APPENDIX A-2 SAMPLE

CLEANROOM SPECIFICATIONS

(BIO-MEDICAL & PHARMACEUTICAL)

SECTION XXXXX - CLEANROOM PERFORMANCE TESTING

PART 1 -- GENERAL

1.1 WORK INCLUDED

- A. This Section specifies the requirements of the NEBB Certified Cleanroom Performance Testing (CPT) firm to measure and record the cleanroom conditions during a ______ occupancy mode(s).
- B. Advise the Owner and the NEBB Certified Testing, Adjusting, and Balancing Firm providing the adjustment and setting of dampers in access floor panels and cleanroom ceiling filters to achieve a final cleanroom certification.

1.2 RELATED WORK

- A. Use this section in conjunction with the following related Contract Documents to establish the total requirements for the testing of the cleanrooms:
 - Specifications: (List)
 - 2. Drawings: (List)
 - 3. Standards: (List)
 - 4. Other: (List)

1.3 SCOPE OF CLEANROOM PERFORMANCE TESTS

A. Perform specific primary and secondary tests described in the Contract Documents. Report the test results in accordance with the acceptance criteria as stated in the Contract Documents.

1.4 REGULATORY AND STANDARD PRACTICES REQUIREMENTS

- A. National Environmental Balancing Bureau (NEBB)
 - Current edition of the NEBB Procedural Standards for Certified Testing of Cleanrooms (NEBB-PSCTC). This specification section contains multiple references to this acronym. When used or referenced in this specification.
 - 2. NEBB-*PSCTC* is meant to identify the current publication and / or various sections, tables, equations, charts, etc. from the current publication.
- B. Other: (List)

1.5 QUALITY ASSURANCE

- A. Firm shall be a NEBB Certified CPT Firm.
- B. Measurement: sampling based upon accepted NEBB sampling and statistical procedures.
- C. Equipment calibration:
 - 1. Traceable by serial number to the National Institute for Standards and Technology (NIST) in accordance with the current edition of the NEBB Procedural Standards for Certified Testing of Cleanrooms.
 - 2. Calibrate test equipment that requires calibration within the project work schedule, prior to any testing with the instrument.
- D. The reference standards for field tests and project record documents shall be in accordance with the current edition of the NEBB Procedural Standards for Certified Testing of Cleanrooms.

1.6 QUALIFICATIONS

A. Firm Qualification:

The firm shall be current, certified, and in good standing with the National Environmental Balancing Bureau (NEBB).

B. Certified CPT Professional:

The Certified Professional shall be current, certified and in good standing with the National Environmental Balancing Bureau (NEBB) and employed by the NEBB Certified CPT Firm.

C. Qualified CPT Technician:

The Qualified Technician shall be current, qualified and in good standing with the National Environmental Balancing Bureau (NEBB) and employed by the NEBB Certified CPT Firm and shall have completed previous training in cleanroom operations and certifying procedures thorough, demonstrable knowledge of test procedures and equipment.

1.7 COORDINATION

- A. Jobsite visits: Provide a minimum of ______ jobsite visits by the NEBB Certified CPT Professional during strategic construction phases for the period that the finished cleanroom envelope is being constructed.
- B. Schedule work activities with the Owner and the General Contractor / Construction Manager. Schedule may require that crucial tests be completed in an alternate sequence to allow selective partial occupancy.

1.8 SUBMITTALS

A. Submit the following:

- Qualifications of the NEBB Certified CPT firm project specific staff.
- 2. Outline of the testing and certification procedures.
- 3. Schedule for the performance tests on this project.
- 4. List of instrumentation and test equipment and specimen certificates of calibration.
- 5. Samples of field reports, charts, and forms proposed to document measurements.
- B. Submit the following to the Owner within 10 working days after completion of work:
 - 1. Preliminary field reports compiled from each of the certification steps.
 - 2. One copy of the working field logs for review and evaluation.
 - 3. Evaluation of any problems which may affect final certification results.

