

### APPLICATION FOR MATERIAL LICENSE

L&L=28042

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.

030-30032

**APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:**

U.S. NUCLEAR REGULATORY COMMISSION  
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS  
WASHINGTON, DC 20545

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
NUCLEAR MATERIALS SAFETY SECTION B  
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  
NUCLEAR MATERIALS SAFETY SECTION  
101 MARIETTA STREET, SUITE 2900  
ATLANTA, GA 30323

**IF YOU ARE LOCATED IN:**

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V  
NUCLEAR MATERIALS SAFETY SECTION  
1450 MARIA LANE, SUITE 210  
WALNUT CREEK, CA 94596

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

1. THIS IS AN APPLICATION FOR (Check appropriate item): <input checked="" type="checkbox"/> A. NEW LICENSE ref#20-19205-01 retired <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code) MetPath, Inc. 63/65 Rogers Street Cambridge, MA 02142
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3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

MetPath, Inc.  
63/65 Rogers Street  
Cambridge, MA 02142

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION James E. Stewart, Ph.D.	TELEPHONE NUMBER 617-864-9200
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SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11 PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT. 9001190018 881125 REG2 LIC30 20-28042-01 PDR	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 3P AMOUNT ENCLOSED \$ 230.00

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 <i>J. E. Stewart</i>	TYPED/PRINTED NAME J. E. Stewart, Ph.D.	TITLE Laboratory Director	DATE 5/15/87
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14. VOLUNTARY ECONOMIC DATA		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)
a. ANNUAL RECEIPTS	b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)	
<input type="checkbox"/> <\$25K <input type="checkbox"/> \$25K-50K <input type="checkbox"/> \$50K-75K <input checked="" type="checkbox"/> \$75K-1M	<input type="checkbox"/> \$1M-3.5M <input type="checkbox"/> \$3.5M-7M <input type="checkbox"/> \$7M-10M <input type="checkbox"/> >\$10M	95 c. NUMBER OF BEDS NOT APPLICABLE <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

FOR NRC USE ONLY				
TYPE OF FEE APP	FEE LOG Jun. 5	FEE CATEGORY 3P	COMMENTS 107295	APPROVED BY <i>S. Kimberly</i>
AMOUNT RECEIVED 230	CHECK NUMBER 225639	DATE 22 MAY 1987	DATE 6/4/87	

5. No change from information in previously submitted applications. This facility uses  $^{125}\text{I}$  exclusively, procured from kit manufacturers in an organically bound form. The application is in vitro analysis of medical specimens. Maximum amounts present in the laboratory at one time are total 20 MCi.
6. No change from previous applications. See above. The purpose is limited to in vitro analysis of analytes of medical interest (drugs, hormones, etc.) in immunoassays.
7. Individuals responsible:
  - A) Radiation Safety Officer: M. Jose, Ph.D., Chemistry.  
Present position: Technical Specialist.  
Experience - The manufacture and use of isotopic reagents, including radioiodination. Experience spanning 15 years.
  - B) Laboratory Director: J.E. Stewart, Ph.D., Biochemistry  
Training: "course in graduate school" - The Safe Use of Isotopes in Biochemical Research".  
Experience: Clinical laboratory applications of RIA using  $^{57}\text{Co}$  and  $^{125}\text{I}$  of 12 years.  
Research laboratory studies of RIA and in vivo applications including  $^{32}\text{P}$ ,  $^3\text{H}$ , and  $^{45}\text{Ca}$  in laboratory animals.
8. Training: All employees are B.S. Chemistry degrees or Medical Technology training. All are trained in the same performance of procedures, and in the safety procedures: "Radioactive spills", "RIA Kit Log-In Manual", "Radiation Safety Rules" and "The RIA Wipe Test Procedure". Copies of each are attached with representative documentation. Training includes orientation to the use of spaces marked: "For RIA Work Only".
9. No change from previous application except as follows
  - 1 - Ludlum Geiger Counter Model 3
  - 1 - Medical & Scientific Design Gamma Counter Model RD-48s
10. See above #8. Additionally, we use the inspector as a resource. Upon his visits, we seek his advice for improvements in our program.
11. No change from previous applications.  
Our usage of water and radioactivity continues to place us well below the maximum limits of  $4 \times 10^{-5}$  microcurie/ml or 1.0 curie/year.

