

WILLSON PRODUCTS DIVISION
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PROPOSED CHANGES IN 30 CFR 11, SUBPART K

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30 JANUARY 1978

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Willson Products, as a major manufacturer of respiratory protective devices for over sixty years, has a deep and abiding concern with regulations governing the respirator industry. The intended reform of 30 CFR 11 is therefore regarded as necessary and desirable, and the opportunity for comment is appreciated.

Although 30 CFR 11 contains other sections which require revision, Willson is primarily interested in Subpart K which deals with particulate filter respirators. Accordingly, our comments pertain only to Subpart K, and a proposed revision is included for your consideration.

To aid in evaluation of the proposed Subpart K, explanatory notes are provided below:

1. Paragraphs 11.130 and 11.131 represent a significant departure from the current standard. Design restrictions, both implicit and explicit, were deleted, and respirator classifications, based upon performance characteristics and tests, were substituted.

In these and other paragraphs, use of such terms as "single-use filter" and "single-use respirator equipped with reusable filter" etc. was intentionally avoided. As a result of confusion and subsequent controversy, these have become emotionally-loaded terms subject to a great many interpretations. And if a pure performance standard is considered, the need for arbitrary nomenclature is unnecessary.

2. Paragraphs 11.131 through 11.139 of the current version were relegated to Subpart G and it is suggested that Subparts H through N be handled in a similar fashion.
3. The addition of a table summarizing performance requirements is advisable. This table should be referenced in paragraph 11.133 (a).
4. The Quantitative Fit Testing requirements in paragraph 11.134 et al are basically similar to those suggested by Los Alamos, however, modifications have been made.

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5. Paragraph 11.134-2 (d) stipulates a minimum of three tests on each subject. Although these tests are time-consuming and expensive, no other solution has yet been proposed which would account for the lack of reproducibility reported by workers in the field.
6. Aerosol concentration stability requirements have been added to the sodium chloride test (11.134-3 (b)) as well as other aerosol tests which appear in the Subpart.

The geometric standard deviations, too, have been toleranced wherever an aerosol is defined in Subpart K by means of a diametric dimension.

These aerosol requirements should minimize inter-laboratory variations and subsequent controversy. It must be recognized, however, that the specifications define a very polydisperse aerosol having a relative standard deviation of approximately three for NaCl and four for silica dust. As such, interlaboratory variation will not be entirely eliminated.

7. Sodium chloride penetration has been defined so that the specification permits the use of either U.S. or European instruments. Significant questions regarding the comparative performance of both designs must be resolved prior to any commitment.

In addition, the effect of lung adsorption has not been factored into the equation. Since some workers have reported lung adsorption percentages as high as 50%, this variable should be considered.

8. No correlation between quantitative fit test values and observed respirator performance in the field has yet been established with any degree of certainty. It would therefore be incorrect to assume that such a correlation exists however logical the extrapolation might appear.

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The above statement is not intended to undermine the NaCl test procedure or quantitative fit testing concepts, but it is Willson's position that the method and resultant data must be viewed from the perspective of its limitations rather than its potential.

When quantitative fit testing is regarded in the same category as silica dust testing and lead fume testing etc., the arithmetic mean is adequate to characterize a respirator facefit for regulatory purposes. If, however, statistical techniques are employed, then all other performance tests in Part II should be handled in a similar fashion in order to maintain a degree of uniformity.

9. Implied in paragraph 11.134-5 is the requirement that all half-mask respirators, including single-use and disposable types, have a maximum penetration value of 10 percent.
10. Airflow resistance values have been standardized for all respirators in the absence of physiological evidence which would indicate otherwise.
11. Initial leakage requirements appear in paragraphs 11.136-1, 11.136-2, and 11.136-3. This change was written into Part II because of common respirator practices. Corporations which have an established respirator program often change particulate filters on a daily basis even though much useful service life remains.

