels, frequency of bioassay, and actions to be taken if those levels are exceeded will be in accordance with U.S. Nuclear Regulatory Guide 8.20, Application for Bioassay for I-125 and I-131. Bioassays for thyroid uptake will be obtained with a scintillation counting system. Measurements of the thyroid will be compared to an iodine-131 capsule housed in an appropriate thyroid phantom to take into account tissue attenuation from the employee's neck. A multichannel analyzer and well counting system is available as back up equipment for thyroid bioassay.

   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

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

Where: T_s = sample count time

T_b = background count time

R_b = background count time (cpm)

LLD = lowest level detectable activity in cpm

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

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

Also:

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

where: F_e = efficiency factor of counting system

MDA = minimum detectable activity

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

Therefore, MDA may be expressed as:

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

when $T_b = T_s$

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

RS14 (5.0) Syncor International Corp # Page
Location:
Run Date: **BIOASSAY TEST RECORD** Run Time:

Thyroid Test:	Standard:	Analyzer Settings:	Observed cpm
Name	Background :	Threshold :	Thyroid Cnt 1:
SSN :	Source/Lot# :	Window :	Thyroid Cnt 2:
Date/time :	Src Activity :	Detector Vlt:	Thyroid Cnt 3:
Perform By:	Source Count :	Count Time :	Maximum Count:
Equip Ser#:	Net Src Count:	LLD :	Net Max Count:
Equip Desc:	Efficiency :	MDA :	
Equip Make:		Action Level:	Thyroid Activ:
Comments :			

June 14, 1996

TELEFAX

Region II
Materials Licensing &
Inspection Branch 2
Suite 2900
101 Marietta St.
Atlanta, GA 30323

FROM: **JOHN POTTER, Chief, MLIB2 Branch**
Voice: 404/331-5571
Fax: 404/331-5559, or 7437
Internet: jpp@nrc.gov

TO: **Justo M. Caamano, M.D.**
Diagnostic Photon Corporation
Voice: 787/727-1313
Fax: 787/791-6114

14 pages + cover)

Per our telecon today, we are returning the fax from Syncor regarding your amendment to add liquid I-131, for your approval.

FYI Dave - Dr. Caamano was concerned that Syncor was not informing him and obtaining his approval prior to communicating with us. The encl. memo F. Comer to J. Sinclair 6/1/96 covers this by saying that Dr. Caamano must sign etc.

JP 6/14/96

Syncor
The Service Difference

Syncor International Corporation

FAX TRANSMISSION COVER PAGE

DATE: 6/14/96

PLEASE DELIVER THE FOLLOWING PAGE (S) TO:

NAME: DAVID J. Collins,

COMPANY: N.R.C.

FAX #: 404-331-7437

FROM: NPI/SYNCOR
WA 15 MARGINAL
URB. LOS ANGELES
CAROLINA, PR 00979

PHONE: (787) 727-1313
FAX: (787) 791-6114

NAME: JAY SIMON

NUMBER OF PAGES: 14 (INCLUDING COVER PAGE)

COMMENTS:

HARD COPY IS IN THE MAIL
THANKS.

Phone Mail Box 1-800-678-6779 X2142

per { Norma Oldham, Diagnostic Photon } Jay Simon replaced Wade Hopkins, Syncor

787-791 6114 fax Diagnostic Photon
787 727 1313 voice " "

6/14/96

Comer Consulting, Inc.

809 S. Orlando Ave.
Winter Park FL 32789
(407)645-2255
Fax: (407)740-5935

FAX TRANSMISSION COVER SHEET

Date: *June 1, 1996*

To: *Jay Simon*

Fax: *(809) 791-6114*

Re: *NRC Responce*

Sender: *Frank M. Comer*

YOU SHOULD RECEIVE 13 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL (407)645-2255.

Copy or type the letter to NRC on your stationary.

To: Jay Simon
From Frank M. Comer
RE: Amendment response letter
Date: 06/01/96

This response letter must be signed by Dr. Carmano and sent to NRC in duplicate. Remember to save a copy of all information for your file.

I am faxing this information today June 1 and I will be sending the originals by priority mail to the pharmacy.

I am also including the amendment information I prepared for Wade in the information mailed. I know that he modified the original information some what and I do not have copies of those modifications. Bioassay information would have been sent with the initial amendment request, but Wade said that they had a bioassay program in place.

If you have questions concerning this information give me a call. I hope the NPI/Syncor name on the labels is not questioned, since the license is issued to Diagnostics Photon Corporation.

June 1, 1996

David J. Collins, Health Physicist
Material Licensing/Inspection Branch 2
Division of Nuclear Material Safety
USNRC, Region 2
101 Marietta Street, N.W., Suite 2900
Atlanta Georgia 30323-0199

Dear Mr. Collins:

RE: Amendment request for License No. 52-16345-02MD, Mail Control No.257008: Docket No. 030-19134.

In accordance with your letter dated May 15,1996 the following additional information is submitted to continue evaluation of the above referenced amendment request.

Item 4, your letter; Please find enclosed actual samples of the labels we intend to use.

Item 5, your letter; Please find enclosed a copy of our iodine bioassay program.

Item 6, your letter; All test results required by the U.S. Department of Transportation are maintained on file for inspection.

Item 7, your letter; Enclosed is a copy of the license upon which Mr. Hopkins is listed as an authorized user. In addition we request that the authorized users listed on this license be added to Condition 11. A. of the above referenced license.

We are aware that changes requested may not be implemented until final approval is received from your agency.

Sincerely,

Justo M. Caamano, M.D.

Dr. Caamano says he did not sign this yet

6/18/96

NPI/SYNCOR
HA 15 MARGINAL
CAROLINA PR 00979 (787)-727-1313

ALEJANDRO OTERO LOPEZ HOP 008 1 1
URBANIZACION ATENAS Rt Run
MAYAGUEZ PR 00674

43650

Doctor

℞ TC-99M MDP

Procedure SKELETAL WHOLE BODY Date 05/21/1996

Lot No 4-05/21/96 1 Expires 05/21/1996 18:00

Qty. Ordered 25.00 mCi

Assay 47.6586 uCi/ml As Of 8:00

Volume 0.52 ml Dispensed By SYD Checked

Qty. Dispensed 25.0017 mCi +/-10%

Caution: To be used under the direct supervision of a physician.

FELIX MENA
Mo-99 content (0.15 uCi/mCi at calibration time

SAMPLE

CAUTION RADIOACTIVE MATERIAL

43650 Syncor 05/21/1996 @ 8:00
TC-99M MDP
25.0017mCi +/-10%
Pt: FELIX MENA

SAMPLE

CUSTOMER COPY

NPI/SYNCOR
HA 15 MARGINAL
CAROLINA PR 00979 (787)-727-1313
ALEJANDRO OTERO LOPEZ HDP 008

Dr.

TC-99M MDP 05/21/1996 43650
4-05/21/96 1 05/21/1996 18:00
Lot 25.0000mCi Expires
Qty. Ordered 47.6586uCi/ml 8:00
Assay 0.52ml As Of
Volume 25.0017 mCi +/-10%

Qty. Dispensed mCi
Qty. Admin By
SKELETAL WHOLE BODY
FELIX MENA
Pt.

SAMPLE

CONTAINER LABEL

NPI/SYNCOR
HA 15 MARGINAL
CAROLINA PR 00979 (787)-727-1313
ALEJANDRO OTERO LOPEZ HDP 008

CAUTION RADIOACTIVE MATERIAL

Dr.

TC-99M MDP 05/21/1996 43650
4-05/21/96 1 05/21/1996 18:00
Lot 25.0000mCi Expires
Qty. Ordered 47.6586uCi/ml 8:00
Assay 0.52ml As Of
Volume 25.0017 mCi +/-10% By
SKELETAL WHOLE BODY

SAMPLE

Caution: To be used under the direct supervision of a physician.

FELIX MENA
Pt.

PRECAUTIONARY MEASURES FOR HANDLING MILLICURIE QUANTITIES OF LIQUID RADIOIODINE

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

In Vivo Thyroid Bioassay

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

2. Procedure: iodine-131 energy = 364 keV
   analyzer window = 100 keV

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

   a. Obtain background of counting system

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

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

   d. Calculate thyroid activity from:

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

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

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

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

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

   b. Sample calculations: Minimum detectable activity

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

$$MDA = 3.3 \times \frac{\sqrt{2 \cdot \frac{R_b}{T_b}}}{CF}$$

R_b = the background counting rate

T_b = time taken to count the background

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

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

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

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

which satisfies the requisite sensitivity.

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

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

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

4. For our bioassay programs, action levels, frequency of bioassay, and actions to be taken if those levels are exceeded will be in accordance with U.S. Nuclear Regulatory Guide 8.20, Application for Bioassay for iodine-125 and iodine-131. Bioassays for thyroid uptake will be obtained with a Single Channel Analyzer or a Multi Channel Analyzer with a 2" probe. Measurements of the thyroid will be compared to an iodine-131 capsule housed in an appropriate thyroid phantom to take into account tissue attenuation from the employee's neck.

   A record of bioassay results on the above test will be maintained. Records will contain the name of the individual, results of testing, and date. All positive bioassay results will be investigated. Corrective actions taken to prevent further uptake will be documented in accordance with NRC Regulatory Guide 8.20.

BIOASSAY TEST RECORD

CAPITAL PHARMACY, INC.