## CLINICAL LABORATORY RADIATION SAFETY RULES

1. Eating, storing, or preparing food, smoking, or applying cosmetics is forbidden in any area where radioactive materials are stored or used.
2. Direct contact with radioactive materials must be avoided by using protective laboratory coats and employing safety pipettors. No pipetting should be done by mouth.
3. All spills of radioactive materials must be wiped up immediately. All surfaces should be thoroughly cleaned with a suitable detergent and all contaminated materials disposed of in a suitable container, or flushed down an appropriate drainage with copious amounts of water.
4. Complete records or receipts, transfers, and disposal of radioactive materials must be kept.
5. RIA and any other radiological work should be conducted in a designated area, away from traffic. Radioactive materials should be stored in specially designated areas.
6. All radioactive materials should be properly labeled displaying the expiration date and should be covered.
7. Liquid and solid wastes should be put into designated containers. Used radioactive test solutions may be disposed of by flushing down a laboratory sink drain with copious quantities of water. The radioactivity may be discharged into the sanitary sewage provided the discharge concentration does not exceed  $4 \times 10^{-5}$  microcuries per ml.
8. Before leaving the laboratory after working with radioactive materials, each person should wash his or her hand thoroughly.
9. Prior to disposal of the empty uncontaminated kit and tracer containers to unrestricted areas, remove or deface the radioactive material labels or clearly indicate that the containers no longer contain radioactive materials.
10. Handle the products derived from human blood as is capable of transmitting Hepatitis.

In conclusion, a clean operation is the key to using radioiodine safely and to protecting laboratory personnel from unnecessary exposure. These guidelines are intended to highlight the important aspects of a radiation safety program.

MetPath




ON THE FOLLOWING PAGES IS A COPY OF THE  
FRONT COVER OF A COMP BOOK TITLED "RIA  
KIT LOG-IN MANUAL FOR 1125 ONLY" AND A  
COPY OF THE FIRST PAGE. THIS PROCEDURE  
WILL BE PUT INTO EFFECT 10/18/83 AND  
KEPT IN THE TOP DRAWER UNDER THE PICKER  
COUNTER.

COMP  
BOOK  
RIA KIT LOG-IN MANUAL

For I<sup>125</sup> only

80 SHEETS • 10x7 $\frac{1}{2}$  • COLLEGE & MARGIN • 43-461

 NATIONAL BLANK BOOK COMPANY, INC.  
Holyoke, Massachusetts 01040 • Made in USA

COMP  
BOOK  
RIA KIT LOG-IN MANUAL

For I<sup>123</sup> only

80 SHEETS • 10x7 $\frac{1}{2}$  • COLLEGE & MARGIN • 43-461



NATIONAL BLANK BOOK COMPANY, INC.  
Holyoke, Massachusetts 01040 • Made in USA

Date	# Kits	Test	Total in C
11-19-86	1	Biorad HCG	< 200 uci
11-21-86	1	Biorad HCG	< 200 uci
11/24/86	4	Digitoxin	< 32 uci
12-3-86	3	Digitoxin	< 32 uci
11/21/86	2	Tryptase	< 20 uci
12/5/86	8	HCG Leeco	< 320 uci
12-8-86	1	Biorad HCG	< 200 uci
12/20/86	8	Leeco Hcg	< 320 uci
<del>12-16-86</del>	<del>8</del>	Biorad HCG	< 200 uci
12-23-86	1	Biorad HCG	< 200 uci
12-23-86	3	Digitoxin	< 30 uci
12/30/86	4	Digitoxin	< 32 uci
12/30/86	3	Digitoxin	< 30 uci
12/31/86	8	HCG LEEO	< 320 uci
1-8-87	3	Digitoxin	< 30 uci
1-14-87	1	Biorad HCG	< 200 uci
1-15-87	3	Digitoxin	< 30 uci
1-22-87	3	Digitoxin	< 30 uci
1-28-87	1	Biorad HCG	< 200 uci
1-28-87	6	Digitoxin	< 48 uci
1-29-87	3	DIGOXIN	< 30 uci

