DETERMINATION OF PARTICULATE FILTER EFFICIENCY LEVEL FOR P95 SERIES FILTERS AGAINST LIQUID PARTICULATES FOR NON-POWERED, AIR-PURIFYING RESPIRATORS STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This test establishes the procedure for ensuring that the level of protection provided by the particulate filter efficiency level test for P95 series filters used on non-powered 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 K, Section 84.181. These filters and filter cartridges may be integral components; mounted individually; used in conjunction with cartridges and canisters for chin-style, front-mounted, and back-mounted gas masks; or used in combination with gas-and-vapor or supplied-air respirators.

2. GENERAL

This STP describes the Determination of Particulate Filter Efficiency Level for P95 Series Filters Against Liquid Particulates For Non-Powered, Air-Purifying Respirators test in sufficient detail that a person knowledgeable in the appropriate technical field can 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%.

3.1.2. Microbalance accurate to 0.0001 grams (g).

3.1.3. Type A/E glass filters 102 mm diameter, high efficiency filters with a 1 micrometer pore size.

3.1.4. Timer (accurate to 0.01 percent).

3.1.5. Dioctyl phthalate ((DOP, di(2-ethylhexyl)phthalate)) min. 98%.

3.1.6. 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.

3.1.7. Thermal printer (supplied) or optional data acquisition system.

3.1.8. TSI, Green Line paper, part number 813010. Lot number must be included on each box. Each lot number must include the "Penetration vs. Resistance graph".

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% at 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 or three unused sheets are stacked on top of the two used sheets 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/m^3 with a short-term exposure limit of 10 mg/m^3. 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. Work Instructions are to be used in conjunction with standard NIOSH test apparatus.

5.1. Respirator filters and filter cartridges will be tested as follows:

5.1.1. The filtering elements of the respirator, including the filter holders and gaskets will be tested for particle penetration.

5.1.2. When filters are not separable from the respirator body, the exhalation valves will be sealed to ensure that any leakage due to the exhalation valve is not included in the filter penetration measurement.

5.1.3. Filters used in conjunction with gas mask canisters and odd or unusually shaped filters may be tested on a headform assembly or assembly provided by the manufacturer.

5.2. Respirator filters will be challenged by a neat cold – nebulized DOP aerosol at 25 ±5° 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 not exceeding 200 mg/m^3.

5.2.1. The DOP aerosol concentration will be determined daily by the following gravimetric method and calculated as milligrams per cubic meter (mg/m^3).

5.2.2. Weigh a 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/m^3 by the following formula:

$$\text{Concentration in mg/m}^3 = \frac{W2 - W1}{(Q / 1000)\,(T)}$$

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:

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

5.2.3. Use the following formula to calculate the test duration:

$$\text{T in minutes} = \frac{(\text{mg load})\,(1000\ \text{L} / \text{m}^3)}{(C)\ \ (Q)}$$

Where:
C = Concentration in mg/m^3 from 5.2.2.
Q = Flow rate for test in Lpm

5.2.4. 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:

$$CF = \frac{\text{Downstream Photometer Voltage} - \text{Downstream Background Voltage}}{\text{Upstream Photometer Voltage} - \text{Downstream Background Voltage}}$$

The correlation factor is used by the software to express the upstream photometer

signal in terms of the downstream photometer signal.

5.2.5. 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. 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.

5.2.6. If the instantaneous filter penetration is not within the acceptance zone for any sample, abort testing and check the aerosol particle size with the TSI Green Line Paper.

5.3. Filters will be mounted and sealed on holders to prevent leakage around the filter holder. Single air purifying respirator filters will be tested at a challenge flow rate of 85± 4 Lpm. Filters used as pairs on a respirator are tested using a single filter of the pair at 42.5 ± 2 Lpm challenge flow rate. Filters used in threes are tested using a single filter of the set at 28.3 ± 1 Lpm challenge flow rate.

5.3.1. The challenge flow rate must be checked for stability for at least 30 seconds prior to testing.

5.4. A sample of 20 filter units will be tested against the DOP liquid aerosol. The filters shall be subjected to aerosol mass loading levels as shown in the table below. This is the mass amount of DOP aerosol that has contacted the filter.

NUMBER OF FILTERS IN RESPIRATOR CONFIGURATION	INITIAL LOADING LEVEL	INCREMENTAL LOADING	MAXIMUM LOADING LEVEL
SINGLE	215 ± 5 mg.	30 ± 5 mg.	415 ± 5 mg.
DOUBLE	115 ± 5 mg.	30 ± 5 mg.	215 ± 5 mg.
TRIPLE	85 ± 5 mg.	30 ± 5 mg.	155 ± 5 mg.

For P95 series filters, if the bandwidth (range) in penetration readings is equal to or less than 0.10% for the last 30 ± 5 mg at the initial loading level or within a subsequent incremental loading level, the filter passes the test. If the bandwidth in penetration readings is greater than 0.10% and not clearly decreasing, then the filter penetration is continuing to increase. The test is continued through the next 30 ± 5 mg of loading until the bandwidth in penetration readings is equal to or less than 0.10% for the incremental loading level, or the penetration level exceeds the maximum allowable level. The test is concluded and the filter is determined to fail the test if the bandwidth in penetration readings is greater than 0.10% for the last 30 ± 5 mg, ending at the maximum loading level indicated in the table above, or the maximum penetration exceeds 5.0%.