1.9 PROJECT RECORD DOCUMENTS

- A. Submit the final NEBB Certified CPT Report within 30 working days after completion of all field activities. Include the following at a minimum:
 - 1. Typed, hand-written or computerized field reports, charts, and forms complete with measured data referenced to sample location.
 - 2. Written description of operating condition of each cleanroom.
 - 3. Reduced set of architectural floor plan drawings, maximum size 280 mm x 432 mm (11in x 17in) inches, made from the project CADD Contract Documents, obtained from the Owner, showing test and sample locations referred to on other field data sheets.
 - 4. Separate narrative section outlining any operating or anomalies at the end of the testing procedures.
 - A list of instrumentation and test equipment used in the certifying process, including manufacturer, model and serial numbers, and NIST-traceable calibration certificate.
 - 6. Written description of tests performed, including the purpose, instrumentation, procedure, results, date tests were taken, names of field technicians performing the tests, and analysis of the data. Present data in tabular form and display graphically to permit full understanding of the tests.
 - 7. Electronic copies of the Final NEBB Certified CPT Report shall be submitted in pdf format.
 - 8. A narrative outline with recommendations relating to test results and operating conditions of each area tested.
 - 9. A statement that cleanroom testing was performed in accordance with the *NEBB Procedural Standards for Certified Testing of Cleanrooms*.
 - B. Provide one hard-bound copy and one unbound reproducible copy of the Final NEBB Certified CPT Report for the Owner's use.

PART 2 – PRODUCTS

2.1 CLEANROOM PERFORMANCE TEST FIRM

A. The NEBB Certified CPT Firm shall be certified by the National Environmental

Balance Bureau to provide cleanroom performance testing.

2.2 MATERIALS

- A. Supply personnel, materials, tools, test equipment, aerosol generators, instrumentation, and computers required to perform and analyze the cleanroom testing procedures described in this Section.
- B. Cleanroom garments and accessories will be furnished by the Owner.

2.3 INSTRUMENTATION

A. All instrumentation requirements are based on standard temperature and pressure conditions (STP).

Test	Equipment/ Instrumentation	Calibration Interval
Airflow Velocity and Uniformity Test (Direct Air Velocity Measurement)	Anemometer	12 Months
Airflow Velocity and Uniformity Test (Indirect Air Velocity Measurement)	Manometer	12 Months
	Tube Array	Not Required
	Pitot Tube or Single-Point Probe	Not Required
Airflow Volume and Uniformity Test	Direct Reading Hood	12 Months
Airflow Volume and Uniformity Test	Manometer	12 Months
	Pitot Tube or Single-Point Probe	Not Required
Leak Testing (w/Photometer)	Aerosol photometer	12 Months
	Aerosol Generator	Not Required
	Scanning Probes	Not Required
Airborne Particle Count Cleanliness Classification Test	Particle Counter	12 Months
	Sampling Probes	Not Required
Room Pressurization Test	Manometer Change Resolution to equal 10 Pa 0.25 in.w.g.) for magnehelic	12 Months
Airflow Parallelism Test	Test Medium	Not Required
	Support Stand & Support Stand with Pointer	Not Required
	Plumb Bob or Spirit Level	Not Required
	Tape Measure	Not Required
Enclosure Integrity Test	Aerosol Generator	12 Months

Test	Equipment/ Instrumentation	Calibration Interval
	Particle Counter	12 Months
Recovery Test	Aerosol Generator	12 Months
	Particle Counter	12 Months
Lighting Level and Uniformity Test	Light Meter	12 Months
Sound Level Test (performed w/SLM)	Sound level meter (SLM)	12 Months
	Full and Third Octave Filters	12 Months
	Acoustic Calibrators	12 Months
Sound Level Test (performed w/Real Time Analyzers)	Real Time Analyzer	12 Months
	Full and Third Octave Filters	12 Months
	Acoustic Calibrators	12 Months
Vibration Level Tests (performed w/SLM)	Sound level meter (SLM)	12 Months
	Accelerometers / Transducers	12 Months
	Vibration Integrators	12 Months
	Vibration Calibrators	12 Months
Vibration Level Tests (performed w/ Vibration Meter)	Vibration Meter	12 Months
	Accelerometers / Transducers	12 Months
	Vibration Integrators	12 Months
	Vibration Calibrators	12 Months
General Temperature and Moisture Uniformity Test	Air Temperature Measurement Instrument	12 Months
	Humidity Measurement Instrument	12 Months
Comprehensive Temperature and Moisture Uniformity Test	Data Recorder - Temperature	12 Months
	Data Recorder - Humidity	12 Months