90' 58

18.7

Date	# kits	Procedure	Total: curies
9-3-86	2	B-HCG (Cli-Assay)	< 12 $\mu$ ci
9-4-86	3	T <sub>4</sub> MSD	< 30 $\mu$ ci SS
8/29/86	15	B-HCG Leeco	< 600 $\mu$ ci / 86
9/7/86	2	Diagnosis <sup>E</sup> B-HCG (Clin-Assay)	< 30 $\mu$ ci SS
9-10-86	2		16 $\mu$ ci
9-17-86	3	Digoxin	< 40 $\mu$ ci $\beta$
9/22/86	2	B-HCG (Clin Assay)	< 16 $\mu$ ci mg
9/23/86	2	Corning T <sub>3</sub> uptake	< 20 $\mu$ ci SS
9/23	1	Bio-Rad Echo HCG	< 40 $\mu$ ci mg
9/23	4	Phase II Thyroxine	< 4 $\mu$ ci SS
9/11	15	B-HCG LEECO	< 600 $\mu$ ci SS
9/25	2	$\beta$ -HCG	< 16 $\mu$ ci SS
9-29	4	$\beta$ -HCG	32 $\mu$ ci SS
10/2/86	5	Diagnosis	< 40 $\mu$ ci SS
10-1-86	2	B-HCG (CA)	< 16 $\mu$ ci SS
10/6/86	3	B HCG	< 20 $\mu$ ci
10/15	2	HCG	< 16 $\mu$ ci
10-16-86	4	Digoxin	< 40 $\mu$ ci SS
10-16-86	2	B-HCG C.A	< 16 $\mu$ ci SS
10-22-86	4	B-HCG C.A.	< 32 $\mu$ ci
10-22-86	4	Digoxin	< 40 $\mu$ ci SS
10/24-86	6	Thyroxine	< 60 $\mu$ ci SS
10/29/86	4	B-HCG	< 32 $\mu$ ci SS
10-29-86	4	Digoxin	< 40 $\mu$ ci SS
11-5-86	4	Digoxin	< 40 $\mu$ ci SS
11-5-86	4	BHCG	< 320 $\mu$ ci SS
11/12/86	4	Digoxin	< 40 $\mu$ ci SS
11-20-86	3	Digoxin	< 30 $\mu$ ci SS
11/31/86	2	Corning T <sub>3</sub>	< 20 $\mu$ ci SS



