OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee			
1.	PharmaLogic W.V., Ltd.	3. License Number	47-25375-01
2.	200 Platinum Drive Suite 200 Bridgeport, West Virginia 26330	4. Expiration Date	January 31, 2002
		5. Docket or Reference No.	030-34289

6. Byproduct, Source, and/or Special Nuclear Material		7. Chemical and/or Physical Form		8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A.	Any byproduct material with atomic numbers 3 through 83, except molybdenum 99, technetium 99m, iodine 131 and xenon 133, listed in Sections 35.100, 35.200, and 35.300 of 10 CFR Part 35	A.	Any, except sealed sources	A.	Not to exceed 300 millicuries per radionuclide and 1 curie total
B.	Molybdenum 99	B.	Any, except sealed sources	B.	100 curies
C.	Technetium 99m	C.	Any, except sealed sources	C.	100 curies
D.	Iodine 131	D.	Any, except sealed sources	D.	900 millicuries
E.	Xenon 133	E.	Any, except sealed sources	E.	1.0 curie
F.	Any byproduct material in a brachytherapy source as listed in 10 CFR 35.400	F.	Sealed sources	F.	500 millicuries
G.	Any byproduct material in a sealed source for diagnosis listed in 10 CFR 35.500	G.	Sealed sources	G.	Not to exceed 1.5 curies per source and 5.5 curies total
H.	Any byproduct material listed in 10 CFR 31.11(a)	H.	Prepackaged units for *in vitro* diagnostic tests	H.	50 millicuries
I.	Any byproduct material authorized under 10 CFR 35.57(a)	I.	Sealed sources	I.	50 millicuries

200119

ML20

9. Authorized use

A. through E. Preparation and distribution of radioactive drugs, production of technetium 99m pertechnetate, compounding of iodine 131 and distribution of unused and used molybdenum 99/technetium 99m generators to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use.

F. and G. Distribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.

H. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labelling remain unchanged.

I. Calibration and checking of the licensee's instruments. Distribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 200 Platinum Drive, Suite 200, Bridgeport, West Virginia.

11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

A. In accordance with 10 CFR 32.72(b)(2)(i) or (4), pharmacists working as authorized nuclear pharmacists.

B. Authorized Nuclear Pharmacists: Glen Palmer, R.Ph.; William M. Chatoff, R.Ph., BCNP; Thomas Defranco, R.Ph.; Jeffrey Letendre, R.Ph., BCNP; Christopher Leon, R.Ph., Dave Lamont R.Ph., BCNP; or Todd Landry, R.Ph., BCNP.

C. At least one individual authorized by Paragraph A or B of this Condition shall be physically present at the authorized place of use whenever licensed material is being used.

12. The Radiation Safety Officer for this license is Glen Palmer, R.Ph.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing financial assurance for decommissioning.

14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three 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 three months.

(continued) CONDITIONS

14. 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.

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

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

(i) they contain only hydrogen-3; or

(ii) they contain only a 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 transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. 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 or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, Materials Licensing and Inspection Branch 2, 101 Marietta Street, S.W., Suite 2900, Atlanta, Georgia 30323. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

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

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

16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

17. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

(continued) CONDITIONS

18. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.

19. 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. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument 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. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

20. Notwithstanding the requirements of 10 CFR 20.1904(b), the licensee is authorized to remove or dispose of empty uncontaminated containers (syringes and vials) to unrestricted areas without removing or defacing the radioactive material labels or otherwise indicating that the container no longer contains radioactive materials provided the waste containers are deposited in waste barrels that will be incinerated and are delivered directly from the licensee's facility to the incinerator without being opened at any point, and for any reason, prior to incineration.

21. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the statements, representations and procedures in the letter dated November 14, 1996.

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

23. A. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: 1) the licensee has constructed facilities and obtained the equipment described in the application and supporting documentation; and 2) the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, Materials Licensing and Inspection Branch 2, 101 Marietta Street, S.W., Suite 2900, Atlanta, Georgia 30323, has been notified in writing that activities authorized by the license will be initiated.

B. In accordance with the requirements set forth in 10 CFR 30.36(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing of a decision not to complete the facility, acquire equipment, or possess and use authorized material.

License Number 47-25375-01

Docket or Reference Number 030-34289

MATERIALS LICENSE
SUPPLEMENTARY SHEET

(continued) CONDITIONS

24. The licensee shall maintain records of information related to decommissioning at the licensee's facilities located at 200 Flatinum Drive, Suite 200, Bridgeport, West Virginia as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

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

A. Application dated November 14, 1996
B. Letter dated January 24 1997 [Fax recieved January 23, 1997] (supplemental information)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

JOHN M. PELCHAT

Date JAN 24 1997

1/24/97

By _____

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

N:\MLICENSE\47-25375.N01

January 27, 1997

PharmaLogic, Ltd.
ATTN: William Chatoff, R.Ph., BCNP
President
200 Platinum Drive
Bridgeport, West Virginia 26330

Dear Mr. Chatoff:

SUBJECT: TRANSMITTAL AND EXPLANATION OF NEW BYPRODUCT MATERIALS LICENSE NO. 47-25375-01 (DOCKET NO. 030-34289, CONTROL NO. 257285)

Enclosed is your new byproduct materials license. Please review the license carefully and be sure that you understand all of the license conditions. If you have any questions or find any errors please notify me or
Mrs. Diane Heim at (404) 331-4673 so that we may answer any questions or issue a corrected copy as necessary.

The NRC has recently revised 10 CFR 20, "Standards for Protection Against Radiation. Your attention is specifically called to the newly amended regulatory requirements in 10 CFR 20.1101 (program audits) and 20.2102 (record keeping requirements). These sections deal with how you are to manage your radiation safety program to maintain exposures as low as reasonably achievable (ALARA) and require that you:

A. Implement a radiation protection program commensurate with your licensed activities.

B. Use to the extent practicable, procedures and engineering controls based on sound radiation protection principles to maintain occupational doses and doses to members of the public as low as reasonably achievable (ALARA).

C. Conduct a review of your radiation safety program's content and implementation at least annually.

Enclosure 3, "Annual Audits of Radiation Safety Programs" is provided for your use in developing and implementing your radiation safety program audit procedures.

Best wishes for a safe and successful licensed program. If you have any questions, please call me at (404) 331-7438.

Sincerely,

José M. Díaz Vélez
License Reviewer
Material Licensing/Inspection Branch 2
Division of Radiation Safety
and Safeguards

Enclosures:

1. NRC License No. 4725375-01
2. Information For New NRC Material Licensees
3. Annual Audits of Radiation Safety Programs

OFC	RII:DNMS	RII:DNMS	RII:DNMS
NAME	J. Díaz Vélez	J. Pelchat	
DATE	01/27/97	01/27/97	01/ /97
COPY?	Yes No	Yes No	Yes No

OFFICIAL RECORD COPY DOCUMENT NAME: G:\DNMS\MLIB2\LICLTR\257285.JMD

From : Glen Palmer RPh.
Pharmalogic WV
109 Platinum Dr. Suite A
Bridgeport, WV 26330

To : Jose M. Diaz Velez
U.S. NRC Region II
101 Marietta St. N.W. Suite 2900
Atlanta, GA 30323-0199

Dear Mr. Diaz,

This letter is in reference to the results of your licensing visit on January 16, 1997 and your request for clarification on the following points.

1. An updated floor diagram has been included.
2. Arrangements have been made with the landlord so that in the event that the suite next door becomes occupied we will have access to this area to ensure compliance with the provisions of 10 CFR 20.1301.
3. An updated facility floorplan has been included and shows intakes and exhausts for airflow.
4. In the application Chris Leon and Tom DeFranco are Christopher Leon and Thomas DeFranco respectively.
5. A copy of the corrected first page of the application is included.
6. No distribution of radiopharmaceuticals will be performed until our facility has been properly licensed by the State of West Virginia Board of Pharmacy.
7. In the event that the exhaust fan on the roof should fail, causing the negative pressure to be lost in the Iodine room, policy will be to turn all hoods in the facility off and not use the Iodine room for compounding until the hood is fixed.
8. The Security company, ADT, has been contacted and has installed a motion detector in the waste room this has been shown on the diagram this will ensure security in the back of the lab.

PHARMALOGIC LTD.

Bridgeport, West Virginia

Fume Hood and Restricted Area Ventilation Check Record

Quarter: 1 st
Date: 1/23/97

Person: G.Palmer

Instrument Used: Make-Alnor Model:8100

Glovebox ID 1	Linear Flow Avg (ft/min) (a)	Dimensions of Opening(in.) ht*wd (b)	Area of Opening (sq.feet) (c)	Exhaust ** (a*c)
	370	114	0.791667	292.9167

Fume Hood and Restricted Area Ventilation Check Record

Quarter: 1 st
Date: 1/23/97

Person: G.Palmer RPh.

Instrument Used: Make-Alnor Model:8100

FumeHood Fume #1	Linear Flow Avg (ft/min) (a)	Dimensions of Opening(in.) ht*wd (b)	Area of Opening (sq.feet) (c)	Exhaust ** (a*c)
	410	609	4.229167	1733.958

Figures are based on the equation (Q=AV), where

Q=quantity of air in standard cubic feet perminute (SCFM);
A=area of the opening in square feet; and,
V=the area-weighted average air velocity in standard feet per minute

PHARMALOGIC LTD.

Bridgeport, West Virginia

Iodine Room Doorway Airflow

Quarter: 1 st
Date: 1/23/97

Person: G.Palmer

Instrument Used: Make-Alnor Model:8100

Doorway 1	Linear Flow Avg (ft/min) (a)	Dimensions of Opening(in.) ht*wd (b)	Area of Opening (sq.feet) (c)	Exhaust ** (a*c)
	65	2680	20	1300

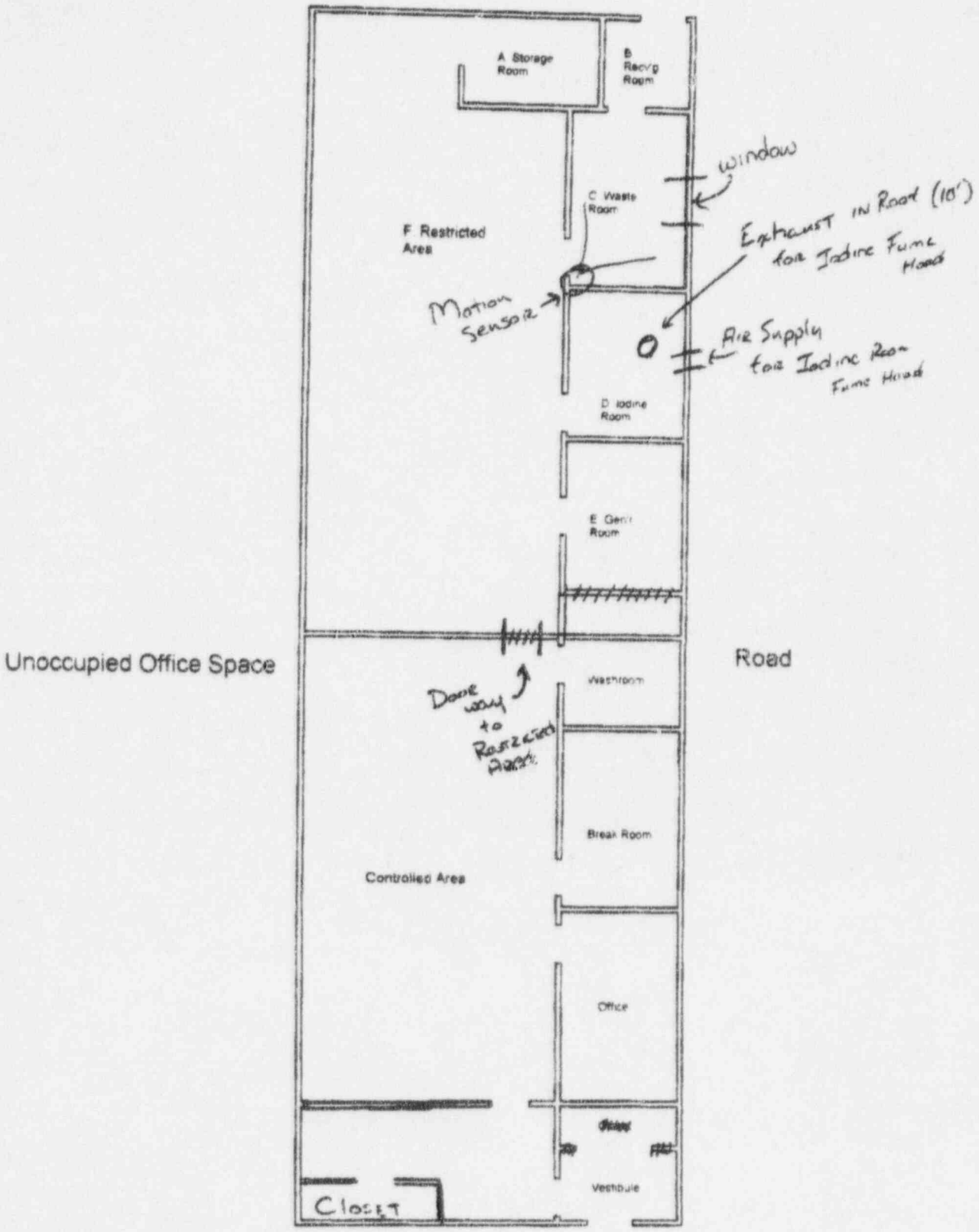
Figures are based on the equation (Q=AV), where

Q=quantity of air in standard cubic feet perminute (SCFM);
A=area of the opening in square feet; and,
V=the area-weighted average air velocity in standard feet per minute

