CTG Certification Network

Certification Protocol

Technical Support
Phone: 317-713-8200
After-hours emergency: 317-753-5312
Fax: 317-713-8201

Protocol Approvals

Engineering:

Hank Rahe 04/15/2008
Technical Director
Containment Technologies Group, Inc.

Quality Assurance:

Mark Blasky 04/15/2008
Extended Services Manager
Containment Technologies Group, Inc.

Protocol prepared by:

Hank Rahe 04/15/2008
Technical Director
Containment Technologies Group, Inc.

CTG Certification Protocol—Version 1.6

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Protocol Acknowledgement

Signature below verifies that you have read and understand the protocols set forth by Containment Technologies Group, Inc. for the certification of CTG, Inc. products. These protocols are CTG, Inc. recommended guidelines.

____
Certification Company Name

____
Address

____
Phone

____
Printed Name of Professional Executing Today's Work

______________________________ ______________________
Signature Date

A copy of this acknowledgement page needs to be sent back to CTG via fax (317-713-8201) along with Appendix A for every certification.

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1.0 PURPOSE

1.1 Purpose of the certification protocol

The purpose of the certification protocol is to verify that the MIC isolator is operating as designed, after installation. The design criteria for the MIC is to provide an ISO Class 5 environment in which aseptic compounding can be performed.

Verification of the internal environment is accomplished by specified testing procedures described in this document. After the testing is complete, the results of the testing are documented on form Appendix A contained in this protocol.

Note: It is acceptable to substitute different formats for certification; given the information required by the regulatory agencies, the owner of the MIC and Containment Technologies Group, Inc. is collected and displayed so as to verify the MIC has been tested to the requirements of the applicable standards.

The current standards for pharmacy compounding sited by state pharmacy boards, federal agencies and the United States Pharmacopia (USP) require an International Organization for Standardization (ISO) Class 5 air quality environment for the aseptic compounding of parenteral products.

The 2004 USP27 published by USP included General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations. The purpose of this chapter is to provide procedures and requirements for compounding sterile preparations. USP produces public standards, but as a private, non-governmental body has no authority to establish law or regulations. Proposed USP changes are submitted each year for consideration. Changes are not considered part of the standard until reviewed and approved by USP. Updates to this document will be provided as changes in the standard and regulations occur. The first approved revision becomes effective June 2008.

ISO is a worldwide federation of national standards bodies that provide standards for the development, manufacturing, and supply of products. The following ISO standards apply to the certification of the MIC Isolator:

1. ISO 14644-1:1999 (E) - Cleanrooms and associated controlled environments
2. ISO 14644-2:2000 (E) - Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
3. ISO 14644-3:2005(E) - Test methods
4. ISO 14644-7:2004(E) - Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

The ISO documents are the basis for the testing protocols described in this document. Consideration has been given to the aseptic nature of the application for selection of the testing and criteria used in developing the test protocols.

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1.2 Verification Approach

Verification will consist of testing all MIC isolators to verify ISO Class 5 conditions are being maintained.

The critical parameters for the MIC Isolator to maintain ISO Class 5 conditions are the blower that moves the air and the HEPA filters that control the number and size of air particles.

The MIC isolators are designed with HEPA filtration for both inlet and exhaust air.
All MIC isolators have re-circulating air systems that move the air through the two HEPA filters. The inlet HEPA is the critical filter that controls the internal air quality. This filter is integrity tested by an Installed Filter Leakage test. The exhaust HEPA filter acts as a support filter and should only be tested in cases where the air stream is exhausted into a facility duct for removal to the outside of the facility.

Note: The sequencing of the testing is important as aerosol generated in the filter challenge test can impact the external and internal isolator environment of the isolator if appropriate precautions are not followed. Chamber particle counts should be taken first followed by the additional testing.

Testing frequency for ISO Class 5 environments is six (6) months per the ISO 14644-2:2000(E) and USP <797>. Check with the state board of pharmacy requirements for the individual state regulations.

