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MS-1.6

June 17, 2005

Thomas K. Thompson  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region 1  
475 Allendale Road  
King of Prussia, Pa. 19406-1415

RE: License 37-28294-01  
Docket No. 03030859  
Control No. 136478

Dear Mr. Thompson:

Enclosed is the information you requested pertaining to the renewal of the Quest Diagnostics NRC License #37-28294-01. The information addresses question #10, Radiation Safety Program, on the License Reviewer Checklist. Also included is the Laboratory layout where testing with radioactive materials is performed.

If you have additional questions or concerns, please do not hesitate to contact me directly. My phone number is 215-442-7656.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda Dickson".

Linda Dickson  
Special Chemistry Manager  
Radiation Safety Officer

136478  
NMSS/RGNI MATERIALS-002

## **RADIOACTIVE MATERIAL**

<b>Element and Mass Number</b>	<b>Chemical and/or Physical Form</b>	<b>Maximum Amount Possessed at any One Time</b>
<b>Iodine 125*</b>	<b>Packaged Kits</b>	<b>6523 Microcuries</b>

\*Iodine 125 is used for in-vitro clinical testing of patient samples.

## **FACILITIES AND EQUIPMENT**

### **FACILITIES:**

The RIA Department is contained within the Immunochemistry Department. Attached is a diagram of the area where use of radioactive material is permitted.

### **EQUIPMENT:**

#### **Gamma Counters:**

IsoData Gamma Counter. Serial #5001646/507215

The gamma counters are calibrated daily using iso-calibrators reference sources supplied by PolyMedco BioMedicals, Inc.

In addition, daily QC is performed and recorded for each instrument to check the following:

- a. Background
- b. Factor Values
- b. % Difference between wells
- c. % Efficiency

**Survey Meters:**

Two survey meters are in use:

Ludlum Model #2/44-3  
Serial #63666/83765

Both of the survey meters are calibrated annually by:  
JRT Calibration Services  
1200 E High Street, Suite 111  
Pottstown, PA 19464

Calibration certificates are on file in the Radiation Procedures and Safety manual.

**RADIATION SAFETY PROGRAM**

1. To ensure an adequate inventory and minimization of the amount of radioactivity kept in the laboratory, the RIA supervisor must review all supply orders.
2. Upon receipt of all radioactive supplies, the RIA test kits are visually inspected for damage or leakage.
  - a. If undamaged, follow proper log in procedures and place in storage.
  - b. If the package is crushed, torn, punctured or wet suggesting leakage, it must be checked for radiation. Perform a Wipe Test. If the wipe test exceeds background counts of 65 DPM, take the appropriate steps as follows:
    - 1) Notify the supervisor, radiation safety officer, or the laboratory manager.
    - 2) Notify the carrier and supplier/manufacturer.
    - 3) Notify the NRC Regional Office:  

Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406
    - 4) Complete and file an incident report documenting the date, time of receipt, condition of package, surface activity, procedures followed and people notified.
    - 5) Give the incident report to the radiation safety officer and lab manager.  
Copies should go to:

Administration  
Safety Officer  
Lab Director

## Lab File

- 6) Place packages in a plastic bag to avoid further leakage and place in storage area.

### LOG IN PROCEDURES

1. All kits are marked with the date received and numbered.
2. All test kits are then logged into the RIA supply logbook and the following information is recorded:
  - a. Date received
  - b. Type of kit received
  - c. Number of each kit received
  - d. Lot number of each kit
  - e. Expiration date of each it
  - f. Total amount of microcuries contained in each test kit
3. All test kits are placed in the designated RIA storage refrigerator, which is secured by a lock.

### RADIATION WASTE DISPOSAL PROCEDURES

1. The NRC permits small amounts of I125 to be disposed of through a selected sink drain flushed with copious amounts of water. The concentration after dilution with the building discharge must not exceed  $2 \times 10^{-5}$  uCi/mL per month. Current disposal is no greater than 100 uCi I125 per day.
2. The sink by the Hepatitis Station is designated as the only radioactive disposal sink in Immunochemistry. All radioactive liquid waste must be flushed down this sink. Flush drain for ten minutes with water after radioactive disposal.
3. All other dry radioactive materials, including test tubes, empty isotope bottles and contaminated absorbent paper must be placed directly into the radioactive waste container.
4. When can is full, close and secure with steel ring provided. Notify stockroom person to have it removed and replaced with an empty can.
5. Solid waste is stored in the warehouse until removed by the Isotope Disposal Service:

ADCO Services, Inc.  
17650 Duvan Drive  
Tinley Park, IL 60477  
(708) 429-1660  
Fax (708) 429-9759
6. No radioactive material is incinerated.

7. In the event the primary vendor is no longer available to remove the radioactive waste, refer to the Emergency Radioactive Waste Removal SOP.