As a result, filters never have a chance to load up and become more efficient, and less protection is afforded the user. This problem is particularly prevalent where disposable respirators are readily available to users. It is not uncommon to find a worker using two to four respirators per day.

European respirator standards recognize this phenomenon and initial filter leakage limitations are accordingly specified.

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12. Only DOP and silica dust tests are currently required for approval of high-efficiency type filters. An assumption is made that lead fume and silica mist test results will be good if the DOP and silica dust results are good.

In the absence of published correlation data, it is suggested that all test be performed for approval.

Subpart K - Particulate Filter Respirators

11.130 Particulate filter respirators; description.

- (a) Particulate filter respirators are defined as respirators equipped with one or more filters designed to remove a single type of particulate matter or a combination of two or more types of particulate matter from ambient air prior to inhalation by the respirator wearer.
- (b) Particulate filter respirators are designed for use as respiratory protection during entry into and escape from hazardous, particulate-containing atmospheres which have a minimum oxygen concentration of 19.5 percent by volume.

11.131 Particulate filter respirators; classification.

- (a) Particulate filter respirators are classified according to the following characteristics:
 - (1) Respirator type
 - (i) Non-powered air purifying respirators
 - (ii) Powered air purifying respirators
 - (2) Protection class
 - (i) Respirators designed for use against particulates having a time-weighted average (TWA) not less than 0.05 milligrams per cubic meter or two mppcf.
 - (ii) Respirators designed for use against particulates having a time-weighted average (TWA) less than 0.05 milligrams per cubic meter or two mppcf.
 - (3) Type of particulate hazard.
 - (i) Dusts
 - (ii) Mists
 - (iii) Fumes
 - (iv) Radionuclides
 - (4) Filter efficiency
 - (i) Standard efficiency filters which can achieve a minimum efficiency of 99 percent against the appropriate test aerosol.
 - (ii) High efficiency filters which can achieve a minimum efficiency of 99.97 percent against the appropriate test aerosol.

11.132 Particulate filter respirators; components.

- (a) The components of each particulate filter respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

11.133 Particulate filter respirators; performance requirements, general.

- (a) Particulate filter respirators and the individual components of each such device shall, as appropriate, meet the requirements for performance and protection specified in the tests described in paragraphs 11.134 through 11.138 and Table . (Note: To be similar to current Table 10.)

