DETERMINATION OF EXHALATION VALVE LEAKAGE TEST, AIR-PURIFYING RESPIRATORS STANDARD TESTING PROCEDURE (STP)

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, Subpart L, Section 84.204.

2. GENERAL

This standard testing procedure (STP) describes the determination of exhalation valve leakage test for air-purifying respirators 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 the item tested passes the test.

3. EQUIPMENT/MATERIAL

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

3.1.1. Vacuum source capable of supplying a minimum negative pressure of 102 mm (4.0 inches) of water

3.1.2. Manometer, with a readability of 0.1 inches, capable of measuring a 102 mm (4.0 inches) water column height of vacuum

3.1.3. Gilibrator Primary Flow Calibrator System, or equivalent, capable of measuring 1 – 250 cc/min (using Bubble Generator Soap Solution p/n 800450), with an accuracy of ±1% of reading. Note: 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 design submitted. Funnels are typically used for this purpose, where the funnels may be in various sizes (dependent on size of the valve assemblies) that accommodate the valve assembly in a manner allowing an airtight seal to be achieved around its perimeter.

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, including 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, confirm that all measuring equipment employed has 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 recognized international standards when available.

4.2. Number of test items: Each valve design subjected to testing requires three individual exhalation valve assemblies of that design.

5. PROCEDURE

5.1. Follow individual instruction manuals for set up and maintenance of equipment used in this procedure prior to beginning any testing. Any equipment found to be malfunctioning must be repaired or replaced and properly set up and calibrated before starting any testing.

5.2. If the items submitted for testing are not exhalation valve assemblies apart from respirators, it is acceptable to remove the exhalation valve assemblies from respirators using care not to distort 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 Attachment A: Figure 1 and as described in Attachment B. 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 Figure 1.)

5.6.1. Close off hose 9. Apply a 102 mm (4 inches) ± 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 Figure 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, for the remaining valve assemblies.

6. PASS/FAIL CRITERIA

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

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. All test data collected will be recorded on the appropriate Determination of Exhalation Valve Leakage Test data sheet (Attachment C).

8. ATTACHMENTS

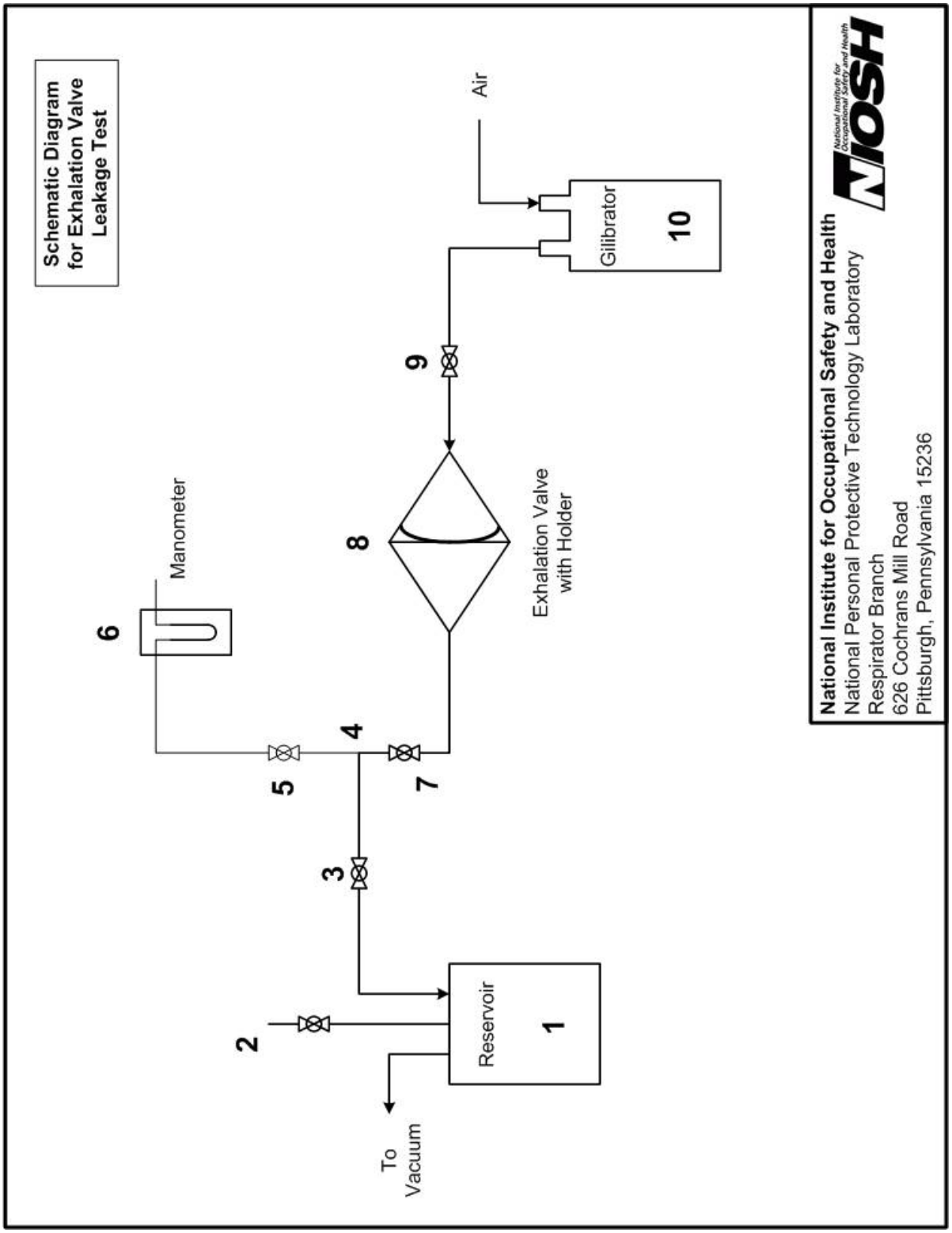
8.1. Attachment A: Figures

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

8.3. Attachment C: Sample Exhalation Valve Leakage Test Data Sheet

8.1 Attachment A: Figures

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


Schematic Diagram for Exhalation Valve Leakage Test
Air
Gilibrator
10
9
Manometer
6
8
Exhalation Valve with Holder
4
5
7
3
2
Reservoir
1
To Vacuum
National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Respirator Branch
626 Cochrans Mill Road
Pittsburgh, Pennsylvania 15236
NIOSH

8.2 Attachment B: 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

8.3. Attachment C: Sample Exhalation Valve Leakage Test Data Sheet

National Institute for Occupational Safety and Health
Test Data Sheet

Task Number: **STP No.: 4**
Test:
Manufacturer:
Item Tested:

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

Comments:

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

Signature: **Date:**

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. -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. -Section 5, Removed note about calibration. -Section 7, 7.1. has been edited to establish a "normal" data format. -Section 8, An example data sheet has been included to better define the normal data format.
2.3	27 January 2023	Removed references to Subpart KK. Updated other sections with minor editorial formatting, including the sample test data sheet.