DETERMINATION OF PARTICULATE FILTER PENETRATION
TO TEST AGAINST LIQUID PARTICULATES FOR NEGATIVE PRESSURE,
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 penetration test on negative pressure respirators against liquid particulate requirements on R100, R99, R95, P100, P99, and P95 filters and filter cartridges designed for negative pressure, air-purifying respirators providing personal protection against any particulates, including oil based aerosols, 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) and Subpart K, Section 84.181; Volume 60, Number 110, June 8, 1995. 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 Penetration to Test Against Liquid Particulates For Negative Pressure, 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 with a forward light scattering detector.
3.1.2. Particle sizing instrument (such as a Scanning or Differential Mobility Particle Sizer) capable of determining submicron particles according to count median diameter (CMD).

3.1.3. Microbalance accurate to 0.0001 grams (g).

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

3.1.5. Timer (accurate to 0.01 second).

3.1.7. Virtis JM-8000 Photometer or equivalent.

3.1.8. Respirator filter holder for specific manufacturer type which is compatible with TSI filter tester. NIOSH will not be obligated to use these holders for actual certification testing.

3.1.9. Optional data acquisition system.

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. Workbenches 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. 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 neutralized liquid (neat DOP) aerosol at
25±5°C. The particle size distribution will be a count median diameter of 0.185±0.020 micrometers and a geometric standard deviation not exceeding 1.6. Each respirator filter unit will be challenged with an aerosol concentration not exceeding 200 mg/m³.

5.2.1. The following procedure will be routinely employed to insure that the DOP particle size distribution will be a count median diameter of 0.185±0.020 micrometers with a geometric standard deviation of less than 1.6. A standard filter instantaneous penetration will be determined using DOP aerosol. The standard filter test will be run two times each day (at least twice in each 8 to 10 hour test period) during testing to verify that the aerosol distribution is optimized and has not changed.

5.2.2. If the instantaneous filter penetration has changed, abort testing and check the aerosol particle size.

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 Lpm ±5 percent. Filters used as pairs on a respirator are tested using a single filter of the pair at 42.5 Lpm ±5 percent 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. These filters of a single filter arrangement will be loaded to 200±5 mg. Load single filters of a pair configuration with 100±5 mg. This method is used for both the R and P series filters. For P-series filters, if the efficiency of any one of these 20 filters is still decreasing when the 200±5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency (i.e. Filter efficiency remains stable for another 30±5 mg of loading). This will be done until there is no further decrease in efficiency or until the filter has reached a 400 mg±5 mg of loading. If the filter continues to degrade at this loading level then it fails the Regulatory requirement. (For P-100, P-99, and P-95 Filters, decrease in efficiency is defined as ≥0.002 percent penetration (P-100 filters) or >±0.012 penetration (P-99 filters) or >±0.05 percent penetration (P-95 filters) at the 200 mg load level and includes two 7-8 mg increments on either side of the 200 mg load for a single filter.) For P-100, P-99, and P-95 series filters, the determination that there is no further decrease in efficiency is based upon five data points centered at 200 mg loading for single filter respirator configurations, 100 mg loading per filter for dual filter configurations, 70 mg for triple filter configurations, etc. If the bandwidth (range) in penetration readings is equal to or less than 0.004 percent for P-100 filters, 0.024 percent for P-99 filters, or 0.1 percent for P-99 filters, through the incremental loading level for the five data points, the criteria for “no further decrease in efficiency” is met. If the bandwidth in penetration readings is greater than 0.004 percent for P-100 filters, 0.024 percent for P-99 filters, or 0.1 percent for P-95 filters and not clearly decreasing, then the filter penetration is continuing to increase. The test is continued through the next five data points incremental level for determination of “no further decrease in efficiency” to these same criteria. This can continue up to 400 mg of loading for single filter.
configurations, 200 mg of loading for dual filter configurations, 140 mg of loading for triple filter configurations, etc. The “no further decrease in filter efficiency” determination made at the test end is used to decide if the performance meets Part 84 requirements. Record the maximum penetration reading and the five data point readings on which the “no further decrease in efficiency” determination is made for P-100, P-99, and P-95 series filters. To ensure that a filter does not exceed the Regulatory requirement the minimum efficiencies allowed by NIOSH may not exceed 99.972 percent, 99.012 percent, or 95.05 percent for P-100, P-99, and P-95 series filters, respectively.

5.4.1. If any one of the 20 filters has a penetration greater than the designated limit, 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, that sample will be considered an invalid sample and another tested in its place.