Attachment 9.3

Mountain

Parking



PARKING

17

EXHIBIT A

NRC FORM 313 [illegible]

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION [illegible]

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

[illegible]

U.S. NUCLEAR REGULATORY COMMISSION, REGION I [illegible]

U.S. NUCLEAR REGULATORY COMMISSION, REGION II [illegible] ATLANTA, GA [illegible]

U.S. NUCLEAR REGULATORY COMMISSION, REGION III [illegible]

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV [illegible] ARLINGTON, TX [illegible]

U.S. NUCLEAR REGULATORY COMMISSION, REGION V [illegible] WALNUT CREEK, CA [illegible]

[illegible]

1. THIS IS AN APPLICATION FOR (Check appropriate item)
   - [x] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER ________
   - [ ] C. RENEWAL OF LICENSE NUMBER ________

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

Pharmalogic WV Ltd.
109 Platinum Drive Suite A
Bridgeport, WV 26330 Attn. Glen Palmer

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

Pharmalogic WV Ltd.
109 Platinum Drive Suite A
Bridgeport, WV 26330 Attn. Glen Palmer

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: William Chatoff RPh, BCNP — TELEPHONE NUMBER: 802 862 9944

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

5. RADIOACTIVE MATERIAL [illegible]
6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.
10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.
12. LICENSE FEES [illegible] FEE CATEGORY — AMOUNT ENCLOSED $ 4650.00

13. CERTIFICATION [illegible] THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. [illegible]

WARNING: 18 U.S.C. SECTION 1001 [illegible] MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
[signature]	William Chatoff	President	11/14/96

[illegible]

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE

PRIVACY ACT STATEMENT ON THE REVERSE

JDV

January 22, 1997

Pharmalogic W.V, Ltd.
ATTN: William M. Chatoff R.Ph., BCNP
President
P.O. Box 786
Williston, Vermont 05495

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING LICENSE APPLICATION DATED NOVEMBER 14, 1996 (MAIL CONTROL NO. 257285, DOCKET NO. 030-34289)

Dear Mr. Chatoff:

This letter is in reference to the radioactive materials license application dated November 14, 1996, and the results of our licensing visit conducted on January 16, 1996. The following information and/or clarification is needed to continue our review of your application:

1. Please submit an updated floor diagram of the facility (as built).

2. Indicate the arrangements made to conduct area surveys in adjacent areas, if needed or alternatively, describe how area surveys will be conducted to ensure compliance with the provisions of 10 CFR 20.1301.

3. Submit facility diagrams showing air supply and exhaust vents, including measured airflow.

4. Please clarify the name of the authorized users referenced in item 7 of your application and confirm that those individuals are the same individuals as listed in NRC Licenses 34-16654-01MD, 44-30124-01MD and 04-26507-01MD.

5. Please confirm that your mailing address is: Pharmalogic W.V., Ltd., 200 Platinum Drive, Suite 200, Bridgeport, West Virginia 26330, and not the address listed under item 2 of the application. Please provide the telephone number for the facility.

6. Submit a copy of your State of West Virginia Board of Pharmacy license or a certification indicating that no distribution of radiopharmaceuticals will be performed until your facility has been properly licensed by the State of West Virginia Board of Pharmacy.

7. Please confirm that the glove box ventilation system (in room D where iodine is used) will be shut down if the main exhaust ventilation system (xenon fume hood and roof ventilation system) fails.

8. Describe how your security system provides protection for the window located in your waste storage area. If a motion detector is used, please indicate its position in a floor diagram, and specify the area covered by the detector.

If you wish to pursue your application, please either contact me by phone or provide your reply within 30 days of receipt of this letter. If you require additional time to respond to this letter, please request an extension in writing, stating the reason for the requested extension. When responding, please refer to Mail Control No. 257285 and provide two copies of your reply.

If you have questions about this letter, please call me at 404/331-7438 (FAX: 404-331-7437).

Sincerely,

/S/

José M. Díaz Vélez
Materials License Reviewer
Division of Nuclear Materials Safety

SEND TO PUBLIC DOCUMENT ROOM?	YES	NO		
OFFICE	RII:DNMS	RII:DNMS	RII:DNMS	RII:DNMS
SIGNATURE				
NAME	J. Díaz Vélez	J. Pelchat	E. Potter	
DATE	01 / 21 / 97	01 / 22 / 97	01 / 22 / 97	01 / / 97
COPY?	YES NO	YES NO	YES NO	YES NO

OFFICIAL RECORDS COPY G:\DNMS\MLIB2\DEFLTR\257285.JMD Last saved: January 22, 1997

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

DEC 12 1996

Pharmacologic W.V., Ltd.
9 Krupp Drive, P.O. Box 786
Williston, VT 05495

Mail Control No. 257285
Docket No. 030-34289
License No. new

SUBJECT: ACKNOWLEDGEMENT OF REQUEST FOR A LICENSING ACTION
(Your: ☐ Letter ✓ Application ✓ Dated ☐ Received **November 14, 1996**)

Dear Sir or Madam:

1. In response to your request, we have performed an administrative review of your application for a:
☑ new ☐ amendment ☐ renewal ☐ termination licensing action.

It should be noted that a technical review may identify additional omissions in the submitted information, technical issues that require additional information, or policy/technical issues that require coordination with headquarters or other NRC regional offices.

2. It appears that your request is ☐ incomplete ☑ complete and: ☑ routine (see 3-5 below);
☐ non-routine, and if necessary, can be completed within ___-___ days, following fee approval and response to any telephone or telefax deficiency requests from our license reviewer.

3. New and amendment actions are normally processed in 20 - 30 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

4. Renewal actions are normally processed in 60 - 90 days, however under timely filing (before expiration) you may continue to operate under your existing license.

5. Termination actions are normally processed in 20 - 30 days, unless confirmatory surveys following decontamination are involved.

6. A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6067) for approval of the fee category and amount.

7. If you have a compelling safety or business-related reason for requesting expedited review, please contact me or our Licensing Assistant, Diane Heim, at 404/331-4673 [voice/ans] or 404/331-7437 [fax] or Internet: ddh@nrc.gov. We will try to complete your request, as stated in 2. above.

8. Please call or write with any questions. I can be reached directly at 404/331-7438 [voice/ans] or via Internet: jxd2@nrc.gov.

Sincerely,

Jose M. Diaz-Velez, License Reviewer
Materials Licensing/Inspection Branch 2

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: ____
Status Code: 3
Fee Category: _____
Exp. Date: 0
Fee Comments: _____
Decom Fin Assur Reqd: _

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED
   Applicant/Licensee: PHARMACOLOGIC W.V.
   Received Date: 961119
   Docket No: 3034289
   Control No.: 257285
   License No.:
   Action Type: New Licensee

2. FEE ATTACHED
   Amount: 4650.00
   Check No.: 257285

3. COMMENTS

Signed DIANE HEIM
Date 11/26/96

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

1. Fee Category and Amount: 3C 3P $4560

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

3. OTHER _____

Signed Rita Meglio
Date 12/2/96

Log DEC 1 II
Remitter
Check No. 6140 $4650
Amount
Fee Category 3C 3P
Type of Fee Appl
Date Check Rec'd.
Date Completed 12/2/96
By: Kem

TO: JOHN PELCHAT

EXHIBIT A

NRC FORM 213
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

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

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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

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

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

PHARMALOGIC W.V., LTD. ATT: William Chatoff
9 Kopp Drive P.O. 766
Williston, Vt 05495

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

Pharmalogic W.V. Ltd.
200 Platinum Drive, Suite 200
Bridgeport, West Virginia 26330

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

William Chatoff RPh, BCNP

TELEPHONE NUMBER: 802 862 9944

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

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 11.D.31)*

FEE CATEGORY

AMOUNT ENCLOSED $ 4650.00

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

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

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

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
William Chatoff	William Chatoff	President	11/14/96

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] <$250K
- [ ] $250K–$500K
- [ ] $500K–$750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER		20725	DATE

PRIVACY ACT STATEMENT ON THE REVERSE

Item 5 NRC - 313

Item 5 RADIOACTIVE MATERIAL

Byproduct , source and/or special nuclear material	Chemical and/or physical form	Maximum amount at any one time.
A. Molybdenum 99	A. Any Molybdenum 99/ Technetium 99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to **Section 32.73 of 10 CFR Part 32** or a special license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations.	A. 100 curies
B. Any byproduct material listed in **Section 31.11(a) of 10 CFR 31.**	B. Prepackaged in vitro diagnostic tests kits.	B. 50 millicuries
C. Any byproduct material authorized under **Section 35.57(a) of 10 CFR Part 35**	C. Any sealed source listed in **Paragraph 35.57(a)** of **10 CFR Part 35** that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued to **Section 32.74 of 10 CFR Part 32** or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations.	C. 50 millicuries

Item 5
Date: 11/14/96

Byproduct , source and/or special nuclear material	Chemical and/or physical form	Maximum amount at any one time
D. Xenon 133	D. Unit dose containers of Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA.	D. 1.0 curie
E. Iodine 131	E. Any form listed in **Sections 35.100, 35.200, 35.300 of 10 CFR Part 35.**	E. 900 mCi
F. Technetium 99m	F. Any form listed in **Sections 35.100, 35.200 of 10 CFR Part 35.**	F. 100 curies
G. Any byproduct material, except Iodine 131 and Tc-99m in **Section 35.100 of 10 CFR Part 35.**	G. Any form in **Section 35.100 of 10 CFR Part 35.**	G. 50 mCi

Item 5
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Byproduct , source and/or special nuclear material	Chemical and/or physical form	Maximum amount at any one time.
H. Any byproduct material, except Iodine 131 and Tc-99m listed in **Section 35.200 of 10 CFR Part 35**	H. Any form listed in **Section 35.200 of 10 CFR Part 35**	H. 300 millicuries total possession limit
I. Any byproduct material except Iodine 131 listed in **Section 35.300 of 10 CFR Part 35**	I. Any form listed in **Section 35.300 of 10 CFR Part 35**	I. 100 millicuries
J. Any byproduct material listed in **Section 35.400 of 10 CFR Part 35**	J. Any sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to **Section 32.74 of 10 CFR Part 35** or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations	J. 500 millicuries
K. Gadolinium-153	K. Sealed source	K. No source to exceed 1.5 Ci with a total 4.5 Ci

Item 5
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Byproduct , source and/or special nuclear material	Chemical and/or physical form	Maximum amount at any one time
L. Iodine-125	L. Sealed source	L. No source to exceed 800 mCi with a total of 1.0 Ci

Item 5
Date: 11/14/96

Item 6 PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

A. Byproduct material under (A) will be used to produce 99m Technetium Pertechnetate. Byproduct material under (A) (99 Molybdenum Generators) unused will be redistributed to our customers from manufacturers licensed or approved to distribute them in accordance with Section 32.73 of 20 CFR, Part 32 or under equivalent regulations of an Agreement State.

1. Redistribution of Reagent Kits

a. Reagent Kits to be redistributed will have been obtained from a manufacturer authorized to distribute reagent kits in accordance with a specific approval issued pursuant to 10 CFR 32.73 or under equivalent regulations of an Agreement State.

b. Reagent Kits will be distributed as received from the manufacturer accompanied by the manufacturer supplied package insert, leaflet, brochure, or other document that describes the procedures to be followed and the equipment and shielding to be used in processing radioactive material with the reagent kit.

2. Redistribution of Generators

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

b. Unused generators will be redistributed without opening the manufacturers packaging

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

1. Redistribution of In-Vitro Kits

a. For redistribution of in vitro kits to GENERAL licensees

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

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

3. Each redistributed in vitro kit is accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provided radiation safety instructions for general licensees.

b. For redistribution of in vitro kits to SPECIFIC licensees

1. PharmaLogic W.V. Ltd. will obtain prepackaged in vitro kits (as described in 10 CFR 31.11(a)) for redistribution to specific licensees.

2. PharmaLogic W.V. Ltd. will ensure that the labels, package insert, leaflets, brochure, or other documents accompanying the redistributed in vitro kits do NOT reference general licensees, exempt quantities or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11)

3. PharmaLogic W.V. Ltd. will ensure that labeling on redistributed in vitro kits conforms to the requirements of 10 CFR 20.1904 and 20.1905

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

1. Redistribution of Sealed Sources - Calibration and Reference Sources

a. These sources will be redistributed to customers licensed under the provisions of 35.57 of 10 CFR, or to customers specifically licensed to receive calibration sources for medical equipment calibration.

b. The calibration or reference sources to be redistributed will have been obtained from a manufacturer authorized to distribute the sources in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent regulations of an Agreement State.

c. The manufacturer's labeling and packaging will not be altered and redistributed sources will be accompanied by the manufacturer supplied calibration certificate and the leaflet, brochure, or handling and storing the sources.

D. Byproduct material listed under (D) will be dispensed in their original containers to the physicians. No patient procedures will be performed in the nuclear pharmacy.
The Xe-133 gas being ordered will be sealed in glass vials with rubber septum's by the manufacturer. The septum will not be punctured nor the sealed vials opened in any way.

Item 6
Date: 11/14/96

E. Byproduct material under (E) will be used for distribution of prepared radiopharmaceuticals to authorized recipients.

F-I. Byproduct material under (F), (G), (H), and (I) will be used for processing, mixing or compounding, and distribution of prepared radiopharmaceuticals to authorized recipients.

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

1. Redistribution of Sealed Sources - Section 35.400 Sources, Gadolinium-153, and Iodine-125

a. Section 35.400, GD-153, and I-125 sources to be redistributed will have been obtained from a manufacturer authorized to distribute these sources in accordance with a specific license issued pursuant to paragraph 32.74 of 10 CFR Part 32 or under equivalent regulations of an Agreement State.