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1.3 Testing Conditions

ISO 1464-3:2005(E) describes three “Occupancy states” or conditions under which testing is to take place:

1. As-built
2. At-rest
3. Operational

The revisions to USP<797> published in December 2007 defines the following conditions under which certification of isolators is to take place:

1. Particulate testing is to occur under dynamic conditions
2. The isolator will maintain ISO Class 5 conditions including transfers and compounding during dynamic conditions

Specific tests to achieve the above conditions are as follows:

A. Particle counts are to be taken 6 to 12 inches upstream of the critical site (see pg 23 of the USP<797> revisions)
B. Particle counts shall not exceed 3,520 particles 0.5 micron or larger with the probe located as close to the door as possible without obstructing the transfer.

Note: USP<797> requires air quality standards defined in ISO 14644-1:1999(E). This document references ISO 14644-2:2000(E) (specifics for testing and monitoring to prove continued compliance to ISO 14644-1:1999 (E)). ISO 14644-3:2005 describes the test methods to be used for compliances to ISO 14644-1:1999(E).

USP<797> references CETA as an example of testing protocols (Page 23, 2nd column, bottom of page. Documentation obtained by CTG from USP chief legal council and provided in your documentation package clearly states the CETA documents are only examples and are not required testing protocols. CTG has chosen to follow the ISO testing methods because CETA is not a recognized standards setting organization.

The following process is common to most compounding operations and may be simulated to create operational conditions:

1. Load materials to be compounded into a tray (syringe, needle, vial, piggyback and supporting items such as alcohol swabs)
2. Place in airlock and sanitize
3. Remove from airlock into compounding chamber
4. Perform manipulations
5. Place finished product in tray and remove from chamber

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2.0 SYSTEM OVERVIEW

2.1 System Boundaries

MIC isolators consist of the following components:

1. The main chamber
2. Airlock(s) for entrance and egress of materials
3. Glove ports for personnel interaction
4. Air handling system
    a. Inlet HEPA filter
    b. Outlet HEPA filter
    c. Blower
5. Instrumentation, switches, and lighting

a. Pressure differential gauge
b. On/Off switches or push buttons
c. External light source

2.2 Equipment and Operational Description

MIC isolators are designed to provide ISO Class 5 air quality for compounding of parenteral products. MIC isolators come in three models and utilize the following features:

<u>MIC-Single</u>

- Consists of one chamber measuring 32-inches or 40-inches in width by 24-inches in depth and 26-inches in height.
- Is equipped with one or two airlocks for material transfers.
- Utilizes through-chutes (with attached containers) to dispose of sharps and trash.
- Operates with either positive or negative pressure.

<u>MIC-Dual</u>

- Consists of two chambers measuring 32-inches or 40-inches in width by 24-inches in depth and 26-inches in height.
- Is equipped with one airlock for material transfers.
- Utilizes through-chutes (with attached containers) to dispose of sharps and trash.
- Utilizes independent air handling systems for each chamber (as described in section 2.1.4.)
- Each chamber operates with either positive or negative pressure.
- Is capable of operating with one chamber with positive pressure, while other chamber operates with negative pressure.

<u>MIC-TPN</u>

- Consists of one or two chambers measuring 40-inches wide (one chamber) or 80-inches wide (two chambers) by 32-inches deep and 34-inches in height.
- Is equipped with one airlock and a large door for material and equipment transfers.
- Utilizes through-chutes (with attached containers) to dispose of sharps and trash.
- Typically operates with positive pressure.

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3.0 REFERENCES

3.1 MIC Owners Manual

1. MIC owners manual

3.2 Industry Standards

1. USP 31-NF26—General Chapter <797> Pharmaceutical Compounding—Sterile Products
2. ISO 14644—Cleanrooms and associated controlled environments
    1.) ISO 14644-1:1999 (E) - Classification of air cleanliness
    2.) ISO 14644-2:2000 (E) - Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
    3.) ISO 14644-3:2005 (E) - Test Methods
    4.) ISO 14644-7:2004 (E) - Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
3. IEST-RP-CC034

3.3 Individual State Pharmacy Board Requirements

Note: Pharmacy Director or Delegate will need to consult state pharmacy board requirements to determine if additional standards are in force that may require additional testing.

