# DETERMINATION OF EXHALATION VALVE LEAKAGE TEST, AIR-PURIFYING RESPIRATORS STANDARD TESTING PROCEDURE

## 1. PURPOSE

This document establishes the testing procedure for ensuring that exhalation valves included as part of air-purifying, or air-supplied respirators submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet the minimum certification standards for leakage set forth in 42 CFR Part 84, Subpart H, Section 84.92, Subpart I, Section 84.123, Subpart J, Section 84.158, Subpart K, Section 84.173, and Subpart L, Section 84.204.

## 2. GENERAL

This standard testing procedure (STP) describes the named procedure in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the product passes the test, and create a record of those results, reporting the measurements obtained in a preestablished, standard format.

## 3. EQUIPMENT/MATERIALS

3.1. Vacuum Source: Capable of supplying a steady negative gauge pressure of 102 millimeters of water ($mmH_2O$), or 4 inches of water ($inH_2O$).

3.2. Manometer: Meriam, model Z10AA25WM, or equivalent. U-tube style manometer, with a 6 inch (in.) scale in 0.1 in. increments.

3.3. Airflow calibrator: Sensidyne, Gilibrator-2 Primary Calibrator System, or equivalent. Range of 1-250 milliliters per minute (mL/min). Accuracy of ±1.0 percent (%) of reading. NOTE: The Gilibrator system requires Bubble Generator Soap Solution, p/n 800450.

3.4. Test fixture: A custom holder or fixture to seal the exhalation valve assembly in the proper position while the vacuum is applied. This holder is not specific and may be modified with each valve design submitted. Generic laboratory funnels are typically used for this purpose, where the funnels may be in various sizes (dependent on size of the exhalation valve assemblies) that accommodate the exhalation valve assembly in a manner allowing an airtight seal to be achieved around its perimeter.

3.5. Hot melt glue: 3M, model 3764, or equivalent. With compatible hot melt glue gun.

3.6. Hot plate: Thermo Scientific, model HPA1915BQ, or equivalent.

3.7. Beaker, stainless steel: Medegen, model 95160, or equivalent.

3.8. Tubing: Generic brand appropriate for laboratory use. Nominal 0.25 in. inner diameter. Suitable for use with a pinch clamp for flow stoppage.

3.9. Beeswax, natural.

3.10. Caulking cord: Mortite, grey, or equivalent.

3.11. Vacuum bottle: Generic brand, approximately 0.5 gallons, suitable for a minimum of 4 in$H_2O$ vacuum. Bottle has been modified to have three 0.25 in. tubing bulkhead ports for connection to the vacuum source, air inlet valve, and tubing to rest of system.

3.12. Various general lab supplies, as needed: Equipment may include hose clamps, eye droppers, flux brush, tubing connectors, and tube fittings.

## 4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Equipment shall be operated and calibrated in accordance with the testing laboratory's operation and calibration procedure(s) or the manufacturer's operation and maintenance manual(s). All measuring equipment utilized for this testing should have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST), when available.

4.2. Normal laboratory safety practices must be observed. Refer to Safety Data Sheets (SDS) for the proper protection and care in handling, storing, and disposing of the chemicals and gases used in this procedure. All applicable local, state, and federal regulations for the safe handling and use of hazardous substances shall be followed.

## 5. PROCEDURE

5.1. Each exhalation valve design subjected to testing requires three individual exhalation valve assemblies for testing.

5.1.1. Items submitted for testing may be individual exhalation valve assemblies or complete respirators. It is acceptable to remove the exhalation valve assemblies from a complete respirator, using care not to distort the exhalation valve assemblies.