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

Item 6
Date: 11/14/96

Item 7 ***INDIVIDUAL(S) RESPONSIBLE for RADIATION SAFETY PROGRAM and THEIR TRAINING and EXPERIENCE***

Authorized Users and Applicable Training:

Glen Palmer R.Ph., **RSO**
William Marc Chatoff R.Ph., BCNP
Jeff Letendre R.Ph., BCNP
Tom Defranco R.Ph., BCNP
Chris Leon R.Ph.
Dave Lamont R.Ph., BCNP
Todd Landry R.PH., BCNP

H. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labelling remain unchanged.

I. Calibration and checking of the licensee's instruments. Distribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.

J. For possession incident to the performance of leak testing of customers' sealed sources.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 9 Krupp Drive, Williston, Vermont.

11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

A. In accordance with 10 CFR 32.72(b)(2)(i) or (4), pharmacists working as authorized nuclear pharmacists.

B. Authorized Nuclear Pharmacists: William M. Chatoff, R.Ph., BCNP; Thomas Defranco, R.Ph.; Jeffrey Letendre, R.Ph., BCNP; Howard Stoops R.Ph., BCNP; Sandra Geyser R.Ph., BCNP; Walter Adichie, R.Ph., BCNP; Todd Landry, R.Ph.; or James West, R.Ph.

C. At least one individual authorized by Paragraph A or B of this Condition shall be physically present at the authorized place of use whenever licensed material is being used.

12. The Radiation Safety Officer for this license is Thomas Defranco, R.Ph.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three 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 three 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.

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
04-26507-01MD

Docket or Reference Number
030-33224

CORRECTED COPY

(Continued)

Aziz A. Makhani	Robert Maluso	Ana Manrique
Ernest L. Marks	Lisa Marmon	Jean Marsh
Mary Jane Masters	Mark P. Masterson	Brian Maxey
James McBrayer	Jolie McCaig	Kent McCann
Mike McCarty	Clifford D. McClendon	Dennis P. McClure
John Robert McElfresh	Brigette L. McGhee	Jon L. McReynolds
David M. Meno	Mario J. Menta	Michael Merchant
Elizabeth Wrzosek Messer	Mike Mettetal	John Miano
Gordon Miller	John A. Miller	John S. Miller
Rick Miller	Stanley R. Miller	Walter B. Miller
Theresa Lynn Minas	Robert C. Mitchell	Daniel Monk
Jack A. Moore	Maura Moore	Matthew E. Morgan
Margaret Morgenstern	Richard Morrill	Michael Mosley
Michael Mullin	Giselle Munroe	Daniel F. Murphy
Timothy Muth	Chris Myers	Julie Ann Myers
Joseph Nacchio	Mary Ndumele	Phillip J. Nelson
Susan Nelson	Gregory Newman	Gene G. Nickman
Brenda K. Norkosky	Roy A. Nylund	Steve Nyquist
Thomas Okunewitch	Christopher Scott Olds	Karen L. Olson
Eleanor Ong	Richard Osnard	
Glen Palmer	Joseph Paoline	Pamela E. Pappas
Steve Pate	Chirag Patel	Mark R. Peters
James W. Peghiny	Mark R. Peters	Stacey L. Petot
Andy Phu	Stephanie Pickett	Saundra Pierce
Phillip Porter	Stephen Potter	Wesley Powers
James Presley	Daren L. Pribyl	Rodney Prosser
Leslie Pudlak	Kyle Pulliam	
Stephan Quesada		
Dana Ramion	Timothy J. Rau	Gary R. Redmore
Trenton Rees	Robert Reyes	Ronald Richardson
Thomas Rimar	Janet Robertson	Steven Robertson
Franklyn J. Robinson	Bradley N. Roff	Mark L. Rosenthal
Michael J. Rossi	John M. Roth	Albert Roybal
Frank Ruddy		
Roger S. Saadeh	Norbert Salamonski	Ernesto Samuel
Thomas Sanders	Michael T. Sanfilippo	Harold Sano
Michael Schmidt	Jane E. Schmitz	Jeff Schultz

01 10

1. **William M Chatoff, Jeffrey L. Letendre, Tom Defranco, Chris Leon, and Dave Lamont, Todd Landry** have been previously listed as an authorized user under **NRC License #34-16654-01MD**.

William M Chatoff, Jeffrey L Letendre, and Tom Defranco are also listed as a user under **NRC Liense #44-30124-01MD**

Glen Palmer has been previously listed as an authorized user under **NRC License # 04-26507-01MD**

PharmaLogic W.V. Ltd. confirms that at least one individual named shall be physically present at the authorized place of use whenever licensed material is being used.

2. The designated **RSO** will be **Glen Palmer R.Ph., RSO**

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

PharmaLogic W.V. Ltd. will provide and maintain the staff, ancillary support and oversight necessary to assure that the day to day RSO will have the time available on a continuing basis for radiation safety officer duties.

Item 7
Date: 11/14/96

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

PharmaLogic W.V. Ltd. has adopted the training program described in Appendix C of Draft Regulatory Guide FC 410-4, dated August 1985.

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

Item 9 **FACILITIES AND EQUIPMENT**

Item 9.1 Site Description

1. PharmaLogic W.V. Ltd. has leased space at 200 Platinum Drive, Suite 200, Bridgeport, West Virginia 26330. This pharmacy is housed in a one-story cement and Steel Building.

2. Please see attached sketches ***att.9.1, 9.2, 9.3***

3. During non-business hours, the pharmacy will be secured by means of locked doors. PharmaLogic W.V. Ltd. will use any supplemental security measures to ensure absolute security from intrusion not limited to intrusion alarm systems, window barriers, etc.

4. The fume hood stack extends about 10 feet above the roof line, and is located over 60 feet from any intake vent or open window.

5. PharmaLogic W.V. Ltd. confirms that the operation of this nuclear pharmacy does not conflict with codes or local zoning laws.

6. Please see the attached letter, which is sent to the local police and fire departments annually.

Referring to Att 9.3, an explanation of common walls and bordering walls is as follow:

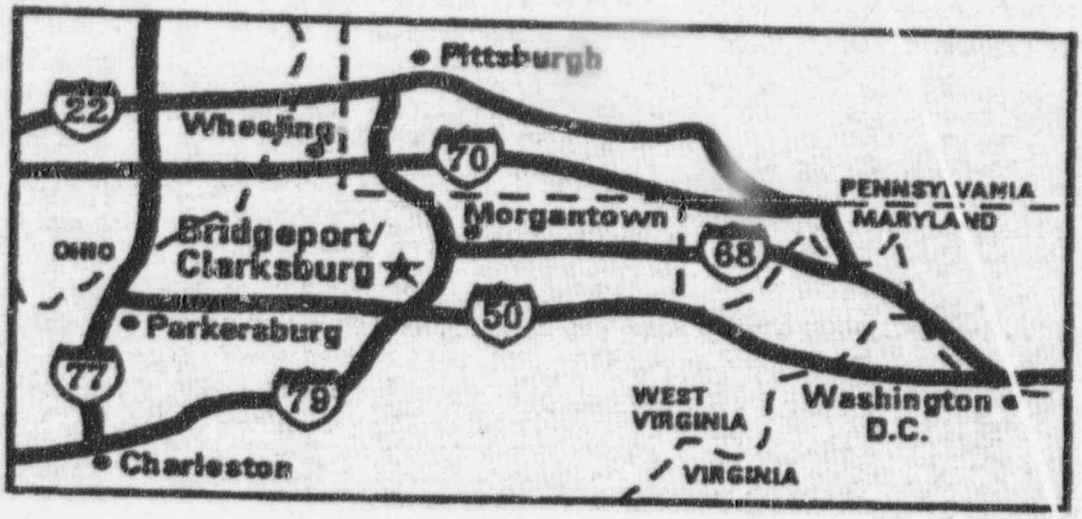
1 The North Wall is common with a parking lot. The front half of the pharmacy will consist of the controlled area and will not have any radioactive materials stored in this area.

2. The South Wall is common with a parking lot. The cars that will be parked outside the pharmacy will be exclusive for PharmaLogic W.V. Ltd. Beyond the parking lot is a mountain with no homes nor businesses.

3. The East wall is common with a vacant space. This wall will not have any stored radioactive material. The nearest radioactive source will be about 20 feet away from this wall.

4. The West Wall is common with a garden. Beyond the garden is an access road. The nearest building is about 100 feet away.

Item 9
Date: 11/14/96



Located ¼ mile off Interstate 79 and 40 minutes from Interstate 68, Eastpointe Business Park is just a five minute drive away from the FBI Research Facility and 15 minutes from the NASA complex. With the convenient interstate system virtually at its front door, Eastpointe Business Park customers are only 1 ½ hours from Pittsburgh, PA, 45 minutes from Morgantown, WV (Home of West Virginia University), 2 hours from Charleston, WV, and 3 hours from Washington, D.C.

TRADE AREA DEMOGRAPHICS

Description	3.0 Mile Radius	5.0 Mile Radius	10.0 Mile Radius
1990 Population	21,282	38,880	64,045
1996 Population	21,348	38,949	65,155
2001 Population	21,468	39,096	66,058
Average HH Income	$39,013	$35,839	$35,893
Median HH Income	$29,421	$27,126	$26,729

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FOR MORE INFORMATION AND MARKETING PACKET
CALL (800) 599-3001 or (304)598-3300

257285

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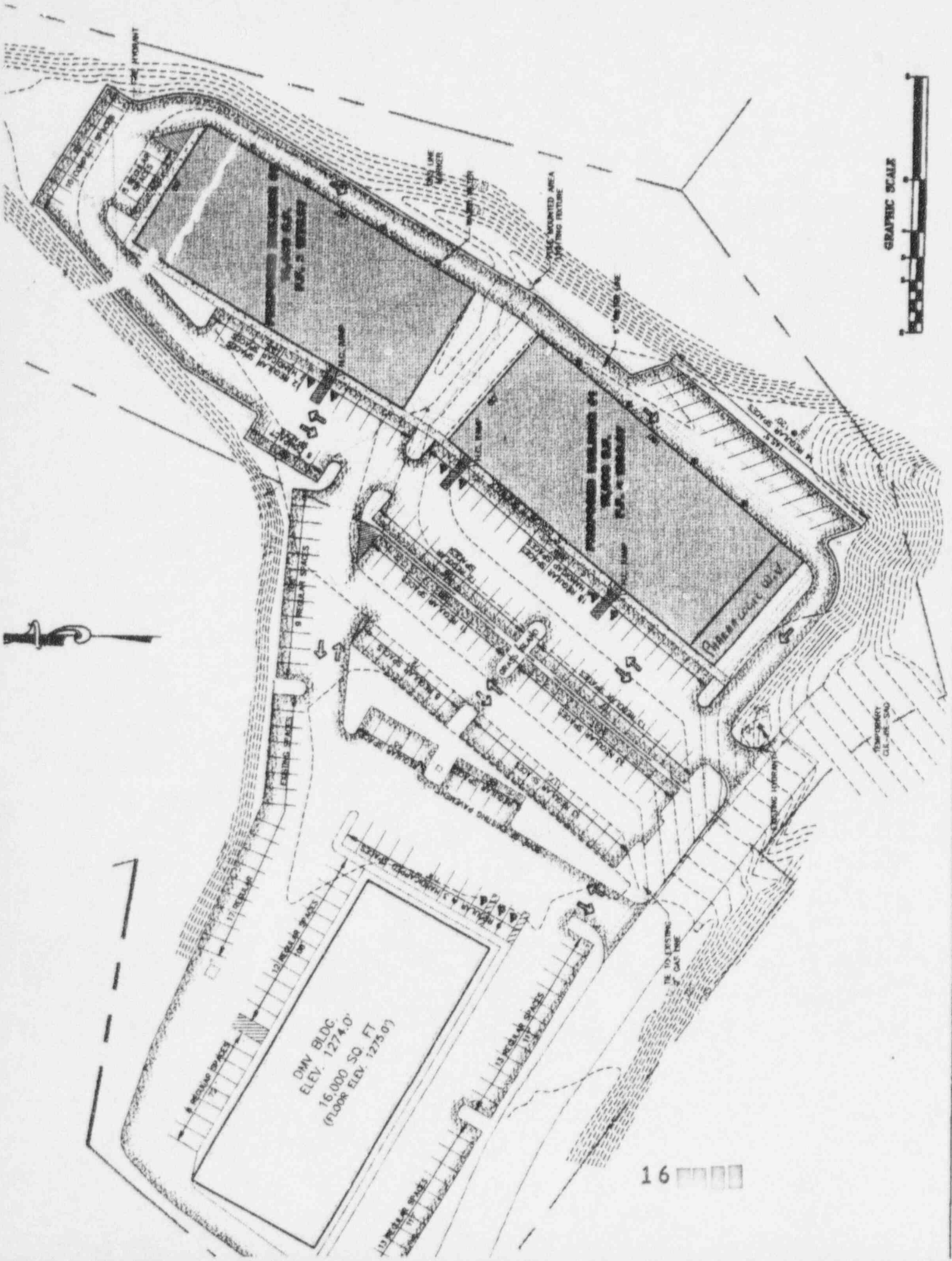
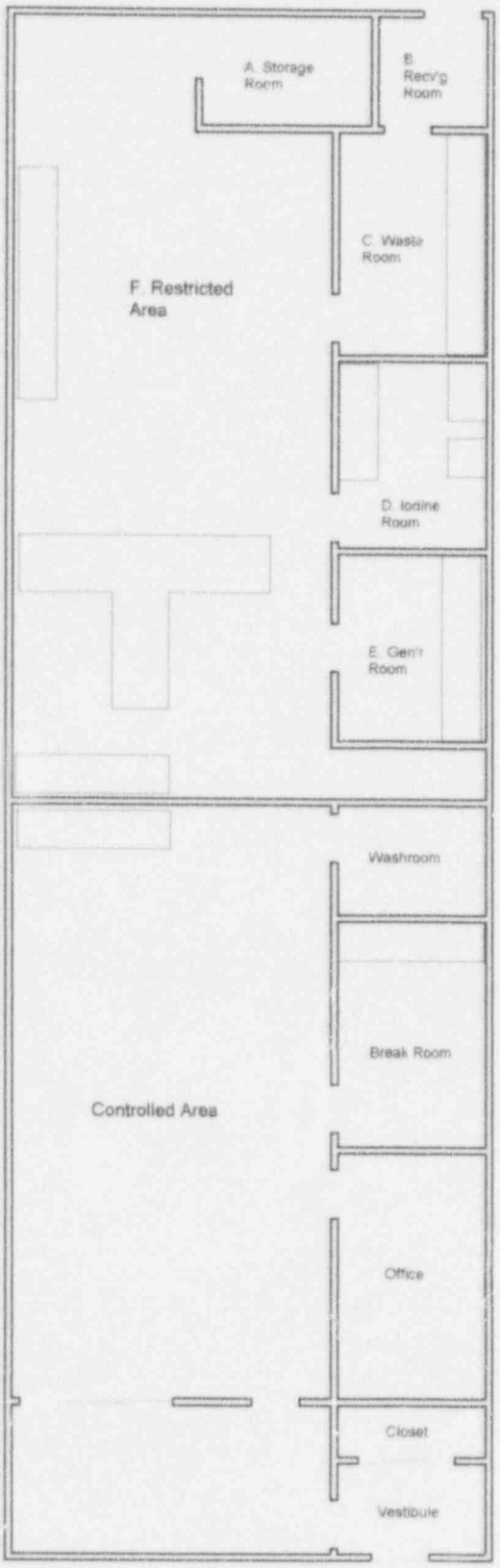