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4.0 Performance Test Procedures

4.1.1 Upstream Test

Item:	4.1.1
Purpose:	This test checks the air quality inside the MIC Isolator, in terms of particle concentration
Acceptance Criteria:	ISO Class 5 = 3520 particles per cubic meter for particles equal to 0.5 µm in size. Reference ISO 14644-1:1999(E)
Equipment required to perform this test:	Particle counter, zero filter and sample probe with stand

Instructions

USP <797> revisions effective June 2008 requires non-viable particle counting to be conducted under dynamic conditions. Dynamic conditions require that the pharmacy perform routine activities while the particle counts are being taken. Typical routine activities will involve a transfer via syringe from a vial to a piggyback of a liquid or a more extensive manipulation would be to reconstitute of a powder in vial and then do the transfer from the vial to a syringe.

Step by step instruction

1. Take an initial air particle count outside of the MIC isolator with the zero filter in place. This is to verify the sample tubing is clean and free of leaks and the particle counter will zero properly.
2. Place the sample probe on top of the airlock, take 2 samples, record results in section 4.1.2 Particle Counts of Appendix A.
3. Set up particle counter and place the sample probe inside the MIC. The particle counter may be external to the MIC isolator. To run the tubing from the particle counter to the sample probe, remove one of the sharps/trash containers from the port. Run the tubing through a glove finger (cut off at pinky location to run tubing). Apply tape to seal fee-through where tubing is going through glove. (Particle counter can generate particles so if an internal particle counter is used verify that it is not a source of particle generation.)
4. Before testing, verify that the MIC has been sealed properly. Check for leaks around the trash and sharps ports, glove ports, and the entry used for the particle counter tubing. This check can be accomplished with the particle counter by looking for spikes in counts in these areas.
5. Typically, the particle counter will be located outside the chamber and will cause a negative pressure in chamber when the counter is turned on. Balance the pressure valves to minimize the pressure change with the pressure control valves located in the rear of the MIC. NOTE: Before adjusting the pressure valves, mark the settings so that after testing, the valves can be returned to their original locations.
6. Test locations are to be 6-12 inches upstream of the critical zone and are shown on the grid on page 11. Locations 1,2,3, and 4 with two counts per location are to be taken. NOTE: Upstream airflow in the MIC enters through the HEPA filter located in the left ceiling area of the MIC.
7. Record results in section 4.1.1 Upstream Test of Appendix A

4.1.2 Door Egress Test

Item:	4.1.2
Purpose:	This test checks the air quality inside the MIC Isolator, in terms of particle concentration
Acceptance Criteria:	ISO Class 5 = 3520 particles per cubic meter for particles equal to 0.5 µm in size. Reference ISO 14644-1:1999(E)
Equipment required to perform this test:	Particle counter, zero filter and sample probe with stand

Instructions

USP<797> revisions effective June 2008 requires non-viable particle counting to be conducted under dynamic conditions. Dynamic conditions require that the pharmacy perform routine activities while the particle counts are being taken. Typical routine activities will involve a transfer on materials into the MIC are placing compounding materials into a tray, placing the tray into the airlock, spraying the materials in the airlock, closing the outer door, entering the gloves, opening the internal door and removing the tray.

The MIC can have either a right side, left side or both sides airlocks. The test location will depend on airlock location.

Step by step instruction

1. Conduct this test after the upstream test
2. Perform one particle count per location. Sample location is shown on the grid located on page 11.
    - For a right hand airlock, sample at location 5
    - For a left hand airlock, sample at location 2
    - For a dual airlock, sample at locations 2 and 5
3. Record results in section 4.1.2 Door Egress Test of Appendix A

Description of pharmacy activity
1. Place typical compounding materials in the carrier tray
2. Open outer airlock door
3. Place tray in airlock
4. Spray down airlock and materials (three sprays)
5. Close outer door
6. Enter gloves and open inner door
7. Place tray on floor under the door
8. Close the door
9. Wait 45 seconds and begin particulate count

