



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
P.O. Box 18070
Pittsburgh, PA 15236

Procedure No. RCT-APR-STP-0004	Revision: 1.1	Date: 3 June 2005
--------------------------------	---------------	-------------------

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

1. PURPOSE

This test establishes the procedure for ensuring that the level of protection provided by the exhalation valve leakage test requirements on air-purifying respirators submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet the minimum certification standards set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c)(d), Subpart I, Section 84.123, Subpart K, Section 84.182, Subpart L, Section 84.204, and Subpart KK, Section 84.1150; Volume 60, Number 110, June 8, 1995.

2. GENERAL

This STP describes the Determination of Exhalation Valve Leakage Test, Air-Purifying respirators test 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 steady suction of 25 mm per minute.

3.1.2. Open end water manometer, capable of holding a 6" vacuum of 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.

3.1.4. Exhalation valve holder to keep the valve and valve seat in the proper position while the suction is applied. This holder is not specific and is modified with each valve that is submitted. Equipment used quite often are funnels in various sizes (dependent on size of valves) that allow the valve to be sealed in with hot melt glue and/or wax on both sides to obtain an airtight seal.

3.1.5. Hot melt glue gun.

3.1.6. Heating plate and 200 ml beaker.

Approvals:	<u>1st</u> Level	<u>2nd</u> Level	<u>3rd</u> Level
------------	------------------	------------------	------------------

- 3.1.7. Miscellaneous Equipment – Hose Clamps, 1/4 inch OD Hose, eye droppers, 3-Way "T" hose 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.
- 3.2.0 Bees' wax.

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 manufacturer's calibration procedure and schedule. At a minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months using a method traceable to the National Institute of Standards and Technology (NIST).
- 4.2. Normal laboratory safety practices must be observed. This includes safety precautions described in the current ALOSH Facility Laboratory Safety Manual.
 - 4.2.1. Safety glasses, lab coats, and hard-toe shoes must be worn at all times.
 - 4.2.2. Work benches must be maintained free of clutter and non-essential test equipment.
 - 4.2.3. When handling any glass laboratory equipment, lab technicians and personnel must wear special gloves which protect against lacerations or punctures.

5. PROCEDURE

- Note: Reference Section 3 for equipment, model numbers and manufacturers. For calibration purposes use those 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. Hot melt glue on the back side of the exhalation valve assembly and position it into the funnel. Carefully wax in place to seal any air holes. Hot melt a larger funnel to the smaller funnel. Make sure the funnel or fixture will cover the valve assembly yet not block the operation of the valve itself. Wax to seal and fill all areas. (See Fig. 1.)

Procedure No. RCT-APR-STP-0004	Revision: 1.1	Date: 3 June 2005	Page 3 of 8
--------------------------------	---------------	-------------------	-------------

- 5.4. Set up test equipment as shown in Figure 2. 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 until it reaches zero.
- 5.5. Test the system for leaks. (See Fig. 2.)
 - 5.5.1. Clamp off hose number 9 completely. Apply a six inch vacuum to the system using the house vacuum valve. If the house vacuum is insufficient to maintain six inches, restrict the flow through the system using a pinch clamp at 2.
 - 5.5.2. 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.
 - 5.5.3. 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.
 - 5.5.4. 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.
 - 5.5.5. Remove all pinch clamps from the interconnecting hoses.
 - 5.5.6. Turn the vacuum off.
 - 5.5.7. Completely open pinch clamp number 2. (See Fig. 2.)
- 5.6. Allow the bubble generator of the Gilibrator to wet the cell by applying a low flow vacuum to the generator. Reset the control unit.
- 5.7. Attach the funnel/exhalation valve assembly to the Gilibrator and apply a 1 inch vacuum of water.
- 5.8. Allow the generator to receive and record the bubble reading. The reading will print out in ml/min.
- 5.9. Repeat steps 5.3 through 5.8 for the other two valve assemblies.
6. PASS/FAIL CRITERIA
 - 6.1. The criterion for passing this test is set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c)(d), Subpart I, Section 84.123, Subpart K, Section 84.182, Subpart L, Section 84.204, and Subpart KK, Section 84.1150; Volume 60, Number 110, June 8, 1995.
 - 6.2. This test establishes the standard procedure for ensuring that:
 - 84.63 Test requirements; general.

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, meet the applicable requirements set forth in subparts H through L of this part.

(c) In addition to the minimum requirements set forth in subparts H through L of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

84.123 Exhalation valve leakage test.

(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.

84.182 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.

84.204 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.

84.1150 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.

7. RECORDS/TEST SHEETS

7.1. All test data collected will be recorded on the DETERMINATION OF EXHALATION VALVE LEAKAGE test data sheet.

7.2. All videotapes and photographs of the actual test being performed, or of the tested equipment shall be maintained in the task file as part of the permanent record.

- 7.3. All equipment failing any portion of this test will be handled as follows:
- 7.3.1. If the failure occurs on a new certification application, or extension of approval application, send a test report to the RCT Leader and prepare the hardware for return to the manufacturer.
 - 7.3.2. If the failure occurs on hardware examined under an Off-the-Shelf Audit the hardware will be examined by a technician and the RCT Leader for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the RCT Leader, or his designee, following the standard operating procedures outlined in Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-0005-00.

8. ATTACHMENTS

- 8.1. Exhalation Valve Holder Assembly and Bench Top Set-Up (Figures 1 and 2).
- 8.2. Description of Bench Top Set-Up in Figure 2.
- 8.3. Data Sheet.

Figure 1. Valve Holder - Assembled Unit with Valve in Place

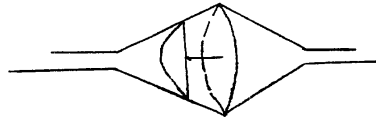
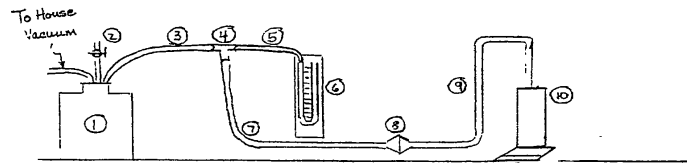


Figure 2. Schematic Diagram of the System



Description of Schematic Diagram of the System

1. 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. Open end water manometer.
7. 1/4 in. O.D. hose 3 to 4 inches in length.
8. Exhalation valve holder.
9. 1/4 in. O.D. hose approximately 2 ½ feet in length.
10. Gilibrator flow system.

NIOSH National Institute for Occupational Safety and Health
RB - RESPIRATOR CERTIFICATION TEAM
 EXHALATION VALVE LEAKAGE DATA SHEET (CFR 84.____) STP No.: [_____]
 Task Number: TN- _____
 Manufacturer: _____ Item Tested: _____

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

Valve #1:

<u>Event No.</u>	<u>Leakage-mm.</u>	<u>Time/Min.</u>	<u>Leakage-mm/Min.</u>
1.			
2.			
3.			
			Average: mm/Min.

Valve #2:

<u>Event No.</u>	<u>Leakage-mm.</u>	<u>Time/Min.</u>	<u>Leakage-mm/Min.</u>
1.			
2.			
3.			
			Average: mm/Min.

Valve #3:

<u>Event No.</u>	<u>Leakage-mm.</u>	<u>Time/Min.</u>	<u>Leakage-mm/Min.</u>
1.			
2.			
3.			
			Average: mm/Min.

Overall Results: Pass ___ Fail ___ Comment: _____
 Was all testing equipment in calibration throughout all testing: Yes ___ No ___

Signature: _____ Date: _____

NIOSH National Institute for Occupational Safety and Health
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