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National Personal Protective Technology Laboratory
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Procedure No. TEB-APR-STP-0004	Revision: 2.0	Date: 9 March 2009

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. Dwyer model 1211-12 U-Tube manometer or equivalent, range 4-0-4 inches, readability of 0.1 inch, capable of measuring a 102 mm (4") water column height of vacuum. To facilitate reading, use 25 mL (¾ oz.) of Dwyer A126 Fluorescein green color concentrate in 0.9 L (1 qt.) of distilled water.

3.1.3. Gilibrator Primary Flow Calibrator System: Gilibrator control unit p/n 800268 with Thermal Printer DPU-40 p/n D800286, Bubble Generator (low), Range: 1-250cc, p/n C-800274, Bubble Generator Soap Solution p/n 800450. Accuracy: ±1% of reading.

3.1.4. Exhalation valve holder to seal the valve and valve seat in the proper position while the vacuum is applied. This holder is not specific and is modified with each valve that is submitted. Equipment used for this purpose are funnels in

Approvals: First Level	Second Level	Third Level	Fourth Level

various sizes (dependent on size of valves) that allow the valve assembly to be sealed with hot-melt glue and/or wax on the back side to obtain an airtight seal.

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, 1/4 inch OD hose (tubing), eye droppers, 3-Way "T" tubing connector and small brush.

3.1.8. Vacuum bottle (approx. 1 gal.) 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.

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 instrument 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.

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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 the funnel using hot-melt glue on the back side of the valve seat. Carefully wax in place to seal any air holes. Use hot-melt glue to seal a larger funnel to the smaller funnel. Make sure the funnel or fixture will cover the valve assembly and will not interfere with the operation of the valve itself. Wax to seal and fill all areas.

5.4. Set up test equipment as shown in Figure 1. Place the exhalation valve assembly with holder in the same orientation as the normal operating position of the exhalation valve in the facepiece when worn. If necessary, mount the facepiece on a headform to determine the normal operating position of the valve assembly.

5.5 Check the water level in the manometer. If the water level is not at zero, remove the top from the unconnected end and slowly add drops of distilled water / fluorescein mixture until it reaches zero.

5.6. Test the system for leaks. (See Fig. 1.)

5.6.1. Clamp off hose number 9 completely. 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 using a pinch clamp at number 2.

5.6.2. Clamp hose number 5 off completely. 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. Remove the clamp from hose 5. Clamp 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. Remove the pinch clamps from hoses 3 and 7. Replace the clamp on 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. Remove all pinch clamps from the interconnecting hoses.

5.6.6. Turn the vacuum off.

5.6.7. Completely open pinch clamp 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 (1 inch) +5 / -0 mm of water vacuum level.