## **HANDLING OF RADIONUCLIDES**

### **Liquids:**

1. Do not pipet or handle radioactive liquids directly. Remove liquid from vials with automatic pipetting devices provided.
2. Wash hands after each procedure.
3. No smoking or eating is permitted in any portion of the laboratory.
4. All test procedures and reagent preparations are performed on plastic backed disposable absorbent paper.
5. At the end of each work shift or after a spill occurs, the absorbent paper is disposed of in the RIA waste container and the work area is cleaned with I Bind followed by 5% Contrad Cleaning Solution. After this procedure is complete the technician will initial the decontamination log sheet.
6. Weekly radiation wipe tests are performed in all designated area where radioactive materials are used.
7. Records of the wipe tests are filed and reviewed monthly by the RIA department manager.

### **Clothing:**

1. Lab coats, face shields and gloves must be worn at all times when handling radioactive material.
2. If lab coat becomes contaminated with radioactive material change immediately. Have coat cleaned or set aside until the radioactivity decays.
3. The technologist performing RIA procedures will survey the PPE worn at the end of the shift for radioactive contamination using the survey meter. Refer to the Geiger Counter Survey SOP.

### **Biomedical Waste and Countertops:**

1. The technologist performing RIA procedures will survey the biomedical waste before disposal and survey the countertops used after decontamination for possible radioactive contamination. Refer to: Geiger Counter Survey SOP.

### **Personnel Monitoring:**

1. All employees in the RIA laboratory are provided with film body badges by Global Dosimetry Solutions.

2. Film badges are evaluated monthly to determine personnel exposure levels.
3. All employee exposure reports are kept on file in the RIA laboratory.

#### **Personnel Notification and Restrictions:**

Federal regulations require posting of the following:

- 1) Regulations pertaining to notices, instructions and reports.
- 2) License and conditions: on file in the laboratory.
- 3) Notices: on bulletin boards

#### **Personnel Safety Procedures**

- 1) Only those who have been instructed in proper techniques and safety precautions will handle radionuclides.
- 2) Declared pregnant women are advised of potential hazards and are excluded from working with radioactive materials.
- 3) No pipetting by mouth is permitted.
- 4) Hands should be covered with gloves during handling of radioactive materials and thoroughly washed after handling.

#### **EMERGENCY PROCEDURES:**

Except for a major accident to a shipping container or a serious spill in the RIA laboratory, the amount of radioactive material in a spill will usually be small and the radiation from it will not constitute a serious hazard. The real danger is the spread of the contamination on shoes or other contaminated garments. The following is a general outline of the procedure to be followed in the event of a spill.

1. Confine the spill immediately by dropping paper towels or other absorbent material onto it.
2. Put on waterproof gloves.
3. Check shoes for visible signs of contamination. If it appears possible that they are contaminated, remove shoes when leaving the contaminated region.
4. If fans or ventilators are operating in the area, they should be turned off. This should be performed by someone not involved in the spill so that the contamination is not spread.

5. Mark off or isolate the entire suspected area and police it to be sure that no one walks through. If any of the spilled material has splashed onto an individual or his/her clothing, immediate steps should be taken to remove it. Lab coats or other outer garments should be removed and left in the contaminated area. Hands or other exposed areas should be washed thoroughly with soap and water immediately and rinsed in the designated radioactive sink.
6. When it has been determined that there is no contamination on the shoes or feet, it is permissible to walk to a washing facility immediately. The washing facility must then be treated as a contaminated area until cleared by the radiation safety officer. If there is doubt about contamination of the feet, a washbowl and soap should be brought to the contaminated area for the individual.
7. The radiation safety officer will bring decontamination materials and a survey meter. The clean up operation will then proceed under his/her direction.
8. If the radiation safety officer is not immediately available, clean up must proceed under the supervision of the manager on duty.
9. Clean up procedure is as follows:
  - a. Put on appropriate protective clothing.
  - b. Place absorbent paper directly on spill and take up using forceps or tongs.
  - c. Immediately place absorbent paper into a waterproof container.
  - d. After spill is removed, clean contaminated surface with damp cloths held with forceps. Always work toward the center of the contaminated
10. Use a survey meter to monitor the contaminated area and personnel. The meter should be operated by someone not involved in the spill to ensure there is no contamination of the survey meter.
11. After a spill and proper decontamination, reduction of the counting rate to background, 200-500 cpm or 1176-2941 dpm is satisfactory. Radiation safety officer should check the area and give it clearance.

In addition, a Wipe Test should be performed to ensure that proper decontamination and a background of 65 DPM or less has been achieved.

12. When the operation is finished, gloves and other protective garments should be carefully checked for residual contamination. If any is found, the garments should remain with the other contaminated material for disposal by the radiation safety officer.

