Scott Dennerlein & Associates, LLC

Radiation Safety Specialists

MS16
J-6

To: Dennis Lawyer, U.S. NRC

Control # 140231

Fax: 610 337-5393

29-31097-01
03037046

Dear Mr. Lawyer,

Attached is the requested information regards Amicus Therapeutics' license amendment. Please call me if there are any other questions. Thank You.

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140231

Collection and Analysis of Air Samples for RadioIodine

Purpose This procedure is intended to measure the radioiodine concentration in either effluent air or breathing zone air. Results will be used to determine bioassay requirements, posting requirements, environmental reporting, or provide input on protective equipment requirements. Sampling is to be conducted when the Health Physicist determines 10% of the applicable limit is likely to be exceeded, or when greater than one millicurie is used or stored in a hood or waste room.

Equipment TEDA impregnated charcoal filters
Calibrated air sampling pumps
Calibrated gamma counter and supplies

Procedure

1. Select either a personal (lapel) air sampler for a breathing zone measurement, or a large volume air sampler for an effluent sample.

2. Install the charcoal "puck" in the sample holder, ensuring the arrow printed on the side is pointing in the direction of the air flow.

3. Fill in the pump ID, location; start time, etc. on the top half of the Air Sampling Record.

4. Run the pump for the minimum time required as calculated on attached form.

   Note: For breathing zone samples clip the sampler on the workers lapel

5. At the completion of sampling, remove the sampling "puck" carefully cut open and transfer all charcoal to a plastic test tube for analysis in a gamma counter.

6. Determine the total activity utilizing the appropriate counting protocol and efficiency for the particular isotope of radioiodine under consideration.

7. Complete the Air Sampling Record and take appropriate action based on the results.

Minimum Air Sampling Time

1. Calculate the sensitivity of your analytical equipment using the equation;

$$MDA = \frac{2.71 + 4.65\sqrt{Br \times t}}{t \times E \times 2.22 \times 10^{6}}$$

where:

MDA = activity in microcuries
Br = background rate in counts per minute
t = counting time in minutes (same for background and sample)
E = detector efficiency

Example: Gamma counters with a background of 100 cpm, and a detection efficiency for I-125 of 50%

$MDA = 4.4 \times 10^{-5}$ microcuries

2. Calculate the volume of air that must be sampled to detect 10% of the regulatory limit using the equation;

$$\text{Required volume of air} = \frac{\text{Minimum detectable activity}}{\text{10\% of limit}}$$

Example: 10% of the breathing zone limit for I-125 is 3E-9 μCi/ml

$$\text{Required volume of air} = \frac{4.4 \times 10^{-5}\ \text{microcuries}}{\text{3E-9 } \mu\text{Ci/ml}} = 14{,}667 \text{ ml}$$

Or approximately 15 liters.

Note: The calculated sampling time is <u>a minimum</u>. Sampling should be conducted for the length of the experiment.

Air Sampling Record

Sample data

Location _____ Date _____

Sample for: I-125 I-131 (requires charcoal collection media)

Occupational ___ Environmental _____ Pump #_____ Rotometer #_____

Start time _____ Flow rate _____ lpm

Stop time _____ Flow rate _____ lpm

Total time _____ minutes X Average flow rate = _____ lpm

Total volume of air _____liters / 1,000 = _____ milliliters

Analysis data

Instrument _____ Count date _____

Net dpm _____ Activity (microcuries)_____

Concentration (μCi/ml) _____

10CFR20 Appendix B limit _____ Percent of Limit _____

Comments: _____

_____

Reviewed by: _____