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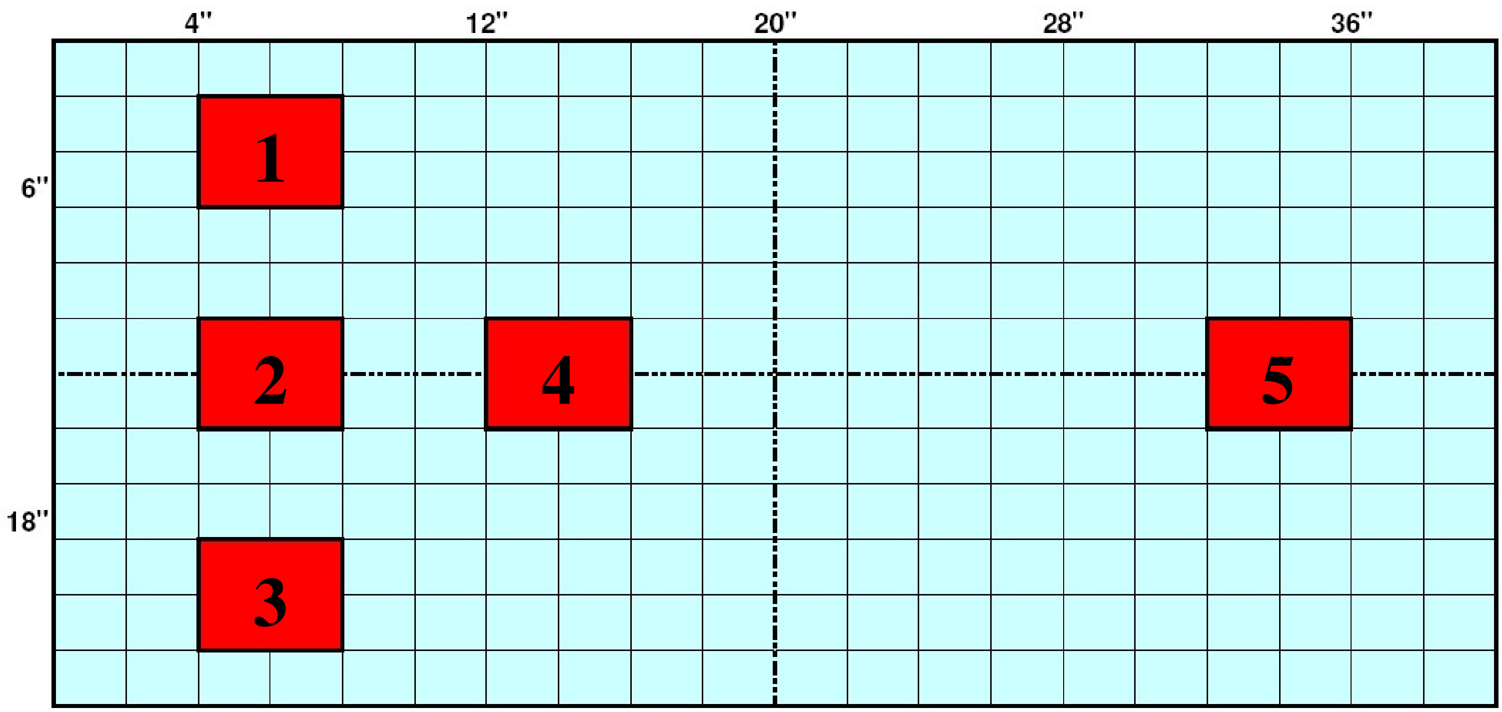
4.1 Particle Counts for ISO Classification (Continued)

8. Sample Grid: Sample on a uniform grid pattern (Aspect ratio nearly 1, Aspect ratio = length / width). Each location is representative and unbiased For example, not all sampled under the HEPA.



Upstream Test 4.1.1
Sample Locations: 1—4

Door Egress Test 4.1.2
Right Airlock: Sample position #5
Left Airlock: Sample position #2
Dual Airlocks: Sample positions #2 & #5

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4.2 Pressure Differential

Item:	4.2
Purpose:	To verify the MIC isolator is operating in the proper pressure range
Acceptance Criteria:	Pressure can be positive range +0.2 to + 0.5 inches of water column or negative range -0.2 to -0.5 inches of water column
Equipment required to perform this test:	None—A visual reading of the pressure differential gauge of the MIC isolator will be preformed

Instructions

1. The differential pressure acts as a secondary containment barrier either protecting the product or personnel. It is important that this feature is operating correctly.

2. Before checking the differential pressure, verify that the MIC has been sealed properly. Check for leaks around the trash ports, sharps ports and glove ports.