PART 3 -- EXECUTION

3.1 INSPECTION

- A. NEBB Certified CPT Firm and the NEBB Certified CPT Professional shall be responsible to visit the facility to verify that the construction of the cleanroom spaces shall be in a condition ready for the specified test occupancy state. Inspection should include, but not limited to, the following items:
 - 1. Building perimeter walls, roof, and accessories installed to create a pressurized

envelope around the cleanroom.

- Cleanroom perimeter walls, ceiling, raised floor panels, doors, and necessary interior partitions installed that are essential to successful system performance. If approved by the Construction Manager or Owner, use temporary barriers for area isolation.
- 3. Laboratory equipment, case work, biological safety cabinets, and fume hood installations are complete and the equipment is operating.
- 4. Permanent personnel gowning area in operation.
- 5. Final wipe down cleaning procedures complete on:
 - a. Cleanroom finished surfaces.
 - b. HVAC system ducts, plenums, and air handler surfaces exposed to airflow.
 - c. Wall and floor cavities used as part of the cleanroom air handling strategy.
 - d. Building structural elements and utility systems in contact with the cleanroom airstream.
- B. NEBB Certified CPT Firm and the NEBB Certified CPT Professional shall be responsible to visit the facility to verify that the building environmental systems shall fully operational, under control and commissioned and shall be in a condition ready for the specified test occupancy state. Verification should include, but not limited to, the following items:
 - 1. Air-handling systems serving the cleanroom installed and operating under automatic controls and fully commissioned.
 - 2. Testing, adjusting and balancing complete for both the air and the hydronic systems serving the cleanroom air-handling systems.
 - 3. Process exhaust systems and pressurization control fans installed and operating to simulate cleanroom pressurization.
 - 4. Cleanroom lights, sprinklers, and safety devices installed and operational.
 - 5. Housekeeping vacuum system operational.
 - 6. Support systems required to perform certification tests operating normally for a minimum stable period of 5 days.

3.2 PREPARATION

- A. Confirm that activities within the facility comply with the requirements of the specified cleanroom occupancy test state. Inspect the entire cleanroom, accompanied by the Construction Manager or Owner, and note existing conditions that could jeopardize the certification results. Obtain the Construction Manager or Owner's written release before proceeding with certification steps.
- B. Coordinate field certification activities with the Construction Manager or Owner to permit

observation of any test procedure.

3.3 CLEANROOM PRIMARY AND SECONDARY TEST PROCEDURES

A. Airflow Velocity and Velocity Uniformity Test: (NEBB-PSCTC Section 10.2 through 10.6)

1. Purpose of Test:

- a. Determine the average supply airflow velocity delivered through each ceiling filter.
- b. Determine the airflow velocity uniformity throughout the cleanroom.
- c. Determine air velocity profile 50 mm,150 mm or 300 mm (2 in, 6in. or 12 in.) below the face screen of each ceiling filter.

2. Test Procedure:

- a. Measure and record the supply airflow velocity delivered through the filter using thermal anemometer or a tube array with a digital manometer.
- b. Measure and record the airflow velocity profiles.
- c. Measure and record the air velocity profile for 5 seconds. Select the average of the two values for the recorded reading.

3. Acceptance Criteria:

- a. The average supply airflow velocity for each filter should be within ±10% of the design airflow supply velocity.
- b. The average or total airflow velocity for the cleanroom shall be within $\pm 10\%$ of the design.
- c. The standard deviation shall not exceed 15%.