LOCATION ID : _____

DATE/TIME : _____

EMPLOYEE NAME : _____

PERFORMED BY : _____

THYROID TEST EQUIPMENT

SERIAL #: _____

MAKE: _____

MODEL #: _____

DESCR : _____

BKG CPM: _____

THYROID TEST RESULTS

ACTUAL THYROID CPM: _____

NET THYROID CPM: _____

ACTUAL SOURCE CPM: _____

SOURCE/LOT #: _____

SOURCE ACTV uCi: _____

NET SOURCE CPM: _____

THYROID uCi: _____

COMMENTS:

NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

CORRECTED COPY

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

Licensee	
1. Syncor International Corporation	3. License number 04-25507-01MD
2. 20001 Prairie Street Chatsworth, California 91311	4. Expiration date March 31, 2001
	5. Docket or Reference No. 030-33224

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 usad 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. 700 millicuries
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. 100 curies
C. Technetium-99m	C. Unsealed	C. 100 curies

NRC FORM 374A (9-91) U.S. NUCLEAR REGULATORY COMMISSION

License Number
04-26507-01MD
Docket or Reference Number
030-33224

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Y. 1500 Tomlyn Street, Richmond, Virginia 23230
Z. Rd 3, Box 367, Route 20 West, Seaford, Delaware 19973
AA. 650 Elmwood Avenue, Sharon Hill, Pennsylvania 19079
BB. 21681 Melrose Avenue, Southfield, Michigan 48075
CC. 3040 East Elm Street, Springfield, Missouri 65802
DD. 1045 Westgate Drive, Suite 100, St. Paul, Minnesota 55114
EE. 1909 Beltway Drive, St. Louis, Missouri 63114
FF. 28 Omega Drive, Building #7, Stamford, Connecticut 06907
GG. 5370 Miller Road, Suite #25, Swartz Creek, Michigan 48473
HH. Mingo Valley Trade Center, 10205 E. 61st Street South, Suite E, Tulsa, Oklahoma 74133
II. 1525 Corporate Woods Parkway, [illegible] Town, Ohio 44685
JJ. 9800 Rockside Road, Suite 550, Valley View, Ohio 44125
KK. 230 Clearfield Avenue, Suite 125, Virginia Beach, Virginia 23462
LL. 11829 W. Ripley Avenue, Wauwatosa, Wisconsin 53226
MM. 3045 Kent Avenue, Suite A, West Lafayette, Indiana 47906
NN. 10-N Roessler Road, Woburn, Massachusetts 01801

11. A. Licensed material shall be used by, or under the supervision of:

1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) and (3), or

2) authorized nuclear pharmacists:

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Alan Alberto
Aatif Al-Hout
Kamal C. Amin
Wajih Araman
Luke C. Augustine

Razmik Abkarians
Jane Adams
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NRC FORM 374A
7-81 U.S. NUCLEAR REGULATORY COMMISSION

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Docket or Reference Number
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Harold Sano
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NRC FORM 374A (7-94) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 04-26507-01MD
Docket or Reference Number: 030-33224

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Lynn Stainbach
David Stith
Richard E. Stotler
Ricky Strickland
Christine L. Surerus

Ralph Bruce Tarleton
James T. Threadgill
Steven P. Torres
Diana Tribbey
Rene W. Tsang
Catherine Turney

Sherri L. Usko

Enrique Velazquez

David Ward
Robert J. Weinberg
Arthur Wenderoth
Ray Wilkinson
Robert E. Wilson
Kok Wayne Wong
Eleanor M. Woods
Michael B. Wyant

Que Yabut
Carol A. Young

Nick Zapletal
Rhoda Zylstra

Michael Schwimmer
Kathy Seifert
Steven A. Shipper
Garcia Simon
Charles Smith
Michael Smith
Tanya Spillum
George H. Starks, Jr.
Janeen Stewart
James S. Stone
Tad J. Straly
Caryn Stumlar
Don E. Svec

Anthony Tascione
William Tompkins
Allen Townsend, Jr.
Leslie A. Triche
Clyde Tucker
Paul A. Tyler

Terry W. Vich

Bill Watts
Eric Weiner
Kirk White
Ben Wilson
Kristina Wittstrom
Wayne H.W. Wong
Ronald L. Worgul

Benson P. Yang
Timothy Younkin

Gary Zimmerman

Shannon Seals
Brian E. Shimley
Khalid Shumburo
David Skripac
Laura Smith
Peter Solomon
Peter J. Sposato
Mark K. Stassen
Duane N. Stimpson
Howard Stoops
Brantley A. Strickla
Kimberly Suhar
Matthew Swift

William Thompson
JoAnn Torchia
Kim L. Travis
Benjamin D. Trickey
Julie A. Turner

Prasathip Pat Vongxa

Marc D. Weichelt
Robert Wellins
Roxanne K. Wiley
Jason J. Wilson
Pamela Wolfson
Steve Wood
J. Wesley Workman

Randy Yates

C. Joe Zipp

May 15, 1996

Diagnostic Photon Corp
ATTN: Justo M. Caamaño, M.D.
P. O. Box 4408
Carolina, Puerto Rico 00984

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ABOUT AN AMENDMENT REQUEST (REFERENCE: MAIL CONTROL NO. 257008; DOCKET NO. 030-19134)

Dear Dr. Caamaño:

This refers to your letter application dated March 25, 1996 for an amendment to License No. 52-16345-02MD. In my review, I have identified areas for which there is insufficient information to make a reasonable decision regarding protection of employees from occupational exposure to radiation and radioactive materials, and the protection of the public health and safety. I have enclosed information which I believe will help you to answer the questions I have raised. I have faxed this letter to your attention, and it is being mailed with its enclosures.

You are already aware of the requirements for transfer of licensed activities to another. I have enclosed Revision 1 to NRC's Information Notice 89-25, which will provide additional guidance. You may transfer all materials to a licensed person, provided you have verified the recipient is authorized to possess the materials being transferred.

With respect to your letter:

1. We will increase the possession limit under item 8.A. for iodine 131 to 2 curies.

2. We will increase the sealed sources quantity in 8.B. to 15 millicuries.

3. The layout of the facility appears to be acceptable.

4. Please submit actual samples of the labels you intend to use. While color is no longer a requirement, we do wish to have samples of the actual labels in use.

5. I do not find an iodine bioassay program description in any of your submitted documents. Enclosed is a copy of Regulatory Guide 8.20, Revision 1, "Applications of Bioassay for I-125 and I-131." Please provide a program equivalent to the guidelines acceptable in the Regulatory Guide. A radiopharmacy bioassay program already accepted by NRC for another licensee (such as Syncor) should be compared to the requirements and conditions of your program for applicability.

6. The details provided are acceptable for amendment. You should maintain copies of the test results as required by the U.S. Department of Transportation regulations. You may not exceed the maximum quantities tested unless additional tests are performed.

7. Please provide a copy of the license upon which Mr. Hopkins is named as an authorized user.

You are aware that you may not make the changes requested until final approval by NRC. Please reply within 30 days of the date of this letter. Please refer to Mail Control No. 257008. If you wish, you may fax your reply to (404) 331-7437, and mail the original. If replying by mail, please provide two copies of the response. I shall be happy to answer any questions by telephone or fax. My telephone number is (404) 331-5624.

Sincerely,

David J. Collins, Health Physicist
Materials Licensing/Inspection Branch 2
Division of Nuclear Materials Safety

Enclosures:
1. Regulatory Guide 8.20
2. Information Notice 89-25, Revision 1

OFFICE	RII:DNMS	RII:DNMS				
SIGNATURE	DJCollins	JPPotter				
NAME	DJCollins	JPPotter				
DATE	05/15/96	05/15/96	05/ /96	05/ /96	05/ /96	05/ /96
COPY?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

OFFICIAL RECORD COPY DOCUMENT NAME: G:\DNMS\MLIB2\DEFLTR\257008.DJC

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02500
Status Code: 0
Fee Category: 3C 2B
Exp. Date: 20050430
Fee Comments: 3C OK-SEE 1984 NOTES
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED
   Applicant/Licensee: DIAGNOSTIC PHOTON CORPORATION
   Received Date: 960327
   Docket No: 3019134
   Control No.: 257008
   License No.: 52-16345-02MD
   Action Type: Amendment

2. FEE ATTACHED
   Amount: $500.00
   Check No.: 3459

3. COMMENTS

Signed Quang Nguyen
Date 3/27/96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_/)

1. Fee Category and Amount: 3C 2B $500

2. Correct Fee Paid. Application may be processed for:
   Amendment /
   Renewal _____
   License _____

3. OTHER _____

Signed Rita Meyer
Date 4/1/96

Log Apr 2 11
Remitter
Check No. 3459
Amount $500
Fee Category 3C 2B
Type of Fee Amd
Date Check Rec'd.
Date Completed 4/1/96
By: Ken

DIAGNOSTIC PHOTON CORP.
INTERNATIONAL NUCLEAR MEDICINE HEALTHSERVICES
P.O. BOX 4408
CAROLINA, PR 00984

March 25, 1996

Jay L Henson
Region II, Nuclear Material
Safety Section
101 Marietta Street NW, Suite 2900
Atlanta, GA 30323

Re: Notice and amendment request for NRC Materials License Number 52-16345-02MD.

Dear Mr. Henson:

Please be advised that I have entered into a management agreement with Syncor International Corporation to assist in the day to day operation of my nuclear pharmacy in Puerto Rico. This agreement will result in the eventual transfer of ownership. Prior to this occurring, sufficient notice of transfer will be provided.

Please amend the above referenced license for the following:

1. authorization to increase our possession limit for iodine-131 to two (2) curies under license Item 8.A.;

2. authorization to increase our possession limit to 15 millicuries under license Item 8.B.;

3. authorization to change the physical layout of our pharmacy. Please find attached in Appendix A sketches of the present physical layout and the proposed layout. This change is necessary to add an iodine-131 handling room and increase our waste handling areas;

4. authorization to begin using new packaging and container labels. Please see attached in Appendix B examples of our new labels and their use;

5. authorization to compound theraputic iodine-131 capsules. Supporting information for this request is attached in Appendix C;

6. authorization to use the Secure™ ,/Unit Dose Container. In support of this request descriptive information and shielding specifications are attached in Appendix D, and

7. authorization to add Wade M. Hopkins, R.Ph. BCNP, #83 208 07 as a user under Condition 11 A. Mr. Hopkins is listed as an authorized user on NRC license Number 34-16654-01MD.

Your consideration in this matter is appreciated.

