

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

Procedure No. TEB-APR-STP-0001

Revision: 2.0 Date: 14 April 2009

DETERMINATION OF PARTICULATE FILTER PENETRATION TEST POWERED AIR-PURIFYING RESPIRATOR FILTERS STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This test establishes the procedure for ensuring that the level of protection provided by powered air-purifying respirator filters submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet the filter penetration requirements set forth in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d) and Subpart KK, Section 84.1151(a)(c), except that the flow requirements of Section 84.1151(a)(c) are not used. In their place, flow requirements specified in Section 84.1156(c)(2) are applied. This is done in order that PAPR filters are tested, to the extent possible, at the minimum required air flow rate of the PAPR.

2. GENERAL

This STP describes the Determination of Particulate Filter Penetration Test, Powered Airpurifying Respirator Filters 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/MATERIALS

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



3.1.1. TSI Model 8130 Automated Filter Tester or equivalent instrument. Air flow control accuracy is 2% of full scale. Pressure measurement accuracy is 2% of full scale. Penetrations can be measured to 0.001%, efficiencies to 99.999%.

Approvals: First Level	Second Level	Third Level	Fourth Level



3.1.2. Particle sizing instrument (such as TSI Model 3936 Scanning Mobility Particle Size Spectrometer or equivalent) that is capable of determining submicrometer particles according to count median diameter (CMD).



3.1.3. Microbalance accurate to 0.0001 grams (g).



3.1.4. Gelman 102 mm diameter, type A/E glass filters or equivalent high efficiency filters with a 1 micrometer pore size.



3.1.5. Timer (accurate to 0.01 second).

- 3.1.6. Dioctyl phthalate ((DOP, di(2-ethylhexyl)phthalate)) min. 98%.
- 3.1.7. Respirator filter holder supplied for specific manufacturer type which is compatible with TSI filter tester. NIOSH will not be obligated to use these holders for actual certification testing. All manufacturer test fixtures must be correlated with the NIOSH test method (see Work Instruction WI- 1611).
- 3.1.8 Thermal printer (supplied) or optional data acquisition system.
- 3.2. Refer to the following Work Instructions for further information on performing this test: TEB-RCT-APR-WI-1011 Laboratory Safety Procedures for Particulate Tests for Powered Air Purifying Respirators

 $\label{temperature} TEB\text{-}RCT\text{-}APR\text{-}WI\text{-}1111-Calibration Procedures for Particulate Test for Powered Respirators}$

TEB-RCT-APR-WI-1211 – Start–Up and Shut–Down Procedures for Particulate Test for Powered Air Purifying Respirators

TEB-RCT-APR-WI-1411 – Reporting Results for Particulate Test for Powered Air Purifying Respirators

TEB-RCT-APR-WI-1511 – Checking System Performance for Particulate Test for Powered Air Purifying Respirators

TEB-RCT-APR-WI-1611 – Correlating Manufacturer – Supplied Test Fixtures for Particulate Test for Powered Air Purifying Respirators

4. TESTING REQUIREMENTS AND CONDITIONS

84.64.

- 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
- 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 is monitored by the validation method which is incorporated in the automated filter tester procedure. This procedure is performed on a daily basis when testing is performed. This procedure is designed to test many aspects of the method, for proper photometer and general system operation. The validation technique uses "green line" filter media discs, 6 inch diameter, HE 1071 grade, H & V brand, P/N 813010, with a known penetration range, which are tested at least once in each 8-hour test period (see 5.2.5).
 - 4.4.1. Two sheets of unused filter media are stacked together and the penetration, flow rate and pressure drop are measured to evaluate the higher range of penetration values. Five unused sheets are stacked together to evaluate the lower range of penetration values.
 - 4.4.2. The analysis of these readings over the long term was used to examine the precision and accuracy of this test method. The table below summarizes the data.

	Two Sheets	Five Sheets
Mean	2.459%	0.011%
Std. Dev.	0.157	0.001
Range	2.04 - 2.97%	0.008 - 0.017%
N	56	56

- 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 the chemicals used in this procedure.
- 4.6. Dioctyl phthalate is considered a low hazard material with a recommended exposure limit (REL) of 5 mg/m³ with a short-term exposure limit of 10 mg/m³. It may cause mild skin or eye irritation. Carcinogenic effects: Classified as a proven animal carcinogen with unknown relevance to humans by ACGIH; classified as a suspect carcinogen by NTP; not listed by IARC. Local exhaust ventilation is used for the potential sources of DOP from the TSI 8310 filter tester. Safety eyewear and a lab coat should be worn. Splash goggles, protective clothing, boots and gloves should be worn in case of a large spill. Discharge, treatment or disposal may be subject to national, state or local laws.

5. PROCEDURE

Note: Reference Section 3. for equipment, model numbers and manufacturers. For calibration purposes use those described in the manufacturers' operation and maintenance manuals.

5.1. Respirator filters will be challenged by a neat cold–nebulized DOP aerosol at $25 \pm 5^{\circ}$ C that has been neutralized to the Boltzmann equilibrium state. The particle size distribution will be a count median diameter of 0.185 ± 0.020 micrometer and a geometric standard deviation not exceeding 1.6. Each respirator filter unit will be challenged with an aerosol concentration of $100 \pm 10 \text{ mg/m}^3$.

5.1.1. The DOP aerosol concentration will be determined daily by the following gravimetric method and calculated as milligrams per cubic meter (mg/m³).

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5.1.2. Weigh a Gelman 102 mm filter to the nearest 0.1 mg., mount in the gravimetric filter holder, subject it to the generated aerosol at 30 Lpm for 40 minutes, and reweigh the filter. Use a timer to monitor the duration of the test. Record the pre- and post-weights, time, and average flow rate on the data sheet and calculate the aerosol concentration in mg/m³ by the following formula:

Concentration in mg/m³ =
$$\frac{\text{W2} - \text{W1}}{(\text{Q} / 1000) \text{ (T)}}$$

Where:

W1 = Initial filter weight in mgs.