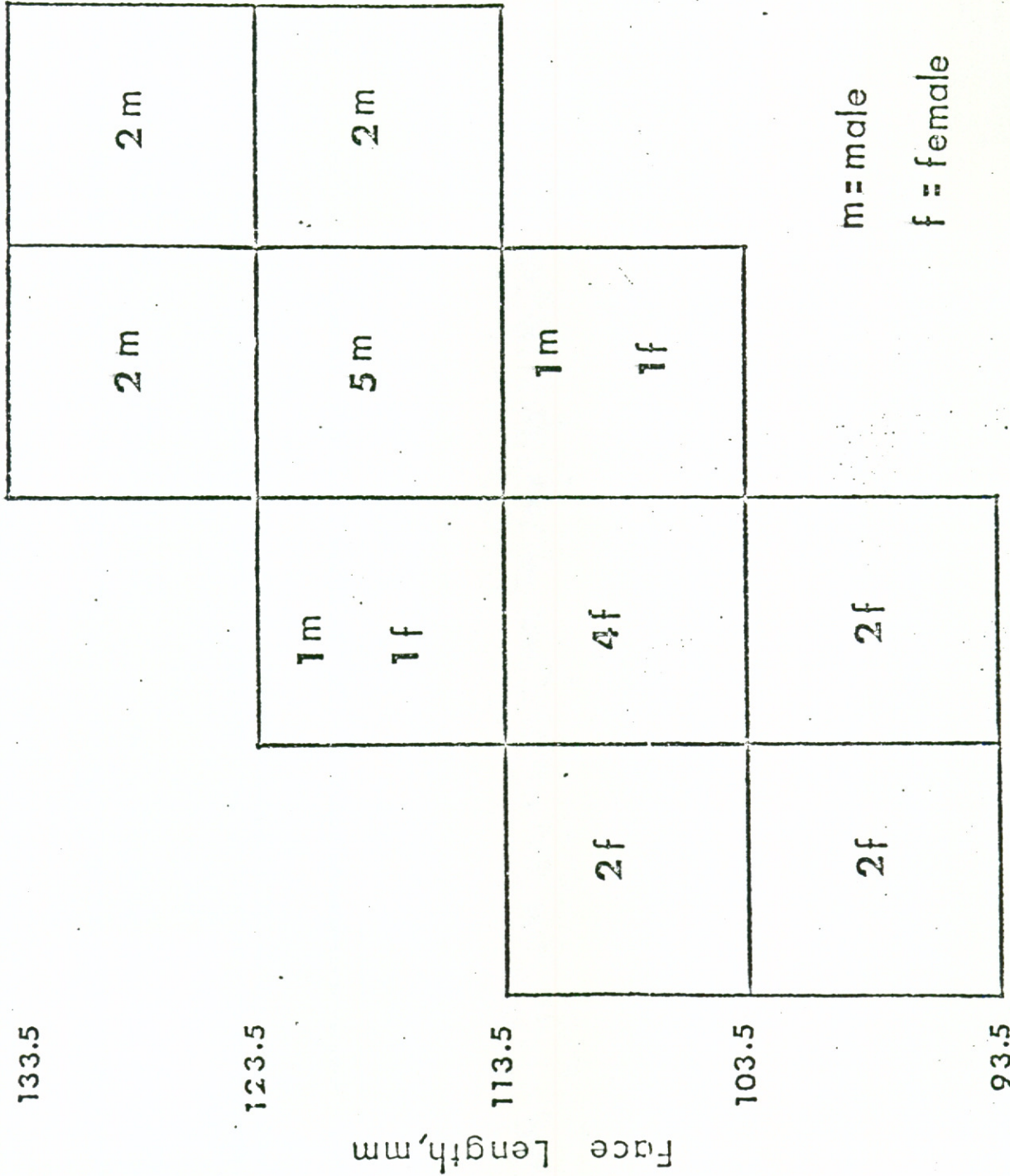
11.134 Quantitative fit testing, particulate filter respirators; general requirements.

- (a) Five samples of each respirator or, where applicable, five samples of each respirator size shall be available for fit testing.
- (b) Where the respirator design is incompatible with the test method employed, modifications to the device shall be permitted provided that physical properties (size, weight, etc.) and airflow resistance (both inhalation and exhalation) of the modified respirator assembly are essentially similar to the original design.
- (c) Respirator fitting instructions shall accompany each application for approval so that all test subjects can be properly trained in wearing the respirator prior to quantitative fit testing.
- (d) Sections 11.134-1 through 11.134-5 shall be employed, as applicable, for determining the fit characteristics of particulate filter respirators.