Sincerely;

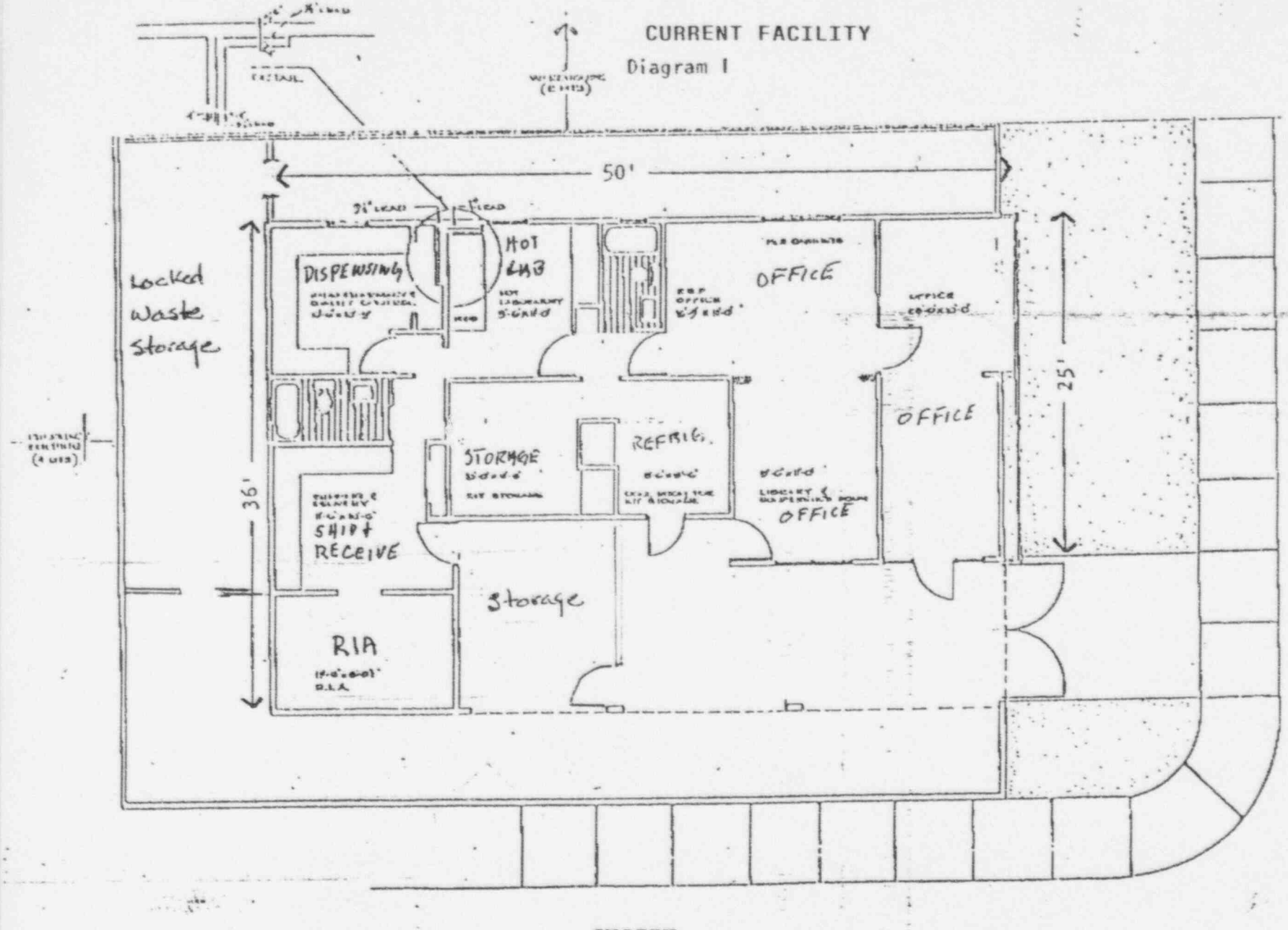
Justo M. Caamaño, M.D.
Member Society of Nuclear Medicine
Member American Board of Nuclear Medicine, Inc.

APPENDIX A

WA 15 Marginal
Los Ange), Carolina P.R.

CURRENT FACILITY

Diagram I



STREET

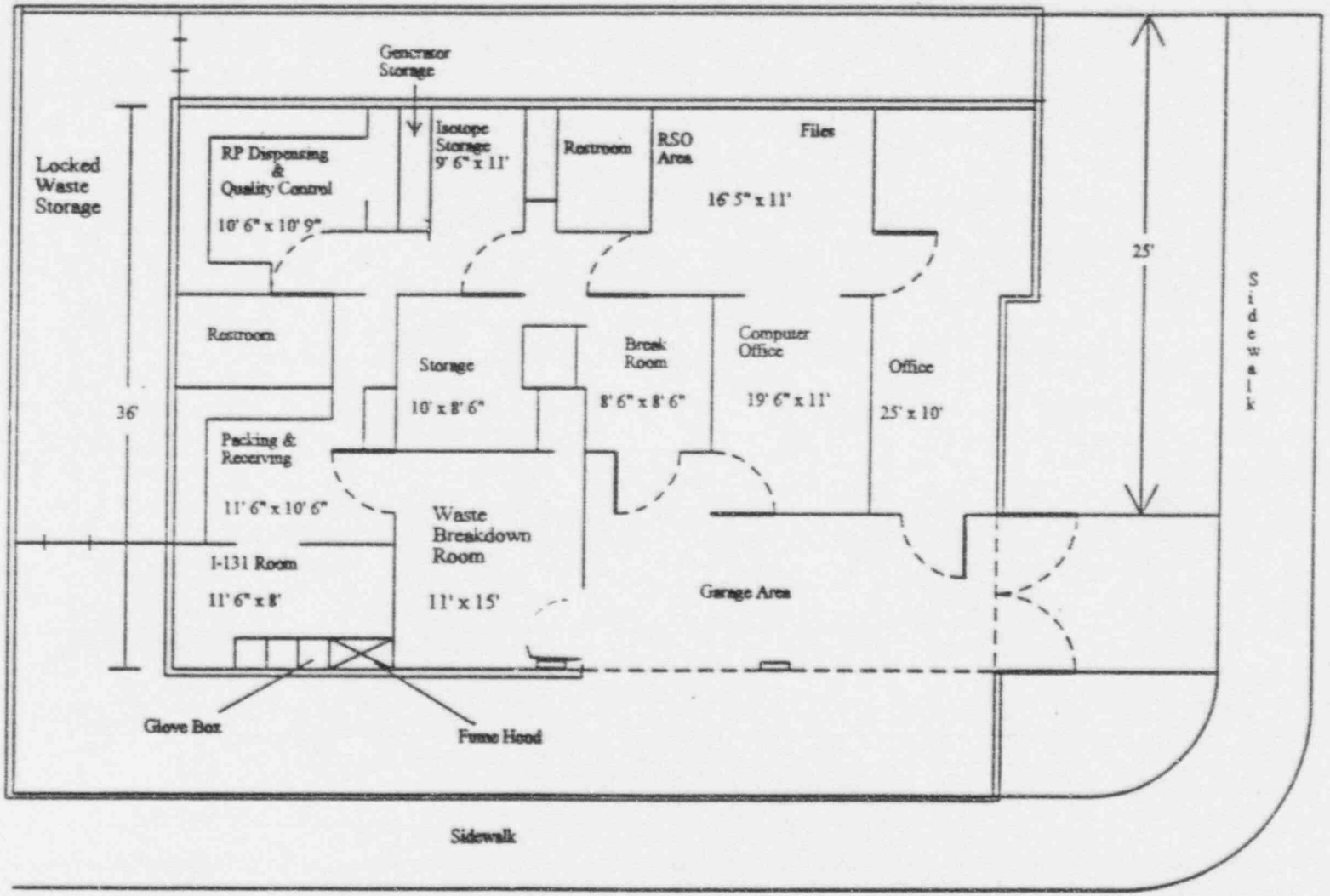
The building is constructed of 12 inch concrete block reinforced with 3/8" steel rods at each corner. Steel bars are at each window. An iron wrought and cement block fence provide perimeter security (see dotted line).

PROPOSED FACILITY

Outside wall Constructed of 12 inch concrete block with 3/8 inch steel rod reinforcement at each corner.

Diagnostic Photon Corp.

A wrought iron and cement block fence provide perimeter security (see dotted line).



APPENDIX B

PRODUCT LABELS

A.

Dr.

#

Lot Expires
Qty. Ordered
Assay As Of
Volume Dispensed By
Qty. Dispensed

CONTAINER LABEL

Caution: To be used under the direct supervision of a physician.

Pt.

C.

#

B.

Dr.

#

Lot Expires
Qty. Ordered
Assay As Of
Volume
Qty. Dispensed
Qty. Admin. By

CUSTOMER COPY

Pt.

These are sample labels. Diagnostic Photon Corporation will have its name and address printed on the labels which it uses.

REQUIRED CONTAINER LABELING

1. VIALS:

   Vials will be labeled with the manufacturers' original label or with label A or C. If label C is used it will be completed to contain all information required as on label A.

2. SYRINGES:

   Syringes will be labeled with label C.

3. VIAL SHIELDS:

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

4. UNIT DOSE CONTAINER SHIELDS:

   Unit dose containers will be labeled with label A.

5. GENERATORS:

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

6. ALL PACKAGES CONTAINING RADIOPHARMACEUTICALS

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

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

NOTE: The form found under B is for customer's use. Label B is given to the customer for their records.

PRESCRIPTION

Rt Run

Doctor	#
℞	
Procedure	Date
Lot No.	Expires
Qty. Ordered	
Assay	As Of
Volume	Dispensed By / Checked
Qty. Dispensed	

Caution: To be used under the direct supervision of a physician.

Pt.

A copy of this prescription is given to the account, and the original is maintained as required by the Board of Pharmacy.

APPENDIX C

SPECIAL EQUIPMENT FOR HANDLING MILLICURIE QUANTITIES OF LIQUID RADIOIODINE

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

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

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

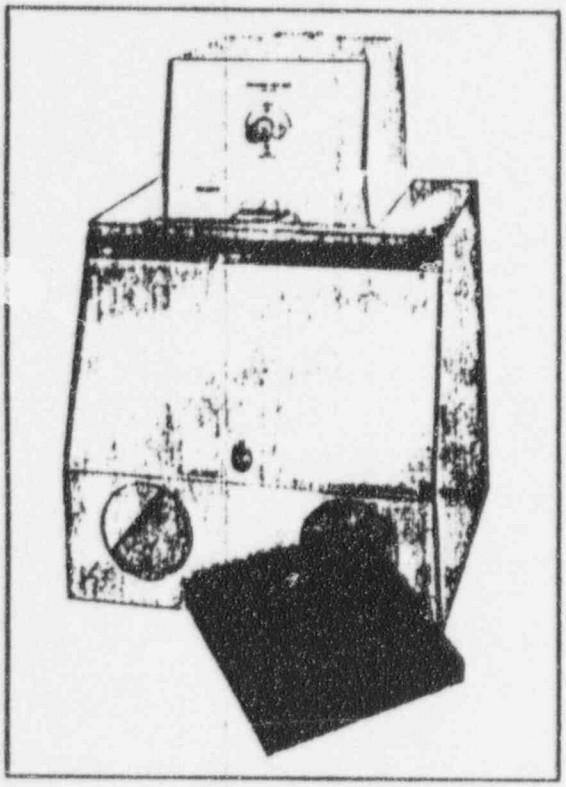
Air sampling for volatile I-131 will be performed in conjunction with the use of the radioiodine fume hood. Please see the following air sampling procedure.

