National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
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Pittsburgh, PA 15236

Procedure No. TEB-APR-STP-0059	Revision: 3.2	Date: 13 December 2019

DETERMINATION OF PARTICULATE FILTER EFFICIENCY LEVEL FOR N95 SERIES FILTERS AGAINST SOLID PARTICULATES FOR NON-POWERED, AIR-PURIFYING RESPIRATORS STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This procedure establishes the means for ensuring that the particulate filtering efficiency of N95 series filters used on non-powered respirators submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meets the minimum certification standards set forth in 42 CFR, Part 84, Subpart K, §84.181. These filters or filter cartridges may be integral to respirator construction; mounted individually, or in sets of up to three; 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 atmosphere-supplying respirators.

2. GENERAL

This STP describes the test method to be used for the Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators test in sufficient detail to allow a person knowledgeable in the appropriate technical field to conduct the test and determine whether or not the product meets the established requirements.

3. EQUIPMENT/MATERIAL

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

3.1.1. TSI Model 8130 or 8130A 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 micron pore size

3.1.4. Timer (accurate to 0.01 percent)

3.1.5. 2% sodium chloride solution in distilled water (NaCl)

3.1.6. Temperature and humidity chamber capable of maintaining 38 ±2.5°C and 85 ± 5% relative humidity

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.

3.1.8. Thermal printer (supplied), or optional data acquisition system

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

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. Respirator filters and filter cartridges shall be tested as follows.

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

4.2.2. 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.

4.2.3. Filters used in conjunction with gas mask canisters, and odd or unusually shaped filters may be tested on a headform assembly or test fixture provided by the applicant.

4.2.4. If a test fixture is supplied by the applicant, the test fixture shall have a serial number or other unique, easily referenced identifier permanently etched, engraved, or affixed.

5. PROCEDURE

Note: Where they have been developed to aid in the consistent operation of standard NIOSH test apparatus, work instructions are to be used.

5.1. Respirator filters will be challenged by a NaCl aerosol at 25 ±5˚C and a relative humidity of 30 ±10% that has been neutralized to the Boltzmann equilibrium state. The particle

size distribution will be a count median diameter of 0.075 ± 0.020 micrometer and a geometric standard deviation not exceeding 1.86. Each respirator filter unit will be challenged with an aerosol concentration not exceeding 200 mg/m^3.

5.1.1. The NaCl aerosol concentration will be determined on the days that initial penetration testing is performed by the following gravimetric method and calculated as milligrams per cubic meter (mg/m^3).

5.1.2. 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, then 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 then 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:

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

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

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

Where:

C = Concentration in mg/m^3 from 5.1.2.
Q = Flow rate for test in Lpm

5.1.4. 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.

5.1.5. The NaCl 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. Respirator filters will be pre-conditioned at 85 ± 5% relative humidity and 38 ±2.5°C for 25 ±1 hours. After conditioning, the filters shall be sealed in a gas tight container and tested within 10 hours.

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 NaCl aerosol. Three filters will be loaded until the aerosol mass loading levels as shown in the table below are reached and evaluated to determine the method for the remaining 17 filters using one of the five type characterizations shown in 5.4.1., through 5.4.5. The mass loading values in the table represent the mass of NaCl aerosol that has contacted the filter.

Respirator Filter Configuration (Inlet Airflow Split)	Aerosol Mass Loading Level
Single	200 ± 5 mg.
Double	100 ± 5 mg.
Triple	66.7 ± 5 mg.

5.4.1. Type 1. If preliminary testing of all three initial test filters consistently results in a straight line (Figure 3), for the remaining 17 filters, record the initial penetration reading.

5.4.2. Type 2. If filter testing of all three initial test filters consistently results in a curve which indicates increased efficiency during the complete run (Figure 3), for the remaining 17 filters, record the initial penetration reading.

5.4.3. Type 3. If filter testing of all three initial test filters consistently results in decreased efficiency over time (Figure 3), load the remaining 17 filters with NaCl to the level specified in the table above and record the maximum penetration reading.

5.4.4. Type 4. If filter testing of all three initial test filters consistently results in

increased efficiency, then a decrease in efficiency, and then flattens out during the remainder of the complete run (Figure 3), for the remaining 17 filters, record the maximum penetration reading after reaching and maintaining a flat line for a period of 20 minutes following the decreasing segment in efficiency.

5.4.5. For any other filter type, determine loading at which maximum penetration consistently occurs and test at that loading value for the remaining 17 filters.

5.4.6. 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. The penetration of the first three filters will be measured, recorded, and printed at approximately 1 minute intervals during the test period. The highest penetration observed throughout the test of each filter will be recorded as the maximum penetration of that filter.

5.6. Determine and record on the data sheet the maximum filter penetration for each of the 20 filters.

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.