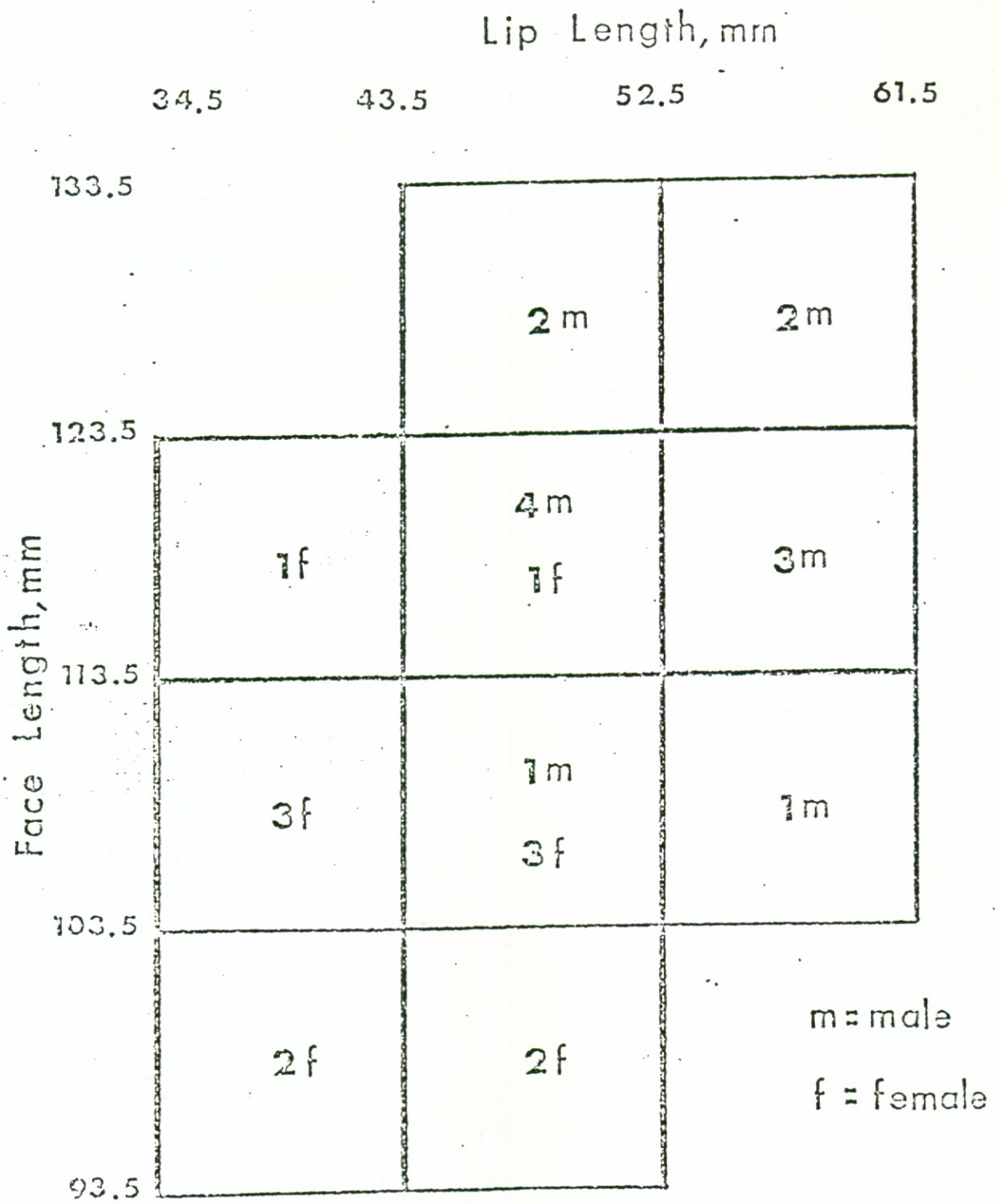
11.134-1 Quantitative fit testing, test panel selection.

- (a) Test subjects shall be chosen from among individuals having normal facial characteristics and complexion.
- (b) Respirators equipped with quarter-mask, half-mask, or mouthpiece respiratory inlet coverings shall be evaluated on a test panel consisting of 25 test subjects in ten size categories as prescribed in Figure II.
- (c) Respirators with full-facepiece respiratory inlet coverings shall be evaluated on a test panel consisting of 25 test subjects in ten size categories as prescribed in Figure I.
- (d) Respirators with hood, helmet, or suit respiratory inlet coverings shall be evaluated on a test panel consisting of ten test subjects in the ten size categories as prescribed in Figure I.
- (e) Where a respiratory inlet covering is designed to fit a particular size category, the device shall be tested on a truncated test panel consisting of no less than three contiguous size categories.