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

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

RADIOIODINE FUME HOOD

AMPLE WORK SPACE FOR COMFORTABLE USE



SPECIFICATIONS:
Motor: 1/15 H.P., 61 Watts, 3/4 Amps, 110 VAC, 50/60 Hz
Glove Box: 24" x 20" base x 36" height (61 x 51 x 91.4 cm)
Swing-Away Front Door: 24" x 13" (61 x 33 cm)
Shipping Weight: 90 lbs (41 kgs.)

The Radioiodine Fume Hood was designed to meet the demanding needs of iodination procedures. Constructed of 3/8" clear, rugged plexiglass, the fume hood provides a large internal work area and spacious arm ports to allow maximum uninhibited manipulation of material within the unit. A swing-away front door permits easy placement and retrieval of items.

The air baffle assures even flow speed of air out of the box while negative air flow speed can be adjusted from 0 to a maximum of 80 CFM. The fume hood includes a 12" x 12" x 1" disposable charcoal filter that traps 90% of the radioiodine produced and can accommodate two filters if needed.

EQUIPMENT AND STANDARDS

Item 1

A TEDA-impregnated carbon cartridge 2¼" in diameter and 1" high (HI-Q Environmental Products Co., La Jolla, CA, 619/549-2820, Catalog #TC-12) will be used with no pre-filter. The manufacturer's stated efficiency factor is 99% at 0.35 CFM or 10 liters per minute for worst case, i.e., for methyl iodide. Please see the attached graph.

Item 2

a. Sampling will be done on a continuous basis.

b. Air sampling cartridges will be exchanged every seven (7) days.

c. For outer dimensions of 2¼" diameter by 1" inch, the volume of the TEDA carbon is calculated using a 3/4" radius with a 3/4" thickness:

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

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

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

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

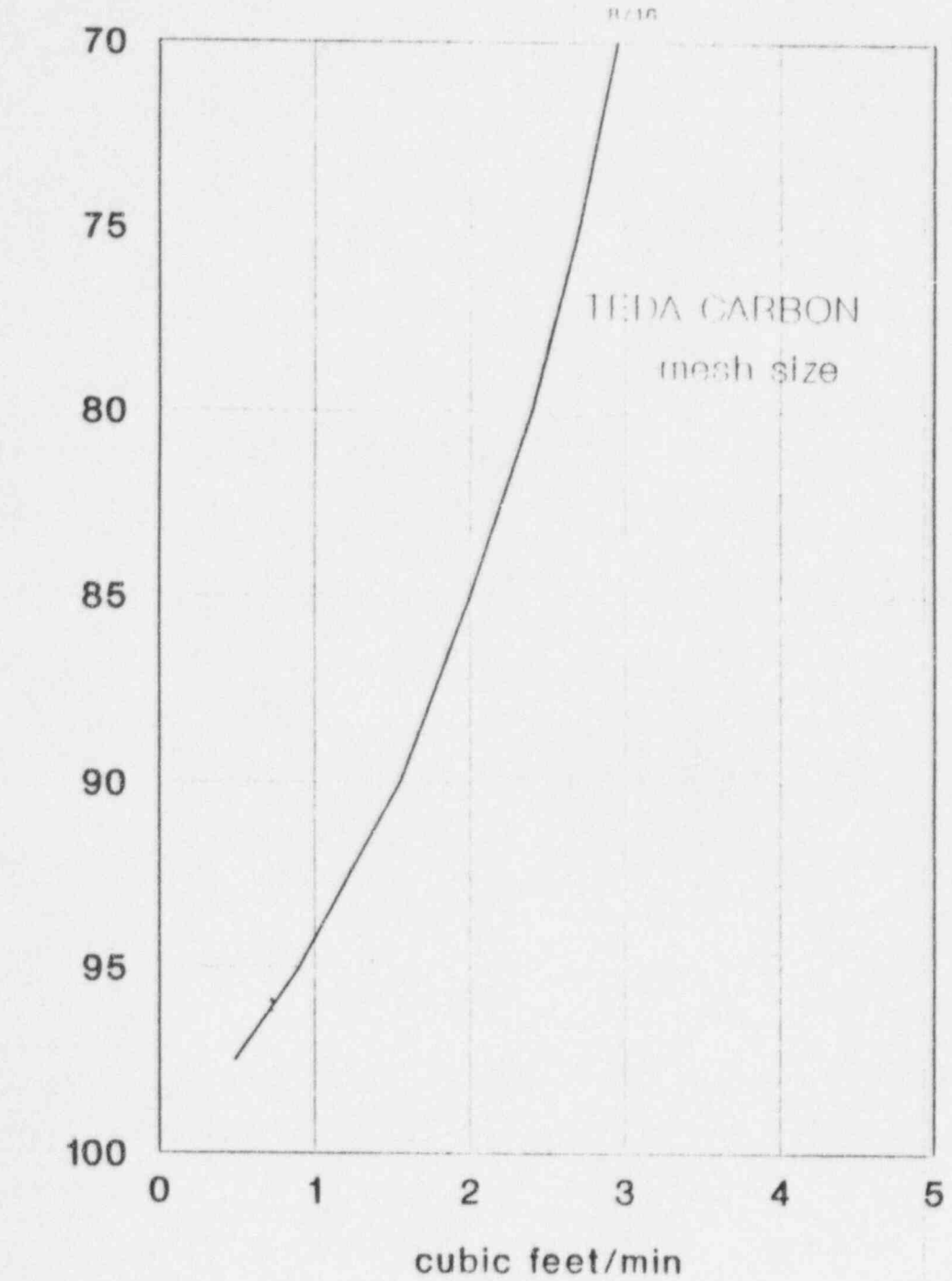
Isotope Products Laboratories (IPL)
1800 N. Keystone Street
Burbank, CA 91504
818/843-7000

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

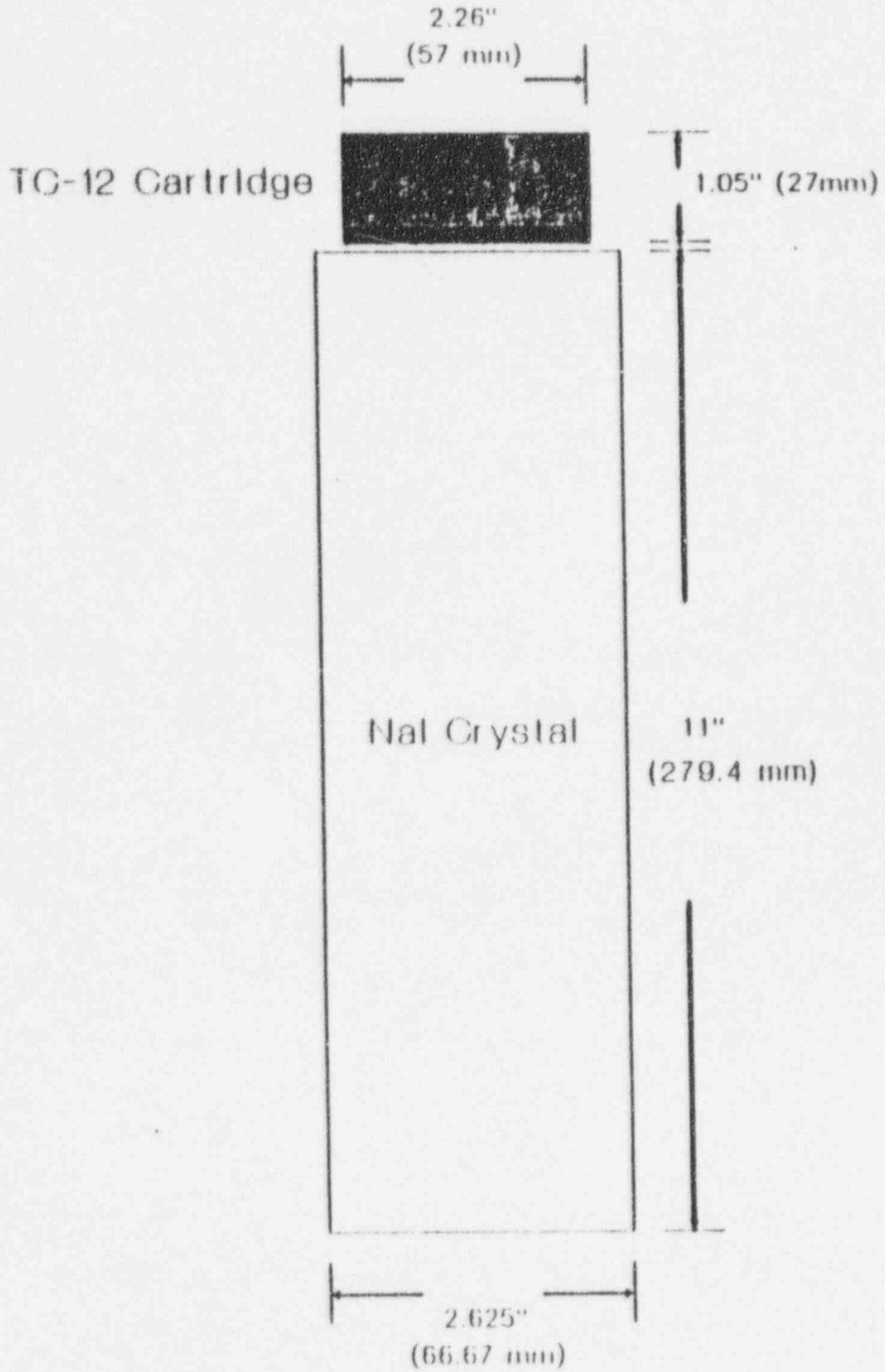
Item 3

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

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


% methyl
iodide retention
8/16
70
75
80
85
90
95
100
0
1
2
3
4
5
TEDA CARBON
mesh size
cubic feet/min

EXAMPLE



(not to scale)

Procedures for Completion of Iodine-131 Air Monitoring

The following pages give detailed instructions for performing iodine-131 air monitoring, including the operating procedures for cartridges. This is followed by the installation instructions.

Procedures for 131-Iodine Air Monitoring

A. Discussion

1. The handling of certain volatile radioactive materials may require that air sampling be performed to document that the Derived Air Concentrations (DAC's) are not exceeded in either the restricted or unrestricted areas.

2. Acceptable methods include: (1) air sampling data and/or (2) calculations, if those calculations can demonstrate that the DAC for a particular substance is not exceeded. If calculations are submitted, it is necessary to document those specifications and measurements (such as fume hood flow in cfm, etc.) are checked periodically to ensure that the conclusions made from the calculations have not changed.