## RIA WIPE TEST PROCEDURE

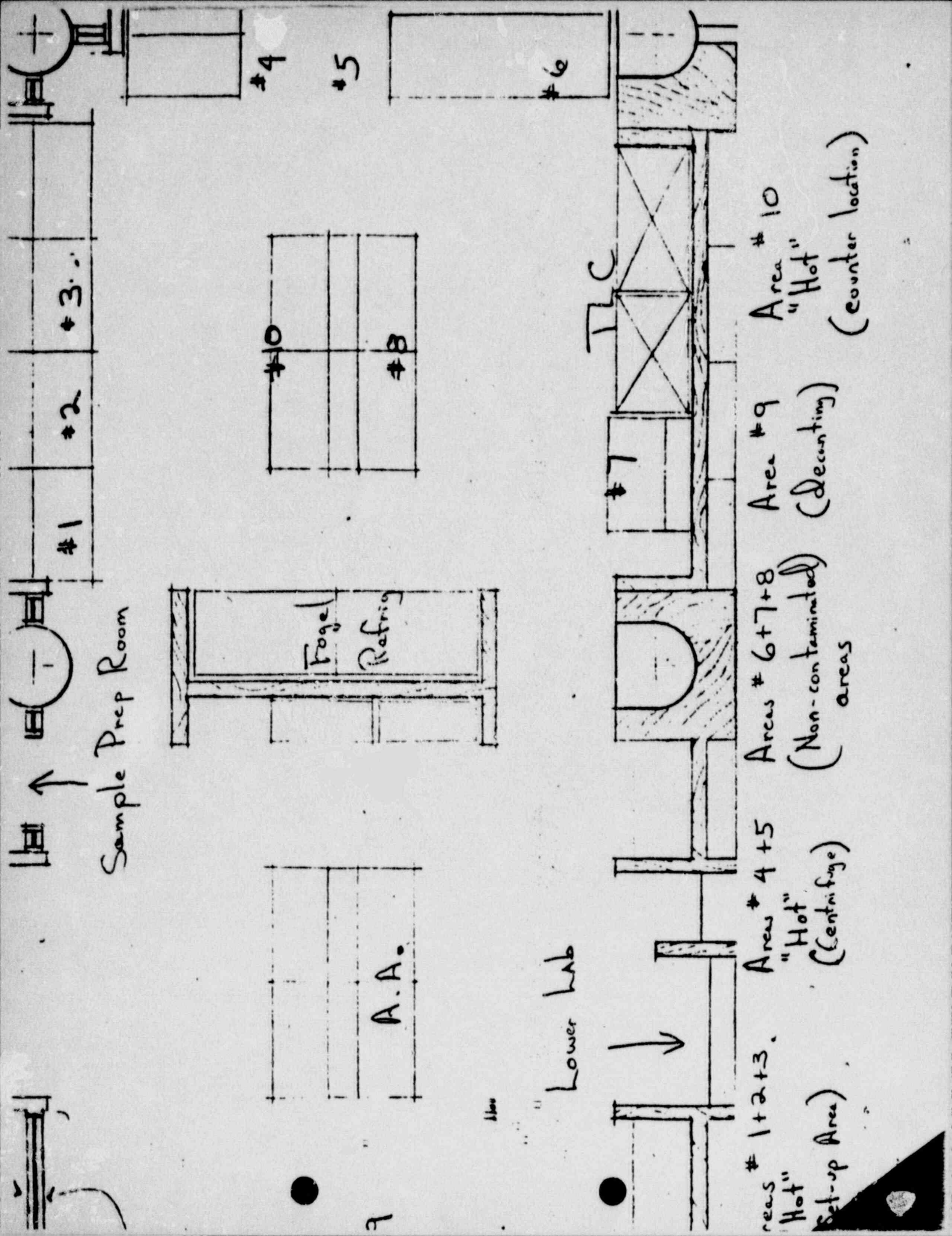
The wipe test involves wiping the decontaminated surface or designated areas with one inch diameter filter paper or a cotton swab, and then counting the filter paper or the swab in a plastic tube (12 X 75 mm) in a Gamma Counter along with a background tube. As a rule of thumb, if the reading in an area exceeds ~~300~~ <sup>100</sup> counts per minute, it should be considered as a "hot" area. *AS 8/20/84*

- 1) Regularity of swabs shall be bi-weekly.
- 2) Number of swabs or wipes shall be ten from areas noted on the attached diagram.
- 3) Type of swab or wipes:
  - a)  $I^{125}$  area will be wiped with a cotton swab or filter paper and counted in a plastic test tube (12 X 75 mm) in a Gamma Counter. A blank test tube with swab or filter paper will be counted as a background for 1 minute.
  - b) Non-RIA bench top area will be wiped with a cotton swab or filter paper and counted in a plastic tube (12 X 75 mm) in a Gamma Counter along with a background with swab or filter paper for 1 minute.
- 4) Data:

A rough schematic drawing of the laboratory, marking where the wipes were taken and a record of the CPM of the wipe and background will be filed in "Wipe Test" file in Radiation Safety Manual. The CPM should not exceed ~~300~~ <sup>100</sup>. *AS 8/20/84*
- 5) Action taken for high count areas:

If absorbent paper is covering bench top, the paper shall be removed and discarded in the radioactive waste drum for iodine. The area is washed with Radiacwash and water and re-monitored. New absorbent paper is placed over the area. The same procedure is used for an area not covered by absorbent paper.

If any of the above situations exist, the supervisor is notified in order to review handling protocol.



Sample Prep Room

Fogel  
Refrig

A.A.