4. Documentation:

- a. Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Sample Location Documentation
- e. As Left Data: Minimum airflow velocity
- f. Maximum airflow velocity
- g. Average airflow velocity
- h. Test Results Data
- i. Report all airflow measurements with corresponding grid locations.
- j. Standard Deviation
- k. Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.
- B. Airflow Volume Test: (NEBB-PSCTC Section 10.7 through 10.9)

1. Purpose of Test:

- a. Determine the supply airflow volume delivered through each ceiling filter.
- b. Determine the airflow volume uniformity throughout the cleanroom.

2. Test Procedure:

- a. Measure and record the supply airflow volume delivered through the filter using a flow hood. Use appropriate size capture enclosure for each filter application.
- b. Measure and record the airflow volumes.

3. Acceptance Criteria:

- a. The average supply airflow volume for every ceiling filter should be within ±10% of the design airflow supply volume.
- b. The average or total airflow volume for the cleanroom shall be within ±10% of the design.
- c. The standard deviation shall not exceed 15%.

4. Documentation:

- a. Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Sample Location Documentation
- e. Duct Size and Individual Velocities
- f. As Left Data: Total Airflow Volume
- g. Test Results Data
- h. Report all airflow measurements with corresponding grid locations.
- i. Standard Deviation (If multiple airflow volume measurements are made on multiple devices).
- Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

C. Cleanroom Ceiling System / Filter Leakage Test (Aerosol Photometer Test Method): (NEBB-PSCTC Section 10.10 through 10.11)

1. Purpose of Test:

- a. Determine integrity of cleanroom ceiling system / filters after installation.
- b. Determine leakage through any component in the ceiling system assembly.

2. Test Procedure:

- a. Verify that the design airflow velocity has been balanced by a NEBB Certified TAB Firm prior to performing the filter installation leak test.
- b. Test the entire ceiling system assembly.
- c. Furnish a source of air or thermal generated aerosol that conforms to the requirements of Part 2 of this specification.

- d. Provide a photometer that conforms to the requirements of Part 2 of this specification.
- e. Provide a scanning probe that conforms to the requirements of Part 2 of this specification.
- f. Introduce challenge aerosol from the generator into the recirculation air system. A minimum challenge shall be 10 μ g/L is required at each filter.
- g. Measure and record the upstream challenge at each individually ducted filter and within the localized ceiling system at least once every 4 hours.
- h. Scan the entire downstream filter face area isokinetically in overlapping strokes, moving the probe at the calculated scan rate, the scan rate is to be no more than 0.05 m/s (10 fpm), at a distance 25 mm (1 inch) below the filter face. Scan the entire perimeter, center support mullions, and corners. If required, provide filter shrouds in partial filter coverage ceilings to block air entrained from adjacent non-airflow components.
- j. Scan joints in the ceiling system assembly, including the gap between the ceiling grid and filter, wall-to-ceiling joint, sprinkler pipe and electrical conduit penetrations, and blank panel edge seals.
- k. Leak(s) defined as a sustained reading greater than 0.01% of the measured upstream challenge concentration, or as specified in the contract documents or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm, shall be documented.
- Repairs, leaks and retesting of cleanroom ceiling systems shall be performed in accordance with the requirements as stated in the contract documents or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

3. Acceptance Criteria:

- a. Reject any component of the cleanroom ceiling system where the leak exceeds 0.01% percent of the measured upstream challenge concentration.
- b. Reject any filter where one dimension exceeds 38 mm (1.5 inch) in length or with an accumulative total repair area of 3 percent of media pleated face area.

Documentation:

- Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Challenge Medium
- e. Upstream Challenge Concentration
- f. Leak:
 - Location
 - 2. Percent of Penetration
 - 3. Type (Media, Grid, Gel, Etc.)

- g. Test Results Data
- Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.
- i. Scan Rate
- j. Repairs (Individual):
 - 1. Number
 - 2. Size
 - 3. Location
 - 4. Area
 - 5. Repairs: Total percentage of repair area

D. Airborne Particle Count Cleanliness Classification Test: (NEBB-PSCTC Section 10.14)

1. Purpose of Test: The airborne particle count cleanliness classification test is performed to determine the actual particle count level within the facility at the specified occupancy state.

