

Standard Operating Procedure <b>Biohazard Class II Cabinet HEPA Filter Leak Test</b>	SOP No. 8.050
---	------------------

DCR No.: 03019  
Revision No.: 1

**Effective:** 3-5-99  
**Supersedes:** 3-5-99  
**Revision Date:** 11-15-03  
**Page No.:** 1 of 4

- 1 Purpose
  - 1.1 To establish a standard procedure to determine the integrity of supply and exhaust HEPA filters, filter housings, and filter mounting frames of Class II Biohazard Cabinets.
- 2 Scope
  - 2.1 This procedure applies to Class II Biohazard Cabinets.
- 3 Reference
  - 3.1 NSF Standard 49, 2002.
- 4 Definition
  - 4.1 HEPA: High Efficiency Particulate Air
  - 4.2 CFM: Cubic Feet per Minute
  - 4.3 PSIG: Pounds per Square Inch Gauge
- 5 Responsibility
  - 5.1 Test and Balance (TAB) technicians shall record all test measurements on Form FN 8.057.3 (Biohazard Safety Cabinet Test Report Details II) in the HEPA Filter Leak Test section and indicate the test results, Pass or Fail, on Form FN 8.057.1 (Biohazard Safety Cabinet Test Report Summary Sheet).
  - 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).

<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
1	8.050	2 of 4

## 6 Materials Requirement

- 6.1 Dioctylphthalate (DOP) or
- 6.2 Poly-alpha olefin (Emery 3004) or
- 6.3 Polystyrene Latex Sphere (PSL)
- 6.4 Ringstand and Clamp

## 7 Test Equipment

- 7.1 Source of 20 PSIG
- 7.2 Total Scattering Aerosol Photometer and Hand Held Probe that meet the criteria in NSF 49, Annex F, Section F.5, Subsection F.5.2
- 7.3 Aerosol Generator that meets the criteria in NSF 49, Annex F, Section F.5, Subsection F.5.2
- 7.4 A pressure gauge for the generator having a maximum range of 0 to 80 PSI with resolution and accuracy of 1 PSI.

## 8 Procedures

- 8.1 Prior to performing the following tasks, verify the appropriate HEPA filter challenge agent (e.g. DOP, PAO or others) that can be used in the customer's facility.
- 8.2 Calculate the HEPA filter challenge concentration. Record HEPA challenge concentration on the Form FN 8.057.3 (Biological Safety Cabinet Test Report Detail II).

Concentration of the challenge, when 20 PSIG is available at the Laskin Nozzle Generator using DOP, can be calculated by using the following formula:

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

- 8.3 Refer to NSF 49, Annex F, Section F.5.3, Subsection F.5.3.1 and F.5.3.2 for procedure.
- 8.4 Refer to NSF 49, Annex F, Section F.5.4 for standards of acceptance.
- 8.5 TAB technicians shall indicate Pass or Fail for the HEPA filter leak test, on Form FN 8.057.1 (Biohazard Safety Cabinet Test Report Summary Sheet).

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
1	8.050	<b>3 of 4</b>

## 9 Review and Approval

- 9.1 TAB technicians shall return the Form FN 8.057.1 (Biohazard Safety Cabinet Test Report Summary Sheet) and the Form FN 8.057.3 (Biological Safety Cabinet Test Report Detail II) to the TAB Department for review.

Revision No.	SOP No.	Page
1	8.050	4 of 4

## Document Approval

  
 Test and Balance Supervisor

10/01/03  
 Date

  
 Engineering Manager

10/01/03  
 Date

  
 Quality Assurance Manager

11-15-03  
 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.