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National Personal Protective Technology Laboratory  
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DETERMINATION OF EXHALATION VALVE LEAKAGE TEST,  
AIR-PURIFYING RESPIRATORS  
STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This test establishes the 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 84.182, Subpart L, Section 84.204, and Subpart KK, Section 84.1150.

2. GENERAL

This STP describes the Determination of Exhalation Valve Leakage Test, Air-Purifying Respirators Standard Testing 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.

3. EQUIPMENT/MATERIAL

3.1. The list of necessary test equipment and materials follows:

3.1.1. Vacuum source to supply a minimum negative pressure of 25 mm (1.0 inch) of water.

3.1.2. Manometer, with a readability of 0.1 inch, capable of measuring a 102 mm (4") water column height of vacuum.

3.1.3. Gilibrator Primary Flow Calibrator System: Capable of measuring 1 – 250cc/min using Bubble Generator Soap Solution p/n 800450. Accuracy:  $\pm 1\%$  of reading. The Gilibrator may not be used in laboratory conditions exceeding 85%RH.

3.1.4. Test 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 that is submitted. Equipment used for this purpose are funnels in various sizes (dependent on size of valves) that allow the valve assembly to be sealed to obtain an airtight seal.

Approvals: First Level	Second Level	Third Level	Fourth Level

- 3.1.5. Hot-melt glue and glue gun.
- 3.1.6. Hot plate and stainless steel beaker of appropriate size.
- 3.1.7. Miscellaneous Equipment – Hose clamps, tubing, eye droppers, 3-Way "T" tubing connector and small brush.
- 3.1.8. Vacuum bottle (approximately a half a gallon to one gallon) with three tube connections for house vacuum source, air inlet valve, and tubing to rest of system. This vacuum bottle apparatus allows an accurate control of small negative pressures to the system.
- 3.1.9. Short hose with pinch clamp for control of flow.
- 3.1.10. Beeswax.
- 3.1.11. Window Caulking.

#### 4. TESTING REQUIREMENTS AND CONDITIONS

- 4.1. Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with the testing laboratory's calibration procedure and schedule. All measuring equipment utilized for this testing must have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST) when available.
- 4.2. Any laboratory using this procedure to supply certification test data as a contractor to NIOSH will be subject to the provisions of the NIOSH Supplier Qualification Program (SQP). This program is based on the tenets of *ISO/IEC 17025, the NIOSH Manual of Analytical Methods* and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the program. Additional details of the Program and its requirements can be obtained directly from the Institute.\*  
**\*Note** 4.2 does not apply to Pretest data from applicants as required under 42 CFR 84.64.
- 4.3. Precision and accuracy (P&A) must be determined for each test setup in accordance with laboratory procedures and NIOSH/NPPTL guidance. Sound practice requires, under *NIOSH Manual of Analytical Methods*, demonstrating a tolerance range of expected data performance of a plus or minus 25% of a 95% confidence interval of the stated standard requirement. NIOSH/NPPTL P&A tolerance can be higher but not lower.
- 4.4. The precision and accuracy of this method was determined by validation testing of a single lot of commercially available exhalation valve assemblies from a NIOSH approved respirator facepiece. Three sample valve assemblies were modified to induce leakage. Each sample was re-mounted three times, and four readings were taken for each mounting, for a total of twelve readings per sample. The results of these tests are shown in the table below.

SAMPLE #	MEAN EXHALATION VALVE LEAKAGE, INDUCED (ML / MIN.)	STD. DEV.
1	18.92	1.52
2	13.06	0.22
3	38.36	1.92

4.5. Normal laboratory safety practices must be observed. Please refer to Material Safety Data Sheets and the current NIOSH Pittsburgh Health and Safety Program for the proper protection and care in handling, storing, and disposing of any chemicals used in this procedure.

## 5. PROCEDURE

Note: Reference Section 3 for equipment, model numbers and manufacturers. Refer to calibration procedures described in the manufacturer's operation and maintenance manuals.