W2 = Final filter weight in mgs.

Q = Flowrate in liters per minute

T = Elapsed time in minutes

With a flowrate of 30 Lpm for 40 minutes, the above formula simplifies to:

$$C = \frac{W2 - W1}{1.2}$$

- 5.1.3. The upstream and downstream photometer readings are used for monitoring stability and for calculating a photometer correlation factor (CF). The correlation factor is determined with an empty filter holder and is calculated internally as shown below:
 - CF = Downstream Photometer Voltage Downstream Background Voltage
 Upstream Photometer Voltage Downstream Background Voltage

The correlation factor is used by the software to express the upstream photometer signal in terms of the downstream photometer signal. Follow Work Instruction WI- 1511 for determining, monitoring and recording the CF.

- 5.1.4. The DOP particle size distribution shall be verified using "green line" filter discs supplied by TSI with a known penetration range. Graphs of penetration vs. resistance for two sheets and five sheets of stacked filter discs are supplied with each lot of the standard filters, with a central line and upper and lower lines representing the expected penetration range at a given resistance. The test data should fall within an acceptance zone having boundaries defined by the upper and lower curves on the graphs. Follow the procedure in Work Instruction WI-1505. The standard filter test using both 2 sheets and 5 sheets will be run at least once in each 8 hour test period to verify that the aerosol distribution is within the acceptance zone.
- 5.1.5. If the instantaneous filter penetration is not within the acceptance zone for any sample, abort testing and check the aerosol particle size with the Scanning

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Mobility Particle Size (SMPS) Spectrometer.

- 5.2. The DOP particle size will be monitored at least once every three months (quarterly) with the SMPS spectrometer to ensure the particle size distribution count median diameter remains in the range of 0.185 ± 0.020 micrometer with a geometric standard deviation of not more than 1.6.
- 5.3. Filters shall be tested as follows:
 - 5.3.1. The filter, including the filter holders and gaskets, shall be tested for particle penetration. When the filtering element is not separable from the cartridge or canister, the complete component shall be tested.
 - 5.3.2. When filters are not separable from the respirator body, any exhalation valves shall be sealed to ensure that any leakage due to an exhalation valve is not included in the filter penetration measurement.
 - 5.3.3. Filters not separable from cartridges, canisters, respirators, and odd or unusually shaped filters may be tested on a headform assembly or an assembly provided by manufacturer. Note: NIOSH is not obligated to use the headform assembly or any assembly provided by the manufacturer for certification testing.
- 5.4. Filters shall be mounted and sealed on holders to prevent leakage around the filter holder. PAPRs are normally designed to use from one to four filters. Filters shall be tested using a single filter regardless of the number of filters used on the unit. Adjustment is made to the flow rate of the test by dividing the specified flow rate for the test, which is based on the minimum required air flow of 115 lpm for tight fitting PAPRs and 170 lpm for loose fitting PAPRs, by the number of filters used. The table below shows the test flow rate depending on the type of PAPR and the number of filters employed. The highest obtainable air flow for the automated filter testers is typically 96 lpm and this flow rate will be used to test single PAPR filters.

	PAPR FILTER TEST - FLOW RATE (LPM)		
NUMBER OF FILTERS	TIGHT FITTING FACEPIECE	LOOSE FITTING FACEPIECE	
1	96 ± 5	96 ± 5	
2	57 ± 3	85 ± 4	
3	38 ± 2	57 ± 3	
4	29 ± 2	43 ± 2	

- 5.4.1. The challenge flow rate must be checked for stability for at least 30 seconds prior to testing.
- 5.4.2. If using a TSI 8130 tester, the tester rise time shall be set at 10 seconds, the tester sample time shall be set at 10 seconds, and the tester purge time shall be set at 9 seconds.
- 5.5. A total of 3 filters shall be tested against the DOP liquid aerosol. Each filter shall be instantaneously loaded and evaluated.

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- 5.5.1. Any filter that exceeds the specified limit shall be remounted and retested to ensure that leakage was not caused by a mounting leak. If retesting eliminates the leakage, that filter shall be considered an invalid sample and another filter shall be tested in its place.
- 5.6. The penetration of the 3 filters shall be measured and recorded.

6. PASS/FAIL CRITERIA

- 6.1. The legal basis for passing this test is set forth in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d) and Subpart KK, Section 84.1151(a)(c); except that the flow requirements of Section 84.1151(a)(c) are not used. In their place, flow requirements specified in Section 84.1156(c)(2) are applied to the extent possible.
- 6.2. The total leakage for the connector and filter shall not exceed 0.03 percent of the ambient DOP concentration for any test sample.

7. <u>RECORDS/TEST SHEETS</u>

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

8. <u>ATTACHMENTS</u>

- 8.1. Data Sheet
- 8.2. Test Setup

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Data	Sheet						
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8.2. Test Setup

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Revision History

Revision	Date	Reason for Revision			
1.0	7 March 2004	Historic doc	Historic document		
1.1	1 June 2005	Update head	der and format to reflect lab move from Morgantown, WV		
		No changes	to method		
2.0	14 April 2008	Section	Change		
		3.2.	List of Work Instructions added		
		4.	Requirements and data for precision and accuracy added		
		5.	Editorial changes to clarify procedures		
		5.1.2.	Example calculation for challenge concentration added		
		5.4.	Clarifications to test flow in light of the maximum total		
			test flow of 96 lpm. A table of appropriate flow values is		
			added.		
		All	Editorial changes to improve clarity throughout		