3. After ensuring there are no leaks in the MIC isolator, turn the isolator off and verify that the pressure gauge reads zero (it may take up to two minutes for the pressure to reach zero).

4. After the zero pressure reading has been verified, turn the MIC isolator on and allow three minutes for it to return to proper operating range. Ensure that the pressure differential gauge reads in the range of +/- 0.2 to 0.5 inches of water column.

5. If applicable, record results in section 4.2: PRESSURE DIFFERENTIAL of Appendix A (Test Report) of this protocol.

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4.3.1 Filter Integrity Leak Test—Recommended Test

Item:	4.3
Purpose:	This test verifies the integrity of the supply HEPA filter, filter housing, and gel seals are in situ at operating conditions.
Acceptance Criteria:	Leak rates greater than 0.01% (direct filter scan) of the up stream aerosol concentration are not acceptable. A leak rate greater than 0.01% is considered a leak (reference ISO 14644-3:2005, Annex B, B.6) *Note 1: Portions of the test methods have been adopted from IEST-RP-CC034.* *Note 2: Some MIC isolators may be set up where access for a direct filter scan is not possible. In these cases, it is acceptable to probe the membrane that separates the chamber from the filter duct.*
Equipment required to perform this test:	Aerosol generator and aerosol photometer

Instructions

1. Introduce the aerosol challenge:

   1. Remove the top of the exhaust HEPA to introduce the challenge. The output of one Laskin nozzle operating at 20 PSI will be introduced to the blower inlet.
   2. PAO ug/l of air—13,500 / airflow volume cfm
   3. Determine supply air volume
      1. Measure velocity 2-3 inches below diffuser (3x3 grid—nine locations—2" from edge)
      2. $Q_{cfm} = V_{fpm} X A_{sq\ ft}$

         V_{fpm} = Average of nine velocity readings

         $A_{sq\ ft}$ = (10" x 10") / 144 sq in / sq ft

2. Setting the photometer gain:

   1. Most digital aerosol photometers will only allow a maximum internal calibration of 100 ug of PAO/liter of air.
   2. Set internal cal to 1/3 of challenge
   3. You must now divide the leak reading size by 3
      1. For example—a .03% photometer reading needs to be divided by 3 and therefore equals .01%

3. Recommended Test Method – Full access for a direct scan of HEPA filter.

   1. Make sure the MIC isolator is on. Gain access to inlet HEPA filter.
   2. Using aerosol generator, add aerosol upstream of HEPA filter.
      Note: Penetration is measured as a percent of the upstream aerosol challenge of cold poly dispersed PAO (Poly-alpha olefins). A forward light scattering aerosol photometer measures downstream penetration.
   3. Scan 100% of the HEPA filter face or media.
      Note: To assure a homogenous mixing of the aerosol to the supply airflow the PAO should be added upstream of the blower. The upstream aerosol concentrations should not vary more than +/- 15% from the average value. Upstream concentration should be verified. Consult IEST-RP-CC034 for additional information.
   4. With a photometer sampling rate set at 2.5 cm (one inch) from filter face, scan the downstream filter face of the HEPA filter. The sampling rate is 1.0 CFM (1.7 meter cube per hour). Leak rate greater than 0.01% of the upstream aerosol concentration is considered a leak.
   5. If applicable, repair any leaks. Record results in section TEST 3: FILTER SYSTEM LEAK TEST (Supply HEPA) in Appendix A (Test Report) of this protocol.

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4.3.2 Filter Integrity Leak Test—Alternate Method

Instructions

1. Introduce the aerosol challenge:

   1. Remove the top of the exhaust HEPA to introduce the challenge. The output of one Laskin nozzle operating at 20 PSI will be introduced to the blower inlet.
   2. PAO ug/l of air—13,500 / airflow volume cfm
   3. Determine supply air volume
      1. Measure velocity 2-3 inches below diffuser (3x3 grid—nine locations—2" from edge)
      2. $Q_{cfm} = V_{fpm} X A_{sq\ ft}$
         V_{fpm} = Average of nine velocity readings

2. Setting the photometer gain:

   1. Most digital aerosol photometers will only allow a maximum internal calibration of 100 ug of PAO/liter of air.
   2. Set internal cal to 1/3 of challenge
   3. You must now divide the leak reading size by 3
      1. For example—a .03% photometer reading needs to be divided by 3 and therefore equals .01%

3. Alternate Test Method – Partial access for direct scan of HEPA filter. This alternate method is acceptable if the direct scan is not accessible.