GRAPHIC SCALE
DMV BLDG.
ELEV. 1274.0'
16,000 SQ. FT.
(FLOOR ELEV. 1275.0')

Attachment 9.3

Mountain

Parking



Unoccupied Office Space

Road

PARKING

Date:

Address:

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

Gentlemen:

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

Address: PharmaLogic W.V. Ltd.
200 Platinum Drive Suite 200
Bridgeport, West Virginia 26330

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

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

Very little danger would exist in case of a fire or disaster; however, precaution should be exercised by fire fighting personnel should it be necessary to enter the room in which the radioactive material is stored. In the case of a fire, the non-volatile material would remain confined to this room due to the nature of this building's construction. **Please see attachments 9.1, 9.2, 9.3**

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

Item 9
Date: 11/14/96

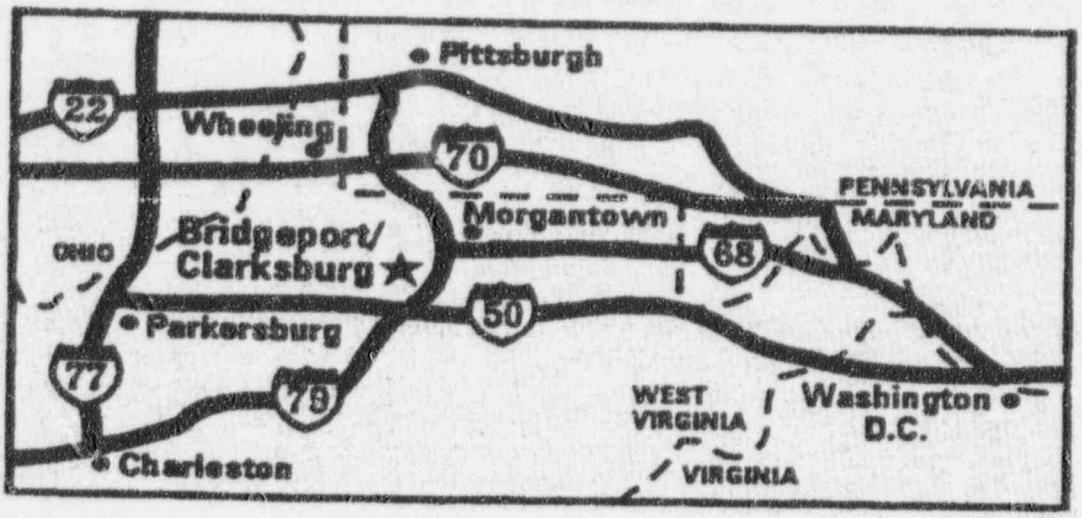
Enclosed also find *Relative Hazards of Common Radionuclides* and telephone numbers of the Radiation Safety Officer(RSO), and NRC's Operations Center telephone number. The radioactive materials being used in this facility is primarily for diagnostic use in nuclear medicine departments of hospitals and clinics and physically consists of liquids and gases.

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

Sincerely,

William Chatoff R.Ph.,

Item 9
Date: 11/14/96



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TRADE AREA DEMOGRAPHICS

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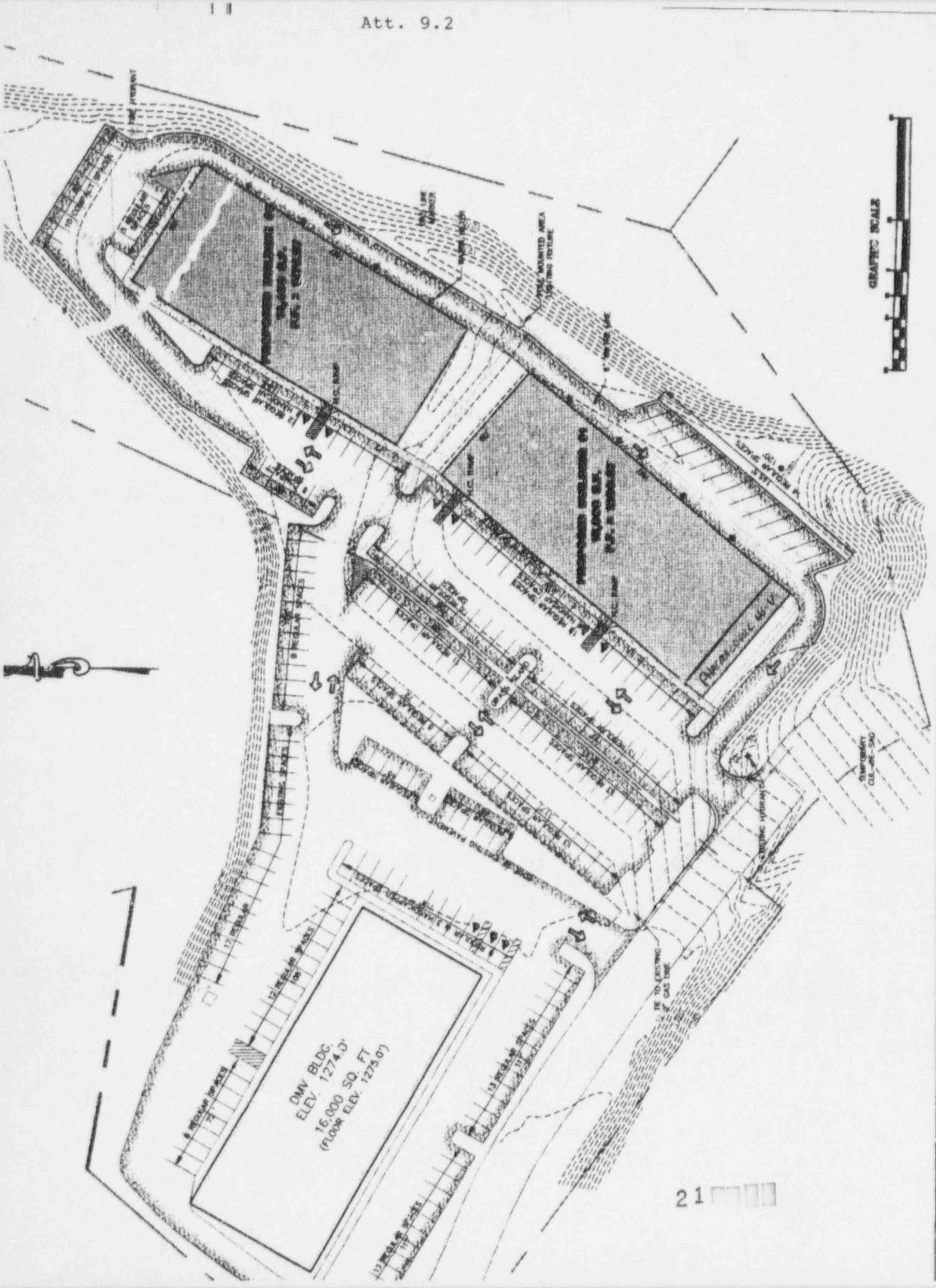
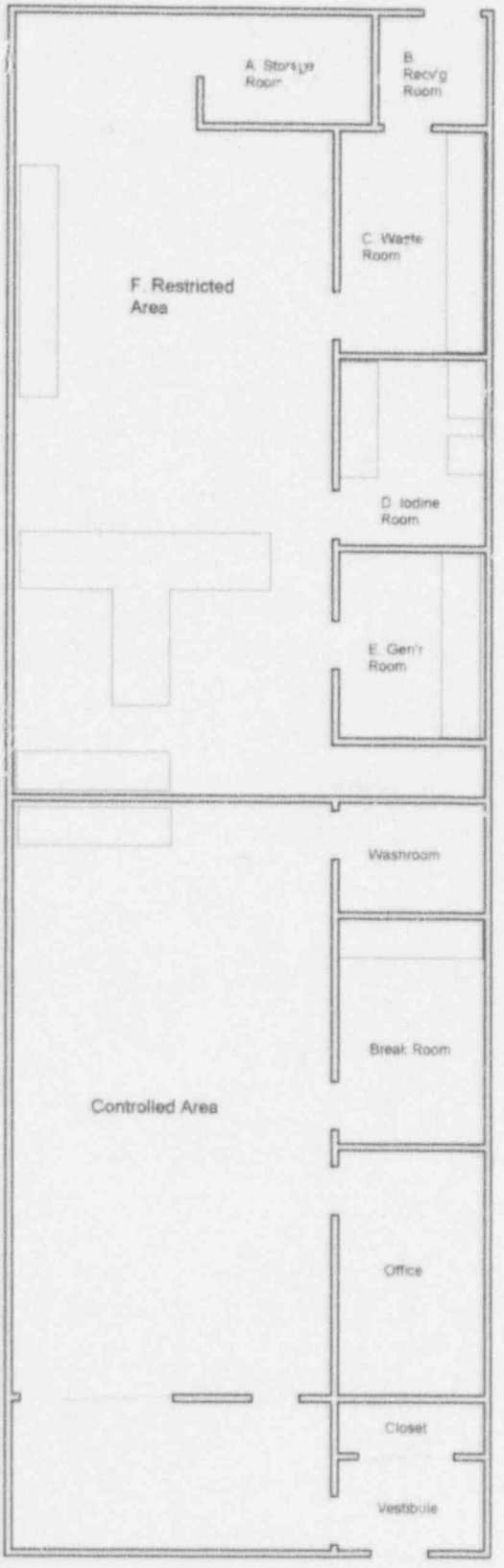

GRAPHIC SCALE
DMV BLDG.
ELEV. 1274.3'
16,000 SQ. FT.
(FLOOR ELEV. 1275.0')
TIE TO EXISTING
GAS LINE
21

Attachment 9.3

Mountain

Parking



Unoccupied Office Space

Road

PARKING

Table 9
Relative Hazards of Common Radionuclides

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
C0-58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	Tl-201	100

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on Table 10. Spills above these millicurie amounts are considered major, below are considered minor.

Item 9
Date: 11/14/96

NRC Operations Center:
(301) 816-5100
(24 hrs per day, Collect Calls Accepted)

PharmaLogic W.V. Ltd.

Radiation Safety Officer(RSO)
Beeper #:

Item 9
Date: 11/14/96

Item 9.2 General Description of Facility

PharmaLogic W.V. Ltd. has leased 2000 square feet of space at **200 Platinum Drive, Suite 200, Bridgeport, West Virginia 26330.**. This space is located in a single story building constructed of concrete block and steel.

The heating system is exclusive for our facility. Sketches of the floor plan and equipment placement are attached to this written description. Area **B** will be used for receipt of radioactive packages during off-duty hours.

CONTROLLED AREA - Approximately 1000 square feet

See attached sketch

RESTRICTED AREA - Approximately 1000 square feet

A Fume Hood/Glove Box - Approximately 238 square feet.
All volatile radiopharmaceuticals (Xe-133, Iodine-131) will be stored in the fume hood. Xenon-133 will be stored in its shipping container, and Iodine-131 will be stored in its shipping container. Negative pressure will be maintained in this room relative to the remaining areas of the facility. The nearest entrance from this area is approximately 20 ft away.

B Generator Room - Approximately 140 square feet.
All actively used generators will be stored in this area in auxiliary shields provided by the manufacturers in generator bins with additional lead shielding on all sides. All non-refrigerated radiopharmaceuticals will be stored in this area in the manufacturers shielding behind additional lead shielding when not in use in the dispensing area. The additional lead shielding will consist of 2"x4"x8" lead bricks weighing 27 lbs each. These will be located around the generators and providing additional shielding for the walls where the generators will be stored.

C Radioactive Waste Storage - Approximately 200 square feet
All radioactive waste materials will be stored 1/2" to 3/4" lead barrels with lead lined tops. The waste will be segregated according to half-lives. As is the case with any waste generated, it will not be removed as trash until it has decayed to background.