2. Test Procedure:

- a. Complete the installed ceiling cleanroom filter leakage scan test, makeup air handler cleanroom final filter media test, parallelism test, pressurization test, air velocity uniformity test, and the enclosure induction leak test before starting airborne particle count sampling.
- b. Measure and record the particle count at a distance 1067 mm (42 inches) above the floor on a sample location grid and sample volume basis as defined in ISO Standard 14644-1.
- c. Retesting of failed particle count sample locations shall be performed in accordance with the requirements as stated in the contract documents or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

3. Acceptance Criteria:

- a. The air in a cleanroom or controlled environment shall have met the acceptance criteria for an airborne particulate cleanliness class (see NEBB-PSCTC Table 10-1). The cleanroom cleanliness classification is acceptable when the averages of the particle concentrations measured at each of the locations fall at or below the class limit. Additionally, if the total number of locations sampled is greater than one and less than ten, the mean of these averages must fall at or below the class limit with a 95% UCL.
- b. If the results are non-compliant based on the 95% UCL calculation due to a single "outlier" value, it does not need to be included in a recalculation of the 95% UCL analysis provided that the outlier is due to procedural error or equipment malfunction. Additionally, the calculation is repeated with all remaining sample locations and at least three samples remain in the

- calculation. Additionally the cause of the outlier is documented. Deletion of the outlier in the 95% UCL calculation shall be as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.
- c. Clean work zones within the cleanroom may also be allowed. These clean work zones shall be classified based on the maximum allowable particle count within that clean work zone.

4. Documentation:

- a. Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Standard Operating Procedure
- e. Test Occupancy State
- f. Test Results Data
- g. Particle Size(s) of Interest
- h. Actual Room Classification
- Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

j.

E. Pressurization Test: (NEBB-PSCTC Section 10.16)

- Purpose of Test:
 - a. Confirm capability of cleanroom air-handling systems to maintain cascaded air pressure differentials between the cleanroom and the adjacent support areas per the design requirements.

2. Test Procedure:

- a. Measure and record the relative pressure differentials between each cleanroom and the adjacent area.
- b. Measure and record the relative pressure differentials sequentially from the area with the highest cleanliness requirement outward through contiguous spaces to the outdoors.

3. Acceptance Criteria:

a. Compare actual pressure differential to design requirements.

4. Documentation:

- Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Test Results Data
- e. Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

F. Airflow Parallelism Test: (NEBB-PSCTC Section 11.2)

1. Purpose of Test:

a. Verify parallel vertical flow paths of supply airflow.

2. Test Procedure:

- a. Measure and record the parallel vertical flow path.
- b. Divide the cleanroom into equal area grids. The maximum grid spacing shall be 3m x 3m (10 ft x 10 ft). Perform the test in the middle of each grid.
- c. Secure the plumb line, spirit level or straight edge as required, mark the plumb line at 305mm (12 inch) intervals.
- d. Introduce the test medium (streamer or vapor) using a support stand at the specified test grid location and height.
- e. Measure the distance from the plumb line to the test medium. The offset is determined at a distance of 915mm (36 inches) and 1525mm (60 inches) above the floor.
- f. Calculate the angle of deflection.

3. Acceptance Criteria:

a. The angle of deflection should not be greater than 14° from center when measured higher than 915mm (36 inches) above the floor.

4. Documentation:

- a. Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Test Results Data
- e. Test Location Diagram
- f. Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

G. Recovery Test: (NEBB-PSCTC Section 11.3)

1. Purpose of Test:

a. Determine ability of cleanroom air-handling system to recover cleanliness levels after an internal particle upset.

2. Test Procedure:

- a. Measure the particle counts at an initial condition in the cleanroom
- b. Generate the particulate challenge at the supply air inlet to the cleanroom to raise the particle count to following levels: ISO Class 5 and Cleaner: 100 times the established target cleanliness level.