7. RECORDS/TEST SHEETS

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

8. ATTACHMENTS

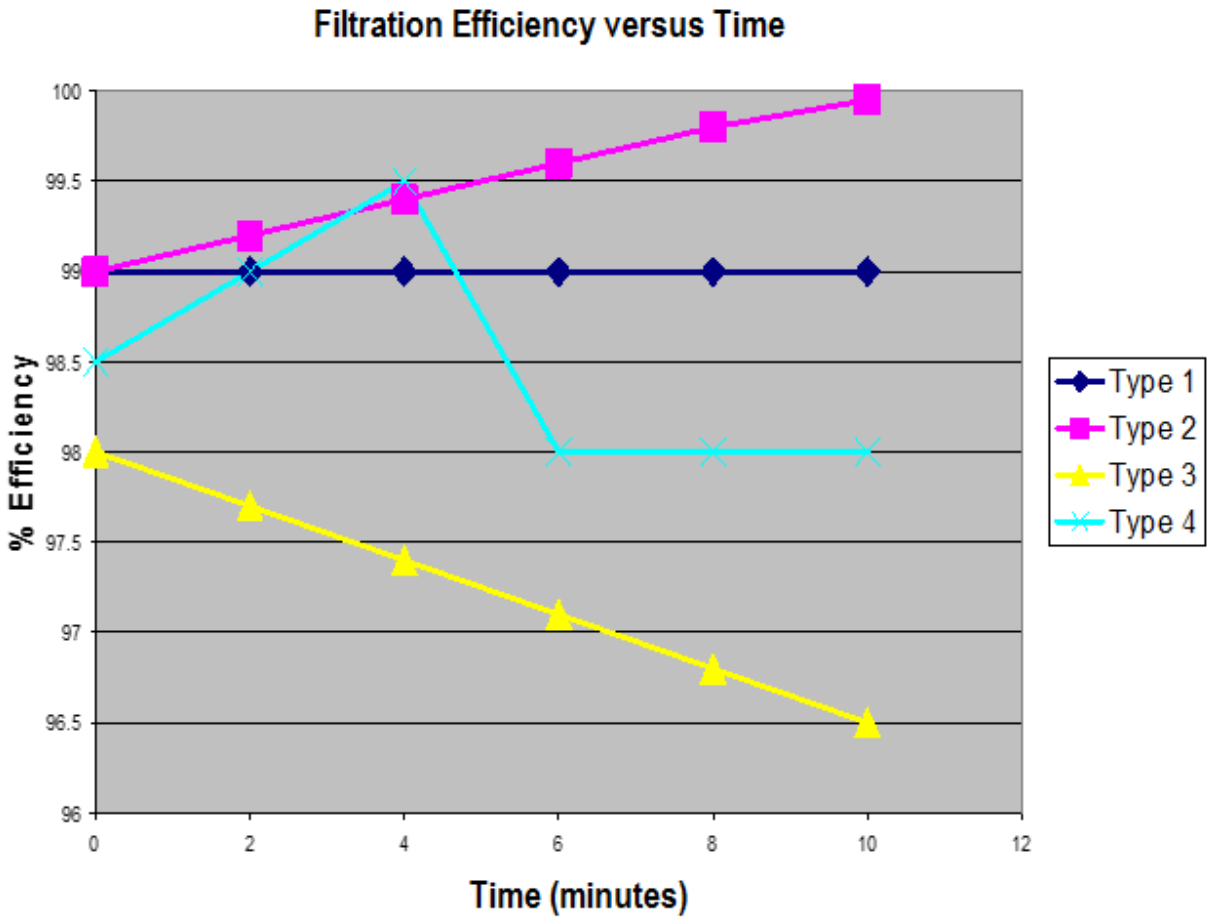
8.1. Figure 1, Graph of Typical Filtration Efficiency versus Time Curves

8.2. Example Data Sheet

8.3. Photograph of TSI 8130 CertiTester with chuck open

8.4. Close up of respirator test fixture in the closed chuck

8.1. Figure 1, Graph of Typical Filtration Efficiency versus Time Curves



8.2. Example Data Sheet

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-NNNNN **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer:
Item Tested:

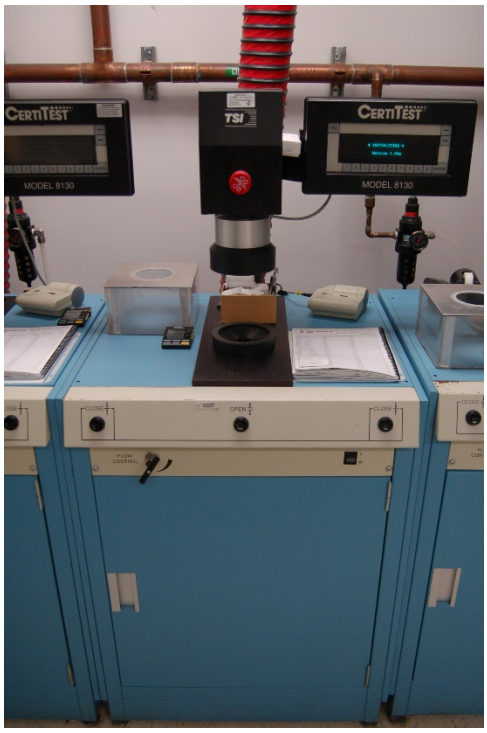
Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	13.9	5.00	1.480	1.740	PASS
2	85	12.9	5.00	0.867	0.867	PASS
3	85	13.9	5.00	0.554	0.554	PASS
4	85	13.9	5.00	0.964	0.964	PASS
5	85	13.8	5.00	0.494	0.494	PASS
6	85	14.1	5.00	1.630	1.630	PASS
7	85	12.3	5.00	1.450	1.450	PASS
8	85	12.5	5.00	1.280	1.280	PASS
9	85	12.3	5.00	1.200	1.200	PASS
10	85	13.1	5.00	0.996	0.996	PASS
11	85	12.9	5.00	1.010	1.010	PASS
12	85	14.0	5.00	0.715	0.715	PASS
13	85	13.3	5.00	1.000	1.000	PASS
14	85	13.3	5.00	1.180	1.180	PASS
15	85	12.2	5.00	0.802	0.802	PASS
16	85	14.2	5.00	0.955	0.955	PASS
17	85	13.6	5.00	1.200	1.200	PASS
18	85	13.3	5.00	1.100	1.100	PASS
19	85	13.0	5.00	1.000	1.000	PASS
20	85	12.4	5.00	1.100	1.100	PASS

Overall Result: PASS

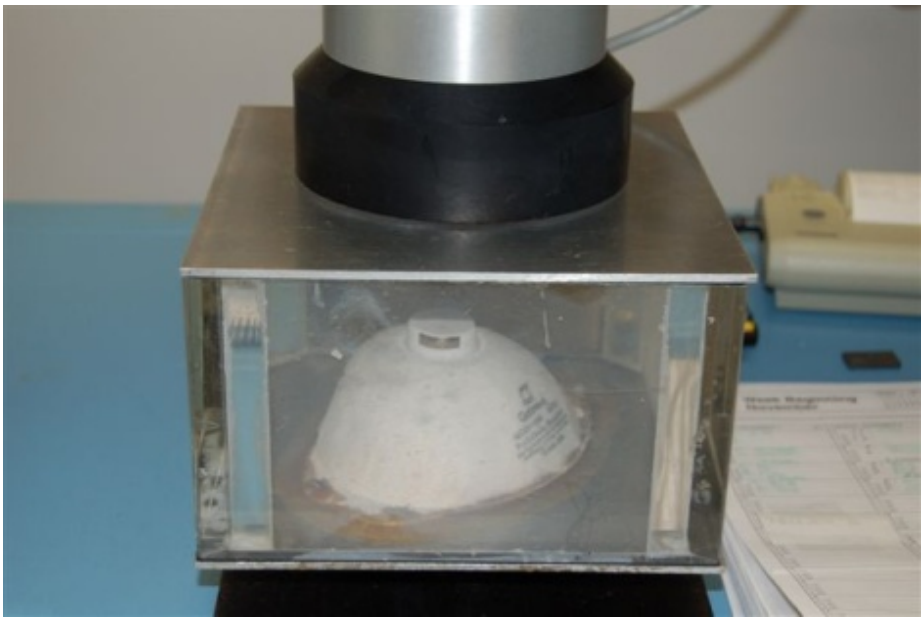
Signature: **Date:** _____

Engineering Technician

8.3. Photograph of TSI 8130 CertiTester with chuck open



8.4. Close up of respirator test fixture in the closed chuck



Revision History

Revision	Date	Reason for Revision
1.0	7 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	05 October 2007	Significant rewrite of RCT-APR-STP-0051-56. Changes affect form and provide clarification of technical content.
2.1	27 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	13 April 2016	Updated facility address in main title block, removed reference to work instruction, changed the accuracy of the timer specified in 3.4.1., now expressed as percent, edited Section 4.4.1., 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, and edited section 5.2.1., to clarify the need to determine NaCl concentration on the days that initial penetration evaluations are performed. Removed section 5.2.6., to comply with practice, this step is not performed. Added a statement to section 5.5.6 about retesting respirators. In addition to an editorial change in 6.1., the graph that was listed as Figure 1, now Figure 3, was also relabeled, with no changes to the graph itself. Corrected the P&A statement in section 4.3.
3.1	31 October 2019	With the greatest impact occurring in Section 4, this revision represents an update to current content and editorial standards, with no change to method or criteria.
3.2	13 December 2019	Correction to Section 2.0, the test name was inadvertently changed to the wrong test in the General desctiption.