Item 9
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D Secured Delivery Area - Approximately 64 square feet
This area will be used for receipt of radioactive packages. The vestibule has been constructed for after hours deliveries of radioactive material. This area will have a locked outer door. Keys to the door will be given to the common carrier making deliveries with instructions for delivering material during off-duty hours. The two(2) inner doors will be secured by combination lock, thereby preventing entrance into the controlled area.

E. Storage Area
This room will be used for storage on non radioactive material.

F Radiopharmaceutical Dispensing Area Approximately 1000 square feet.
This area is used for preparation and dispensing of radiopharmaceuticals. Two(2) drawing stations will be located as shown on the attached sketch. Drawing stations will consist of : a laminar flow hood, leaded glass L-Block shield, a dose calibrator, a leaded waste barrel, and tongs or forceps. Installed in the walls of the laminar flow hood are lead sheets. This laminar flow hood is designed specifically for Nuclear Pharmacies. Technetium and Technetium products will be prepared and stored in elution vial shields supplied by the various generator manufacturers, all of which have a minimum thickness of 1/4" of lead. Package preparation and dispatching will also be done in this area. Product quality control will be performed in this area.

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Radioactive Waste Handling and Disposal

A. Waste Generated

1. All waste generated is related to radiopharmaceuticals used by the medical profession. Since none of the radioactive materials used have long half-lives, PharmaLogic W.V. Ltd. has established a waste classification system to be used for segregating various types of material according to half-life, and the quantity of waste generated.

2. Methods for Holding Waste

a. 1/2" to 3/4" lead barrels, 18" in diameter, 24" high on casters are provided for storage. A 1/4" lead plate is used as a lid. This type of container is supplied for each classification of waste. Each container has a plastic bag liner or cardboard liner supplied by a waste disposal service. These containers are identified by the waste classification name, and/or a color code.

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

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

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

B. Waste Disposal Procedures

1. Used generators will be stored in their original shipping containers until they have decayed to levels suitable for dismantling for core storage.

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

a. Open unit dose shield, identify material by Rx label.

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

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

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

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

b. Record background of survey meter on waste disposal record.

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

d. Remove bag from lead container.

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

f. If RAM waste measures background;

1. Remove all radioactive tags or obliterate RAM labels.

2. Dispose of into normal trash.

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

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

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Item 9.3 Adequacy of Facility for Handling Xenon-133

A. Quantities to be Used

The desired possession limit is 1.0 Ci of Xenon-133 in gas form. The only forms of Xenon-133 PharmaLogic W.V. Ltd. is requesting are sealed glass vials of the NEN and Medi-Physics type of glass vial containing gas. The rubber septum's on these vials will not be punctured nor the contents of the vials altered in any way. These vials will be shipped from the Nuclear Pharmacy in the same containers and form in which they are shipped to the pharmacy, reducing the possibility of Xenon-133 leaks, spills, or contamination essentially to zero.

B. Use and Storage Areas

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

2. Xenon is not to be used in the pharmacy; it will be stored in the fume hood. The exhaust fan from the fume hood is used to maintain a high flow rate through the hood. The fume hood will have a measured air flow in excess of 450 CFM. The Xenon will be dispensed and packaged on a prescription basis in the radiopharmacy dispensing area.

3. The fume hood will be checked every six(6) months with a velometer to determine if the fume hood is operating adequately.

C. Procedures for Routine Use

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

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D. Emergency Procedures

Since PharmaLogic W.V. Ltd. is not performing ventilation studies on patients, and since we are not opening or puncturing the septum in these vials, there is virtually no chance of an accidental release of Xenon-133. Should some unexpected accident occur, we will be monitoring the area in front of the fume hood, and if levels should increase, the room will be evacuated until levels return to background.

E. Air Concentrations of Xenon-133 for Unrestricted Areas

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

2. The maximum amount of activity on hand at any one time per week in mCi is 1000. This will be the maximum amount stored in the fume hood.

3. Using an estimated loss factor of 0.05% per day of Xenon-133 from its unit dose vials, the following calculations are submitted.

If we have a leakage of 0.005% per day (see attached Xe-133 leakage results) and we assume that we will continually have 1000 mCi on hand seven days a week (both assumptions are excessive), then;

$$F = \frac{0.05\%}{\text{day}} \times \frac{7 \text{ days}}{\text{week}} \qquad F = 3.5 \times 10^{-2}/\text{week}$$

4. The exhaust across the fume hood is 450 cubic feet per minute. Calculating (V) in metric terms:

$$V = \frac{450 \text{ cubic ft}}{\text{min}} \times \frac{60 \text{ min}}{\text{hr}} \times \frac{24 \text{ hr}}{\text{dy}} \times \frac{7 \text{ dys}}{\text{wk}} \times \frac{1728 \text{ cu in}}{\text{cu ft}} \times \frac{16.39 \text{ ml}}{\text{cu in}}$$

$$V = \frac{450}{\text{wk}} \times (1.008 \times 10^{4}) \times (2.83 \times 10^{4}) \frac{\text{ml}}{\text{wk}}$$

$$V = \underline{1.28 \times 10^{11}} \text{ ml/wk}$$

5. For unrestricted areas Part 20 requires that the maximum allowed concentration is:

$$\frac{A}{V} \times f = 5 \times 10^{-7} \text{ uCi/ml}$$

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In our case:

$$\frac{A}{V} \times f = \frac{1 \times 10^{6}\ uCi}{1.28 \times 10^{11}\ ml/wk} \times \frac{3.5 \times 10^{-2}}{wk} = 2.73 \times 10^{-8}\ uCi/ml$$

F. Methods for Xenon-133 disposal

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

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

H. The exhaust stack from the fume hood is exclusive for this fume hood, and is located over 70 feet from the nearest intake vent or access to the building.

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XENON-133 LEAKAGE DATA SHEET

Dose Calibrator CAPINTEC Serial # 10859

Calibration Factor Xenon-133 Background 0.1 uCi

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

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

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

Signature signed by Verne Y. Tabacon

Date 6/7/85

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

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

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

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

AVERAGE LOSS PER DAY = 0.0049%

Signature signed by Verne Y. Tabacon

Date 6/7/85

Item 9.4 **Special Equipment for Handling Millicurie Quantities of Liquid Radioiodine**

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

Two(2) 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 minimum linear air flow of 50-70 feet/min with a minimum total exhaust of 25 CFM.

The efficiency of this trapping system is checked weekly using a survey meter. The filters are removed and the radiation levels at their surfaces is measured with a pancake probe type survey meter. When the mr/hr level of the top filter is equal to or greater than 10% of the mr/hr level of the bottom filter, the bottom filter will be replaced. Air sampling for volatile 131-Iodine will be performed in conjunction with the use of the radioiodine fume hood.

Procedures for Completion of 131-I Air Monitoring

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

Procedures for 131-Iodine Air Monitoring

A. Discussion

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

2. Acceptable methods include:

a. Air sampling data and/or

b. Calculations (if those calculations can demonstrate that the DAC for a particular substance is not exceeded.) A good example of the use of calculations for this purpose is the information which is submitted for authorization to use 133-Xenon. If calculations are submitted, it is necessary to document those specifications and measurements (such as fume hood flow in CFM, etc.) and check them periodically to ensure that the conclusions made from the calculations have not changed.

3. For volatile 131-Iodine, the approach of using calculations may be taken to document that the DAC is not exceeded. The concentration of volatile 131-Iodine will be calculated using the "Worksheet for Radioactive Air Monitoring" which is enclosed.

B. Equipment

1. Vacuum pump with air flow gauges.
Because PharmaLogic will operate its air sampling equipment continually, evaluation of the effluent concentration should be done in 24 hour increments or multiples of 24 hour increments. The activity in the filters must be measured within 24 hours from the time that liquid Iodine-131 is handled for liquid doses or therapy capsules.

2. Appropriate tubing.

3. Filter holders.

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4. Charcoal impregnated filter or filter paper.

5. Scintillation well counter assembly and appropriate counting vials.

C. Operating Procedure for Air Filters

1. Mount the air sampling apparatus in a manner which will ensure that effluents being released to both restricted and unrestricted areas will be sampled. Sampling may be done in the exhaust vent pipe on the up stream side of any additional air filtering system.

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

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

a. Fold or roll up the filter if applicable using clean disposable gloves;

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

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

4. Record the well counter background and net 131-Iodine count on the "Worksheet for Radioactive Air Monitoring".

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

D. Procedure for Calculating Concentration of Volatile Iodine.

1. The following calculations may be used to determine the concentration of volatile iodine in uCi/ml in the restricted and unrestricted areas.

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

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

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$$\textbf{131-Iodine uCi} = \frac{\textbf{Net cpm(Filter)}}{\textbf{2.2x10}^{6}\ \textbf{dpm/uCi x F}_{e}\ \textbf{131-I}}$$

c. Determine ml air flow through sampling pump from:

(i) Direct pump flow data x time
(ii) Pump flow data converted to ml/min x time

d. Calculate uCi/ml of 131-Iodine concentration using formula below:

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

e. The maximum permissible Derived Air Concentrations (DAC) are:

(i) For occupational limits DAC = $2x10^{-8}$ uCi/ml
(ii) For effluent limits DAC = $2x10^{-10}$ uCi/ml

2. Useful conversion factors are:

a. 1 ft^3 = 2.832 x 10^{-2} M^3 = 2.832 x 10^4 ml

b. 1 ft^3/min - 2.832 x 10^4 ml/min

c. 1 ft^3/min = 28.3 liters/min

d. ratio of Photon yield $\frac{\text{I-131}}{\text{Ba-133}} = R_p$

Procedures for Installation

A. Filter holder #1 should be mounted on the OUTSIDE of the 131-Iodine hood above the area where an individual would be working. This filter monitors the air in a RESTRICTED area.

B. Filter holder #2 should be mounted to sample air from the fume hood stack. This filter monitors the air in an UNRESTRICTED area, i.e., the air being vented to the environment.

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If a barium-133 standard is used, F_e may be corrected for photon yield. However, the actual correction factor is dependent on the equipment used to obtain your data. The theoretical rate peak abundance is:

$$\frac{\text{I-131(E)}}{\text{Ba-133(E)}} = \frac{82.0}{61.6} = 1.33$$

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WORKSHEET FOR IODINE-131 AIR MONITORING
(Restricted)

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

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

2. Sample count (cartridge) = _____ cpm.

3. Barium - 133 x R_p = _____ cpm *

4. Ba - 133 Standard Activity = _____ uCi.

5. Efficiency factor of well counter (F_e) = _____

Iodine - 133 Activity (uCi) = $\frac{\text{Net Sample count (cpm)}}{F_e \text{ (cpm/uCi)}}$ = _____ uCi

Where: F_e (cpm/uCi) = $\frac{\text{Net Ba-133 Standard Count (cpm)}}{\text{Activity of Ba-133 Standard (uCi)}}$ = ___ cpm/uCi

I-131 Act. on Cartridge (uCi) = $\frac{\text{Net Cartridge Count (cpm)}}{\text{Efficiency (cpm/uCi)}}$ = _____ uCi / **F_e of cartridge**

or: Iodine -133 Activity (uCi) = $\frac{\text{Net Sample Count (cpm)}}{2.22 \times 10^6 \text{ dpm/uCi} \times F_e}$ = _____ uCi

B. Determine flow through sampling pump:

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

2. Pump-on Duration = _____ min.

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

C. Determine concentration in uCi/ml:

I-131 Concentration in Air (uCi/ml) = $\frac{\text{I-131 Act. on Cartridge (uCi}}{\text{Flow through pump (ml)}}$ ___

Instrument_____ Analyzer Setting_____ keV to _____ keV

Signature_____ Date: _____

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

WORKSHEET FOR IODINE-131 AIR MONITORING
(Unrestricted)

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

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

2. Sample count (cartridge) = _____ cpm.

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

4. Ba - 133 Standard Activity = _____ uCi.

5. Efficiency factor of well counter (F_e) = _____

Iodine - 133 Activity (uCi) = $\frac{\text{Net Sample count (cpm)}}{F_e \text{ (cpm/uCi)}}$ = _____ uCi

Where: F_e (cpm/uCi) = $\frac{\text{Net Ba-133 Standard Count (cpm)}}{\text{Activity of Ba-133 Standard (uCi)}}$ = ___ cpm/uCi

I-133 Act. on Cartridge (uCi) = $\frac{\text{Net Cartridge Count (cpm)}}{\text{Efficiency (cpm/uCi)}}$ = _____ uCi / **F_e of cartridge**

or: Iodine -133 Activity (uCi) = $\frac{\text{Net Sample Count (cpm)}}{2.22 \times 10^6 \text{ dpm/uCi} \times F_e}$ = _____ uCi

B. Determine flow through sampling pump:

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

2. Pump-on Duration = _____ min.

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

C. Determine concentration in uCi/ml:

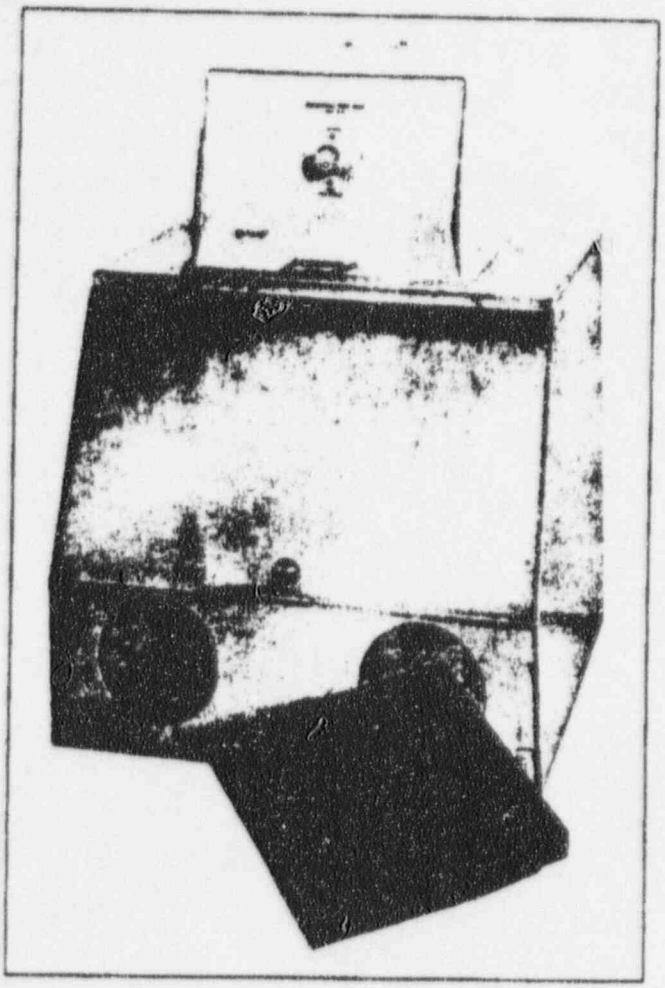
I-131 Concentration in Air (uCi/ml) = $\frac{\text{I-131 Act. on Cartridge (uCi}}{\text{Flow through pump (ml)}}$

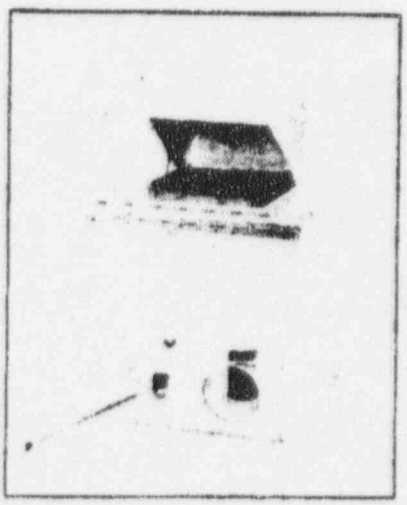
Instrument_____ Analyzer Setting_____ keV to _____ keV

Signature_____ Date: _____

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

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.)