- 5.1. Follow individual instruction manuals for set up and maintenance of equipment used in this procedure prior to beginning testing. Malfunctioning equipment must be repaired or replaced and properly set up and calibrated before starting all tests.
- 5.2. Use submitted exhalation valve assemblies, or remove the exhalation valve assemblies from the respirators without distortion of the valve or valve seat.
- 5.3. Position and seal the exhalation valve assembly in a funnel (unless a manufacturer's supplied test fixture has been provided and is being used), using beeswax, window caulking, and/or hot-melt glue. Use wax or hot-melt glue to seal a second funnel to the valve funnel to complete the test fixture. It is important to make sure that neither the funnels nor supplied test fixtures will cover the valve assembly and will not interfere with the operation of the valve itself.
- 5.4. Set up test equipment as shown in Figure 1 (if necessary the Gilibrator, item 10, and exhalation valve holder, item 8, may be switched in the sequence, to accommodate unusual valve assemblies). Place the exhalation valve assembly in test fixture, in the same orientation as the normal operating position of the exhalation valve in the facepiece when worn.
- 5.5. Check the water level in the manometer; adjust as necessary.
- 5.6. Test the system for leaks. (See Fig. 1.)
  - 5.6.1. Close off hose 9. Apply a 102 mm (4 inches)  $\pm$  5 mm vacuum to the system using the house vacuum valve. If the house vacuum is insufficient to maintain four inches, restrict the flow through the system by closing off hose 2.

- 5.6.2. Close off hose 5. If 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.
  - 5.6.3. Open hose 5. Close off hoses 7 and 3 in that order. If the manometer falls, then there is a leak around the "T" connector and it must be corrected before proceeding to the next step.
  - 5.6.4. Open hoses 3 and 7. Close off hose 3. If the manometer falls, then there is a leak around the valve holder and it must be corrected before conducting the actual leakage test.
  - 5.6.5. Open hoses 3 and 9.
  - 5.6.6. Turn the vacuum off.
  - 5.6.7. Open hose number 2. (See Fig. 1.)
  - 5.7. Allow the bubble generator of the Gilibrator to wet the cell by applying a low flow vacuum to the generator. Reset the control unit.
  - 5.8. Attach the funnel/exhalation valve assembly to the Gilibrator and apply a 25 mm +5 / -0 mm (1 inch +0.2 / -0 inches) of water vacuum level.
  - 5.9. Allow the generator to receive and record the bubble reading. The reading will be in ml/min.
  - 5.10. Repeat steps 5.3 through 5.8, excluding 5.6, for the remaining valve assemblies.
6. PASS/FAIL CRITERIA
- 6.1. The legal basis for passing this test is established at 42 CFR Part 84, Subpart I, Section 84.123, Subpart K, Section 84.182, Subpart L, Section 84.204, and Subpart KK, Section 84.1150.
  - 6.2. Exhalation valve leakage test; minimum requirements.
    - (a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm. water column height while in a normal operating position.
    - (b) Leakage between the valve and valve seat shall not exceed 30 milliliters per minute.
    - (c) The three (3) readings for each of three (3) samples are averaged. The average rate of leakage for each of the three (3) samples shall not exceed 30 mL / minute.