5.2. Position and seal the exhalation valve assembly in the test fixture. If available, a test fixture provided by the applicant may be used. Typically, a test fixture is fashioned by seating the exhalation valve assembly in a funnel and sealing using beeswax, window caulking, and/or hot-melt glue. A second funnel is attached to the first funnel using beeswax or hot-melt glue to seal the assembled test fixture. It is important to make sure that neither the funnels nor supplied test fixtures distort or cover the exhalation valve assembly and will not interfere with the operation of the valve itself. NOTE: NIOSH will not be obligated to use applicant supplied test fixtures for approval testing. Applicant supplied test fixtures must be correlated with the NIOSH test method.

5.3. Set up test equipment as shown in Attachment A: Exhalation Valve Holder Assembly and Bench Top Set-Up. Further details are described in Attachment B: Description of Schematic Diagram of the System. NOTE: The numbers shown and described in Attachment A and Attachment B are repeatedly referenced in this document.

5.3.1. If necessary, the airflow calibrator, item 10, and test fixture, item 8, may be

switched in the sequence to accommodate unusual exhalation valve assemblies.

5.4. Seal the exhalation valve assembly in the test fixture in the same orientation as the normal operating position of the exhalation valve in the facepiece when worn.

5.5. If necessary, verify and adjust the water level in the manometer.

5.6. If necessary, wet the flow cell of the airflow calibrator by applying a low flow vacuum to the system and take multiple readings in quick succession. Reset the control unit.

5.7. Test the system for leaks.

5.7.1. Completely close off tubing at 9 using a pinch clamp. Apply a 102 ±5 mm$H_2O$ (4 in$H_2O$.) vacuum to the system using the vacuum source. If the vacuum source is insufficient to maintain 4 in$H_2O$ vacuum pressure, restrict the flow through the system using the needle valve at 2.

5.7.2. Close valve 5. If the pressure reading of the manometer starts to fall, then there is a leak at the manometer connection, and it must be corrected before proceeding to the next step.

5.7.3. Open valve 5. Close off valves 7 and 3 in that order. If the pressure reading of the manometer falls, then there is a leak at or near the "T" connector, and it must be corrected before proceeding to the next step.

5.7.4. Open valves 3 and 7. Close off valve 3. If the pressure reading of the manometer falls, then there is a leak around the test fixture, and it must be corrected before conducting the actual leakage test.

5.8. Attach the test fixture with mounted exhalation valve assembly at 8 and apply a 25 +5/-0 mm (1 +0.2 /-0 in.) in$H_2O$ vacuum pressure.

5.9. Measure the exhalation valve leakage using the airflow calibrator.

5.10. Repeat step 5.9 for a total of 3 measurements per exhalation valve assembly.

5.11. Repeat steps 5.2 through 5.10 for the remaining exhalation valve assemblies.

6. PASS/FAIL CRITERIA

6.1. The basis for passing this test is set forth in 42 CFR Part 84, Subpart H, Section 84.92, Subpart I, Section 84.123, Subpart J, Section 84.158, Subpart K, Section 84.173, and Subpart L, Section 84.204.

6.2. Exhalation valve, seat, seal leakage test.

6.2.1. Dry exhalation valves, valve seats, seals, or assemblies will be subjected to a vacuum of 25 mm$H_2O$ while oriented in a normal operating position.

6.2.2. The average rate of leakage of three (3) readings for a single exhalation valve assembly shall not exceed 30 mL/min.

## 7. RECORDS/TEST SHEETS

7.1. Record the test data in a format that shall be stored and retrievable. Data should be reported similar to Attachment C: Sample Test Data Sheet.