NOTE: The radioiodine fume hood pictured above, or equivalent, will be used to dispense liquid I-131 sodium iodine solution and capsules.

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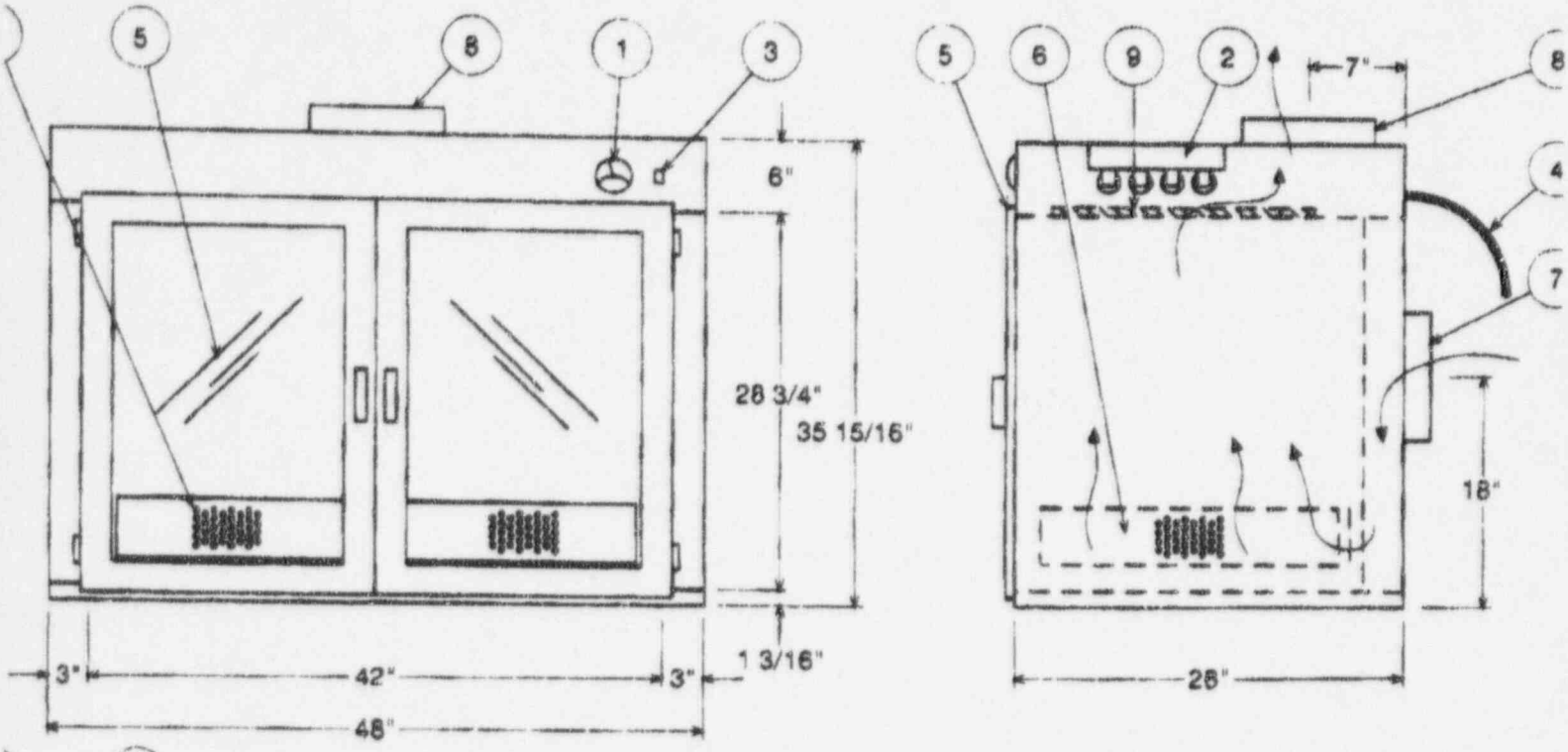
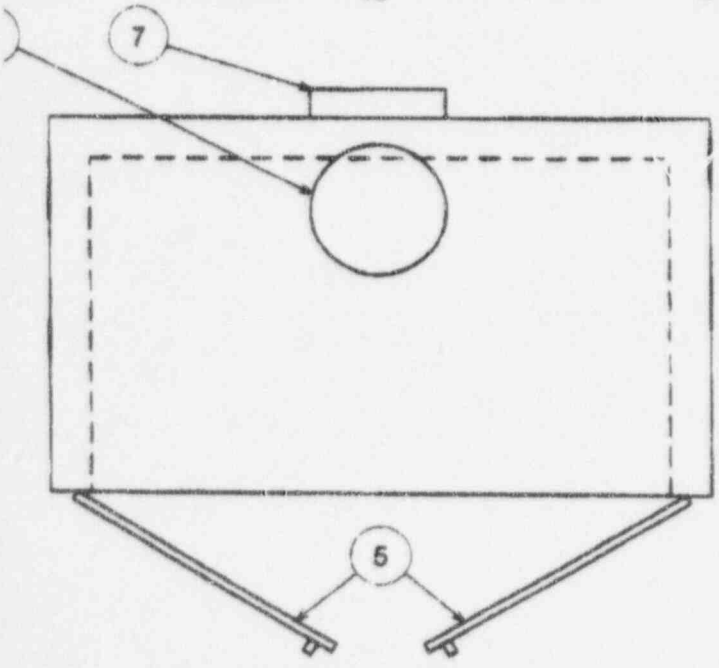
Stainless Steel Exhaust Cabinet

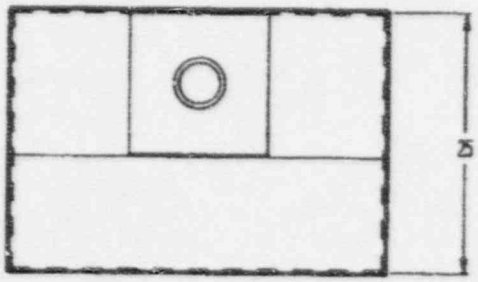


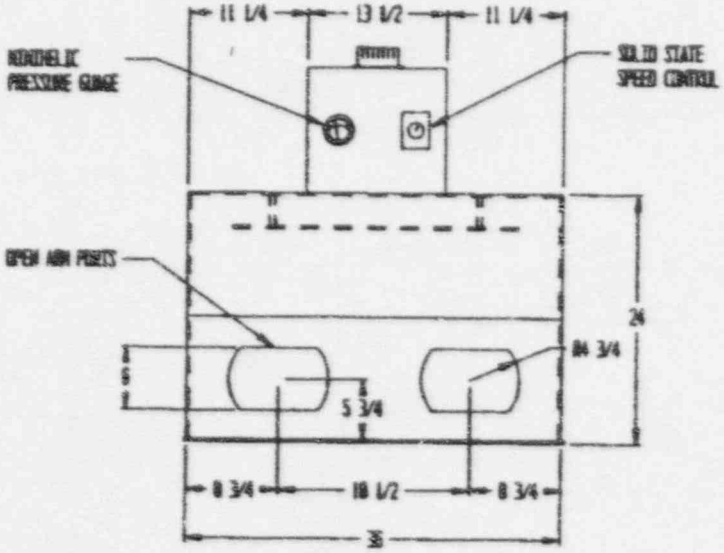


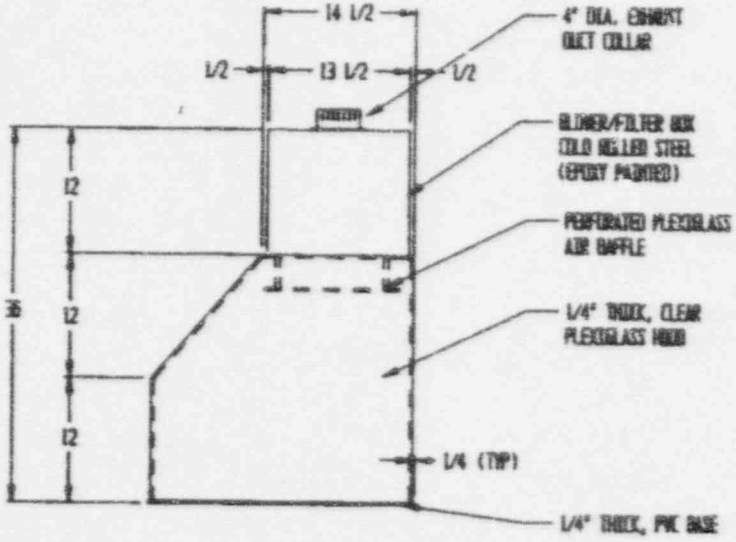
KEY

1. Minihelic pressure gauge
2. Fluorescent light fixture with 4 ea. F30T12CW Lamps
3. Light Switch
4. 8 ft. electrical cord with 115 volt, 15 amp plug
5. Anodized aluminum framed doors with acrylic glazing, self-closing hinges and brass ball catches
6. 4" high perforations on interior side and back walls for intake air. 1/4" diameter holes on 3/8" staggered centers
7. 10" diameter intake collar
8. 10" diameter exhaust collar
9. acrylic eggcrate protective grill

REVISIONS			
REV	DESCRIPTION	DATE	APPROVED







DRAWN FOR: STANDARD	MID-AMERICA ISOTOPES, INC. 705 E. LIBERTY LANE, ASHLAND, MISSOURI 65010			
	TITLE: PLASTIC GLOVE BOX WITH FILTERED EXHAUST			
DRAWN BY: LWB	SIZE	JOB NO.	DWG NO. 1670008A	REV
APPROVED BY	SCALE 1"= 1'- 0"		DATE 2-21-92	SHEET

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Sodium Iodine I-131 Capsule Preparation
*****Compounding Procedures*****

1. Turn on the fume hood and I-131 glove box if not already operating. Check to make sure the equipment is operating properly.

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

3. Wear two(2) pair(s) of gloves. Put on 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 assure that it is contamination free. If not decontaminate the work area before you start. Always use ALARA principles!

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 is for the next day. Also residual volume left in the LO-DOSE syringe will be approximately 200-400uCi. 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.

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 NEN 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 capsule (from the freezer) into the shielded size "0" capsule.

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12. Take an empty LO-DOSE syringe and bore a pilot hole through the center top of the sodium phosphate capsule.

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.

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 modified straw, pick up the other size "0" capsule half and place the empty I-131 syringe in its' holder and store in the fume hood out of the way.

16. Remove the capsule by inverting the Squibb gen. lead piece onto a second orange lead container that has a "dispensing container" within. With an empty LO-DOSE syringe push the capsule through the Squibb gen. lead piece so it drops into the dispensing container.

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

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

19. Remove your latex gloves and replace with new ones.

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

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

22. Perform an area survey of the I-131 glove box and other immediate work areas to assure it is contamination free. Decontaminate if necessary.

23. Follow the air monitoring procedure as outlined in your NRC or Agreement State License.

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Item 10 **RADIATION SAFETY PROGRAM**

Item 10.1 Personnel Monitoring Program
We confirm that we have established and agree to implement written personnel monitoring procedures. As a minimum, these written procedures will require:

a. That whole body film badges be provided to personnel who enter restricted areas under circumstances described in **10 CFR 1501**.

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

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

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

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

Item 10.2 Instruments

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

Item 10.3 Calibration of Survey Instruments

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

2. Survey instruments will be calibrated by the manufacturer.

3. PharmaLogic W.V. Ltd. will maintain records of each calibration for at least two(2) years after each calibration.

Item 10.4 Calibration of Dose Calibrators

PharmaLogic W.V. Ltd. has adopted the dose calibrator calibration program described in appendix E of the "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" dated August 1985.

