MALLINCKRODT, INC.
Diagnostic Imaging Services
9455 Midwest Avenue
Garfield Heights, OH 44125

SUBJECT: Air Monitoring Program

OBJECTIVE: Measurement and Control of Airborne Concentrations of Radionuclides

RESPONSIBILITY: Site RSO

SCHEDULE: As specified in this procedure

PROCEDURE:

1. Measurement Frequency

   1.1 Monthly measurements shall be taken in any restricted areas wherein airborne radioactivity concentrations are less than 0.25 MPC (25 percent of permissible).

   1.2 Weekly measurements shall be taken in any restricted areas wherein airborne radioactivity concentrations exceed 0.25 MPC (25 percent of permissible) but are less than 1.0 MPC.

   1.3 Daily measurements shall be taken in any areas restricted wherein airborne radioactivity concentrations exceed 1.0 MPC (100 percent of permissible).

2. Instrumentation

   2.1 Measurements are performed with a NaI well-crystal scintillation detector connected to either a single-channel or multi-channel analyzer.

   2.2 The lower energy level is set at 10 keV.

   2.3 The upper energy level is set at 1 meV.

   2.4 Specific regions of interest (ROI) may be set for any photopeaks which are identified.

3. Calibration

   3.1 Calibrate with an I-131 source of known activity or a calibration source traceable to NBS Standards.

   3.2 Obtain calibration standards for other specific radionuclides which are identified in air samples by gamma spectroscopy (if applicable).

   3.3 Place the calibration source in the well. Count the source for at least 2 minutes and record the countrate.

3.4 Place an unused air sampling cartridge in the well. Count the cartridge for 10 minutes and record as background.

3.5 Determine the instrument calibration factor (F) by dividing the source activity by the net countrate.

F = source activity (uCi)/Net source countrate (CPM)

4. Sampling System

4.1 Centralized vacuum pump with manifold for multiple sampling lines.

4.2 Limiting orifices (21 gauge needles) installed to limit air flow to between 1 and 2 liters per minute.

4.3 Dropper lines from the ceiling at various points of interest.

4.4 Two sampling points in the glovebox exhaust duct - one on the upstream (unfiltered) side, and one on the downstream (filtered) side of the glovebox HEPA/charcoal filter.

4.5 Labels to indicate air flow direction and sample identification number.

5. Air Sample Collection

5.1 Label and number the air sampling cartridges and connect them to the air sampling lines with the arrow in the direction of flow.

5.2 Start the pump and record the sample start time.

5.3 Record the initial flow rate through each of the in-line rotometers for the glovebox. Connect the hand-held rotometer sequentially to the other cartridges and record the initial flow rates.

5.4 Sample for 24 hours and record the final flow rates.

5.5 Stop the pump and record the sample stop time.

5.6 Collect the air sampling cartridges for counting.

6. Air Sample Measurement

6.1 Insert the air sampling cartridge in the well.

6.2 Set the analyzer to count from 10 Kev to 1 Mev.

6.3 Record the sample identification number, count the sample for 10 minutes, and record the countrate.

6.4 Attribute all counts to I-131 if no photopeaks are identified from other radionuclides.

6.5 Set the analyzer for specific regions of interest if other radionuclides are identified and repeat step 6.3.

6.6 Subtract the background countrate from the sample countrate to obtain net sample CPM.

6.7 Calculate the sample activity in microcuries.

A = net sample countrate (CPM) x F (uCi/CPM)

6.8 Calculate the total ml sampled for each station.

V = average LPM x 1000ml/L x minutes sampled

6.9 Calculate the air concentration for each station.

C = A (uCi) / V (ml)

7. Contingency Measures

7.1 In case of a spill or other release of radioactive materials, a set of air samples shall be taken during cleanup operations and another set shall be taken after completion of cleanup.

7.2 Unused air sampling cartridges should be installed at each sampling station whenever the air sampling system is not in operation (standby mode).