   1. Turn MIC isolator on. Gain access to inlet HEPA filter.

   2. Using aerosol generator, add aerosol upstream of HEPA filter.
      Note: Penetration is measured as a percent of the upstream aerosol challenge of cold poly dispersed PAO (Poly-Alpha Olefins). A forward light scattering aerosol photometer measures downstream penetration.

   3. Scan 100% of the HEPA filter face or media
      Note: To assure a homogenous mixing of the aerosol to the supply airflow the PAO should be added upstream of the blower. The upstream aerosol concentrations should not vary more than +/- 15% from the average value. Up-stream concentration should be verified. Consult IEST-RP-CC034 for additional information.

   4. With a photometer sampling rate set at 2.5 cm (one inch) from filter face, scan the downstream filter screen of the HEPA filter from the inside of the MIC chamber. The sampling rate is 1.0 CFM (1.7 meter cube per hour). Leak rate greater than 0.005% of the upstream aerosol concentration is considered a potential leak. Gain access to the rear access panel and follow the procedures of 4.3.1.3 to determine actual leak size location for repairs.

   5. If applicable, repair any leaks. Record results in section 4.3: FILTER INTEGRITY LEAK TEST (Supply HEPA) in Appendix A (Test Report) of this protocol.

4.3.3 Filter Integrity Leak Test—Alternate Method 2

Instructions
1. Test Method B using alternate technology - Scanning with particle counter using aerosol challenge microspheres. 1. Gain access to inlet HEPA filter. 2. Turn MIC isolator on. 3. Using aerosol generator, add aerosol upstream of HEPA filter. *Note: Penetration is measured as a percent of the upstream aerosol challenge microspheres. A particle counter with a 28.3 lpm (1.0 cfm) sample rate with an appropriate probe will be used to scan the downstream of the membrane.* 4. Introduce a minimum microsphere aerosol challenge concentration of six (6) million particles per cubic foot. Verify the concentration using an appropriate aerosol dilutor and particle counter that will be used for scanning. Record the value on the test report. *Note: To assure a homogenous mixing of the aerosol to the supply airflow, the microspheres should be added upstream of the blower. Consult IEST-RP-CCO34 for additional information* 5. Using a square or rectangular probe that is equal to or greater than 0.4 inches in the axis of the scan, scan approximately one (1) inch below the membrane at a rate not to exceed 2 inches per second. 6. A burst of particles exceeding 10 counts per second indicates a possible leak. When such an event occurs, set the particle counter to "Concentration mode". Position the probe under the defect in a position to capture the maximum concentration of particles. Reset the counter and sample until the display concentration remains consistent. Record this value and divide it by the previously determined aerosol challenge concentration. If the resulting value is greater than –.010% record the defect as a leak. 7. Repair the defect using an appropriate sealant (Dow Corning RTV 732 or 734 or GE RTV 108 or 112). Retest the area.

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4.4 Sound

Item:	4.4
Purpose:	This test verifies the sound level created by the MIC.
Acceptance Criteria:	Less than 70 dBA for the MIC isolators.
Equipment required to perform this test:	Sound level meter within the "A" weighting mode.

Instructions

1. Sound readings are taken with a sound level meter in the "A" weighting mode.
2. With the MIC isolator running , position the sound meter approximately 12-inches in front of the MIC and 24-inches above the centerline of the glove ports. Record sound level reading.
3. Repeat the reading with the MIC turned off to determine the ambient sound or background levels.
4. Correct the operating sound level for the background sound level using the following table:

Difference Between MIC ON and Background (in dBA)	Correction Factor (subtract from ON reading)
0—2	Reduce background noise
3	3
4—5	2
6—10	1
> 10	0

5. If applicable, record results in section 4.4: SOUND in Appendix A (Test Report) of this protocol.

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Test Report

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Date of Test: ______________________