ISO Class 6 and Above: 10 times the established target cleanliness

level.

- c. Shutoff the aerosol challenge
- d. Take particle counts for 6 second sample periods for each minute until the particle count is returned to the target cleanliness level measured prior to the introduction of the challenge particles.
- e. Document the recovery time.

3. Acceptance Criteria:

a. Acceptance of the facility is subject to approval of satisfactory recovery rate as agreed to by the Owner.

4. Documentation:

- a. Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Initial Particle Counts at Particle Size(s) of Interest
- e. Challenge Medium
- f. Challenge Concentration
- g. Test Results Data: Recovery Time
- h. Ending Particle Count at Particle Size(s) of Interest
- Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

H. Lighting Level Test: (NEBB-PSCTC Section 11.4)

1. Purpose of Test:

a. Determine that the installed lighting levels and lighting uniformity meet the specified requirements.

2. Test Procedure:

- a. For high intensity, or fluorescent systems, in relatively new lamp installations, verify that lamps have been in operation for a minimum of 100 hours before measurements are taken.
- b. Verify that high intensity discharge or fluorescent systems have been illuminated for at least two hours before measurements are taken.
- c. Luminance measurements should be made under actual working conditions. All lighting in the area including general lighting, task lighting and supplementary lighting should be in normal use.
- d. Measurements shall be made at work surface elevation and from a specified work point location with the combinations of daylight and electric lighting facilities available.
- e. Prepare a measurement grid based on room size and type of luminaries, spacing and location.
- f. Measure lighting intensity at 915mm (36 inches) above the finish floor using the appropriate equations from the NEBB-PSCTC. Use the appropriate equation for the cleanroom lighting layout.

- 3. Acceptance Criteria:
 - a. Compare actual lighting levels to design criteria requirements.
- 4. Documentation:
 - a. Technician's Name
 - b. Test Date(s)
 - c. Instrument Identification
 - d. Test Location Diagram
 - e. Test Results Data
 - f. Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.
- I. Sound Level Test: (NEBB-PSCTC Section 11.5)
 - 1. Purpose of Test:
 - Determine the operating sound level in the cleanroom produced by the facility support systems based on the specified occupancy state during the test.
 - 2. Test Procedure:
 - a. Measure and record the operating noise in the cleanroom when the cleanroom is at the specified occupancy test state.
 - b. Place pickup sensors to achieve a direct line of sight between the sound source and the sound meter at 1220mm (48 inches) above the floor and at least 915mm (36 inches) from a wall, column, or any other large surface capable of altering the sound measurements.
 - c. Record sound pressure data in all eight-octave bands.
 - 3. Acceptance Criteria:
 - a. Compare actual sound pressure levels to design noise criteria requirements.
 - Documentation:
 - a. Technician's Name
 - b. Test Date(s)
 - c. Instrument Identification
 - d. Test Location Diagram
 - e. Test Results Data: Operating Sound Pressure Levels: NC Curve, RC Curve or A-Weighted Value
 - f. Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.
- J. Comprehensive Temperature and Humidity Uniformity Test: (NEBB-PSCTC Section

11.7 through 11.9)

1. Purpose of Test:

- a. Confirm the capability of the facility support systems to control temperature and relative humidity to meet the project criteria.
- b. Verify uniformity of environmental conditions throughout contiguous areas of the cleanroom.
- c. Confirm stability of environmental conditions at control sensing points.

Test Procedure:

- a. Designate a minimum of one temperature and relative humidity measurement location in each temperature control zone.
- b. Verify that the HVAC system(s) TAB work has been completed prior to performing this test.
- c. Verify that the airflow uniformity test have been competed and accepted.
- d. Allow the HVAC system to operate under automatic control for a minimum of 24 hours prior to beginning this test. Support systems shall have been in normal automatic operation under control of calibrated permanent controllers for at least 7 days.
- e. Uniformly place each temperature and humidity sensor at each designated work level sampling location and allow the sensor to stabilize.
- f. Measure and record the temperature and humidity measurement simultaneously at each location every 6 minutes for a minimum period of 2 hours.