7.3 If a release has occurred and system is in standby mode, start the pump and record the sample start time.

7.4 After cleanup, measure and record the flow rate through each air sampling cartridge.

7.5 Stop the pump and record the sample stop time.

7.6 Collect the air sampling cartridges for counting.

7.7 Follow Step 5 of this procedure and collect another set of samples for at least one hour.

7.8 Measure all air samples by following Step 6.

8. Interpretation of Results

8.1 Restricted areas

8.11 Calculate the fractional maximum permissible concentration for each station using the MPC in Table 2, Column 1.

FMPC = C / MPC

8.12 Perform this step only if the FMPC exceeds 0.25 (25 percent of permissible). Calculate the MPC-hrs based upon an individual's occupancy time per week.

MPC-hrs = FMPC x hours per week

8.13 Compare the MPC-hrs from Step 8.12 to the action levels specified in Step 9.1 of this procedure.

8.2 Effluent to unrestricted areas

8.21 Calculate the fractional maximum permissible concentration for each station using the MPC in Table 2, Column 2.

FMPC = C / MPC

8.22 Perform this step only if the FMPC from Step 8.21 exceeds 1.0. Check action levels specified in Step 9.2 of this procedure.

8.3 HEPA/charcoal filtration efficiency

8.31 Perform this step only if the concentration on the downstream (filtered) side of the filter exceeds 1 FMPC.

8.32 Calculate the removal efficiency of the air handling system filter.

Cf = concentration filtered
Cu = concentration unfiltered

%E = (1 - Cf/Cu) x 100

8.33 Compare the removal efficiency from Step 8.32 to the action levels specified in Step 9.3 of this procedure.

9. Investigational and Action Levels

9.1 Restricted areas

9.11 Process or engineering controls shall be used to limit exposure in restricted areas to 10 MPC-hrs per week (25 percent of permissible).

9.12 An evaluation shall be made of any occurrence which results in exposure in a restricted area in excess of 40 MPC-hrs per week (100 percent of permissible). A written report shall be maintained and include any preventative corrective actions taken or planned.

9.13 Individuals shall be restricted from work in any restricted area within which exposure to airborne concentrations of radioactivity would occur in excess of 520 MPC-hrs per quarter.

9.14 Exposures in excess of 520 MPC-hrs shall be reported to the individuals and to regulatory agencies.

9.2 Effluents to unrestricted areas

9.21 Process or engineering controls shall be used to limit the FMPC in unrestricted areas to below unity (1.0) and as low as is reasonably achievable (ALARA).

9.22 Concentration limits apply at the boundary of the restricted area.

9.3 HEPA/ charcoal filtration efficiency

9.31 Change the filter if the effluent from the stack exceeds unity (1.0) at the boundary of the restricted area (10 meters from the stack).

9.32 A dilution factor of 232.2 can be applied to stack exhaust to calculate concentrations at 10 meters from the exhaust point. (Calculations to support this dilution factor are available upon request.)

10. Requirement

An airborne radioactivity program is required if I-131 is dispensed from opened containers in quantities which exceed the guidelines in Table 1 of this procedure, or if other radionuclides are dispensed in quantities which exceed 10 times the guidelines specified in Table 1.

11. Table 1.

ACTIVITY LEVELS ABOVE WHICH AIR SAMPLING IS NECESSARY

Types of Operations	Activity Handled in Unsealed Form: Volatile or* Dispersible*	Activity Handled in Unsealed Form: Bound Nonvolatile*
Dispensing within laminar flow hoods	1 mCi	10 mCi
Dispensing within closed gloveboxes	100 mCi	1000 mCi

* Quantities may be considered the cumulative amount dispensed over a 3-month period, or on one or more occasions in that period, by opening stock reagent containers from which radioactive iodine may escape. Quantities in the right-hand column may be used when it can be shown that activity dispensed is always chemically bound in such a manner that I-131 will remain in nonvolatile form and diluted to concentrations less than 0./1 mCi/mg of nonvolatile agent.