## 8. LIST OF ABBREVIATIONS AND ACRONYMS

Table 1: List of Abbreviations and Acronyms Used Within This Document

| Abbreviation or Acronym | Definition |
|---|---|
| % | percent |
| CFR | Code of Federal Regulations |
| in. | inch(es) |
| in$H_2O$ | inches of water |
| mL/min | milliliters/minute |
| mm$H_2O$ | millimeters of water |
| NIOSH | National Institute for Occupational Safety and Health |
| NIST | National Institute of Standard and Technology |
| NPPTL | National Personal Protective Technology Laboratory |
| SDS | safety data sheet |
| STP | standard testing procedure |

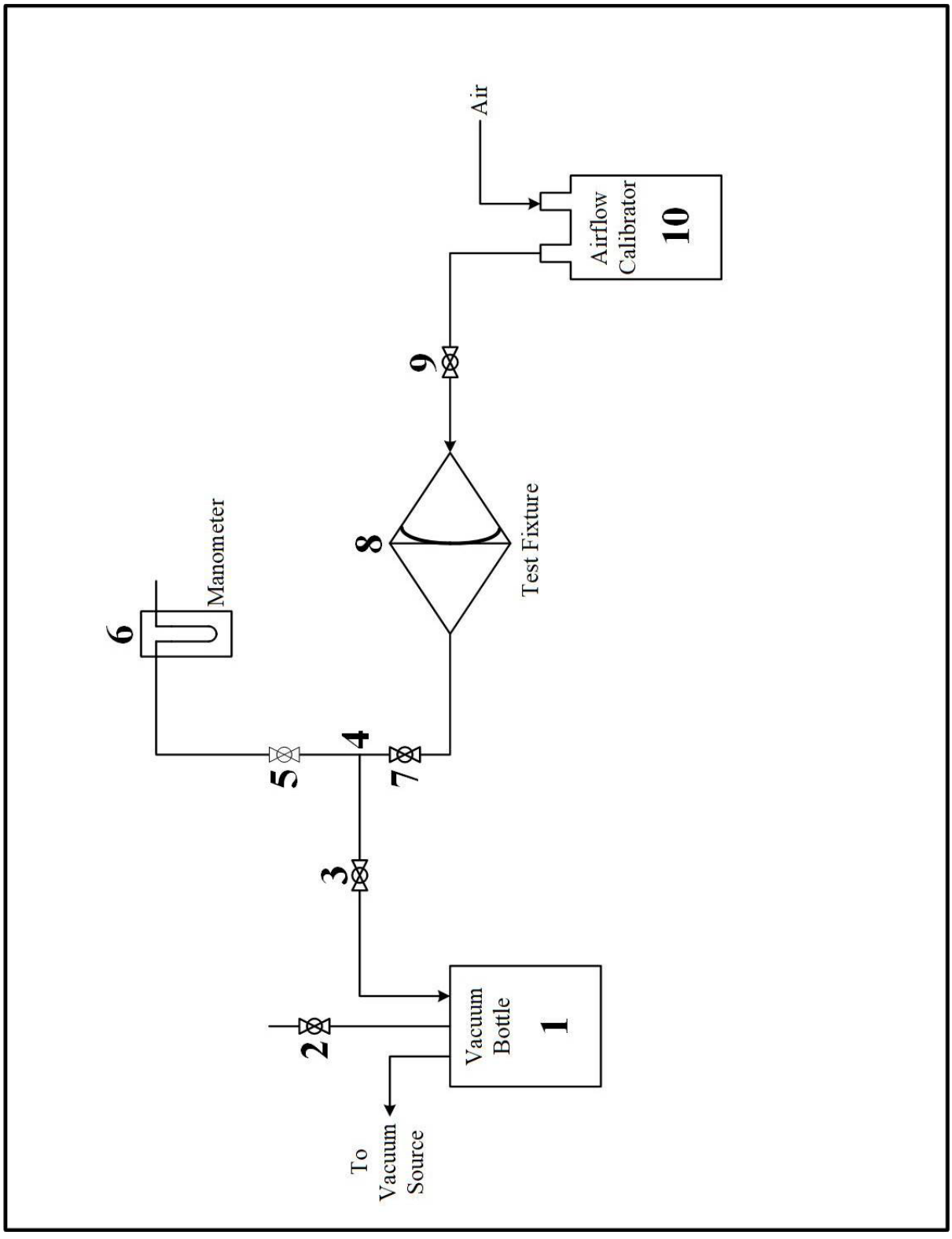
## 9. ATTACHMENTS

9.1. Attachment A: Exhalation Valve Holder Assembly and Bench Top Set-Up

9.2. Attachment B: Description of Schematic Diagram of the System

9.3. Attachment C: Sample Test Data Sheet

Attachment A: Exhalation Valve Holder Assembly and Bench Top Set-Up



Attachment B: Description of Schematic Diagram of the System

## Description of Schematic Diagram of the System

This attachment is a written description of Attachment A: Exhalation Valve Holder Assembly and Bench Top Set-Up, with each number written here corresponding to a number shown in Attachment A. NOTE: The components described here are approximations and may vary depending on the equipment used.

1. Vacuum bottle. The vacuum bottle assembly allows an accurate control of small negative pressures to the system.
2. 0.25 in. needle valve for control of flow.
3. 0.25 in. ball valve.
4. 3-Way "T" tube fitting.
5. 0.25 in. ball valve.
6. Manometer.
7. 0.25 in. ball valve. Tubing, approximately 30 in. in length.
8. Test fixture.
9. Tubing, approximately 30 in. in length, with pinch clamp.
10. Airflow calibrator system. For airflow measurement.

Attachment C: Sample Test Data Sheet

**National Institute for Occupational Safety and Health**

**Test Data Sheet**

**Task Number:**
**Test:** **STP No.:**
**Manufacturer:**
**Item Tested:**

| LEAKAGE | | | | | | |
|---|---|---|---|---|---|---|
| **Sample** | **Trial #1 (mL/min.)** | **Trial #2 (mL/min.)** | **Trial #3 (mL/min.)** | **Average (mL/min.)** | **Maximum Allowable (mL/min.)** | **Result** |
