L = 19205
030-22109
03123

METPATH

NEW ENGLAND REGION

February 12, 1985

Mr. John D. Kinneman, Chief
Nuclear Materials Section A
Division of Engineering and
Technical Programs
U.S. Nuclear Regulatory Commission
Region 1
631 Park Avenue
King of Prussia, PA 19406

Dear Mr. Kinneman:

Enclosed is the application, supportive documentation, and fee for new application for our license. I regret not having seen the earlier correspondence received by my office, and ask your forbearance with our laboratory's lack of compliance. Please call or write to me at the address below if there are questions about this application or my documentation.

Sincerely,

James E. Stewart

JES:nl

James E. Stewart, Ph.D.
Laboratory Director

Enc.

"OFFICIAL RECORD COPY"

ML18 03428

8510280250 850906
REG1 LIC30
20-19205-01 PDR

RECEIVED-REGION 1
1985 FEB 14 AM 11: 33

FEB 14 1985

4 Fenway Plaza • Boston, Massachusetts 02215 • (617) 262-6100

030-22109 L-19205

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

03123

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)*

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 20-19205-01

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

MetPath Stat Toxicology Service
of Boston, Inc.
4 Fenway Plaza
Boston, MA 02215

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

MetPath Stat Toxicology Service
of Boston, Inc.
4 Fenway Plaza
Boston, MA 02215

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James E. Stewart, Ph.D.

TELEPHONE NUMBER: 617-262-6100

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 170.31)*
FEE CATEGORY | AMOUNT ENCLOSED $

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

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
James E. Stewart	James E. Stewart	Laboratory Director	3/4/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] < $250K
- [ ] $250K – 500K
- [ ] $500K – 750K
- [X] $750K – 1M
- [ ] $1M – 3.5M
- [ ] $3.5M – 7M
- [ ] $7M – 10M
- [ ] > $10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*
60 F T E

c. NUMBER OF BEDS
Not applicable

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)*
- [X] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
CAT. L	FC169 I	3P	"OFFICIAL RECORD COPY" (Verified) 03123E	Frances Brown
AMOUNT RECEIVED	CHECK NUMBER			DATE
$140 + 190	336/353		ML18 No refund due if application denied. EB 14 1985	3/11/85

PRIVACY ACT STATEMENT ON THE REVERSE

DUPE 8510080276 58

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY**: Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)**: The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES**: The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION**: Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS**: U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

5. No change from information in previously submitted applications. This facility uses ^{125}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 200 µCi.

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}Co and ^{125}I of 12 years.
   Research laboratory studies of RIA and *in vivo* applications including ^{32}P, ^{3}H, and ^{45}Ca in laboratory animals.

8. Training: All employees are B.S. Chemistry degrees or Medical Technology training. All are trained in the safe 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-48

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 4×10^{-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 4×10^{-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.

JE:/nl
9/26/83
JES 8/20/84

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~~ 100 counts per minute, it should be considered as a "hot" area. JS 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~~ 100. JS 8/20/84

5) Action taken for high count areas:

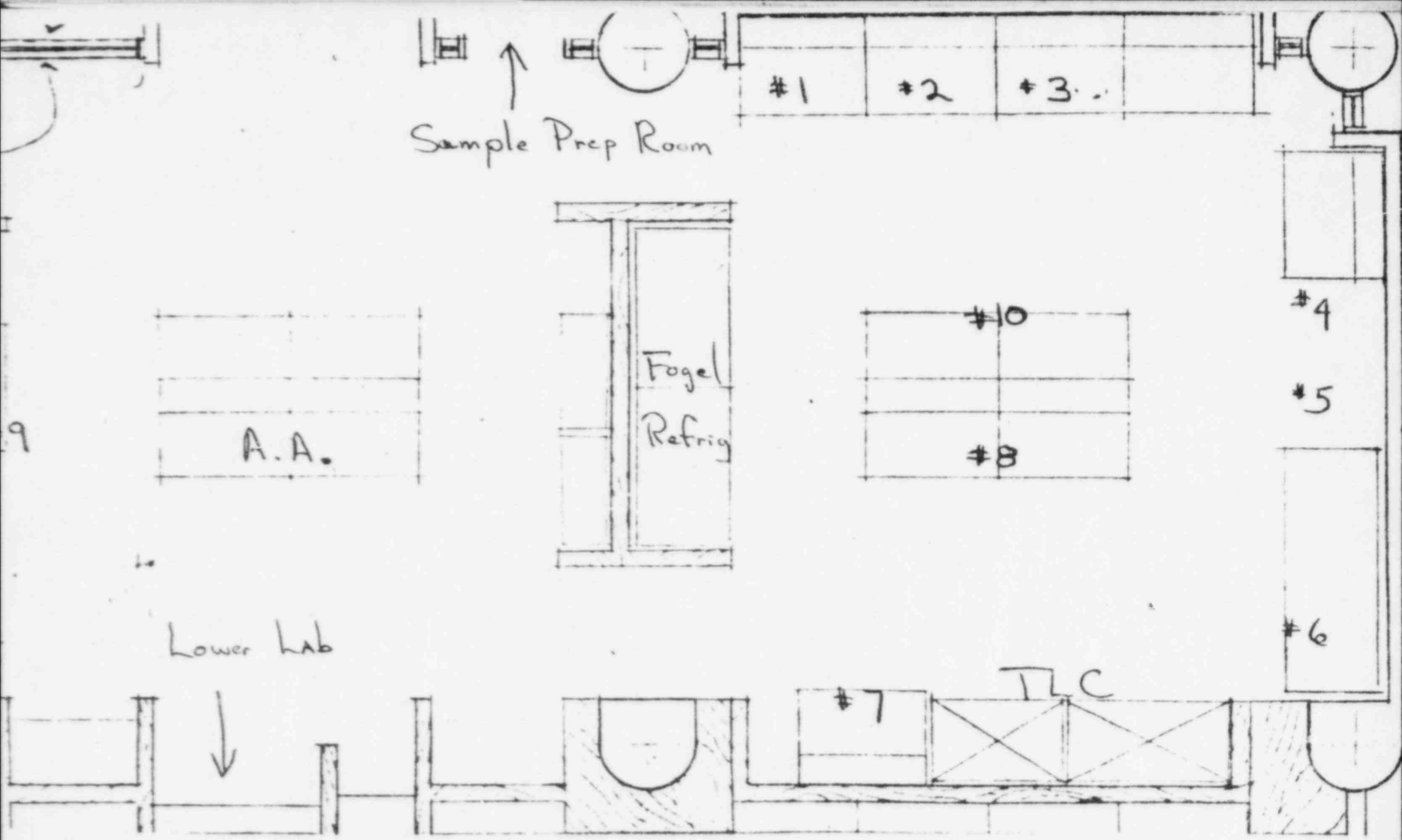
   If absorbent paper is covering bench top, the paper shall be removed and discarded in the radioactive waste drum for iodine. The area is washed with Radiacwash and water and re-monitored. New absorbent paper is placed over the area. The same procedure is used for an area not covered by absorbent paper.

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

JES/nl
10/12/83

JE Shurvell
10/14/83

8/20/84


#1
#2
#3
Sample Prep Room
#4
#5
#6
#10
#8
Fogel
Refrig
A.A.
Lower Lab
#7
T L C
reas # 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)

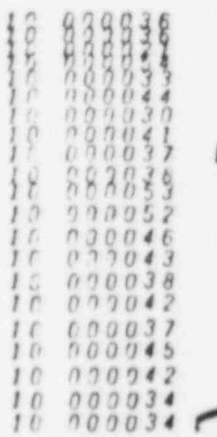
DATA FROM BI-WEEKLY RIA WIPE TEST

Date 8/19/84
Tech JM

Area	# (RIA or Non-RIA)	CPM	Action taked if CPM is greater than 1000	CPM after action take
			All the CPM are below the hot area limit for	
#1	(RIA)			
#2	(RIA)			
#3	(RIA)			
#4	(RIA)			
#5	(RIA)			
#6	(Non-RIA)			
#7	(Non-RIA)			
#8	(Non-RIA)			
#9	(RIA)			
#10	(RIA)			

