Essential Isotopes
1513 Research Park Dr
Columbia, MO 65211

Kevin Null
Nuclear Regulatory Commission
Region III Office
2443 Warrensville Rd, Suite 210
Lisle, IL 60532-4352

October 22, 2010

Kevin,

The enclosed documents are in response to the requests for clarification regarding the Radiopharmacy application for Essential Isotopes NRC application control number 318475 and 318478. I hope that you find the responses satisfactory, if not please call me for further clarification.

Sincerely,

Marc D. Weichelt RPh, BCNP
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Null, Kevin

From: Marc Weichelt [mweichelt@centurytel.net]
Sent: Friday, October 22, 2010 9:26 AM
To: Null, Kevin
Subject: EI Bioassay and filter monitoring
Attachments: MURR Bioassay.pdf; EI RC 15.pdf; MURR FM.pdf; EI RC 16.pdf

Kevin,

Attached for your review are four documents concerning the procedures for bioassay and air filter monitoring and maintenance.

The first document is the MU bioassay procedure for cyclotron produced radionuclides. The second document is the radioactive spill procedure for EI which has been updated to incorporate the bioassay procedure. The third document is an explanation of how MU monitors and decides when to replace filters in the air filtration system. The fourth document is the corresponding EI procedure for monitoring and replacing the filters on the air handling system. Give me call if you have any questions or concerns.

Best regards,

Marc

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Essential Isotopes

Health Physics

EI-HP-001

BIOASSAY

RESPONSIBLE GROUP: Health Physics

PROCEDURE OWNER: Marc Weichelt

APPROVED BY: Ronald J. Dobey, Jr., CHP_____ Date:_____

This procedure contains the following:

Pages	1	through	8
Attachments	None	through	
Tables	None	through	
Figures	None	through	
Appendices	None	through	
Check-Off Lists	None	through	

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BIOASSAY

1.0 PURPOSE

1.1 To establish guidelines for obtaining, analyzing, and documenting personnel internally deposited radionuclide levels.

1.2 Radionuclide analyses of air and *bioassay* samples are performed when ingestion or inhalation of F-18 or other nuclides are suspected. (Reference 8.2).

2.0 SCOPE

2.1 Contains procedural steps and precautions necessary to obtain and analyze urine samples for radionuclides.

2.2 Establishes and describes action levels for radionuclide concentrations.

3.0 DEFINITIONS

3.1 *Bioassay* - The determination of kinds, quantities or concentrations and in some cases, the locations, of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed (in vitro) from the human body (Reference 8.1).

3.2 *MDA* - Minimum detectable activity (μCi / liter).

4.0 PRECAUTIONS AND LIMITATIONS

4.1 The Radiation Safety Officer must be notified if any suspected airborne contamination involving F-18 presents the possibility of ingestion or inhalation so that this procedure can be activated.

5.0 PREREQUISITES AND INITIAL CONDITIONS

5.1 The Liquid Scintillation Counter (LSC) operability has been verified.

6.0 SPECIAL TOOLS OR EQUIPMENT

- LSC
- F-18 standard solution
- Specimen cups

7.0 PROCEDURE

7.1 SELECTION CRITERIA:

NOTE: *Bioassay* sampling is performed when ingestion or inhalation of activity is suspected by the EI radiopharmacy group staff. The Radiation Safety Officer may require more frequent sampling if the possibility of higher than normal radionuclide concentrations exist.

7.1.1 Sampling for *bioassay* MAY include individuals from the following groups:

- Radiation Safety
- Pharmacy Operations
- Other personnel who may be present in the Pharmacy area

7.2 SAMPLING:

7.2.1 Label a specimen cup with the name of the person being tested.

7.2.2 Place labeled specimen cup in men's or women's restroom.

7.2.3 NOTIFY selected individual that he or she has been selected for testing.

Note: F-18 has a 1.8 hour half life so analysis must be done on a timely basis.

7.2.4 Collect filled specimen cup AND store in dedicated refrigerator until time of analysis.

7.3 ANALYSIS:

7.3.1 Prepare radionuclide test sample as follows:

a. Place 10 ml of scintillation fluid in a 20-ml scintillation vial.

b. Add 1 ml of urine to the scintillation vial.

7.0 PROCEDURE (CONT.)

7.3.2 IF a blank background check vial does not exist, THEN prepare blank vial as follows:

a. Place 10 ml of scintillation fluid in a 20-ml scintillation vial.

b. Add 1 ml of tap water to scintillation vial.