5.9. Allow the generator to receive and record the bubble reading. The reading will print out in ml/min.

5.10. Repeat steps 5.3. through 5.9. for the other two 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.

7.2. Refer to Work Instruction WI-1411 for procedures to follow for reporting passing or failing results for this test.

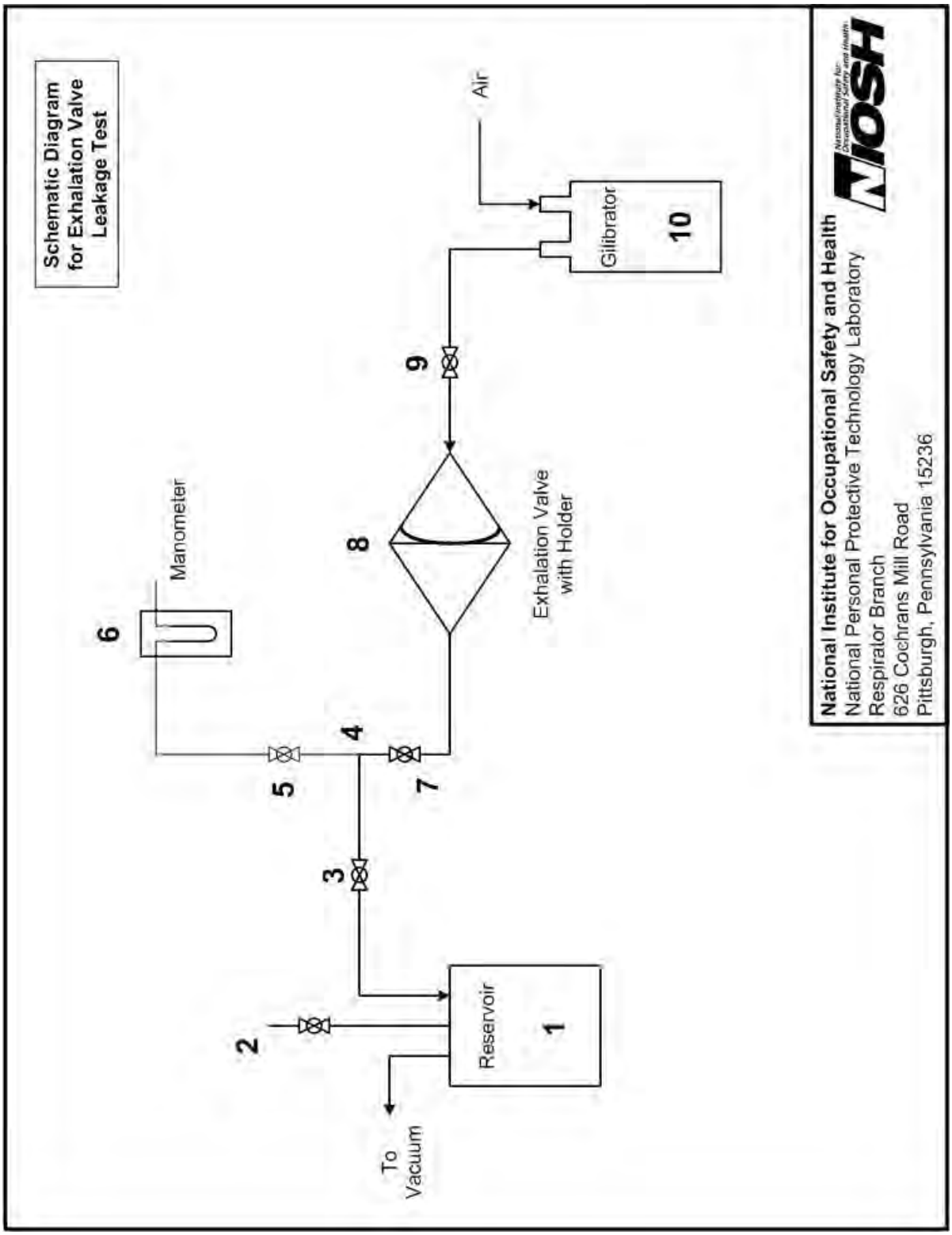
8. ATTACHMENTS

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

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

8.3. Sample Data Sheet

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

1. Reservoir (vacuum bottle -approx. 1 gal.) 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. U-Tube water 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

Attachment 8.3. Sample Data Sheet

NIOSH *RB - RESPIRATOR CERTIFICATION TEAM*

EXHALATION VALVE LEAKAGE DATA SHEET (CFR 84.____) **STP No.: [_____]**

Task Number: TN-

Manufacturer: _____ Item Tested:

Requirement: Shall not exceed 30ml/min. at a suction of 25mm of water.

Valve #1:

Event No.	Leakage-ml.	Time/Min.	Leakage-ml/Min.
1.			
2.			
3.			

Average: ml/Min.

Valve #2:

Event No.	Leakage-ml.	Time/Min.	Leakage-ml/Min.
1.			
2.			
3.			

Average: ml/Min.

Valve #3:

Event No.	Leakage-ml.	Time/Min.	Leakage-ml/Min.
1.			
2.			
3.			

Average: ml/Min.

Overall Results: Pass ___ Fail ___ Comlent:

Was all testing equipment in calibration throughout all testing: Yes __ No

Signature: _____ Date:

NIOSH *RB - RESPIRATOR CERTIFICATION TEAM*

EXHALATION VALVE LEAKAGE DATA SHEET (CFR 84.__) **STP No.: [_____]**

Task Number: TN-

Manufacturer: _____ Item Tested:

Additional Comments:

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.