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

5.5.1. Weigh a Gelman 102 mm filter to the nearest 0.0001 g, mount in the gravimetric filter holder, subject it to the generated aerosol, 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 Particulate Filter Penetration To Test Negative Pressure Respirators Against Liquid Particulates data sheet and calculate the aerosol concentration in mg/m³. The weight change should be a significant value over the pre-weight.

5.5.2. The DOP aerosol concentration can be monitored by a calibrated photometer placed in line on the mixing chamber exhaust.

5.6. The DOP particle size will be monitored routinely with an appropriate particle sizing instrument to ensure the particle size distribution count median diameter remains in the range of 0.185 ± 0.020 micrometers with a geometric standard deviation of not more than 1.6.

5.7. 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. An optional data acquisition system can be used for data collection and evaluation.

5.8. Determine and record the maximum filter penetration for each of the 20 filters, and the five data point readings on which the “no further decrease in efficiency” determination is made for P-series filters.

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) and Subpart K, Section 84.181; 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.

84.181 Non-powered air-purifying particulate filter efficiency level determination.

(a) Twenty filters of each non-powered air-purifying particulate respirator model shall be tested for filter efficiency against:

(1) A solid sodium chloride particulate aerosol as per this section, if N-series certification is requested by the applicant.

(2) A dioctyl phthalate or equivalent liquid particulate aerosol as per this section, if R-series or P-series certification is requested by the applicant.

(b) Filters including holders and gaskets; when separable, shall be tested for filter efficiency level, as mounted on a test fixture in the manner as used on the respirator.

(c) Prior to filter efficiency testing of 20 N-series filters, the 20 to be tested shall be taken out of their packaging and placed in an environment of 85±5 percent relative humidity at 38±2.5 °C for 25±1 hours. Following the pre-conditioning, filters shall be sealed in a gas-tight container and tested within 10 hours.

(d) When the filters do not have separable holders and gaskets, the exhalation valves shall be blocked so as to ensure that leakage, if present, is not included in the filter efficiency level evaluation.

(e) For non-powered air-purifying particulate respirators with a single filter, filters shall be tested at a continuous airflow rate of 85±4 liters per minute. Where filters are to be used in pairs, the test-aerosol airflow rate shall be 42.5±2 liters per minute through each filter.
(f) Filter efficiency test aerosols.

(1) When testing N-series filters, a sodium chloride or equivalent solid aerosol at 25±5 °C and relative humidity of 30±10 percent that has been neutralized to the Boltzmann equilibrium state shall be used. Each filter shall be challenged with a concentration not exceeding 200 mg/m³.

(2) When testing R-series and P-series filters, a neat cold- nebulized dioctyl phthalate (DOP) or equivalent aerosol at 25±5 °C that has been neutralized to the Boltzmann equilibrium state shall be used. Each filter shall be challenged with a concentration not exceeding 200 mg/m³.

(3) The test shall continue until minimum efficiency is achieved or until an aerosol mass of at least 200±5 mg has contacted the filter. For P-series filters, if the filter efficiency is decreasing when the 200±5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency.

(g) The sodium chloride test aerosol shall have a particle size distribution with count median diameter of 0.075±0.020 micrometer and a standard geometric deviation not exceeding 1.86 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent. The DOP aerosol shall have a particle size distribution with count median diameter of 0.185±0.020 micrometer and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

(h) The efficiency of the filter shall be monitored and recorded throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation.

(i) The minimum efficiency for each of the 20 filters shall be determined and recorded and be equal to or greater than the filter efficiency criterion listed for each level as follows:

- **P100, R100 and N100:** Efficiency ≥ 99.97 percent
- **P99, R99 and N99:** Efficiency ≥ 99 percent
- **P95, R95 and N95:** Efficiency ≥ 95 percent

6.3. For the sample of 20 filters or filter cartridges to demonstrate acceptable performance, each filter must meet or exceed the specified (≥95 percent, ≥99 percent, ≥99.97 percent) at the end point of the test.

7. RECORDS/TEST SHEETS

7.1. All test data will be recorded on the PARTICULATE FILTER PENETRATION TO TEST NEGATIVE PRESSURE RESPIRATORS AGAINST LIQUID PARTICULATES 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.
National Institute for Occupational Safety and Health
Certification and Quality Assurance Branch
Air-Purifying Respirator Section
Test Data Sheet

Task Number: TM-1000
Test: Desolenator Diaphragm (DOP) - P100
Manufacturer: Desolenator
Item Tested: Single Filter (A-D), Dual Filter (E-F)

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Overall Result: PASS

All test equipment within calibration: Yes
Comments: TESTING

Signature: [Signature]
Date: [Date]
## Revision History

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