## 11. CHANGES IN 10CFR PART 20

### Occupational Dose Limits:

#### External Exposure

- a. The annual dose limit of 5 REMS per individual is the Total Effective Dose Equivalent (TEDE). The TEDE is the sum of the deep dose equivalent (DDE) at a depth of 1 CM and the Committed Effective Dose Equivalent (CEDE) to a person. The CEDE for a person is the sum of the CEDE for 11 organs. No organ or tissue is allowed to receive more than 50 REMS, DDE plus CDE, in a year.
- b. Licensees are required to provide individual monitoring for workers likely to receive more than 10% of the annual limits on external dose.
- c. In use are Global Dosimetry Solutions Film Badges that must be worn daily in the Immunochemistry Department. The Dose Equivalent is reported in millirems for a period of time indicated on the report. If an asterisk is reported, the film indicates exposure is less than 10 millirems. All values above 10 millirems will be investigated as to the source of possible exposure.
- d. Limits for minors are 10% lower than those established for workers who are in a restricted area.

#### Internal Exposure

- a. The amount of I125 in use is extremely small and monitoring the amount of radioactive intake is not required.

#### Dose to an Embryo/Fetus:

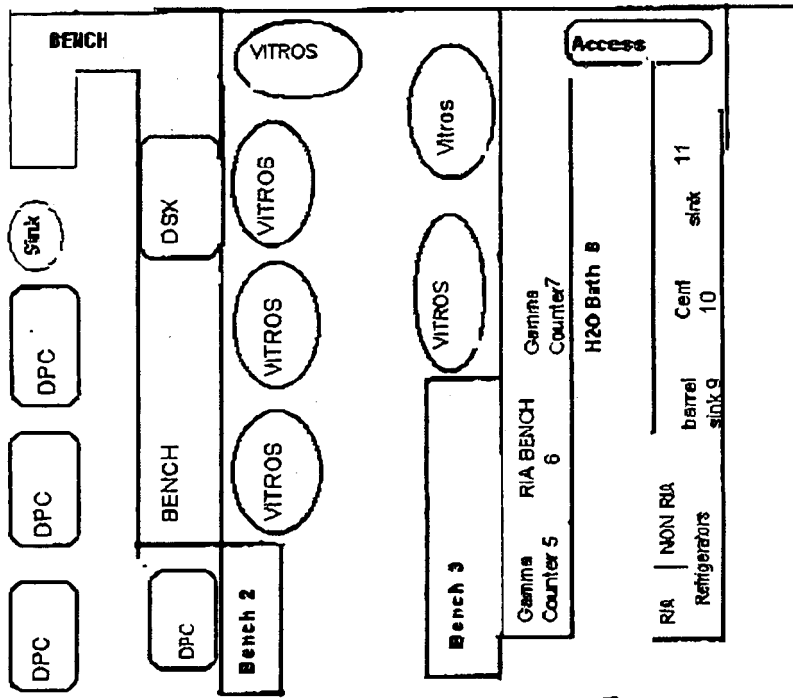
- a. The human organism from conception to birth is defined as an embryo/fetus.
- b. Licensees must make efforts to avoid doses to declared pregnant women in excess about 55 mRem in a month.
- c. The amount of radiation received in working with I125 is below 55 mRem/month. Declared pregnant women are advised of potential hazards and are excluded from performing RIA testing.

#### Radiation Dose Limits for Members of the Public.

- a. The limit is established as 0.1 REM TEDE in a year.
- b. The limit of 2 mREM in an hour in an UNRESTRICTED area. An unrestricted area is the area outside the Immunochemistry Department.
- c. Personnel other than workers trained in the use and handling of radioactive are limited to 0.1 REM TEDE in a year.



**IMMUNOCHEMISTRY ENVIRONMENTAL RADIATION SURVEY: SURVEY  
METER & SWIPE TEST**



1

KEY	DESCRIPTION	METER COUNT
1	Entrance by the DPC AREA	
2	Hepatitis Counter Top Area 2	
3	Hepatitis Counter Top Area 3	
4	Entrance by Refrigerator	
5	Gamma Counter (Across from Refrigerator)	
6	RIA Counter Top	
7	Gamma Counter (Across from the Sink)	
8	Water Bath	
9	Sink (Near Radiation Barrel)	
10	Centrifuge	
11	Counter Top Next to Access	

<b>DATE:</b>	<b>ANALYST:</b>
<b>REVIEWED BY:</b>	<b>SURVEY METER #:</b>
<b>BCGD. CPM:</b>	<b>DATE CALIBRATED:</b>
<b>EXPIRATION DATE:</b>	<b>I-125 SWIPE TEST ACCEPTABLE RANGE &lt; 65 DPM</b>

*Approved 5/19/05  
Linda Richardson, DC.*