7.3.3 Place blank background check vial in first test tray slot in LSC.

7.3.4 Place radionuclide test sample(s) in next test tray slot(s).

NOTE:	All LSC analyses are performed using the appropriate LSC protocol.

7.3.5 Count background sample for 10 minutes, AND RECORD counts (cpm).

7.3.6 Count urine samples for 10 minutes, AND

a. RECORD counts (cpm).

b. RECORD counts (dpm).

7.3.7 IF any concentration of F-18 is greater than 1 µCi / liter, THEN NOTIFY the EI Radiation Safety Officer.

7.4 CALCULATIONS AND REPORTING:

7.4.1 DETERMINE isotope activity, using the following formula:

$$A = \frac{S * 1000}{2.22E6}$$

A =	Nuclide concentration in the urine sample (µCi / liter)
S =	Count rate in LSC channel for 1 ml of urine (dpm / ml)
1000 =	Conversion factor (ml / liter)
2.22E6 =	Conversion factor (dpm / µCi)

7.0 PROCEDURE (CONT.)

7.4.2 DETERMINE the sample minimum detectable concentration (MDC), using the following formula:

$$MDC = \frac{\left[4.65*(B/t)^{1/2}\right]}{Eff*2220}$$

NOTE: Use the formula below if background is not subtracted automatically.

$$MDC = \frac{\left[B+(4.65*(B/t)^{1/2})\right]}{Eff*2220}$$

MDC =	Minimum detectable concentration of isotope in the urine sample (µCi / liter)
B =	Background count rate (cpm / ml)
4.65 =	Factor corresponding to a 5% prob. of Type I error and 5% prob. of Type II error
t =	Count time (min)
Eff =	Efficiency of detection for the urine sample (counts / disintegration)
2220 =	Conversion factor (dpm / µCi) and (L / ml)

7.4.3 IF any radionuclide concentrations are greater than MDC, THEN:

a. Total the concentrations that are greater than MDC.

b. DETERMINE the total activity (ACT) in standard man whose volume is set at 40 liters, using the formula:

ACT (µCi) = (40 liters) [sum of isotope concentrations in urine sample (µCi / liter)]

7.0 PROCEDURE (CONT.)

7.4.4 IF no concentrations of isotopes for the person are greater than MDC, THEN:

a. total the MDC values.

b. DETERMINE the *MDA* in standard man whose volume is set at 40 liter, using the formula:

$$MDA\ (\mu Ci) = (40\ \text{liters})\ [\ \text{sum of MDC values}\ (\mu Ci / \text{liter})\ ]$$

7.4.5 DETERMINE the lifetime dose per unit concentration, using the following formula:

$$CEDE = \frac{[(950\,ACT)(3.7E-2)]}{10}$$

CEDE =	Committed effective dose equivalent - estimated (mRem)
950 =	Constant [(μSv) (liters)] / MBq) (for F-18)
ACT =	Total fluorine concentration for the year (μCi / liter)
3.7E-2 =	Conversion factor (MBq / μCi)
10 =	Conversion factor (μSv / mRem)

7.4.6 DETERMINE concentration of F-18 and MDC for each sample AND RECORD values on individual's *Bioassay* History Card (Record 9.2).

7.4.7 WHEN end-of-year dose summary report received from dosimetry provider, THEN DETERMINE total concentrations for each person that are greater than MDC. Use the value to calculate total activity in μCi.

7.4.8 IF no samples were greater than MDC, THEN DETERMINE the *MDA* using the MDC total.

7.4.9 RECORD the applicable information on each person's NRC Form 5 equivalent, as follows: (Record 9.3)

a. Enter total activity or *MDA* calculated in Step 7.4.3 or Step 7.4.4, in column 10D. RECORD an *MDA* level as "Less Than."

b. Enter "F-18" in column 10A.

c. Enter "V" (for vapor) in column 10B.

d. Enter "H" (for inhalation) or "G" (for ingestion) in column 10C.

7.0 PROCEDURE (CONT.)

e. IF all recorded concentrations for the year were less than MDC, THEN RECORD "< *MDA*" in blocks 15 and 16 AND STOP this procedure.

f. IF the result of Step 5.4.5 (CEDE calculation) is less than 10 mRem, THEN RECORD "< 0.001" in blocks 15 and 16.

g. IF the result of Step 5.4.5 (CEDE calculation) is greater than 10 mRem, THEN RECORD value in blocks 15 and 16 AND add this value to the existing value in blocks 17 and 18.