Item 10.5 Procedures for Receiving Shipments Containing Radioactive Material

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

Item 10.6 Procedures for Safely Opening Packages Containing Radioactive Material

PharmaLogic W.V. Ltd. has adopted the package opening procedure described in Appendix G of the "Guide for the Preparation of Applications for a Nuclear Pharmacy License" dated August 1985.

Item 10.7 General Procedures for the Safe Use of Radioactive Material

PharmaLogic W.V. Ltd. has adopted the general rules for safe use of radioactive material described in Appendix H of the "Guide for the Preparation of Applications for a Nuclear Pharmacy License" dated August 1985.

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Item 10.8 Emergency Procedures

PharmaLogic W.V. Ltd. has adopted the emergency procedures described in Appendix I of the "Guide for the Preparation of Applications for a Nuclear Pharmacy License" dated August 1985.

10.9 Procedures for Retrieving Radioactive Waste from Customers

It will be the policy of PharmaLogic W.V. Ltd. of not to routinely pick up radioactive waste from customers.

Request for Authorization to Collect Radioactive Waste

1. Packaging and pick up from customers.

A. Type of radioactive waste

Radioactive waste picked up will be comprised of plastic syringes, needles, needle covers, and vials which have been used by nuclear medicine departments serviced by PharmaLogic W.V. Ltd..

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

1. With the exception of vials, which have contained radiopharmaceuticals, the syringes will have been flushed out with patient blood in the process of injecting the patient. Also, because of the routine of a Nuclear Pharmacy, these materials will be retrieved 24 hours after use; therefore, the Tc-99m products will have decayed at the user's site for a least three half-lives. Those vials retrieved as waste represent a very small portion of the waste in this system. Each unit dose syringe or vial is identified by prescription number and radiopharmaceutical.

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

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

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

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c. Survey unit dose container for contamination with a low level survey meter. If a unit dose shield demonstrates activity levels greater than background, remove from service, and place in storage area for decay to background levels. When surveying unit dose shields for reuse, any unit dose shield which demonstrates a survey meter response greater than background must be wipe tested. If wipe test samples demonstrate contamination levels greater than 200 dpm/100 cm^2, the unit dose shield should be decontaminated until less than 200 dpm/100 cm^2 contamination is detected.

C. PharmaLogic W.V. Ltd. uses a unit dose shield developed by Willard Industries, Inc. The shield is comprised of a top and bottom lead cylinder which is threaded together to form a safe and effective lead shield for syringes containing radiopharmaceuticals. All multiple dose containers are transported in their original containers or the equivalent. These lead shields are then placed in a specifically designed cases which have Polystyrene foam inserts that accommodate the exact size of the shield. These cases are positively sealed when used to transport radiopharmaceuticals.

All radiopharmaceuticals will be transported in our vehicles by delivery personnel employed by PharmaLogic W.V. Ltd.. Only waste syringes, needles, needle covers, and vials will be accepted for pick up, and placed in the cased for return to the Nuclear Pharmacy.

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

PROCEDURE FOR RETURNING UNIT
DOSE CONTAINERS TO PharmaLogic W.V. Ltd.

PharmaLogic W.V. Ltd. has been licensed by the Nuclear Regulatory Commission to pick up those materials which after use, represent radioactive waste. Only those materials supplied to you by PharmaLogic W.V. Ltd. may be returned to the pharmacy as waste.

Note: It will be the policy of PharmaLogic W.V. Ltd. of not picking up any biohazardous waste.

A. Syringes, Needles, and Needle Covers:

1. Only unit dose syringes, needles, and needle covers that **have not been used for patient injections** and are not considered to be **Biohazardous** will be picked up by PharmaLogic W.V. Ltd.

B. Unit Dose Vials; Depleted Sealed Calibration Sources:

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

C. Returning Packages:

1. Beacause you, the customer, may be returning radioactive waste to PharmaLogic W.V. Ltd., you now become a shipper of radioactive material and therefore must utilize the provisions of **49 CFR 173.421**.

2. **49 CFR 173.421** states that if a package meets the following requirements, it is exempted from the specification packaging, and labeling requirements:

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

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

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

d. Other provisions of this regulation are satisfied by PharmaLogic W.V. Ltd.'s present packaging.

3. The three(3) tasks we ask you to perform for us are:

a. That you insure that the waste being returned does not exceed the specified limits for limited shipment quantities.

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

c. Wipe the container as specified in **49 CFR 173.443(a).**

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

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Limited Shipment Quantities for Each Commonly Used Radiopharmaceutical

Radionuclide		Limited Shipment Quantity (mCi) $A_2 \times 10^{-4}$
57-Co		9
58-Co		2
51-Cr		60
67-Ga		10
123-I		5
125-I		7
131-I		1
111-In		2.5
99-Mo		2
32-P		3
75-Se		4
99m-Tc		10
201-Tl		20
133-Xe(Uncompressed)	($A_2 \times 10^{-3}$)	1 Ci
169-Yb		8

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

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

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

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Item 10.10 Precautionary Measures for Handling Millicurie Quantities of Liquid Radioidodine

Thyroid bioassay will be performed in accordance with the provisions of NRC Regulatory Guide 8.20, with respect to action levels 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 handing 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 Necessary

    a. Scintillation counting system with
    b. Thyroid neck phantom
    c. I-131 capsule

2. Procedure:

    131-I energy = 364 KEV
    Analyzer window = 100 KEV

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

    a. Determine background of counting system.

    b. Determine 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 give you the highest count rate.

    d. Calculate thyroid activity from:

$$\text{131-I thyroid activity} = \frac{(\text{neck CPM} - \text{Bg CPM})\,(\text{uCi of capsule})}{\text{Capsule CPM} - \text{Bg CPM}} = \text{uCi in thyroid}$$

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3. Comment: Since NRC Guide 8.20 specifies an action level with respect to thyroid burden of 0.12 uCi, it will be necessary for you to determine the sensitivity of the equipment, and the thyroid counting time necessary to demonstrate a level of 0.12 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 per 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:

$$CF = \frac{20{,}000\ CPM}{5\ uCi} = 4000\ CPM/uCi$$

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:

$$MDA = \frac{3.3 * \angle 2R_b/t_b}{CF}$$

R_b = the background counting rate
t_b = time taken to count the background
CF = calibration factor , i.e., the counts per minute per uCi of a standard source

In the above example, CF - 4000 CPM/uCi

If background was counted for one(1) minute and yielded 240 total counts, then the MDA is determined to be:

$$MDA = 3.3\ X \frac{\angle(2\ X\ 240\ cpm)/1\ min.}{4000\ cpm/uCi} = MDA = 0.0057\ uCi$$

which satisfies the requisite sensitivity.

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

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

$$Q = \frac{\text{Net thyroid cpm}}{CF}$$

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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. NRC Regulatory Guide 8.20, Application of Bioassay for 125-I and 131-I. Bioassays for thyroid uptake will be obtained with a Ludlum 2200 and Scintillation Probe, or equivalent. Measurements of the thyroid will be compared to an Iodine 131 capsule housed in a appropriate thyroid phantom to take into account tissue attenuation from the employees 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 **Section 20.1204, 10 CFR, Part 20.**

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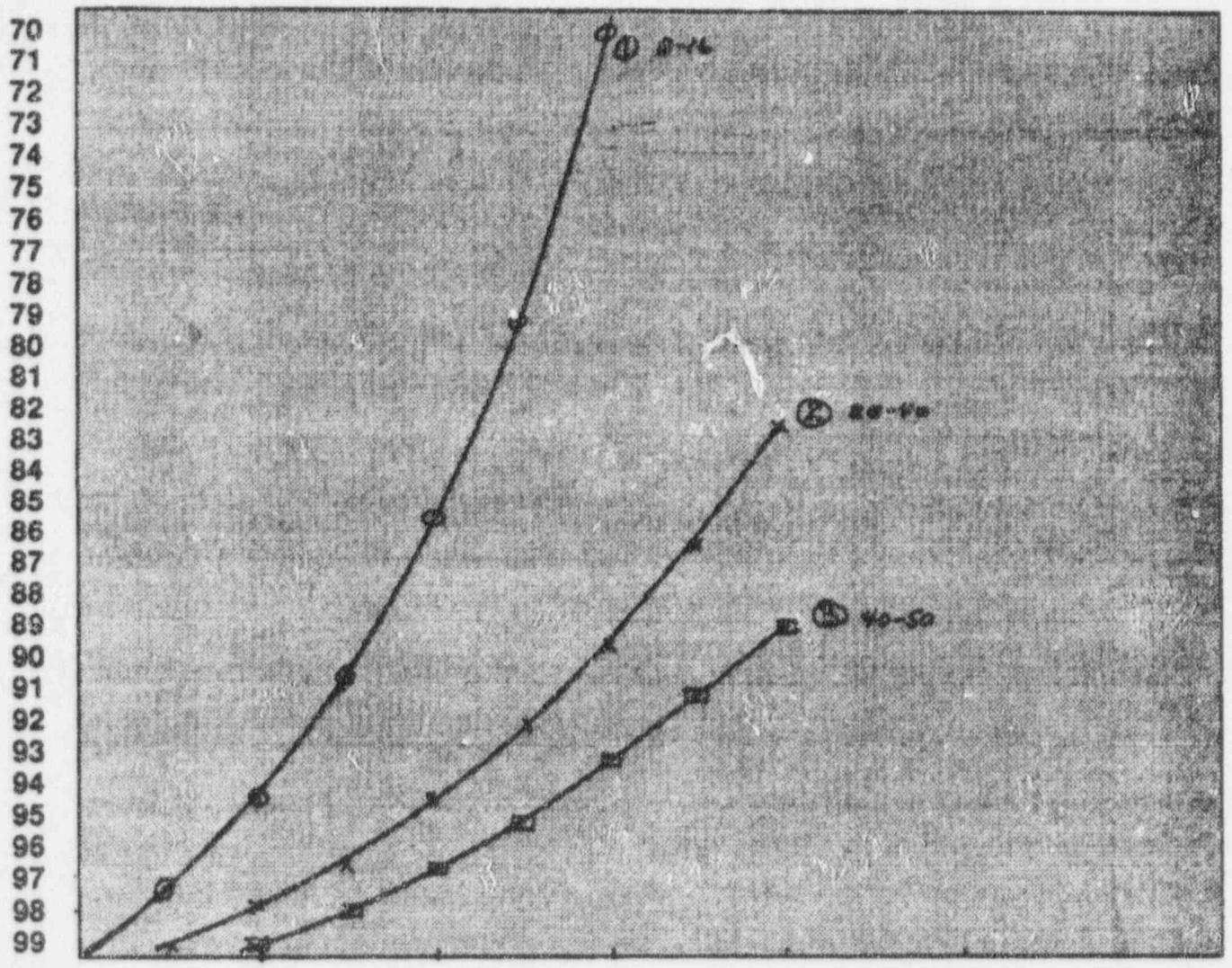
ATTACHMENT 1

HI-Q ENVIRONMENTAL PRODUCTS COMPANY
Division of the La Jolla Scientific Co. Inc.
POST OFFICE BOX 2847 LA JOLLA, CALIFORNIA 92038-2847
Phone: (619) [redacted]

COMPARRISON OF THE RETENTION EFFICIENCES OF THE THREE MESH SIZE AVAILABLE IN ANALYTICAL RADIOIODINE CARTRIDGES. PERCENT RETENTION VS. FLOW RATE



Comparison of Methyl Iodide retention efficiencies with 5% TEDA Impregnated Carbo
(1) 8-16 Mesh, TC-12, (2) 20-40 Mesh, TC-30, (3) 40-50 Mesh, TC-45. Conditions for th
test are the same as ASTM-D-3803, but under various flow rates of 1 to 4 CFM.

THYROID BIOASSAY RECORD

LOCATION:

EQUIPMENT/MAKE:_____ MODEL:_____ SERIAL:_____

EFFICIENCY FACTOR (Fe):_____

NAME	DATE	BK6 (CPM)	(A) NET THYROID (CPM)	(B) CAPSULE (uCi)	(C) NET CAPSULE (CPM)	(D) THYROID (uCi)

NOTES:

1) Frequency is weekly for each employee in bioassay program.

2) Personnel compounding I-131 capsules must perform weekly bioassay.

3) I-131 thyroid activity in uCi (D) = $\frac{(A)(B)}{(C)}$

4) Thyroid action level is 0.12 uCi.

Reference: NRC Regulatory Guide 8.2.

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CURRENT LIST OF
PERSONNEL IN BIOASSAY PROGRAM

Location: _____

Month: _____ Year: _____

INSTRUCTIONS: The following employees are listed as participants in the Bioassay program for the above location and month. To verify this, please: 1) Give the name and date added for any new employees in the Program. 2) Line through the name of any employee deleted from the Program and give the date deleted. 3) IF THERE ARE NO CHANGES, sign and date the "No Changes?" line.

Name	Date Added or Deleted

NO CHANGES? Name: _____

Date: _____

Item 10

SURVEY OF IODINE GLOVE BOX CHARCOAL FILTERS

Instrument Used

Make: _____ Model: _____ Serial #: _____

DATE	TOP FILTER (Second filter in line of flow) Specify cpm or mR/hr a	BOTTOM FILTER (cpm or mR/hr) b	TOP/BOTTOM* a/b	INT.

Comments: WHEN THE BOTTOM FILTER IS LESS THAN 1000 cpm AND LIKEWISE FOR THE TOP FILTER, THE 10% (FILTER CHANGE DOES NOT APPLY) SURVEY READINGS ARE BACKGROUND.