3. For volatile iodine-131, air sampling will be done. Following is our procedure.

B. Equipment

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

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

2. Appropriate teflon tubing

3. Charcoal Cartridge holder

4. TEDA impregnated charcoal cartridge

5. Scintillation counting assembly and barium-133 cartridge standard

C. Operating Procedure for Air Cartridges

1. Mount the air sampling apparatus in a manner which will ensure that effluent being released to both restricted and unrestricted areas will be sampled. Sampling must be done in the exhaust vent pipe on the down stream side of any additional air filtering system. Be sure that the standard laboratory fume hood sash opening is closed as far as possible so that the face velocity across the fume hood opening is increased. This decreases the amount of volatile iodine-131 that will escape into the restricted area.

2. The charcoal cartridges will be counted and exchanged every seven (7) days.

   NOTE: IN THE EVENT OF A SPILL THE CHARCOAL CARTRIDGES WILL BE COUNTED IMMEDIATELY.

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

   a. Put on disposable gloves.

   b. Calibrate the counting system by placing the barium-133 cartridge standard directly on the scintillation probe housing. Set the analyzer transmission with the lower discriminator at 300 keV and the upper discriminator at 430 keV and peak the instrument by adjusting the high voltage potentiometer or gain control. Obtain a count on the standard. Remove the standard and obtain a background count. Record the background and standard counts on the form being used.

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

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

   e. Record the iodine-131 count on data form, if available enter your data into your computer program.

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

5. Record the activity in uCi of the barium-133 standard.

D. Procedure for Calculating the Concentration of Volatile Iodine

The following calculations may be used to determine the concentration of volatile iodine in uCi/ml in the restricted and unrestricted areas. (See the attached worksheet).

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

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

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

   t = 1/2 of the sampling period (e.g., for 7 days, t = 4 days)

   CF = the efficiency for the Ba-133 standard in cpm/uCi.

   $e^{\lambda t}$ is the correction factor for decay.

   A simplifying assumption is to back-decay the activity for 1/2 of the sampling time to correct for sample decay. Since we normally sample once every seven days, we say that 1/2 of seven days is four days to err on the conservative side.

3. Determine the air flow through the sampling pump in ml from pump flow data in ml/min x sampling time in minutes.

4. Calculate the iodine-131 concentration in uCi/ml using the formula below.

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

5. The Derived Air Concentrations are:

   i. Effluent Concentration = 2×10^{-10} uCi/ml
   ii. Occupational DAC = 2×10^{-6} uCi/ml

E. Procedures for Installation

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

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

WORK SHEET FOR IODINE-131 AIR MONITORING

A. Determine the activity of iodine-131 in the cartridge in uCi:

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

2. Sample count (cartridge) = _____ cpm.

3. Net Barium-133 count = _____ cpm.

4. Ba-133 Standard Activity = _____ uCi.

5. CF = $\frac{\text{Net Ba-133 Standard Count (cpm)}}{\text{Activity of Ba-133 Standard (uCi)}}$

   = _____ cpm/uCi

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

   = _____ uCi

B. Determine the flow through the sampling pump in ml:

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

2. Pump-on Duration = _____ min.

3. Pump Flow _____ ml/min x Pump-on Duration _____ min
   = _____ ml

C. Determine the concentration of iodine-131 in uCi/ml:

I-131 concentration in air (uCi/ml)

= $\frac{\text{I-131 uCi from A6 above}}{\text{Flow through pump (ml) from B3 above}}$

= _____ uCi/ml

Instrument _____

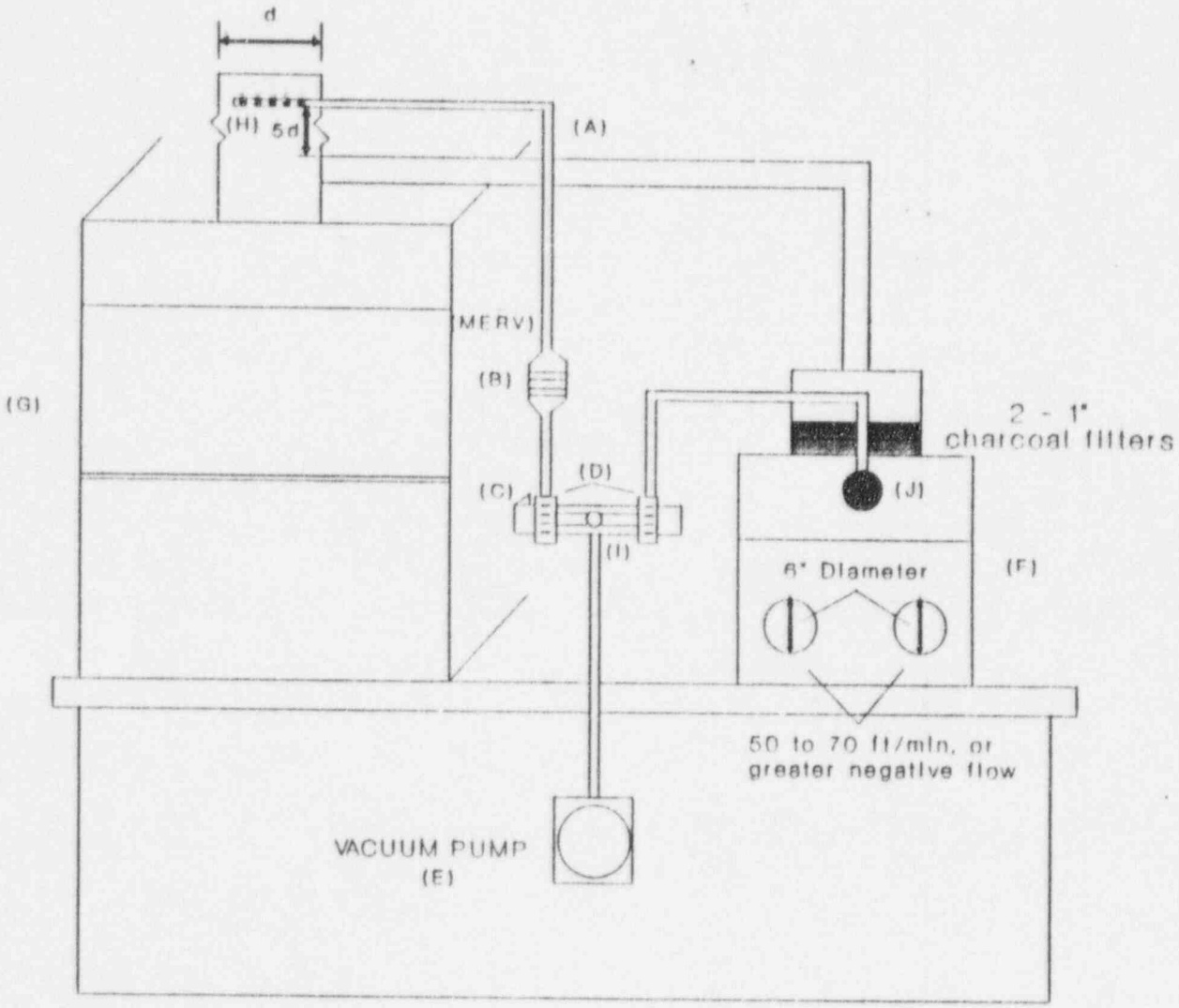
Analyzer Setting _____ keV to _____ keV

Signature _____ Date _____

* $e^{\lambda t}$ = decay correction where t = 4 days or 1/2 the time between samples.

VOLATILE SUBSTANCE HANDLING AND SAMPLING SYSTEM

NOTE: FUME HOOD MOTOR IS LOCATED ON THE ROOF.



A. 1/2" TEFLON SEMI-RIGID TUBING
B. FILTER HOLDER (CONTAINS CHARCOAL CARTRIDGE)
C. L-BRACKET
D. ROTAMETER
E. VACUUM PUMP
F. GLOVE BOX I-131 HOOD
G. STANDARD LABORATORY FUME HOOD
H. SAMPLING PROBE
I. "T" CONNECTION
J. RESTRICTED AREA AIR SAMPLING CARTRIDGE

EXAMPLE of "I-131 COMPUTER GENERATED AIR MONITORING RECORD"

Diagnostic Photon Corportation

I-131 Air Monitoring Worksheet

Location Id: Sample Date:
WC Serial #: Make:
Desc:

Well Counter Bkg : cpm
Unrestr Sample Count: cpm Net Unrestr Sample Count: cpm
Restr Sample Count: cpm Net Restr Sample Count : cpm

Ba133 Src Count: cpm
Net Count: cpm
Ba133 Src Lot# :
Ba133 Src Actv : uCi

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

	effluent concentration	occupational
Total uCi of I131 :	uCi	uCi
Air Conc' of I131:	uCi/ml	uCi/ml
% Maximum Emission Concentration:	%	%

Test Performed By :

EXAMPLE of "I-131 RELEASED YTD"

Diagnostic Photon Corporation

I-131 Released (YTD)

Location Id :
Year-to-Date :

Total I131 'Collected' (YTD): uCi
Total Air Flow Sampled (YTD): ml

'Average' I131 Concentration (YTD): uCi/ml
'Average' Fume Hood Flow (YTD) : cfm

Total Milliliters of Fume Hood Flow (YTD): ml

Total I131 Released to Environment (YTD) : uCi

SODIUM PHOSPHATE CAPSULE PREPARATION

* * * MATERIALS NEEDED * * *

(1) Sodium phosphate di-basic anhydrous, powder

Two commercially available products:

1.	J.T. Baker	500 mg	cat.	# 3828-1
2.	Mallinckrodt	500 mg	cat.	# 7917-1

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

The sodium phosphate should be stored "tightly sealed" to assure freshness. By leaving the jar uncapped for extended periods of time defeats the purpose of "being anhydrous".

(2) Size #1 gelatin capsules

SPECIAL NOTE: GELATIN CAPSULES SHOULD NOT BE BRITTLE. THEY SHOULD BE PLIABLE TO THE TOUCH. THE CAPSULES WILL BECOME BRITTLE WITH AGE, IF STORED NEXT TO EXCESSIVE HEAT.

(3) Latex gloves

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

(4) Glass pill tile/spatula

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

(5) Air-tight storage container

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

SODIUM PHOSPHATE CAPSULE PREPARATION

* * * FILLING PROCEDURE * * *

(1) On a clean glass pill tile place a small portion of sodium phosphate powder.

(2) Use a spatula (or piece of waxed paper) to pack down the powder. Be sure the sodium phosphate powder is packed tightly.

(3) Wearing latex gloves, fill the long end of the #1 capsule with as much di-basic sodium phosphate powder as possible. The piggy-back filling method often taught in pharmacy school is not the preferred method since it does not allow you to pack the capsules to their fullest. Instead be sure to hold the capsule directly in your hand and punch until the capsule is full. Fill the shorter-half capsule approximately two-thirds full. Place the two ends firmly together. The packed capsule should be moderately firm (not hard), with gelatin edges overlapping about 2 mm to maximize powder volume, without compromising patient acceptance.