8/20/84

CPM



Bkg
8/19/84

This file shows sufficient information to warrant lowering the wipeable limit to max 100cpm above bkg. JS 8/20/84

FROM BI-WEEKLY RIA WIPE TE

Date 10/16/
Tech M. JJ

Area #	(RIA or Non-RIA)	CPM - B.G.	Action taken if CPM is greater than 1000	CPM after action - B.G.
#1	(RIA)	11		
#2	(RIA)	9		
#3	(RIA)	6		
#4	(RIA)	00		
#5	(RIA)	4		
#6	(Non-RIA)	8		
#7	(Non-RIA)	2.		
#8	(Non-RIA)	8.		
#9	(RIA)	725	Washed.	35
#10	(RIA)	10		

8/20/84

METPATH

ON THE FOLLOWING PAGES IS A COPY OF THE FRONT COVER OF A COMP BOOK TITLED "RIA KIT LOG-IN MANUAL FOR I^{125} 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.

John F. Bom

10-17-83

COMP
BOOK

RIA KIT LOG-IN MANU

For I^{125} only

80 SHEETS · 10x7⅞ · COLLEGE & MARGIN · 43-461

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

4 Sheets
1-2/12/85

Date	# Kits Received	Test procedure	# Micuries received
10/4/84	8	Digoxin	8uci afm
10/8/84	1-500 tube	Genta	11uci BT
10/8/84	1-500 tube	Tobra	1 10uci BT
10/9/84	1	Estriol	7uCi Afm
10/15/84	1-500 tube	Genta	11uci BT
10/17/84	7	B sub	56uci BT
10/18/84	6	Digoxin	6uci afm
10/22/84	1-500 tube	Genta	11uci BT
10/23/84	T4 bulk 500 tube	T4	25uci SS
10/25/84	4	Digoxin	4 uci afm
10/25/84	2	Digoxin	< 20 µCi ee
10/27/84	7	B Sub	56 uci TR
10/29/84	1	Estriol	7uci Afm
10/30/84	3	T3 Uptake	<30 uci SS
10/31	7	B-SUB	56 uci RB
11/1/84	2	Dig	20uci afm
11-7-84	4	Digoxin	4 uci jm
11/7/84	7	B Sub	56 uci TR
11/14/84	1-500 tube	Genta	10uCi jm
11-14-84	7	B-HCG	56 µCi ee
11-21-84	7	B-HCG	56 uCi TR
11-29-84	3	T3 Uptake	<30 µCi SS
12/1/84	6	Dig	6uci afm
12/4/84	1	Amikacin	~ 5 µCi LT
12/6/84	1	B HCG	56 uCi afm
12/6/84	0	Dig	6uci afm
12/7/84	1 Bulk	T4	<25 µCi SS
12/10/84	1-500 tube	Genta	1 10uci Afm
12/11/84	4	Digitoxin	28 µCi KT
12/12/84	7	5-HIAA	56 uci R

12/11/85

Date	# Kits Recd	Test Procedure	# mcuries Recd
12/11/89	1-500s tube	Genta	440uci apn
12/20/84	6	Digoxin	35uci BG
12/20/84	7	B Hcg	56uci BG
12/26/84	1 - 500 tube	Genta	100uCi LT
12/27/89	6	Dig	35uci LT
12/27/89	~~6~~ 4	B Hcg	56uci apn
12/31/8-	1 - SW tube	Genta	1.0uCi RT
1/3/85	7	B-HCG	56 uCi LT
1/7/85	1-500 tube	Genta	100 uci apn
1/11/85	~~6~~ 6	Dig	35 uci hn
1/15/85	4	Digoxin	28 uci jnn
1/18/85	500 Tube Bulk	Dig	90 uci apn
1/22/85	5	T4	25 uci SS
1/22/85	1	T3 uptake	30 uci SJ
2/6/85		Amikacin	5 uCi G