7. RECORDS/TEST SHEETS

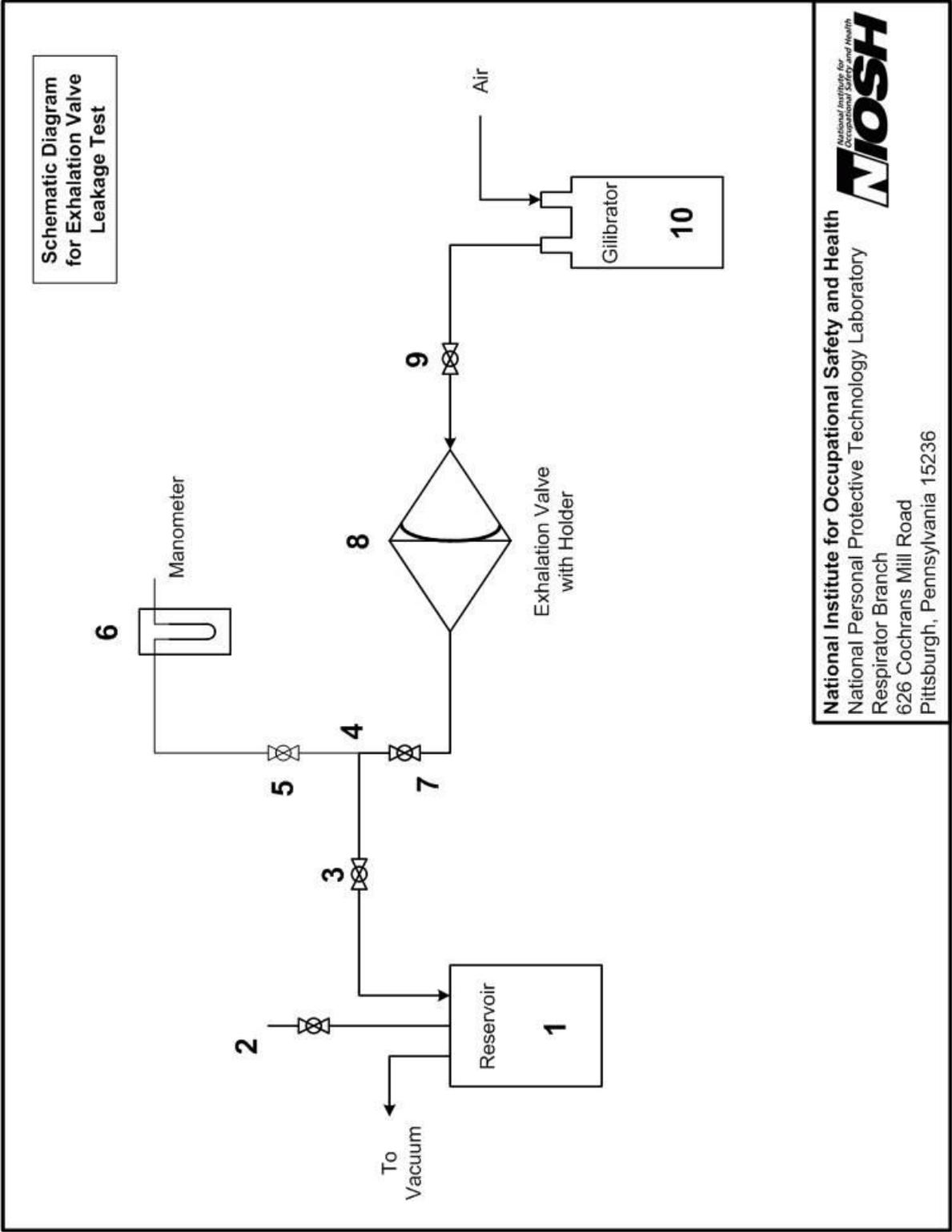
7.1. Record all test data in a format that shall be stored and retrievable.

8. ATTACHMENTS

8.1. Exhalation Valve Holder Assembly and Bench Top Set-Up (Figure 1)

8.2. Description of Bench Top Set-Up in Figure 1.

Attachment 8.1. Figure 1. Exhalation Valve Holder Assembly and Bench Top Set-Up



## Attachment 8.2. Description of Bench Top Set-Up in Figure 1

## Description of Schematic Diagram of the System

Note: The following components are approximations and may vary depending on the equipment used.

1. Reservoir (vacuum bottle -approx. a half a gallon to one gallon) with three tube connections for house vacuum source, air inlet valve, and tubing to rest of system. This vacuum bottle apparatus allows an accurate control of small negative pressures to the system.
2. Short hose with pinch clamp for control of flow
3. 1/4 in. O.D. hose approximately 2 ½ feet in length
4. 3-Way "T" hose connector
5. 1/4 in. O.D. hose approximately 2 feet in length
6. Manometer
7. 1/4 in. O.D. hose 3 to 4 inches in length
8. Exhalation valve with holder
9. 1/4 in. O.D. hose approximately 2 ½ feet in length
10. Gilibrator flow system

### Revision History

<b>Revision</b>	<b>Date</b>	<b>Reason for Revision</b>
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.