DIANON SYSTEMS

Diagnostic Innovations for Oncology

MS16
P2

January 9, 1987

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region 1
631 Park Avenue
King of Prussia, Pennsylvania 19406

Re: Docket No. 030-29575
Control No. 119933

Dear Dr. Glenn:

This is in response to your letter of December 15, 1986.

1. I have enclosed a copy of our procedures for receiving incoming packages of I-125 Reagents. Incoming packages of I-125 contain less than 20 microcuries each. My understanding of 10 CFR 20.205 (b)(1)(ii) is that such packages are exempt from the requirement of monitoring the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents. If I am mistaken, please advise me.

2. Enclosed find our procedures and forms for performing area surveys with a Geiger counter and work surface monitoring (wipe tests). Included in these procedures are the method of converting counts per minute detected in the wipe test to dpm per 100 cm^2.

3. Enclosed please find a copy of our Radiation Safety Procedures in the RIA laboratory. You will notice that these procedures do not include a provision for monitoring hands and clothing for contamination after each procedure or before leaving the area. Medical technologists wear laboratory coats and rubber gloves at all times when handling radioactive reagents. These laboratory coats are laundered once a week and are left at the laboratory when the technologist goes home in the evening. The gloves are thrown into the waste. Each vial of I-125 reagents used contains less than 20 uCi of radioactivity and and most

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contain less than 10 uCi. Microliter amounts of this radioactivity is used at any one time. Technologists are also instructed to wash their hands frequently, not only to protect themselves from radioactive contamination but particularly because of the biological hazard of the human specimens with which they are working.

As noted in our original application, all personnel wear a badge which contains lithium fluoride thermoluminescent dosimeters. These badges are submitted quarterly to TMA/Eberline of Albuquerque, New Mexico, and records of occupational radiation exposure are retained on all employees. It is my belief that these procedures, plus the fact that we use low levels of radioactivity, eliminate the necessity of daily monitoring of hands and clothing. I would appreciate your guidance in this regard.

4. Sewage disposal - At the present time we use approximately 10^5 uCi of I-125 per year. This is equivalent to approximately 33 uCi per day. At least 50% of this is disposed of as solid waste. Procedural processing in the laboratory dilutes this radioactivity to approximately 5×10^{-3} uCi/mL. A conservative estimate of the water usage by our laboratory and its forty personnel is 1.4×10^6 mL per day. My estimate, therefore, is that our disposal of radioactivity to the sewage system each day is in a concentration of approximately 1.4×10^{-5} uCi/mL which is within the limits specified in Section 20.303 of 10 CFR Part 20.

Sincerely,

Phillenore D. Howard

Phillenore D. Howard, Ph.D.
Vice President of
Laboratory Operations

PDH:mbt

enclosures

LABORATORY PROCEDURES

PREPARED BY:	TITLE:	EFFECTIVE DATE:
P. HOWARD	RECEIPT OF PACKAGE CONTAINING I-125	1/8/87
		PAGE: 1 OF 1

1. Upon receipt of reagents containing I-125, document the number of kits received on the packing slip.

2. Write on the outside of the package the data of receipt and place packages in the refrigerator with the oldest packages to the front.

3. Record the total amount of radioactivity (in microcuries) in the Radioactivity Log by product.

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STRATFORD, CT 06497

RADIOACTIVE MATERIALS LOG

Specific Test

Test _____

	Date Rec'd	MFGR	Lot #	Expire Date	# of kits	uCi/ kit	Total Rec'd	Total on hand	
1									1
2									2
3									3
4									4
5									5
6									6
7									7
8									8
9									9
10									10
11									11
12									12
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26									26
27									27
28									28
29									29
30									30
31									31

PREPARED BY:	TITLE: PROCEDURE FOR USE OF CONTAMINATION MONITOR Minimonitor 125, Model 05-572	EFFECTIVE DATE: 1/8/87
P. HOWARD		PAGE: 1 OF 1

1. Set Dial on range 0-500.

2. Test battery. Replace if necessary.

3. Determine background count on desk surface in office area:

   a) Turn monitor on leaving protective plastic cap on.

   b) Place monitor 5 mm from the surface to be tested and wait ten seconds for the meter to equilibrate.

   c) Record counts per minute on Form C.

4. Determine counts in the following areas and record location and counts per minute detected on Form C.

   Floor at entrance to lab
   Accessioning area
   Around all gamma counters
   All work surfaces
   Sinks

5. If counts greater than background are found at entrances to the lab notify the Laboratory Director.

6. Any area found to have counts greater than background should be scheduled for a Wipe Test.

FORM C

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RADIATION MONITORING LOG

DATE	LOCATION	CPM	INITIALS

LABORATORY PROCEDURES

PREPARED BY:	TITLE:	EFFECTIVE DATE:
P. D. Howard	WORK SURFACE MONITORING Wipe Test	1/8/87
		PAGE: 1 OF 1

Perform wipe tests in the designated areas on a monthly basis. Document on Form D.

A. Moisten a cotton swab and wipe an 10cm x 10 cm area.

B. Place the swab into a 12 x 75 non-disposable tube for counting. Label to identify area.

C. Repeat the above process for all designated areas.

D. Count a background count and the "wipes" from each area for one minute in the gamma counter.

E. Convert cpm to DPM per 100 cm^2 by using the following formula:

$$\frac{cpm}{0.81} = dpm/100\ cm^2$$

Where 0.81 is the average efficiency of the Gamma counter.

F. Record the final value on Form D in the DPM row.

G. If any "wiped" area exceeds the background count, significantly, (2 times) decontaminate with detergent, rinse with water and wipe dry. Repeat "wipe test". Repeat the process until wipe test is in the same range as the background counts.

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FORM D

WIPE TEST (CPM)

DATE		1	2	3	4	5	6	7	8	9	10	11	12	13	14	BKG.	* INITIALS
	CPM																
	DPM																
	CPM																
	DPM																
	CPM																
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Wipe Areas: (see diagram)
1-3 Sinks
4-12 Work Benches
13-14 Gamma Counter Areas

* Your initials in this column verify that a function test was performed on the Gamma Counter before counting.

LABORATORY PROCEDURES

PREPARED BY:	TITLE:	EFFECTIVE DATE:
P. HOWARD	LABORTATORY SAFETY PRECAUTIONS	1/8/87
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1. Kits contain human blood components. No known test method can offer complete assurance that products derived from human blood will not transmit hepatitis and other viral infections. Therefore, all blood derivatives should be considered potentially infectious. In addition, some kit components contain radioactive I-125 which can be damaging to internal tissues and organs if ingested.

2. Do not pipette by mouth.

3. Do not smoke, eat, drink or apply cosmetics in areas in which specimens or kit reagents are used or handled.

4. Laboratory coats and gloves shall be worn at all times when handling reagents and specimens, and when performing analyses.

5. All reagents, including radioactive reagents, are to be stored in stoppered containers, clearly marked with name of compound, concentration, radionuclide, activity, and date prepared.

6. Avoid splashing or forming an aerosal.

7. Avoid contact of OPD, sulfuric acid, and other toxic chemicals with skin and mucous membranes. If these reagents come in contact with skin, wash with water.

8. Decontaminate and dispose of specimens and all potentially contaminated materials by autoclaving according to standard procedures.

9. Food will be stored and used only in the kitchen area and in the front office area.