(4) Make twenty (20) or more sodium phosphate capsules depending on your usage. Store in an air-tight container in the freezer.

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

SODIUM IODIDE I-131 CAPSULE PREPARATION

* * * MATERIALS NEEDED * * *

(1) CIS I-131 TX SOLUTION

(2) SODIUM PHOSPHATE SIZE #1 CAPSULES

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

(4) DISPENSING CONTAINER

(5) LEAD DISPENSING/SHIPPING CONTAINER

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

(7) 1 CC TUBERCULIN SYRINGE SHIELD

(8) TONGS

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

(10) LATEX GLOVES

(11) SHOULDER LENGTH PLASTIC GLOVES

One Commercially available product:

1. Lab safety supply "disposable polyethylene gloves" order no. 3217

LEAD CAPSULE HOLDER

MATERIALS NEEDED:

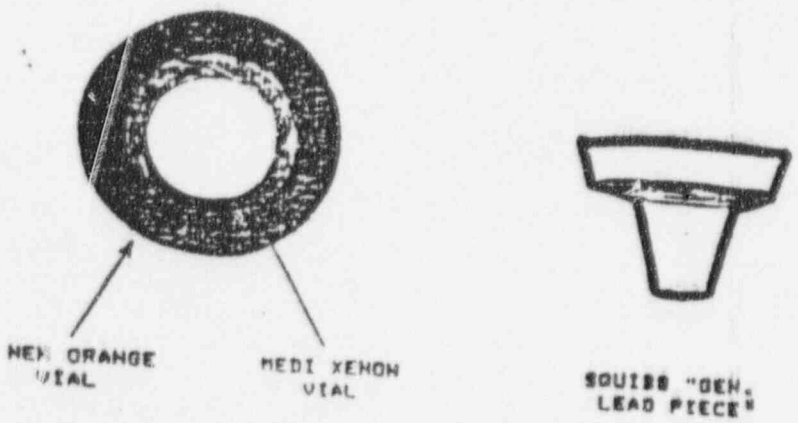
ONE ORANGE DUPONT LEAD CONTAINER
(DUPONT GA-67 LEAD CONTAINER)

ONE MEDI-PHYSICS XENON LEAD CONTAINER

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

Insert the Medi lead xenon container into the orange Dupont lead container. Hammer the xenon lead container until it is all the way into the orange one. Place the Squibb "generator lead piece" on top of the orange lead container.

(DIAGRAM A)



SODIUM IODIDE I-131 CAPSULE PREPARATION

* * * COMPOUNDING PROCEDURE * * *

(1) Turn on the standard laboratory fume hood and the radioiodine fume hood if not already operating. Check to make sure the equipment is operating properly.

(2) Turn on the vacum pump for the air monitoring if it is not already operating. Check to make sure the gauges and vacuum pump are operating properly.

(3) Wear two (2) pairs of gloves. First, put on a pair of shoulder length plastic gloves. Next, put on a pair of latex gloves over the shoulder length gloves you are wearing.

(4) Perform an area survey of the I-131 glove box and work area to make sure that it is contamination free. If not, decontaminate the work area before you start. Always use ALARA principles!

> **Special note:** A survey meter equipped with a pancake probe is ideal for isolating I-131 contamination. This probe is extra sensitive to beta radiation; more so than a GM sidewall probe.

(5) Calculate the amount of I-131 solution needed to fill the prescription. Remember to take into consideration "decay" if the therapy capsule is for the next day. Also the residual volume left in the lo-dose syringe will be approximately 200-400 uci. This must also be taken into consideration, especially when very low millicurie capsules are made.

(6) In the iodine glove box vent the I-131 solution through a charcoal syringe. Next, draw up the activity needed in a shielded lo-dose syringe and assay.

> **Special note:** Do not exceed the capsule volume capacity. If the prescribed dose exceeds this, a second capsule should be made. In addition, only fill the syringe with that amount of solution to be injected into a single capsule.

(7) Place the shielded I-131 lo-dose syringe and I-131 solution in the fume hood so it is out of the way.

(8) Set up the orange Dupont lead vial with the Squibb gen. lead piece on top. This set-up will be referred to as the "lead capsule holder".

(9) Take a small piece of saran wrap (approx. 3" X 3") and place it on top of the lead capsule holder.

(10) Separate a size "0" gelatin capsule. Take the long end and push the plastic wrap into the lead capsule holder.

(11) Remove a size "1" di-basic sodium phosphate capsule from the freezer. Puncture the packed gelatin capsule slightly (using a 20-22 gauge needle) with a pair of holes at each end about 2-4 mm apart (see figure 1). This allows air trapped in the capsule to escape as the powder fills and hardens, maximizing the absorbent capacity. A conservative option is to place the air escape holes just at the top of the capsule.

(11A) Place the size "1" capsule into the shielded size "0" capsule so that the seams of the two are not lined up, as a safeguard against overflow.

(12) Bore a pilot hole (using the same 20-22 gauge needle) from top center of the packed capsule to the bottom, taking care not to puncture the bottom of the capsule. This allows the capsule to fill from the bottom up.

> **Special note:** This procedure will prevent coring which very often clogs the needle.

(13) Inject up to .35 ml of sodium iodide(131) solution , slowly and smoothly into the capsule, using a fully inserted low-dose syringe. Exercise caution when compounding above 0.3 ml and observe the powder at the top to tell if you are approaching the volume limit as you near the endpoint. Clear size #1 capsules are recommended.

> **Special note:** If your injection is made too slowly, you increase the chances that the sodium phosphate powder will harden prematurely before you are able to make the entire injection. If your injection is made too quickly, the sodium phosphate's ability to absorb the solution will be exceeded. This will be obvious by the distorted appearance of the finished capsule.

(14) Once the injection is complete, remove the needle from the capsule and cap. Place the empty I-131 syringe in its holder and store in the fume hood out of the way.

(15) Using a "Brower's" modified straw, pick up the other size "0" capsule half and place on the capsule in the lead capsule holder. Invert the straw and tap it down tightly.

(16) Remove the capsule by injecting the Squibb gen. lead piece onto a second orange lead container that has a "dispensing container" within. With an empty lo-dose syringe, push the capsule through the Squibb gen. lead piece so it drops into the dispensing container.

(17) Remove the Squibb gen. lead piece and cap the dispensing container inside. Cover the orange lead container with it's lead top.

(18) Assay the I-131 therapy capsule; account for decay; and assure that the finished capsule strength is not greater than 10% of that which was ordered.

(18A) Clear the work area.

(19) Remove your latex gloves and replace with new ones (make this step a part of your normal routine).

> **Special note:** If, for any reason your outer gloves are contaminated it is important to change them now to assure that you don't contaminate the lead shipping container;

(20) Make a final check for capsule integrity before dispensing. Occasional capsule deterioration occurs a short time after preparation and may not be immediately apparent.

(21) Dispense the I-131 therapy capsule in a heavy lead container.

Special note: It is recommended that a wet smear be performed on the lead container to assure that there is no removable contamination.

(22) Remove the shielded I-131 syringe from the fume hood and place it in the I-131 glove box. Rinse the syringe into a shielded 10 cc or 20 cc saline "wash vial". Store the I-131 "wash vial" in the fume hood for future use. Dispose of the I-131 syringe in the appropriate radioactive waste bin.

Special note: this rinse procedure will help contain the I-131 if it becomes volatile and therefore help reduce airborne I-131 contamination.

(23) Perform an area survey of the I-131 glove box and other immediate work areas to assure they are contamination free. Decontaminate if necessary!

(24) Follow the air monitoring procedure as outlined in your NRC or Agreement State license.

(25) Follow the thyroid bioassay procedure as outlined in your NRC or Agreement State license.

Discussion: Diagnostic Photon Corporation is using I-131 therapy solution which comes in sealed containers. The I-131 solution is a very high concentration material. If any contamination exists as a result of handling this material, the contamination can contribute to volatile iodine levels.

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

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

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

A. CHECK IN PROCEDURE

1. Follow the routine procedures for receipt of radioactive material.

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

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

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

5. If no contamination greater than 6600 dpm is found on the sealed tin can, place it in storage until it becomes necessary to use it. If significant contamination is found, report your findings to the RSO and double seal the container and place it in storage. Zip lock or heavy plastic bags are recommended.

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

B. PREPARATION FOR USE

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

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

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

4. To prevent the possibility of volatile I-131 escaping from the therapy solution, and as a precaution to prevent contamination, release the partial pressure over the liquid I-131 by venting it

through a 10 cc or larger charcoal filled syringe barrel. To prepare this syringe, add a cotton pledget to the syringe, fill with charcoal, and add a cotton pledget to the top of the charcoal.

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

C. CONTAMINATION CONTROL

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

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

3. Open containers of liquid I-131 must be handled in the double charcoal filtered glove box. The effluent from this glove box is piped to the laboratory fume hood, thereby, ensuring that DAC levels are not exceeded and contamination is isolated to the glove box area. This prevents cross contamination between the volatile materials handling and storage areas.

D. RSO PROCEDURES FOR CONTAMINATED SOURCES

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

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

E. Use and Maintenance of the Radioiodine Fume Hood

NOTE: At installation and prior to use, the linear flow across the arm ports of the hood will be determined with an anemometer under conditions of normal operation, i.e., with the negative air flow speed adjusted to maximum with both charcoal filters in place, and the laboratory fume hood on. Quarterly measurements will be obtained and documented to ensure that the unit continues to operate at this base line level determination, with respect to negative linear flow.

1. <u>Procedures for Use</u>

   a. Put on disposable gloves.

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

c. Set up the apparatus, vials, shields, etc., in the hood behind the L-block shield prior to the I-131 transfer to ensure that the transfer time is minimal.

d. Placed the sealed stock solution of iodine-131 in the hood behind the L-block shield on the absorbent pad.

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

f. Transfer the iodine-131 from the stock solution to the prescribed unit dose form. Make sure to recap or seal the vials immediately after transfer.

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

h. Prepare for shipping.

i. Replace the stock I-131 in storage.

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

k. Clean up and change the absorbent pad, if necessary (survey meter readings will indicate if the pad is contaminated).

l. After the radioiodine fume hood is cleaned up, survey again, and record the results on the form provided.

NOTE: If the initial survey, with a pancake probe, indicated radiation levels no greater than background or no contamination, it is unnecessary to survey after clean up. If contamination was present on the initial survey and on the after clean up survey, perform wipe tests and decontaminate the hood until removable contamination is less than 2200 dpm/100 cm^2.