3. Acceptance Criteria:

a. Acceptance of the facility is subject to approval of satisfactory temperature and humidity uniformity as agreed to by the Owner.

4. Documentation:

- a. Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Test Location Diagram
- e. Work Height Level
- f. Test Results Data
- g. Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

K. Room Air Change Rate Test: (NEBB-PSCTC Section 11.3)

1. Purpose of Test:

a. Determine the number of times the air is being exchanged within the cleanroom on an hourly basis. The room air change rate per hour

(ACH) is determined by measuring the total airflow volume being supplied or returned from the cleanroom (whichever is greater) and by calculating the overall volume of the cleanroom.

2. Test Procedure:

- a. Determine if the cleanroom is under a positive or negative pressure.
- b. If the pressure is positive, measure and record the supply airflow volume delivered through the filter using a flow hood. Use appropriate size capture enclosure for each filter or supply diffuser application.
- c. If the pressure is negative, measure and record the return / exhaust airflow volume being captured by all return openings and process exhaust devices using a flow hood for return openings and appropriate traverse points on all process exhaust devices. Use appropriate size capture enclosure for each return opening application. Use appropriate traverse locations and traverse grid spacings for each process exhaust device.
- d. Measure the volume of the cleanroom space.
- e. Calculate the ACH by dividing the airflow volume by the cleanroom volume.

3. Acceptance Criteria:

 Acceptance of the facility is subject to approval of satisfactory ACH rate as agreed to by the Owner.

4. Documentation:

- a. Technician's Name
- b. Test Date(s)
- c. Instrument Identification
- d. Room Identification
- e. As Left Data: Total Airflow Volume per Hour, ACH
- f. Test Results Data
- g. Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.

L. Bench-Scan Filter Leakage Test: (NEBB-PSCTC Section 11.4)

1. Purpose of Test:

a. Determine integrity of each filter shipment by spot testing random statistical samples.

2. Test Procedure:

- a. Test every filter, or if owner approved, develop a statistical sample based on the following:
 - 1. Test all filters which show signs of damage.
 - 2. Test every fifth filter and upon failure, test additional untested filters

as agreed to between the NEBB Certified CPT Firm and the Owner.

- b. Provide flow test bench, aerosol photometer and oil generator (either Laskin nozzle or thermal) and a particle controlled environment.
- c. Introduce aerosol oil challenge or microsphere challenge upstream of the filter. A minimum upstream challenge shall be 10µg/L
- d. Measure the upstream challenge of each filter.
- e. Scan the entire downstream filter face area in overlapping strokes, moving at the calculated scan rate (See NEBB-PSCTC) spaced a distance of 25 mm (1 inch) from the filter face.
- f. Repairs, leaks and retesting of filters shall be performed in accordance with the requirements as stated in the contract documents or as agreed to between the Owner / Buyer and the NEBB CPT Firm.

3. Acceptance Criteria:

- Reject any component of the cleanroom ceiling system where the leak exceeds 0.01% percent of the measured upstream challenge concentration.
- b. Reject any filter where one dimension exceeds 38mm (1.5 inch) in length or with an accumulative total repair area of 3 percent of media pleated face area.
- 4. Documentation (Failed Filters only):
 - a. Technician's Name
 - b. Test Date(s)
 - c. Instrument Identification
 - d. Challenge Medium
 - e. Upstream Challenge Concentration
 - f. Leak:
- 1. Location
- 2. Percent of Penetration
- 3. Type (Media, Frame, Etc.)
- g. Test Results Data
- h. Identify all performance data that exceeds the acceptance criteria as specified herein or as agreed to between the Owner / Buyer and the NEBB Certified CPT Firm.
- i. Scan Rate
- j. Repairs (Individual):
 - 1. Number
 - 2. Size
 - 3. Location

NEBB CPT PROCEDURAL STANDARDS

APPENDIX A-2 BIOMEDICAL & PHARMACEUTICAL

- 4. Area
- k. Repairs (Total):
 - 1. Total percentage of repair area