

Standard Operating Procedure HEPA Filter Leak Test (Oil-Based Challenge) Aerosol Total Penetration Method	SOP No. 8.060
--	------------------

DCR No.: 03056
Revision No.: 0

Effective: 12-23-03
Supersedes: New
Revision Date: New
Page No.: 1 of 4

1 Purpose

- 1.1 To establish a standard procedure to ensure and confirm the integrity of the High Efficiency Particulate Air (HEPA) and/or Ultra-Low Penetration Air (ULPA) filter system installation by verifying the absence of bypass leakage in the physical installation and that the filters themselves are free of defects and pinhole leaks.

2 Scope

- 2.1 This procedure applies to leak testing of HEPA and ULPA filters when the filter media is inaccessible for a direct scan.

3 References

- 3.1 National Environmental Balancing Bureau (NEBB) Procedural Standards for Certified Testing of Cleanrooms, 1996.
- 3.2 Institute of Environmental Sciences and Technology (IEST) IEST-RP-CC006.2, Testing Cleanrooms.
- 3.3 Institute of Environmental Sciences and Technology (IEST) IEST-RP-CC001.3, HEPA and ULPA Filters.
- 3.4 NSF International Standard / American National Standard for Biosafety Cabinetry – Class II (laminar flow) biosafety cabinetry (2002).

4 Definitions

- 4.1 HEPA: High Efficiency Particulate Air
- 4.2 ULPA: Ultra-Low Penetration Air
- 4.3 CFM: Cubic Feet per Minute
- 4.4 PSIG: Pounds per Square Inch Gauge
- 4.5 TAB: Test and Balance

THIS DOCUMENT CONTAINS PROPRIETARY INFORMATION OF THERMA CORPORATION. ALL INFORMATION SHALL (A) BE RETAINED IN CONFIDENCE; (B) NOT BE REPRODUCED IN WHOLE OR IN PART; AND (C) NOT BE USED OR INCORPORATED IN ANY PRODUCT EXCEPT UNDER EXPRESSED WRITTEN AGREEMENT WITH THERMA CORPORATION.

Revision No.	SOP No.	Page
0	8.060	2 of 4

5 Responsibilities

- 5.1 Test and Balance (TAB) technicians shall record all test readings on Form FN 8.059.1 (Filter Leak Scan).
- 5.2 All test reports shall be saved in files, located in the TAB department of Therma.
- 5.3 All test equipment utilized shall be in calibration in accordance with National Environmental Balancing Bureau (NEBB) Standards and traceable to the National Institute of Standards and Technology (NIST).

6 Materials Requirements

- 6.1 Dioctylphthalate (DOP) or
- 6.2 Poly-alpha olefin (Emery 3004)
- 6.3 Ringstand and Clamp

7 Test Equipment

- 7.1 Source of air-generated aerosol using equipment indicated in NEBB Procedural Standards for Certified Testing of Cleanrooms, 1996, Section 14.6 (Aerosol Generation).
- 7.2 Aerosol Photometer and Hand Held Probe that meet the criteria in NEBB Procedural Standards for Certified Testing of Cleanrooms, 1996, Chapter 6, Section 6.2, Subsection 6.2.1, Paragraph 6.2.1.2.

8 Procedures

- 8.1 Produce a sketch or drawing indicating the relative location of each filter that is to be tested.
- 8.2 Record the clients identification number on Form FN 8.059.1 (Filter Leak Scan).
- 8.3 Record the filter serial number on the Form FN 8.059.1 (Filter Leak Scan).
- 8.4 Introduce the challenge aerosol into the airstream upstream of the filter(s) to be challenged in a manner, which will produce a uniform challenge concentration. Follow the procedure found in NEBB Procedural Standards for Certified Testing of Cleanrooms, 1996, Chapter 6, Section 6.6, Subsection 6.6.2, Paragraph 6.6.2.2.

<p>THIS DOCUMENT CONTAINS PROPRIETARY INFORMATION OF THERMA CORPORATION. ALL INFORMATION SHALL (A) BE RETAINED IN CONFIDENCE; (B) NOT BE REPRODUCED IN WHOLE OR IN PART; AND (C) NOT BE USED OR INCORPORATED IN ANY PRODUCT EXCEPT UNDER EXPRESSED WRITTEN AGREEMENT WITH THERMA CORPORATION.</p>

Revision No.	SOP No.	Page
0	8.060	3 of 4

- 8.5 Adjust the concentration of aerosol in micrograms per liter ($\mu\text{g/l}$) upstream of the filter(s) to be challenged to a minimum level of 10 $\mu\text{g/l}$ and a maximum level of 20 $\mu\text{g/l}$.


If the upstream challenge cannot be measured and a Laskin Nozzle generator at 20 PSIG is used, the upstream concentration can be calculated using the following formula:

$$\text{Concentration in } \mu\text{g/l} = 13,500(\# \text{Laskin Nozzles} \div \text{CFM})$$

- 8.6 Record upstream filter challenge concentration on the Form FN 8.059.1 (Filter Leak Scan).
- 8.7 Perform filter leak scanning using the procedures listed in NEBB Procedural Standards for Certified Testing of Cleanrooms, 1996, Chapter 6, Section 6.6, Subsection 6.6.2, Paragraph 6.6.2.4.
- 8.8 Analyze the results using the acceptance standard specified by customer or customer representative. If an acceptance standard is not specified, filter performance will be considered acceptable if downstream concentration measurement do not exceed 0.005% of the upstream concentration (From NSF International Standard / American National Standard for Biosafety Cabinetry – Class II (laminar flow) biosafety cabinetry (2002), Annex F, Page F8, Paragraph F.5.4.2).
- 8.9 Record filter leak test results, Pass or Fail, on the Form FN 8.059.1 (Filter Leak Scan).
- 8.10 If authorized by the customer, repair filter following the guidelines in NEBB Procedural Standards for Certified Testing of Cleanrooms, 1996, Chapter 6, Section 6.2, Subsection 6.2.4, Paragraph 6.2.4.2 and/or Subsection 6.2.5, “Repairs”.
- 8.11 After repairs are completed, retest filters utilizing steps 8.4 to 8.9.
- 8.12 Return the Form FN 8.059.1 (Filter Leak Scan) to the TAB Department for review and approval.

Revision No.	SOP No.	Page
0	8.060	4 of 4

Document Approval



Test and Balance Supervisor

12/23/03

Date



Engineering Manager

12/23/03

Date



Quality Assurance Manager

12/23/03

Date

THIS DOCUMENT CONTAINS PROPRIETARY INFORMATION OF THERMA CORPORATION. ALL INFORMATION SHALL (A) BE RETAINED IN CONFIDENCE; (B) NOT BE REPRODUCED IN WHOLE OR IN PART; AND (C) NOT BE USED OR INCORPORATED IN ANY PRODUCT EXCEPT UNDER EXPRESSED WRITTEN AGREEMENT WITH THERMA CORPORATION.