A Performing Site Assessment

1 Verify User Requirements

a Obtain purchase order
b Meet with client representative
c Determine use of facility to be tested
d Determine applicable standards
e Determine site specific tests to be performed
f Determine acceptance criteria
g Determine room availability
h Determine customer equipment availability

2 Perform safety assessment

a Determine room status
b Assure smoke detectors are disabled
c Determine personal protective equipment requirements
d Determine gowning requirements
e Determine other safety equipment requirements (ladders etc.)
f Comply with OSHA requirements
g Determine potential hazards

3 Evaluate Cleanroom Devices

a Perform visual inspection
b Locate handwashing sink
c Verify proper positioning of line of demarcation
d Verify absence of floor drains
e Verify presence of pressure monitoring devices

4 Evaluate Surface Finishes

a Visually verify ceiling tiles are caulked in place
b Visually verify penetrations are caulked (sprinkler heads, pipe penetrations, etc.)
c Visually verify seamless floor

5 Manage Certification Equipment

a Select Test Equipment
b Ensure equipment calibration
c Ensure equipment meets minimum accuracy requirements
d Maintain equipment condition

B Counting Total Particles

1 Select Test Equipment

a Determine particle counter meets minimum threshold
b Ensure particle counter is calibrated
c Ensure equipment is operational

2 Determine Sample Plan

a Measure area to be tested
b Calculate required number of samples
c Determine sample locations
d Create sample location map
e Determine sample volumes

3 Collect Air Samples

a Warm-up particle counter
b Perform zero count verification
c Setup sampling probe

d Check for flow rate
e Select particle size range
f Identify sample locations based on sample location map
g Perform particle counts at all locations
h Record individual particle count data

4 **Analyze Particle Count Data**

a Tabulate sample data
b Compare sample data to requirements
c Advise client of preliminary results

C Performing Environmental Monitoring

1 **Determine Sample Plan**

a Coordinate with accredited microbial laboratory
b Select sample type (air, surface, fingertip)
c Select sample media (TSA bacterial, MEA fungal)
d Select sample equipment
e Create sample location map
f Determine sample volume

2 **Collect Air Samples**

a Select sample volume
b Disinfect the sampling head
c Calibrate the sample flow
d Insert the media
e Draw air sample

3 **Collect Surface Samples**

a Select sample area
b Capture surface sample
c Disinfect surface area

4 **Collect Fingertip Samples**

a Assemble designated personnel
b Instruct personnel to don gloves
c Capture the fingertip sample
d Instruct personnel to dispose of tested gloves

5 **Process Collected Samples**

a Retrieve growth medium
b Document sample paperwork
c Label growth medium container
d Seal growth medium container
e Store collected samples
f Transport collected samples

6 **Analyze Sample Data**

a Verify data meets standard requirements
b Advise client of viable growth
c Acquire genus identification
d Acquire species identification
e Disclose results of each sample to client

D Determining Air Change Rate

1 Determine Test Plan

a Acquire volumetric room size
b Determine if capture hood alternative is required
c Select test equipment
d Select documentation method

2 Setup Primary Test Equipment

a Choose appropriate size capture skirt
b Assemble capture hood
c Select unit of measure (CFM)

3 Setup Alternative Test Equipment

a Choose velocity measuring device
b Determine sample point locations
c Assemble sample equipment
d Select unit of measure (FPM or Vp)
e Drill holes for duct traverse
f Determine effective airflow delivery area

4 Collect Airflow Volumes

a Measure the supply air volume
b Measure airflow velocity for alternative test
c Convert velocity pressure from alternative test to velocity
d Convert velocity from alternative test to volume
e Record individual airflow volumes
f Seal duct penetrations
g Calculate air change rate

E Testing Airflow Velocity

1 Determine Test Plan

a Select test equipment
b Determine sample locations
c Determine number of sample points

2 Collect Air Velocity Data

a Setup test equipment
b Determine sample time constant
c Acquire velocity data at sample locations
d Record individual velocity data points
e Document air velocity data
f Analyze air velocity data

F Proving Room Segregation

1 Determine Test Plan

a Identify segregation points
b Select appropriate test equipment
c Select documentation materials
d Establish velocity grid for alternative test

2 **Execute Primary Test Plan**

a Zero the pressure sensing device
b Place sample tube across areas of differential pressure
c Engage measurement device
d Perform visual verification of pressure direction
e Document all test data
f Compare test data to user requirements

3 **Execute Secondary Test Plan**

a Set time constant
b Collect velocity readings
c Perform visual verification of pressure direction
d Document all test data
e Compare test data to user requirements

G Testing HEPA Filters

1 **Determine Test Plan**

a Determine test method
b Determine aerosol generation method
c Determine aerosol injection location
d Determine aerosol injection method
e Secure fire suppression system

2 **Execute Test Plan**

a Setup photometer to manufacturer's instructions
b Inject challenge aerosol upstream
c Set photometer to measure upstream concentration
d Measure upstream aerosol concentration
e Record upstream aerosol concentration
f Set photometer to upstream concentration
g Zero the photometer
h Scan HEPA filter
i Assess leaks for repair
j Document all test results
k Analyze test data

H Performing Airflow Visualization

1 **Determine Test Plan**

a Select airflow visualization medium
b Determine distribution strategy
c Determine documentation strategy
d Communicate with compounding supervisor

2 **Execute Test Plan**

a Distribute visualization medium
b Analyze influence of compounding personnel and equipment
c Analyze ISO Class 5 unidirectional flow pattern
d Analyze impact of room air patterns on ISO Class 5 areas
e Provide operational adjustments based on observed results
f Document final air flow pattern results

I Preparing Certification Reports

1 Document Implemented Procedures

- a Describe test procedures
- b Document acceptance criteria
- c Document standards applied
- d Document guidelines applied
- e Document user requirements
- f Document test equipment
- g Provide test equipment calibration documentation
- h Document test personnel qualifications
- i Describe test conditions
- j Document dates of testing

2 Summarize Test Results

- a Consolidate test data
- b Analyze data
- c Document pass/fail decision
- d Document corrective actions
- e Quality check report