| Valve 1 | | | | | 30.00 | |
| Valve 2 | | | | | 30.00 | |
| Valve 3 | | | | | 30.00 | |
| **Overall Result:** | | | | | | |

**Comments:**

**Was all equipment verified to be in calibration throughout all testing?** ◯ **Yes** ◯ **No**

**Signature:** **Date:** _____

**Test Administrator**

# Revision History

| Revision | Date | Reason for Revision |
|---|---|---|
| 1.0 | 7 March 2004 | Historic document |
| 1.1 | 3 June 2005 | Update header and format to reflect lab move from Morgantown, WV No changes to method |
| 2.0 | 09 March 2009 | Significant re-write of RCT-APR-STP-0004. Changes affect form and provide clarification of technical content. |
| 2.1 | 15 December 2014 | Modified the equipment / material descriptions of 3.1.2 through 3.1.4, making the specifications the primary identification of the equipment. 3.1.8 the size of the mixing chamber was changed to match that in use. Also modified sections 5.3 to reflect current practice. Section 5.5, from rev 1, which indicated that the water level needed to be at zero was modified, since 1" can be generated from any starting point and the level doesn't always start at zero. Section 5.10 added a step indicating that section 5.6 can be excluded on remaining valves. Removed attachment 8.3 because the data sheet is out-of-date. Modifications to 5.4 make it possible to switch the order of the Gilibrator and the valve to test different types of exhalation valves, because the order in the series isn't feasible. References to clamps in 5.6 were removed to reflect current practice. |
| 2.2 | 22 March 2019 | -Section 1 through 3, Minor clarifying editorial updates have been made.<br>-Section 4, Updated to current laboratory standards omitting P and A exercise, and practices for lab safety in favor of those employed by the lab.<br>-Section 5, Removed note about calibration.<br>-Section 7, 7.1. has been edited to establish a "normal" data format.<br>-Section 8, An example data sheet has been included to better define the normal data format. |
| 3.0 | 18 August 2025 | Editorial rewrite of the document. Equipment model numbers updated. Updated Attachment B to match current test setup. |