12. Table 2.

MAXIMUM PERMISSIBLE CONCENTRATIONS (MPC) uCi/ml

Nuclide	Column 1. Restricted	Column 2. Unrestricted	Note
Co-57	2 E-7	6 E-9	
Co-58	5 E-8	2 E-9	
Cr-51	2 E-6	8 E-8	
Fe-59	5 E-8	2 E-9	
Ga-67	3 E-9	1 E-10	*
I-123	3 E-9	1 E-10	*
I-125	5 E-9	8 E-11	
I-131	9 E-9	1 E-10	
In-111	3 E-9	1 E-10	*
Mo-99	2 E-7	7 E-9	
P-32	8 E-8	3 E-9	
Se-75	1 E-7	4 E-9	
Tc-99m	1 E-5	5 E-7	
Tl-201	9 E-7	3 E-8	
Yb-169	3 E-9	1 E-10	*

* Default values if not listed in regulations

NOTE: Data may be processed on this form or by the computer program. Mallinckroct action levels are the same for both procedures. Both procedures follow the same format for calculation of air concentrations in the pharmacy.

DATE: _____

D.I.S. LOCATION _____

AIR MONITORING WORKSHEET

SAMPLE COLLECTION DATA

Sample #	START Date/Time Time	START Flow (LPM)	STOP Date/Time Time	STOP Flow (LPM)	Average Flow (LPM) $\frac{\text{Start + Stop}}{2}$	Total Sampling Time (min)	Volume (ml) Avg. flow x total min x 1000 ml/l
#1							
#2							
#3							
#4							
#5							
#6							
#7							
#8							
#9							

SAMPLE MEASUREMENT

Sample # and Location	Gross Counts	Time (Min)	Gross CPM	Net CPM (Gross CPM-Bkg.)
Background				[redacted]
Source uCi				
#1				
#2				
#3				
#4				
#5				
#6				
#7				
#8				
#9				

CALCULATIONS

A. Complete sample collection and measurement data worksheet.

B. Using collection and measurement data, calculate the following:

1. Determine calibration factor (F):

   F = Source Activity (uCi)/Net Source Countrate (CPM)

   F = _____uCi/ _____CPM = _____uCi/CPM

2. Calculate Sample Activity (A) in microcuries:

   A = net sample countrate (CPM) x F (uCi/CPM)

Sample #1.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi
2.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi
3.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi
4.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi
5.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi
6.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi
7.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi
8.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi
9.	A =	_____	CPM x	_____	uCi/CPM =	_____	uCi

3. Calculate the air concentration (C) for each sample:

   C = A (uCi)/Volume (ml)

Sample #1.	C =	_____	uCi /	_____	ml =	_____	uCi/ml
2.	C =	_____	uCi /	_____	ml =	_____	uCi/ml
3.	C =	_____	uCi /	_____	ml =	_____	uCi/ml
4.	C =	_____	uCi /	_____	ml =	_____	uCi/ml
5.	C =	_____	uCi /	_____	ml =	_____	uCi/ml
6.	C =	_____	uCi /	_____	ml =	_____	uCi/ml
7.	C =	_____	uCi /	_____	ml =	_____	uCi/ml
8.	C =	_____	uCi /	_____	ml =	_____	uCi/ml
9.	C =	_____	uCi /	_____	ml =	_____	uCi/ml

4. Calculate the Fractional Maximum Permissible Concentration for each sample using the MPCs listed in Table 2, Column 1 (restricted areas) or Table 2, Column 2 (unrestricted areas).

MPC for 131-I =	Restricted	9×10^{-9} uCi/ml
	Unrestricted	1×10^{-10} uCi/ml

   FMPC = C/MPC

Sample #1.	FMPC =	_____ /	_____	=	_____
2.	FMPC =	_____ /	_____	=	_____
3.	FMPC =	_____ /	_____	=	_____
4.	FMPC =	_____ /	_____	=	_____
5.	FMPC =	_____ /	_____	=	_____
6.	FMPC =	_____ /	_____	=	_____
7.	FMPC =	_____ /	_____	=	_____
8.	FMPC =	_____ /	_____	=	_____
9.	FMPC =	_____ /	_____	=	_____

5. According to Mallinckrodt ALARA program, FMPC should be less than or equal to .25 (25% of permissible) for restricted areas and below unity (1.0) for unrestricted areas. If these values are exceeded, check the Investigational and Action Levels in Step 9 of Standard Operating Procedures DIS-15.