Lower Lab

TLC

# 1+2+3. "Hot" Set-up Area

Areas # 4+5 "Hot" (Centrifuge)

Areas # 6+7+8 (Non-contaminated) areas

Area # 9 (Decanting)

Area # 10 "Hot" (counter location)

# DATA FROM BI-WEEKLY RIA WIPE TEST

Date 12-30-86

Tech JM

<u>Area # (RIA or Non-RIA)</u>	<u>CPM</u>	<u>Action taken if CPM is greater than 1000</u>	<u>CPM after action taken</u>
<u>#1 (RIA)</u>	_____	_____	_____
<u>#2 (RIA)</u>	_____	_____	_____
<u>#3 (RIA)</u>	_____	_____	_____
<u>#4 (RIA)</u>	_____	_____	_____
<u>#5 (RIA)</u>	_____	_____	_____
<u>#6 (Non-RIA)</u>	_____	_____	_____
<u>#7 (Non-RIA)</u>	_____	_____	_____
<u>#8 (Non-RIA)</u>	_____	_____	_____
<u>#9 (RIA)</u>	_____	_____	_____
<u>#10 (RIA)</u>	_____	_____	_____

Wipe Test  
Tubes were counted for: 60 seconds -  
12-30-86

<u>WELL</u>	<u>COUNTS</u>
1	0
2	0
3	0
4	0
5	0
6	0
7	56
8	4
9	0
10	0
11	0
12	0

# DATA FROM BI-WEEKLY RIA WIPE TEST

Date 1-15-87

Tech Jim

Area # (RIA or Non-RIA)    CPM    Action taken if CPM is greater than 1000    CPM after action taken

#1 (RIA)

#2 (RIA)

#3 (RIA)

#4 (RIA)

#5 (RIA)

#6 (Non-RIA)

#7 (Non-RIA)

#8 (Non-RIA)

#9 (RIA)

#10 (RIA)

WIPE TEST  
TUBES WERE COUNTED FOR: 60 SECONDS

1-15-87

WELL	COUNTS
1	39
2	0
3	0
4	58
5	55
6	0
7	10
8	0
9	60 (Sink)
10	0 Refr
11	12 P. chn.
12	0 BL

# DATA FROM BI-WEEKLY RIA WIPE TEST

Date 11/30/87

Tech jm

<u>Area # (RIA or Non-RIA)</u>	<u>CPM</u>	<u>Action taken if CPM is greater than 1000</u>	<u>CPM after action taken</u>
<u>#1 (RIA)</u>	_____	SAMPLE 1 TIME CPM ISO CONC	_____
<u>#2 (RIA)</u>	_____	SAMPLE 1 2 31 RIA	_____
<u>#3 (RIA)</u>	_____	4 25 RIA	_____
<u>#4 (RIA)</u>	_____	NO CONC - 1+/-EXT	_____
<u>#5 (RIA)</u>	_____	SAMPLE 1 5 27 RIA	_____
<u>#6 (Non-RIA)</u>	_____	6 23 RIA	_____
<u>#7 (Non-RIA)</u>	_____	NO CONC - 1+/-EXT	_____
<u>#8 (Non-RIA)</u>	_____	SAMPLE 1 7 24 RIA	_____
<u>#9 (RIA)</u>	_____	8 33 NM RIA	_____
<u>#10 (RIA)</u>	_____	NO CONC - 1+/-EXT	_____
		SAMPLE 1 9 28 NM RIA	_____
		10 29 RIA	_____
		NO CONC - 1+/-EXT	_____
		SAMPLE 1 11 25 - RIA	_____

BETWEEN: C. James Holloway, Chief  
License Fee Management Branch  
Office of Resource Management

John E. Glenn, Chief  
Nuclear Materials Safety & Safeguards Section B  
Division of Radiation Safety and Safeguards

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: Met Path, Inc.  
Application Dated: 5-15-87  
Control No.: 107295  
License No.: New

2. FEE ATTACHED

Amount: \$230  
Check No.: 225639

3. COMMENTS

Signed: SLJ  
Date: 5-22-87

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3P \$230

2. Correct Fee Paid. Application may be processed for:

Amendment \_\_\_\_\_  
Renewal \_\_\_\_\_  
License  \_\_\_\_\_

Signed: A. Kimberly  
Date: 6/4/87