# 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 test establishes the procedure for ensuring that the level of protection determined by the particulate filter efficiency level test for N95 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 G, 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 N95 Series Filters Against Solid 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/MATERIAL

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 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 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 | 2.692% | 0.033% |
| Std. Dev. | 0.318 | 0.007 |
| Range | 1.89 – 3.56% | 0.015 – 0.058% |
| N | 182 | 182 |

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.

## 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 manufacturer.

5.2. 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 $mg/m^3$.

5.2.1. 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 ($mg/m^3$).

5.2.2. 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:

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

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 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.

5.3. 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.

5.4. 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.

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

5.5. 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. This is the mass amount of NaCl aerosol that has contacted the filter.

| NUMBER OF FILTERS IN RESPIRATOR CONFIGURATION | AEROSOL MASS LOADING LEVEL |
|---|---|
| SINGLE | 200 ± 5 mg. |
| DOUBLE | 100 ± 5 mg. |
| TRIPLE | 66.7 ± 5 mg. |

5.5.1. 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.

5.5.2. 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.

5.5.3. 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.

5.5.4. 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.

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

5.5.6. 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.

5.6. 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.

5.7. 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.

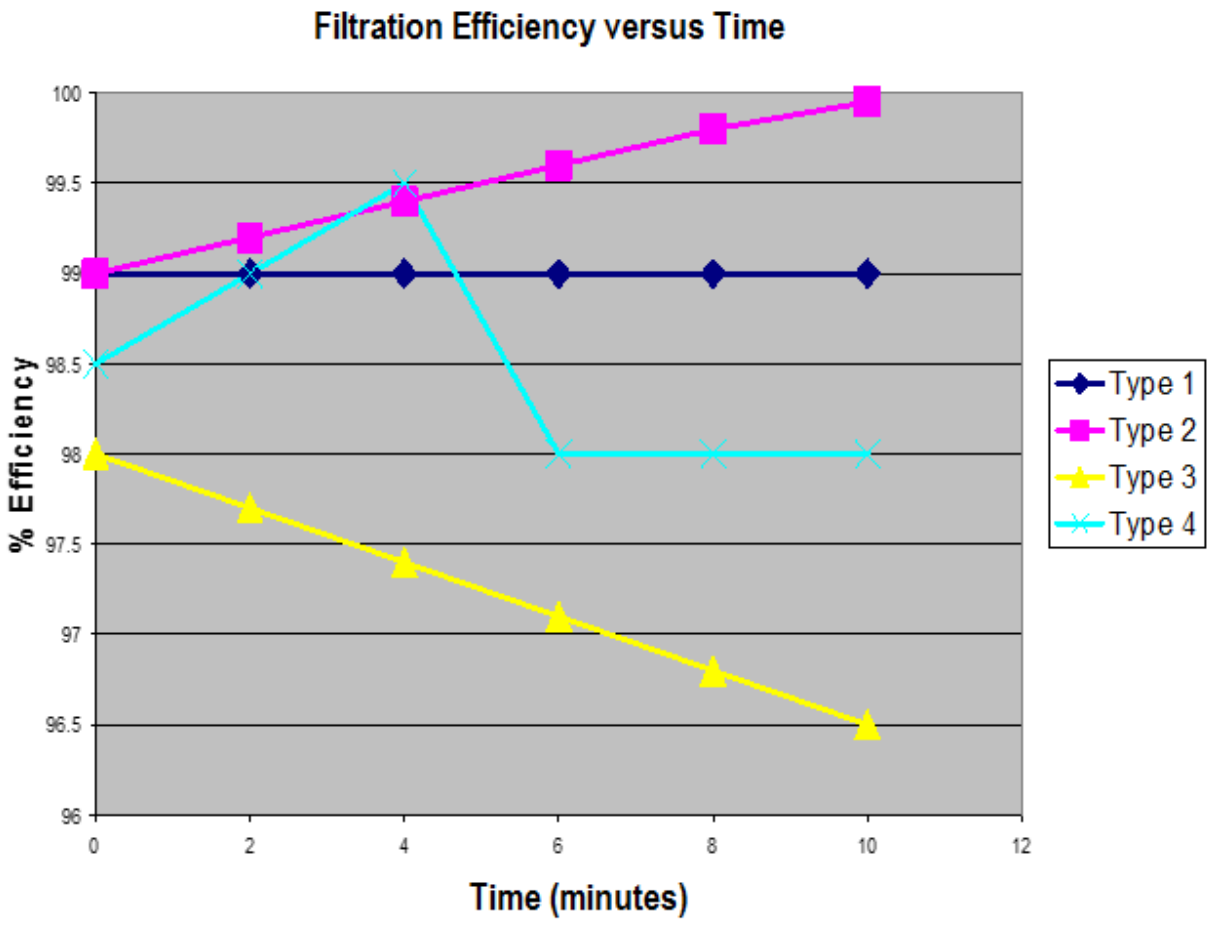
## 8. ATTACHMENTS

8.1. Figure 3

8.2. Typical Data Sheet

8.3. Test Setup

8.1. Figure 3


Filtration Efficiency versus Time
% Efficiency
100
99.5
99
98.5
98
97.5
97
96.5
96
0
2
4
6
8
10
12
Time (minutes)
Type 1
Type 2
Type 3
Type 4

8.2. 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-2000 **Reference No.:** CFR 84.181
**Test:** Sodium Chloride (NaCl) - N100 **STP No.:** 57
**Manufacturer:**
**Item Tested:**

| 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

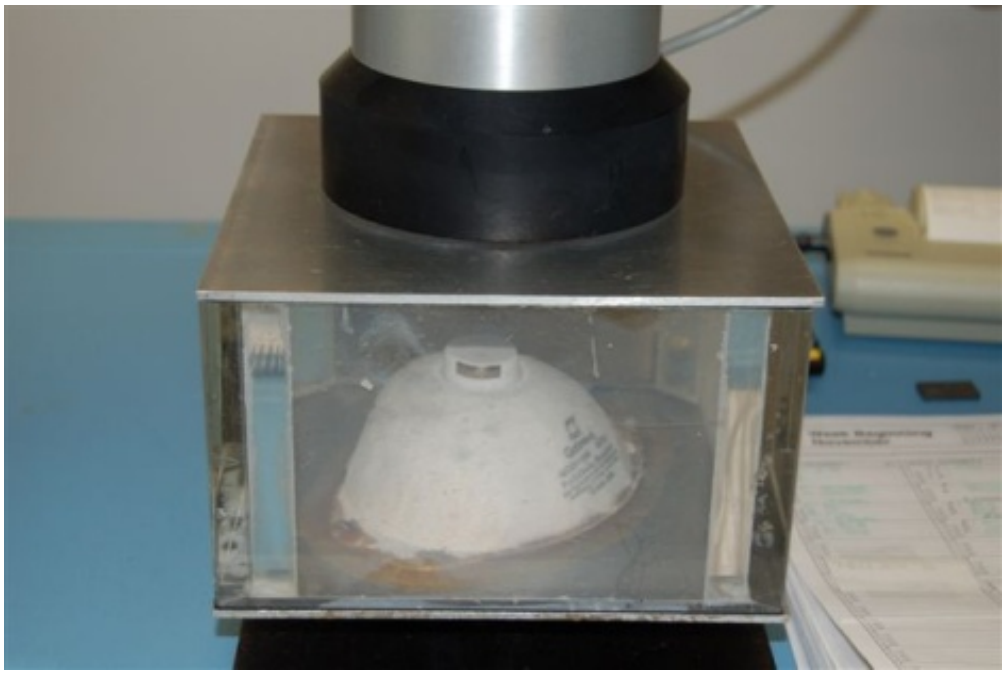
**All test equipment within calibration:** Yes

**Comments:**
TESTING

**Signature:** Jeffrey A Robinson **Date:** 4/5/94

**Engineering Technician**

8.3 Test Setup



# 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. |