5.4.1. If any one of the 20 filters has a penetration greater than 5.0%, further testing of

that filter will be terminated. 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 excessive leakage, and testing has gone beyond the initial penetration, that sample will be considered an invalid sample and another tested in its place.

5.5. Determine and record on the data sheet the maximum filter penetration for each of the 20 filters, and the bandwidth readings over the 30 ± 5 mg on which the "no further decrease in efficiency" determination is made or the initial unacceptable bandwidth readings.

6. PASS/FAIL CRITERIA

6.1. The requirement for passing this test is set forth in 42 CFR, Part 84, Subpart K, Section 84.181.

6.2. The minimum efficiency for each of the 20 filters shall be determined and recorded and shall be equal to or greater than 95%.

6.3. For the sample of 20 filters or filter cartridges to demonstrate acceptable performance, each filter shall meet or exceed the specified minimum efficiency level at the end point of the test, and the bandwidth of the last 30 ± 5 mg for each filter shall be less than or equal to 0.10% if not clearly decreasing, before the maximum loading level shown in section 5.4 is reached.

7. RECORDS/TEST SHEETS

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

8. ATTACHMENTS

8.1. Typical Data Sheet

8.2. Test Setup

8.1 Typical Data Sheet

National Institute for Occupational Safety and Health
Certification and Quality Assurance Branch
Air-Purifying Respirator Section
Test Data Sheet

Task Number: TN-1000 **Reference No.:** CFR 84.181
Test: Dioctyl Phthalate (DOP) - P100 **STP No.:** 51
Manufacturer:
Item Tested: Single Filter (A-D) Dual Filter (E-F)

Filter	Flow Rate	Maximum Allowable Percent Leakage	Actual Percent Leakage	Result
A	85	0.03	0.030	PASS
B	85	0.03	0.030	PASS
C	85	0.03	0.030	PASS
D	85	0.03	0.030	PASS
E	42.5	0.03	0.030	PASS
F	42.5	0.03	0.030	PASS
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		

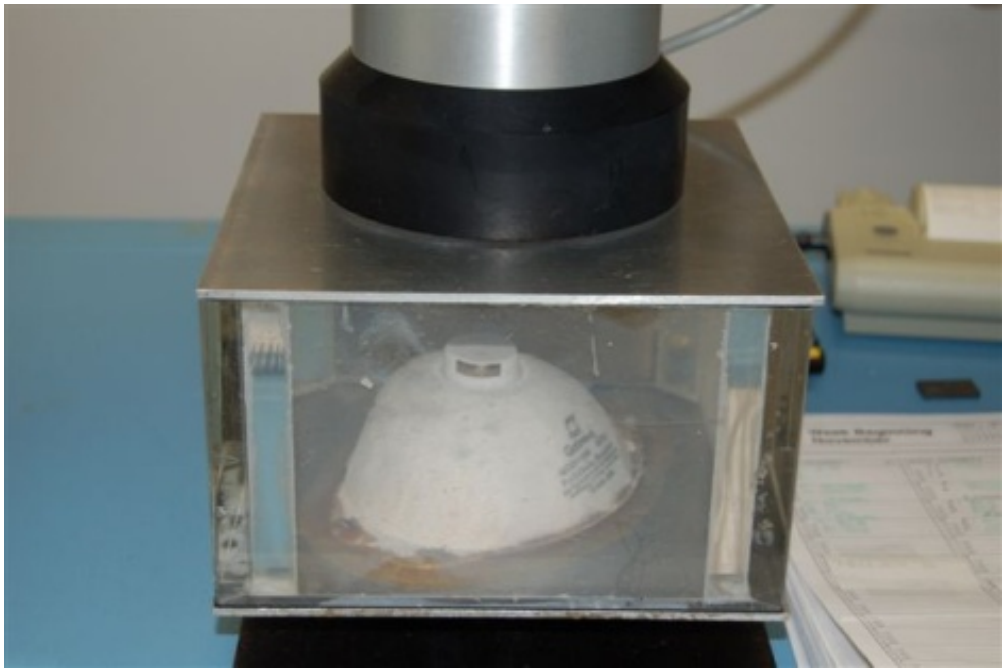
Overall Result: PASS

All test equipment within calibration: Yes
Comments:
TESTING

Signature: Jeffrey A. Bateman **Date:** 4/5/94

Engineering Technician

8.2 Test Setup



Revision History

Revision	Date	Reason for Revision
1.0	20 March 2002	Historic document
1.1	24 August 2005	Update header and format to reflect lab move from Morgantown, WV No changes to method
2.0	06 August 2007	Significant rewrite of RCT-APR-STP-0051-56. Changes affect form and provide clarification of technical content.
2.1	21 August 2012	Removed reference to SMPS, removed product-specific reference for Type A/E glass filter, added information on green-line media, removed references to 6 work instructions, removed photographs of outdated equipment.
3.0	25 March 2014	The requirement for "the final 5 readings to 30 ± 5 mg of loading" was rewritten to the "bandwidth of the last 30 ± 5 mg for each filter" which matches current laboratory procedures in sections 5.4, 5.4.1, and 6.3. Section 5.5 has been modified from 5 data point readings to the bandwidth readings over the 30 ± 5 mg on which the "no further decrease in efficiency" determination is made or the initial unacceptable bandwidth readings.
3.1	12 April 2016	Update to facility address in main title block, the accuracy of the timer specified in 3.4.1., is now expressed as percent, and Section 4.4.1., has been changed to allow for three unused sheets of media to be added to the two used sheets in lieu of five new (unused) sheets of media. Corrected the P&A statement in section 4.3.