* ACTION LEVEL: WHEN THE TOP FILTER EXCEEDS 10% (0.1) OF THE BOTTOM FILTER, THE BOTTOM FILTER WILL BE CHANGED. Item 10

100- WINDOW
314- THRESHOLD

Notes:

1. Monitoring of the air flow in the Iodine Hood will be obtained daily or prior to use of the hood system for handling Iodine-131. A flow meter will be placed at all locations for evaluating linear flow through the arm ports of the glove box and face of the standard fume hood. PharmaLogic W.V. Ltd. will be using an anemometer by Alnor Instrument Company, Model No. 8100 or equivalent. PharmaLogic W.V. Ltd. will remeasure airflow every six(6) months.
2. Enlcosed please find illistrations of the fume hood and mini hood systems. The blower unit is located at the furthest point of the roof line from the nearest inlet and/or vent or window. The charcoal filters are inside the Blower/Filter Box of the mini-hood system. The unrestricted air samples will be collected approximately three(3) feet from the actual release point on the roof. The restricted area air samples will be collected in front of the mini-hood system, at eye level of any practicing pharmacist mimicking actual air individuals will be breathing.
3. Air flow values will be checked quarterly with an anemometer and documented accordingly. Fume Hoods will be adjusted or repaired of hood face velocities drop below 100 LFM. All fume hood repairs will be done by the manufacturer or others certified to do such repairs and/or adjustments. PharmaLogic W.V. Ltd. will take airflow checks immediately after any maintenance of the fume hood motor or fan to ensure proper direction and volume of fume hood airflow.
4. The radioactive materials hood exhaust will be a minimum of ten feet high above the local roof line and as far as practical from any HVAC fresh air intakes.
5. PharmaLogic W.V. Ltd. understands and recognizes that excessive face velocities across fume hood openings will create eddies that may result in drawing loose radioactive material out into the room. Procedures for proper optimum air flow will be set at the suggested optimum hood face velocities range of 100 to 125 LFM.

Item 10.11 Area Survey Procedures

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

Item 10.12 Operations

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

The Nuclear pharmacy is licensed by the State Board of Pharmacy and is therefore subject to laws and regulations set forth by the State Board of Pharmacy. The nuclear pharmacy will be required to comply with the applicable provisions of the Federal Food, Drug, and Cosmetic Act.

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

It is our intention to prepare radiopharmaceuticals which have been manufactured by manufacturers such as Squibb, Mallinckrodt, New England Nuclear, Medi-Physics, and others and to distribute or redistribute these products in dose form to nuclear medicine departments licensed to use them.

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

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

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

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

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State Pharmacy License

Pharmacy license will be sent under separate cover.

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Item 10.13 Product Labels

A.

PHARMALOGIC LTD 802/862-9944
9 KRUPP DRIVE P.O. 786
WILLISTON, VT 05495
STUDY 66524
DATE 11/19/96
HOSPITAL [redacted]
DOCTOR HEITZ/JOHNSON
P.O.#: 474
PT. [redacted]
PROCEDURE 0000111-SKELETAL WHOLE BODY
DRUG 0105-200 TC-99M MDP (NEDRONATE)
LOT NO. 6-11/19/96
ASSAY 55.0361 mCi/ml
EXP. TIME 15:00
CAL. TIME 11/19@ 7:45
DOSE REQUESTED 20.0000 mCi
EXP. DATE 11/19/96
VOL. 0.36 ml
ACT. DISP. ±10%
SPECIAL INSTRUCTIONS Mo-99 content ⟨0.15 uCi/mCi at calibration time
CAUTION: To be used under the direct supervision of physician.
WARNING: The U.S. Nuclear Regulatory Commission has approved this radiopharmaceutical for distribution pursuant to
35.200
10 CFR Part 35, or under equivalent licenses of Agreement States.
BY
CAUTION
RADIOACTIVE MATERIAL

B.

TC99M MDP-SKELETAL WHOLE BODY
20.0000 mCi @ 7:45 11/19/96
Study #: 66524 [redacted]

C

[redacted]

TC99M MDP-SKELETAL WHOLE BODY
20.0000 mCi @ 7:45 11/19/96
Study #: 66524 [redacted]

C.

D. A label bearing the radiation caution symbol and the words "**CAUTION, RADIOACTIVE MATERIAL**" or "**DANGER, RADIOACTIVE MATERIAL**" will be placed on all vial shields and all unit dose container shields.

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Required Container Labeling

1. VIALS:
   Vials will be labeled with manufacturers' original label or with label **C**.

2. SYRINGES:
   Syringes will be labeled with Rx. label **C**.

3. VIAL SHIELDS
   All vial shields will be labeled with the manufacturers' original label and/or label **A** and label **D**.

4. UNIT DOSE SHIELDS
   Unit dose containers will be labeled with label **B** and label **D**.

These are sample labels. The pharmacies name and address will be printed on the labels as per Pharmacy State Regulations.

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Item 10.14 Product Shielding

Radioactive Material	Chemical/ Physical Form	Max. mCi per vial/syringe	Shield to be used for Dispensing	Maximum Radiation Level on Shield or Vial in mR/hr
Iodine-131	Sodium Iodide/Soln/cap/tagged drug	per manufacturer	X *	
Iodine-131	Tagged Drug Soln	300.0 uCi	W.I.P.P **. 1/4" Pb	6.0
Iodine-125	Tagged Drug Soln	2.0 mCi	W.I.P.P 1/4" Pb	0.03
Chromium-51	Sodium Chromate Soln	2.0 mCi	W.I.P.P 1/4" Pb	0.03
Gallium-67	Gallium Citrate	10.0 mCi	W.I.P.P 1/4" Pb	26.0
Thallium-201	Thallous Chloride	3.0 mCi	W.I.P.P 1/4" Pb	0.5
Iodine-123	Sodium Iodide	1.0 mCi	W.I.P.P 1/4" Pb	<1.0
Indium-111	Indium Chloride, DTPA, or Oxine	3.0 mCi	W.I.P.P 1/4" Pb **or X**	<1.0
Rubidium^{81}/ Krypton^{81}	Special Form/ gas	25.0 mCi	**X**	
Cobalt-57	Cyanocobalamin	10.0 uCi	W.I.P.P 1/4" Pb	<0.2
Tc-99m	Sodium Pertechnetate Tagged Drug Soln	500 mCi	W.I.P.P 1/4" Pb	0.1
Tc-99m	Tagged Drug Soln	200 mCi	W.I.P.P 1/4" Pb	0.07
Tc-99m	Tagged Drug Soln	100 mCi	W.I.P.P 1/4" Pb	0.06
Tc-99m	Tagged Drug Soln	50 mCi	W.I.P.P 1/4" Pb	0.05

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* **X - has more shielding than W.I.P.P (Manufacturers Shield)** Therapy doses and 133-Xe will be shipped in manufacturer's containers and shielding devices as supplied by the commercial manufacturers.

** **W.I.P.P - Willard Industries Protection Plus radiopharmaceutical syringe shipping carriers. Consist of screw-capped carriers with rubber gasket, containing fluids.** (These syringe carriers are constructed with identical features to the carriers made by General Design Development, Albuquerque, NM)

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Item 10.15 Procedures for Packaging and Transporting Radiopharmaceuticals

The Nuclear Pharmacy will comply with applicable regulations for packaging and transportation of radioactive material as specified in Title 10, Part 71, and Department of Transportation 49 CFR, Part 170-189. All outgoing packages will be wipe tested in accordance with DOT 49 CFR, Part 173.443.

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

a. The radioactive material will be placed into appropriate shielding. i.e., Willard Industries Protection Plus Syringe Shield Carrier or original shielding supplied by the manufacturer.

b. The unit dose container will contain absorbent material.

c. The unit dose container will be put into a polystyrene holder specifically designed for the unit dose container which will be in a certified transport container.

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

	Surface (in mrem/hr)	3 Feet (in mrem/hr)
Radioactive-White I	0.5	0
Radioactive-Yellow II	50	1
Radioactive- Yellow III	200	10

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

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

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

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

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

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

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

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

e. The label affixed to each package of the radiopharmaceutical will contain information as to the radionuclide, its chemical form, the quantity and the date of assay. The label affixed to each package or the leaflet or brochure which accompanies each package will contain a statement that the radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 of Group I, or Group II or Group IV, or Group V of 10 CFR, Part 35. All labeling requirements set forth by DOT will be met.

3. Vehicle

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

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

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

d. Packages of radioactive material bearing "Radioactive Yellow II" or "Radioactive Yellow III" will not be placed closer to passengers than is specified in 49 CFR 177, para 177.842.

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4. Miscellaneous directives

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

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

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

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Training Program for Delivery Personnel

Individuals who deliver radiopharmaceuticals and who collect radioactive waste from our customers and transport it to our facility will be required to attend lectures before assuming their duties with or in the vicinity of radioactive materials, annually for refresher training, and whenever there is a significant change in duties, regulations, or terms of the license. The training program will be of sufficient scope to ensure that all personnel will receive proper instruction in the items specified in Section 19.12 of 10 CFR, Part 19 and will include:

A. Areas where radioactive material is used or stored;

B. Potential hazards associated with radioactive materials;

C. Radiological safety procedures appropriate to their respective duties;

D. Pertinent NRC regulations;

E. The rules and regulation of the license;

F. The pertinent terms of the license;

G Their obligation to report unsafe conditions;

H. Appropriate response to emergencies and unsafe conditions;

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

Individuals hired as delivery personnel will have little or no experience; however, they will be trained with respect to delivery by an experienced radiopharmacist. All initial deliveries and retrieval of used material will be by the pharmacist who will train the delivery personnel on the job. As delivery personnel gain experience, they, in turn, will be used to train new drivers at established accounts.

All new drivers will accompany an experienced driver to hospitals we service.

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

1. The sequence of hospital delivery.

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

3. Retrieval and return of all cases.

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

5. Delivering all doses to the Nuclear Medicine Department unless directed otherwise. In consideration of the above, each driver is to be furnished with written interactions for proper delivery to each institution which we supply. These instructions shall include:

   a. Where to park upon arrival at the hospital;

   b. What entrance by which to enter the hospital;

   c. Whether or not to check in with security;

   d. Route to take from entry into the hospital to Nuclear Medicine;

   e. Area where doses may be left during off-duty hours, it not Nuclear Medicine;

   f. Any special instructions such as checking in at desk, special area in Nuclear Medicine to leave doses, having security personnel unlock doors, etc.

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

7. Driver will ensure that the deliveries are made only to secured places that have been designated by the customer.

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

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Instructions for individuals collecting radioactive waste from our customers:

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

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

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

4. Upon arrival to the pharmacy, check in with the pharmacist on duty and indicate that you have returned containers which may contain radioactive waste materials.

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Emergencies Involving Motor Vehicles
Acting as Carriers of Radioactive Material

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

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

Phone numbers:

1. Police:_____ **Fire:**_____

2. Nuclear Pharmacist (RSO) or on-call

Office:_____ **Home:**_____

Answering Service:_____

b. All traffic should be detoured around the scene of the accident. If this is nit possible, vehicles should be moved the shortest distance necessary to clear the right-of-way. If radioactive material is spilled, passage through areas should be prevented unless absolutely necessary. If the right-of-way must be cleared before assistance has arrived, the spill should be washed to shoulders of right-of-way with minimum dispersal of wash water, or covered with at least four inches of earth or sand.

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

Phone - NRC Region I -
Phone - NRC Operations Center - (301) 816-5100

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

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

f. Contaminated injured should be removed from the area of the accident with as little contact as possible and held at a transfer point. All life-saving measures should be performed promptly, but elective first aid and surgical procedures should be delayed until advice or help can be obtained from a physician familiar with radiation medicine. Except in extreme emergency, patients should not be moved to local hospital or doctor's office before a radiological survey has been made.

g. If the accident involves fire, attempts to extinguish it should be made from as great a distance as possible. The fire should be treated as as one involving toxic chemicals. Suspected material should not be handled until it has been monitored and released by monitoring personnel. Clothing and tools used at the fore should be segregated until they can be checked by the monitoring teams.

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

i. Careful attention and consideration should be given in matters of public relation to:

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

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

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

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Item 10.16 Independent Audit Program

The Radiation Safety Program will be generic in nature and a centralized approach to regulatory compliance, training, and health physics practices will be utilized. The basic premise of the radiation safety program is compliance with NRC/Agreement State regulations. An ongoing audit will be performed quarterly or semi-annually by the RSO and/or the staff Nuclear Pharmacists. A comprehensive compliance survey form will be utilized to ensure compliance with NRC and/or agreement state regulations.

The audit will be an examination of activities conducted under the license as they relate to radiation safety and to compliance with NRC and/or agreement state rules and regulations and the conditions of the license. The audit will consist of examinations of procedures and representitive records, interviews with personnel, measurements, and observations.

If poor health physics practices are identified or items which may represent items of noncompliance, the following will be conducted:

1. Corrective steps which have been taken and the results achieved.
2. Corrective steps which will be taken to avoid further items of noncompliance.
3. The date when full compliance was achieved.

Item 10
Date: 05/26/95

Item 11 **WASTE DISPOSAL**

Item 11.1 NA

Item 11.2 Licensing Criteria for Decay in Storage

We, PharmaLogic W.V. Ltd., will dispose of radioactive waste in accordance with the requirements in **10 CFR 20.2001**. We, PharmaLogic W.V. Ltd., have established written procedures covering this disposal method and these procedures include as requirements the criteria in Item 11.2.2 of Draft Regulatory Guide FC 410-4,dated August 1985.

PharmaLogic W.V. Ltd. Confirms that we are requesting an exemption from **CFR 20 1904(b)** for wastes that are to be incinerated. PharmaLogic W.V. Ltd. Would assure that the waste containers will be delivered directly from our facility to the incinerator and that the containers would not be opened at any point for any reason prior the incineration.

PharmaLogic W.V. Ltd. Confirms that for all waste for which do not have specific exemption, PharmaLogic W.V. Ltd. Will comply with the requirement in **10 CFR 20.1904(b)** for removing or defacing radioactive material waste.