Test Report Number: ______________________

Re-certification Due Date: ______________________

Date of prior certification: ______________________

Certified by: ______________________

UNIT DESCRIPTION:

Make: ______________________

Model: ______________________

Serial Number: ______________________

MIC Location: ______________________

CERTIFIER INFORMATION:

Name: ______________________

Company: ______________________

Phone: ______________________

CLIENT INFORMATION:

Client: ______________________

Contact: ______________________

Address: ______________________

City, State, Zip: ______________________

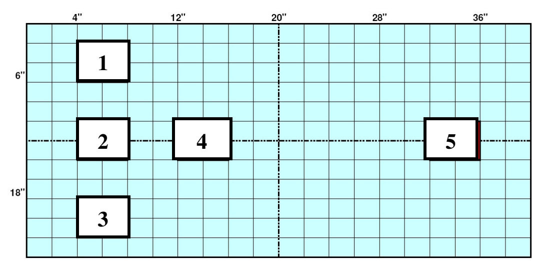
Phone: ______________________

E-mail: ______________________

4.1.1: UPSTREAM TEST—ISO Requirement

External Probe location:

Air Sample 1 __________ **Air Sample 2** __________



Internal Probe Locations:	**1**	**2**	**3**	**4**
Air Sample 1	____	____	____	____
Air Sample 2	____	____	____	____
Average of 1 & 2	____	____	____	____
Is average at each location < 3520 / cubic meter ***(Yes or No)***	____	____	____	____

Right airlock __________ **Left airlock** __________

Statistical Analysis of Data [Annex C ISO 14644-1:1999(E)]

Mean of the Averages: ______________________

Standard Deviation of the Averages: ____________

Standard Error of the Mean: ______________________

Upper Confidence Limit: ______________________

MIC Meets ISO Class 5: (Y/N) ______________

Initial and Date: ______________________

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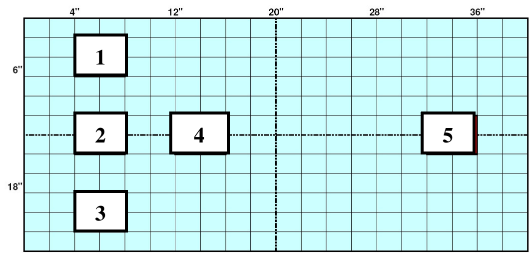
4.1.2: Door Egress Test—ISO Requirement

Right Airlock-
Sample Position #5: ___________

Left Airlock-
Sample Position #2: ___________

Dual Airlocks-
sample positions
#2 & #5



4.2: PRESSURE DIFFERENTIAL—Optional Test per ISO

Positive Pressure Range: 0.2 to 0.5 — Record gauge reading: ______________________________

Meets Acceptable Criteria: (Y/N) _________ — Initial and date: ______________________________

Negative Pressure Range: -0.2 to –0.5 — Record gauge reading: ______________________________

Meets Acceptable Criteria: (Y/N) _________ — Initial and date: ______________________________

4.3: FILTER INTEGRITY LEAK TEST (Supply HEPA) - Optional Test per ISO

Leak detected: (Y/N) ______________ Initial and date: ______________________________

Leak location: Size of leak(s): ________ %, ________ %, ________ %

Media ______________ Gasket ______________ Frame ______________ Housing ______________

Indicate leak location on diagram:

FRONT

Leak detected, repaired and retested: (Y/N) ___________ Initial and date: ________________________

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4.4: SOUND—Optional Test per ISO

MIC Running Sound Level Ambient: ____________ dba

Ambient Sound Level: ____________________________ dba

MIC Running Sound Level:______________________ dba

Acceptable Criteria for MIC: 70 dba for the MIC

Meets Acceptable Criteria: (Y/N) ____________ Initial and date: ______________________

The MIC may not be a significant contributor to over all sound level.

Containment Technologies Group Certification Network expects that all test equipment be in compliance with current calibration standards at all times. Please document the equipment being used with the model, serial number and calibration date.

Equipment	Serial number	Calibration Date
Particle Counter		
Photometer		
Other: ______________________		

NOTES

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____
____
____

______________________ Re-certification Due Date

______________________ Date of Certification

______________________ Signature of Certifier