7.4.10 Complete Bio-Assay Report AND file (Record 9.1).

8.0 REFERENCES

8.1 Nuclear Regulatory Commission Basic Reference "Glossary"

8.2 NRC Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"

9.0 RECORDS

9.1 Health Physics Form, "Bio-Assay Report" (Generated by Health Physics Spreadsheet)

9.2 Health Physics, "*Bioassay* History Card"

9.3 Form (NRC Form 5 equivalent), "Occupational Exposure Record for Monitoring Period"

Essential Isotopes

Building Filtration Monitoring

The building that houses the cyclotron (North Office Addition) for Essential Isotopes is equipped with a large filter bank located on the roof of the NOA. This filter bank is equipped with both HEPA type box filters along with a pre-filtering material located immediately upstream from the HEPA bank. In conjunction with both sets of filter banks are Magnahelic ® type gauges that measure the pressure drop across the filter faces. The pre filters are changed out on a periodic basis or when the pressure drop exceeds 1 inch of water. The HEPA filters are changed out when the differential pressure across the filter reaches 3 inches of water. Experience at the University of Missouri Research Reactor, which utilizes the same type of filtering system, has shown that the above noted maintenance and replacement schedule is adequate to maintain the operability of this type of filtration system.

I. PURPOSE

To establish the procedure for responding to emergencies involving radioactive material

II. RESPONSIBLE

Radiation Safety Officer (RSO) or designee

III. SCHEDULE

As Needed

IV. EQUIPMENT AND MATERIALS

i. Calibrated radiation survey instrument
ii. Spill kit:
   a. 1 copy of SOP RC-15 "Emergency Procedures – Spills"
   b. 6 pairs disposable gloves, 1 pair housekeeping gloves
   c. 2 disposable lab coats
   d. 2 pair disposable sleeve covers
   e. 2 paper head covers
   f. 4 pairs shoe covers
   g. 1 roll absorbent paper with plastic backing
   h. 6 plastic trash bags with twist ties
   i. Radioactive material labeling tape
   j. 1 marking pen or pencil for labeling glass or plastic
   k. 3 "Radioactive Material" labeling tags
   l. 1 container of wipe sample papers or swabs
   m. 1 container of Radiac Wash or some other decontamination cleaner
   n. 1 can of foaming shaving cream
   o. Clipboard with a copy of "Radioactive Spill Report"

V. PROCEDURE

Spill Definitions
Minor Spill: < 500 mR/hr at 1 foot
Major Spill: ≥ 500 mR/hr at 1 foot
Use the table below to determine the activity of the spill based on the exposure rate at 1 foot.

F-18 Activity from Exposure Rates at 1 ft			
Exposure (mR/hr) @ 1ft	Activity (mCi)	Exposure (mR/hr) @ 1ft	Activity (mCi)
1	0.22	250	55.0
5	1.1	300	66.0
10	2.2	350	77.0
25	5.5	400	88.0
50	11.0	450	99.0
75	16.5	500	110.0
100	22.0	600	132.0
125	27.5	700	154.0
150	33.0	800	176.0
175	38.5	900	198.0
200	44.0	1,000	220.0

i. Minor spills of liquids and solids
   a. **Notify** persons in the area that a spill has occurred
   b. **Prevent** the spread of contamination by covering the spill with absorbent paper, and prevent access to the area by unauthorized personnel.
   c. **Survey** the area with an energy compensated probe/GM meter.
   d. **Wearing** personal protective equipment (gloves, lab coat), **clean up** the spill using radiacwash/isoclean, absorbent paper and remote handling tongs.
   e. Carefully fold the absorbent paper and place it in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
   f. Survey the area with a low range survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
   g. If no significant level is detected, perform wipe testing of the affected and surrounding areas to ensure no removable contamination is detected.
   h. **Report** the incident to the radiation safety officer (RSO).
   i. The RSO will follow-up on the cleanup of the spill and will complete the Radioactive Spill Contamination Survey (Attachment 1).

