

Standard Operating Procedure Operational Procedure for HEPA Filter Challenge	SOP No. 8.014
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Revision No.: 1

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Revision Date: 5-7-97
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- 1 Purpose
 - 1.1 To establish a standard procedure for insuring that the HEPA filter system is properly installed by verifying the absence of bypass leakage, and that HEPA filters are free of defects and pinhole leaks.
- 2 Scope
 - 2.1 This procedure applies to the HEPA filter system, challenged by ambient and aerosol methods.
- 3 Reference
 - 3.1 NEBB Procedural Standards for Certified Testing of Cleanrooms, Second Edition, 1996.
- 4 Definition
 - 4.1 CFM Cubic Feet per Minute
 - 4.2 HEPA High Efficiency Particulate Air
 - 4.3 PSIG Pounds per Square Inch Gauge
 - 4.4 TAB Test, Adjust, and Balance
- 5 Responsibility
 - 5.1 TAB technicians shall record all test readings on Form FN 8.014.1 (HEPA Filter Location).
 - 5.2 TAB technicians shall save all test reports in files, located in the TAB department of Therma.
 - 5.3 All test equipment utilized shall be in calibration in accordance with NEBB Standards and traceable to the National Institute of Standards and Technology (NIST).
- 6 Materials Requirement

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- 6.1 Dioctylphthalate (DOP)
- 6.2 Poly-alpha olefin (Emery 3004)
- 6.3 Polystyrene Latex Sphere (PSL)
- 7 Test Equipment
 - 7.1 Aerosol Generator
 - 7.2 Aerosol Photometer
 - 7.3 Hand Held Probe
 - 7.4 Optical Particle Counter with audible alarm

8 Procedures

8.1 Ambient Aerosol Particle Challenge Method

Note: This method is used to find leaks in the HEPA filters, their holding frame assemblies and mounting devices, or other passageways from the upstream side to the clean side.

- 8.1.1 Verify HEPA airflow.
- 8.1.2 Measure the ambient particle concentration upstream of HEPA filter system using the optical particle counter.
- 8.1.3 Calculate the acceptable scan rate (Sr) using the following equation:

$$Sr = \frac{Cc \times Ls \times Fs \times Dp}{60 \times Np} \quad (\text{EQ. \#1})$$

Where:

	Sr	=	Acceptable Scan Rate, in/s
Cc	=	Upstream challenge concentration, particles/ft ³	
Ls	=	Significant Leak, % of upstream	
Fs	=	Sample flow rate of instrument used, cfm	
Dp	=	Probe dimension parallel to scan direction, in	
Np	=	Number of particle counts that indicate the leak	
60	=	Conversion, 60 sec/min	

- 8.1.4 Record all data on the Form FN 8.014.1 (HEPA Filter Location).

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8.1.5 Scan the face and the perimeter of the filter pack by passing the hand held probe approximately 1 inch (25 mm) from the area to be tested during the scanning.

8.1.6 Mark off the locations with a visible sign when the audible alarm is on. Report the leaky locations on the Form FN 8.014.1 (HEPA Filter Location).

8.2 Aerosol Particle Challenge Test (If Required)

Note: This test is performed by introducing one of the following challenges: Dioctylphthalate (DOP), Poly-alpha olefin (Emery 3004) or Polystyrene Latex Sphere (PSL) upstream of HEPA filters and searching for leaks by scanning the downstream side of the filters with the photometer probe. Note: Currently, FDA approved to use Dioctylphthalate (DOP) or Poly-alpha olefin (Emery 3004) as the only test challenge materials.

8.2.1 Verify HEPA airflow.

8.2.2 Measure and record the ambient particle concentration prior to generation of any particle challenge.

8.2.3 Set the aerosol generator air supply pressure at 20 psig minimum.

8.2.4 Introduce the particle challenge at the blower inlet(s) or another location that will produce a uniform mixture over all filters being tested.

8.2.5 Measure the upstream aerosol concentration using either a linear or logarithmic photometer scale and record the readings on Form FN 8.014.1 (HEPA Filter Location). Adjust meter to indicate 100%.

8.2.6 Scan the filter face and the perimeter of the filter pack by passing the photometer probe approximately 1 inch (25 mm) from the area to be tested during the scanning.

8.2.7 Calculate the acceptable scan rate (Sr) using the EQ. #1 in the previous step 8.1.3.

8.2.8 Record all data on the Form FN 8.014.1 (HEPA Filter Location).

8.2.9 Report all leaks which exceed the following requirements on the Form FN 8.014.1 (HEPA Filter Location).

8.2.9.1 For linear readout photometer: a reading > 0.01% of the upstream challenge aerosol concentration.

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8.2.9.2 For logarithmic readout photometer: a reading > 1 scale division.

8.2.10 Perform the previous steps by introducing Polystyrene Latex Spheres (PSL) as the specific aerosol if this is in the customer's specification.

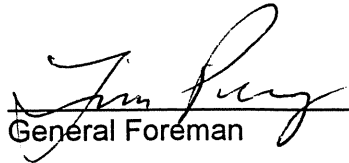
9 Review and Approval

9.1 Return the Form FN 8.014.1 (HEPA Filter Location) to the TAB Department for review.

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Document Approval


General Foreman

4-15-97
Date


Service Manager

4-15-97
Date


Quality Assurance Manager

4-16-97
Date

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