NOTE: Liquid I-131 used by Diagnostic Photon Corporation is obtained from a sealed system (similar to a multidose vial for parenteral use).

2. Maintenance Procedures

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

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

b. To ensure that the system is operating properly, a determination of linear flow at the arm ports will be taken quarterly using an anemometer. If the flow decreases below 50 lfm, the filter(s) will be changed to ensure proper operation.

3. Procedure for Surveying and Changing Filters

a. Put on disposable gloves.

b. Lift the filter housing lid.

c. Disconnect (if necessary) the exhaust pipe connector to the fume hood.

d. Remove the top filter and survey with low level survey meter and pancake probe. Record mR/hr or CPM on the form provided.

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

f. Remove the bottom filter and survey with a low level survey meter. Record mR/hr or CPM on the form provided.

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

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

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

i. Insert a new (unused) filter into the unit as the top filter. Close the baffle housing lid and reconnect the unit to the fume hood.

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

APPENDIX D

NEW UNIT DOSE CONTAINER

We request authorization to use a new unit dose container in addition to the containers we are currently using. Please see the below description.

NEW UNIT DOSE CONTAINER DESCRIPTION

This new unit dose container is a variation on the design of previous containers that we have used. The variation is that the new unit dose container has inside of it a plastic sharps container for use in the transportation of medical waste. When shipping the dose to the customer, the lower sleeve of the sharps container is inserted into the lower half of the leaded shield, and then the top half of the leaded shield is screwed on. The top of the sharps container is transported separately from the unit dose shield. After injection of the dose, the customer returns the used syringe to the unit dose shield, and locks down the top half of the sharps container onto the bottom half of the sharps container. The top piece of the unit dose shield is then screwed on, and the entire unit is returned to the pharmacy.

At the pharmacy, the unit dose shield is identified (by label/prescription), opened, and the sharps container is dumped into the appropriate bin *in its entirety* without opening the sharps container. Please see the attached procedures for handling waste at the nuclear pharmacy using this new system.

PRODUCT SHIELDING

Product shielding will be in accordance with 10 CFR 32.72(a)(3) and 10 CFR 20.1101(b).

The following information regards the radionuclide, chemical and physical form, packaging (including maximum activity per package) and shielding provided by the packaging of the byproduct material that is appropriate for safe handling and storage of radiopharmaceuticals of group licensees:

Isotope	Chemical/Physical Form	Maximum Activity per Syringe	Maximum Exposure Rate at 1 cm From the Surface of the Shield (mR/hr)	Maximum Exposure Rate at 1 m From the Surface of the Shield (mR/hr)
Tc-99m	sodium pertechnetate, tagged drug solution	100 mCi	0.10	0.0
Cr-51	sodium chromate solution	50 uCi	0.0	0.0

The shielding characteristics of Syncor International Corporation's new unit dose container were tested with the following results:

Isotope	Chemical/Physical Form	Maximum Activity per Syringe	Maximum Exposure Rate at 1 cm From the Surface of the Shield (mR/hr)	Maximum Exposure Rate at 1 m From the Surface of the Shield (mR/hr)
Tc-99m	sodium pertechnetate, tagged drug solution	634 mCi	0.67	0.0
Cr-51	sodium chromate solution	203 uCi	0.33	0.0
I-123	sodium iodide capsule	3.48 mCi	8.70	0.01
I-131	sodium iodide capsule, solution	1.33 mCi	66.9	0.1
Ga-67	gallium citrate solution	12.17 mCi	65.6	0.09
Tl-201	thallous chloride solution	10.5 mCi	4.01	0.05
In-111	indium chloride, DTPA, or oxine solution	12.05 mCi	37.5	0.05

NOTE: The above values were taken with a Victoreen Model 470-A Ion Chamber. Values reflect correcting for distance using the inverse square law from 8.15 cm (distance from the virtual center of the ion chamber to the center of the container), to 3.15 cm (distance from 1 cm from the surface of the container to the center of the container).

Isotope	Chemical/Physical Form	Maximum Activity per Syringe	Maximum Exposure Rate at 1 cm From the Surface of the Shield (mR/hr)	Maximum Exposure Rate at 1 m From the Surface of the Shield (mR/hr)
I-123	sodium iodide capsule	200 uCi	0.7	0.0
I-131	sodium iodide capsule, solution,	1 mCi	33.5	0.05
Ga-67	gallium citrate solution	10 mCi	50.3	0.05
Tl-201	thallous chloride solution	4 mCi	0.7	0.02
In-111	indium chloride, DTPA, or oxine solution	1 mCi	1.0	0.01

NOTE: The above values were taken with a Victoreen Model 470-A Ion Chamber. Values reflect correcting for distance using the inverse square law from 8.15 cm (distance from the virtual center of the ion chamber to the center of the container), to 3.15 cm (distance from 1 cm from the surface of the container to the center of the container).

	TOP PIECE	BOTTOM PIECE	TOTAL
Thickness of Lead	sides: 3.9 mm top: 3.6 mm	6.4 mm	---
Length	16.3 cm	8.4 cm	22.2 cm (some overlap)

Additional Ga-67 testing was performed:

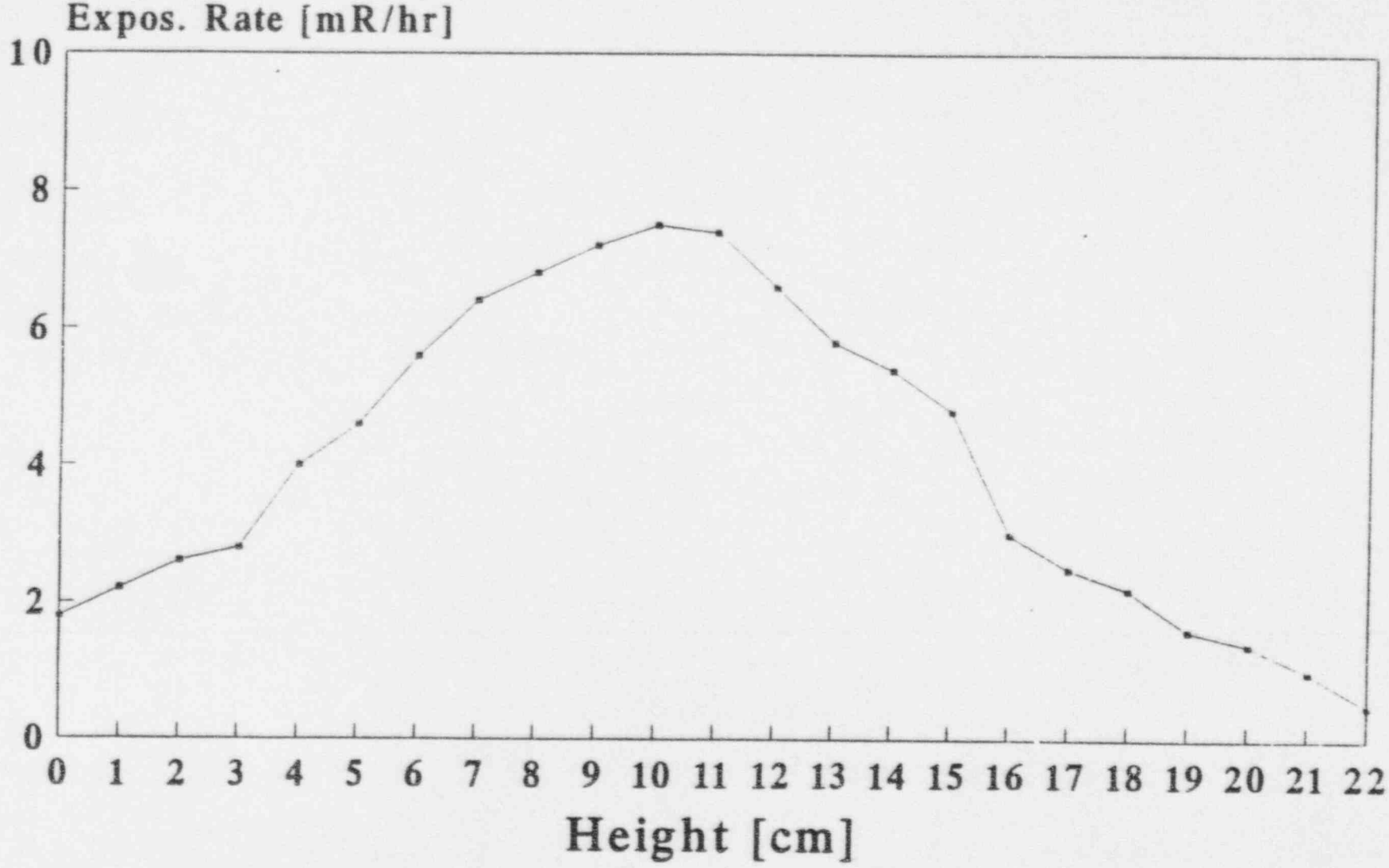
Configuration	Surface Exposure Rate (mR/hr)	Exposure Rate at 1 meter (mR/hr)
NEW Pig in ammo can	42.8	0.07
NEW Pig-I-131 Light Ring	11.7	0.0
NEW Pig-I-131 Hvy Ring	2.67	0.0
OLD Pig-Big	36.1	---
OLD Pig-Big in ammo can	25.4	0.01
OLD Pig-Small	56.2	---
OLD Pig-Small in ammo can	38.8	0.01

Additional I-131 testing was performed:

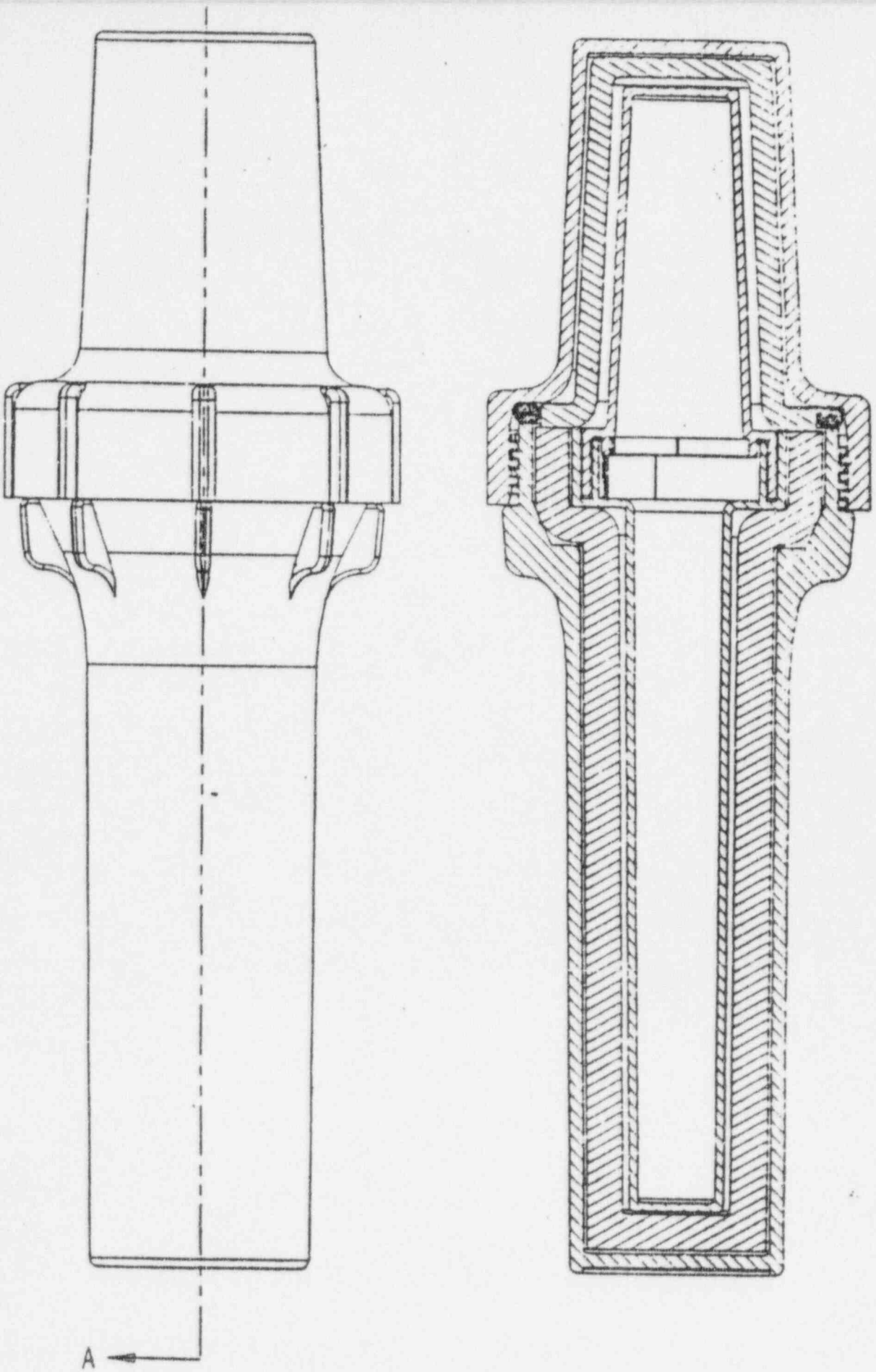
Configuration	Surface Exposure Rate (mR/hr)	Exposure Rate at 1 meter (mR/hr)
NEW Pig in ammo can	40.8	0.09

Isoresponse Curve

At 6 cm using 9.6 mCi of Ga-67

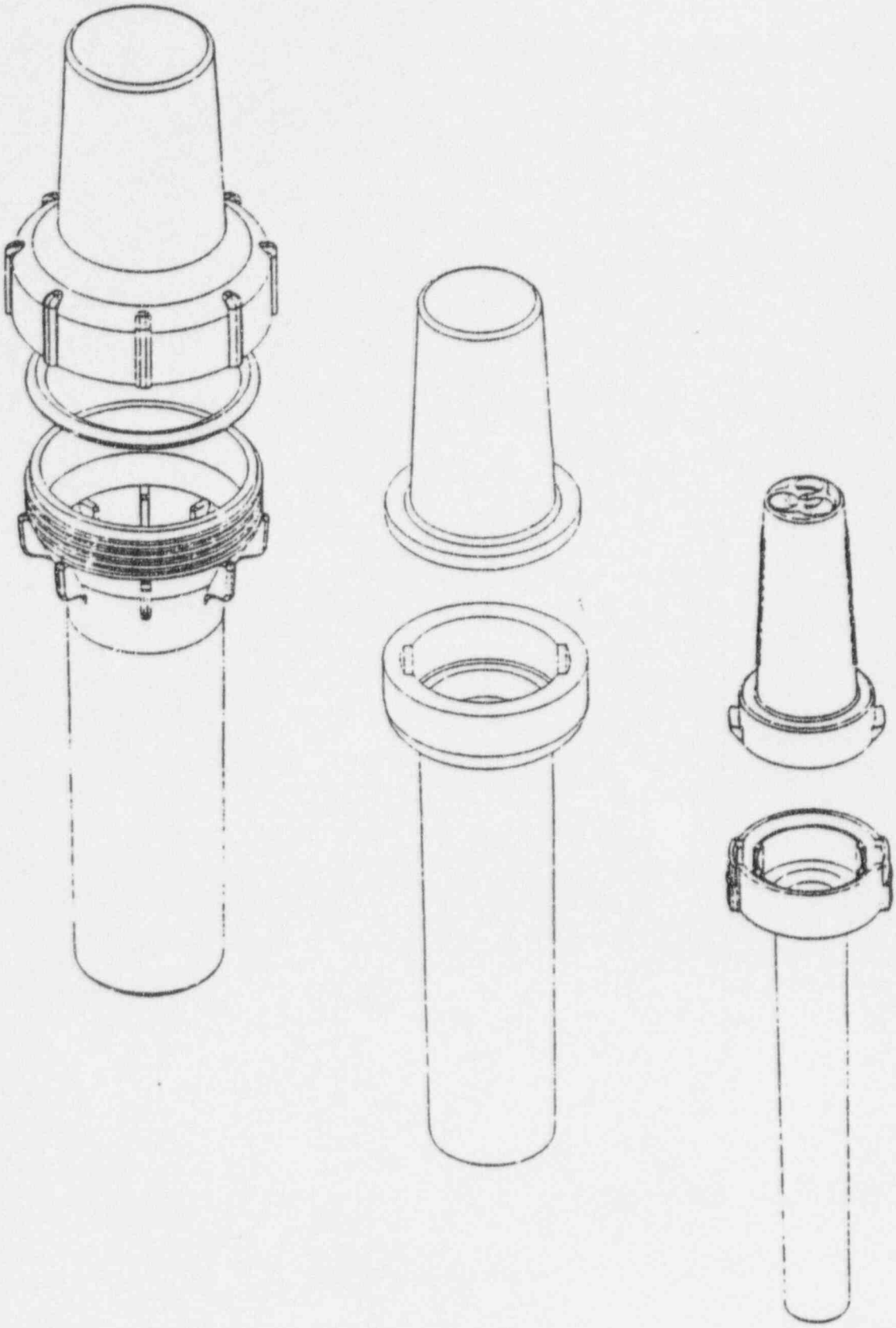


0 cm = bottom; 22 cm = top



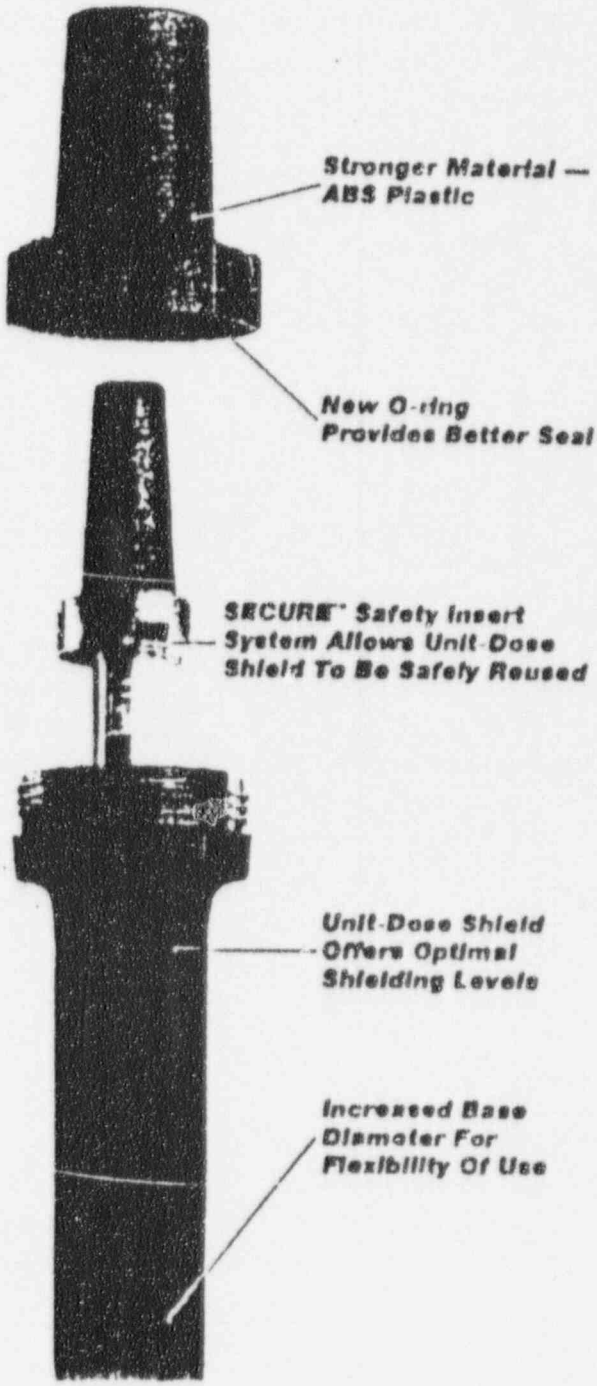
SCALE 1.000

SECTION A-A
SCALE 1.000



New, Improved Unit-Dose Shield (Lead Pig)... Designed For Greater Protection And Ease Of Use

Used with the SECURE™ Safety Insert System to comply with OSHA regulations regarding unit-dose sharps containment



Constructed for optimal lead shielding

- Provides optimal shield levels to reduce exposure to as low as reasonably achievable (ALARA)
- New shielding distribution contributes to increased unit stability when standing upright

Redesigned for greater flexibility of use

- Stabilizing ridges prevent the unit dose shield (lead pig) from rolling off of flat surfaces when laid on its side
- Larger base diameter allows unit to stand safely upright to reinsert used syringe into SECURE™ Safety insert
- Increased unit stability reduces the need for a separate base to hold shield upright in the hot lab or at the patient injection site

New O-ring design

- Provides an improved seal on the unit-dose shield (lead pig)

Designed with stronger ABS plastic

- Resists chipping and splintering along edges