ii. Major spills of liquids and solids
   a. **Clear** the area. Notify all persons not involved in the spill to vacate the room.
   b. **Prevent** the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up.
   c. **Survey** the area with an energy compensated probe/GM meter.
   d. Perform personnel contamination surveys and to prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

e. Calculate the estimated exposure for the clean up by estimating the time it will take to perform the job. If the estimated exposure is greater than 100 mR whole body or will cause the employee to exceed his/her ALARA level II for the quarter, allow more decay before performing the clean up.
f. **Shield** the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
g. **Close the room** and lock or otherwise secure the area to prevent entry.
h. **Notify** the RSO/EI management or call an HP for help immediately.
i. The RSO or designee will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. (Attachment 1)

iii. Spill Inside Mini/Hot Cell
a. Survey the spill area with an energy compensated probe/GM meter to determine the exposure rate.
b. Calculate the estimated exposure for the clean up by estimating the time it will take to perform the job. If the estimated exposure is greater than 100 mR whole body or will cause the employee to exceed his/her ALARA level II for the quarter, allow more decay before performing the clean up.
c. Wearing personal protective equipment (gloves, lab coat), clean up the spill using absorbent paper and remote handling tongs.
d. Carefully fold the absorbent paper and place it in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
e. Survey for residual contamination with a low range survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
f. If no significant level is detected, perform wipe testing of the affected and surrounding areas to ensure no removable contamination is detected.
g. Report the incident to the radiation safety officer (RSO).

iv. Personal Contamination
a. Decontaminate personnel by carefully removing contaminated clothing.
b. Flush contaminated skin with lukewarm water for about 15 minutes and then washing with mild soap (shaving cream is also good for removing contamination).
c. If non-removable contamination remains, induce perspiration by covering the area with plastic or gloves. Then wash the affected area again to remove any contamination that was released by the perspiration.
d. Injured persons must be administered first aid and then decontaminated as necessary.

e. If life-threatening injuries are present, the individual must be given immediate life-saving first aid and transported to a hospital for further medical treatment regardless of any contamination present. The hospital must be given prior notification that the patient is contaminated so that the appropriate controls can be implemented.

v. Bioassay
   a. A bioassay will be performed according to MURR procedure EI-HP-001 under the following conditions:
      1. If the spill results in personal contamination greater than 100 mCi of a nuclide.
      2. There is a suspected airborne release.
         Note: A release is determined to be airborne when there is uniform increase of activity detected by the room monitors and stack monitor.

vi. Loss, Theft, or Damage to a Source of Radioactive Material
   a. In the event of a loss, stolen, or damaged radioactive source, notify the RSO immediately.
   b. If a spill occurs as a result of damage to a radioactive source, follow the above steps for responding to a spill.

STANDARD OPERATING PROCEDURE	
Radiological Spill/Contamination Report	**RC-15F**
Originator: Marc Weichelt	**Revision: A**
Management Approval: RSO	
[redacted]	

RADIOLOGICAL SPILL/CONTAMINATION REPORT

Facility: _____ Incident Date: _____Time: _____

Instrument used to check for personnel contamination:

Manufacturer:_____ Model:_____ S/N:_____ Probe S/N:_____
Calibration Date: _____

Initial Survey: _____mR/hr @ _____ distance

Personnel Involved: Name Contamination level (cpm)

_____ _____

_____ _____

_____ _____

On the back of this sheet indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots then begin decontamination. When finished, conduct a repeat contamination wipe test.

Radioisotopes present or suspected in the spill:

Nuclide: _____ Estimated Activity: _____

Was the release of activity airborne? Yes___ No____
Was there personal contamination greater than 100 mCi? Yes___ No___
If you answered yes to either question perform a bioassay according to MURR SOP EI-HP-001 and record the results below.

Bioassay results
Concentration of nuclide in urine _____uCi/liter.
MDC value _____
MDA value _____
Was the RSO notified of the results? Yes___ No___

Give a brief description of the accident:

_____

_____

_____

Give a brief description of the corrective/follow-up actions taken to prevent recurrence:

_____

_____

_____

_____

Report Prepared By: _____ Date: _____

RSO Review: _____ Date: _____

STANDARD OPERATING PROCEDURE	
Air Filtration Monitoring and Maintenance	**RC-16**
Originator: Marc Weichelt	**Revision: A**
Management Approval: RSO	
[redacted]	Page 1 of 1

I. PURPOSE

To establish the procedure for monitoring and maintaining the air filtration system

II. RESPONSIBLE

Facility Radiation Safety Officer (RSO)
Qualified staff

III. SCHEDULE

Annually or as needed

IV. PROCEDURE

a. The air handling system will be periodically checked for decreases in pressure differential as indicated by the Magnahelic gauges installed before and after the filters.
b. The Pre-filters will be replaced when there is a change in pressure differential greater than 1 inch of water.
c. The HEPA filters will be replaced when there is a change in pressure differential greater than 3 inches of water.