Face Width, mm
 117.5 126.5 135.5 144.5 153.5



PANEL FOR FULL-FACE MASKS
 FIGURE 1



PANEL FOR HALF-MASKS
FIGURE 2

- (f) Detailed information on test panel selection and anthropometric measurement is available in Los Alamos Scientific Laboratory Report LA-5488, "Selection of Respiratory Test Panel Representative of U.S. Facial Sizes" which can be purchased from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22151, Reference PB-LA-5488.

11.134-2 Quantitative fit testing, test exercises.

- (a) The following exercises shall be performed by each test subject while wearing a respirator equipped with a tight-fitting respiratory inlet covering in a test atmosphere.
- (i) Two minutes, normal breathing with head held still.
 - (ii) Two minutes, deep breathing with head held still.
 - (iii) Two minutes, turning head slowly from side to side, pausing for two breaths before changing directions.
 - (iv) Two minutes, nodding head slowly up and down, pausing for two breaths before changing directions.
 - (v) Two minutes, reading prepared text slowly, loud enough to be heard by test operator (not applicable to mouthpiece respirators.)
 - (vi) Smiling for half and quarter masks or frowning for full facepieces.
 - (vii) Two minutes, normal breathing with head held still.
- (b) The following exercises shall be performed by each test subject while wearing a respirator equipped with a loose-fitting respiratory inlet covering in a test atmosphere.
- (i) Two minutes, standing still, arms hanging downward along the side of body, normal breathing.
 - (ii) Two minutes, bending forward and touching toes repeatedly.
 - (iii) Two minutes, raising arms above head and looking up repeatedly.
 - (iv) Two minutes, bending knees and squatting repeatedly.
 - (v) Two minutes, standing still with 36' dowel rod held in hands (spray nozzle), twisting from waist to simulate body motions of a sand-blaster.
 - (vi) Two minutes, standing still, arms hanging downward along sides of body, normal breathing.
- (c) While testing respirators equipped with quarter- or half-mask respiratory inlet coverings, test subjects shall wear safety glasses, as described in the latest edition of ANSI-Z87 during the tests specified in paragraph 11.134-2 (a) (i) through (vii).
- (d) The prescribed test regimen shall be performed by each test subject on a minimum of three separate occasions.
- (e) Where one test subject produces a poor facefit performance, that subject will be replaced by another subject of substantially the same facial size. Only one subject shall be replaced.

11.134-3 Quantitative fit testing, sodium chloride test aerosol.

- (a) The test aerosol employed in quantitative fit testing shall be formed by atomizing an aqueous solution of sodium chloride to produce an aerosol having the following characteristics:
 - (i) Sodium chloride aerosol concentration shall be 15 milligrams per cubic meter plus or minus 5 milligrams.
 - (ii) The particle size distribution of the aerosol shall have a mass median aerodynamic diameter of 0.6 ± 0.1 micrometer and a geometric standard deviation of 2.0 ± 0.2 .
 - (iii) Relative humidity shall be 40 to 60 percent.
 - (iv) Temperature shall be $20 \pm 2^\circ\text{C}$.
- (b) Test chamber aerosol concentration shall not vary by more than five percent during the evaluation of any test subject.
- (c) Aerosol penetrations and concentration measurements shall be permanently recorded on a strip chart recorder.

11.134-4 Quantitative fit testing; calculations.

- (a) Average penetration values shall be calculated for each individual exercise except 11.134-2 (a) (vi) where penetration is defined as:

$$\text{Penetration (percent)} = \frac{C_2 - C_3 - C_4}{C_1 - C_3} \times 100$$

Where C1 - aerosol concentration in chamber.
C2 - aerosol concentration in respiratory inlet covering.
C3 - zero effect of apparatus.
C4 - concentration of aerosol passed by filter element in respirator.

- (b) The average penetration for each exercise shall be averaged to obtain the mean penetration value for the test subject.

11.134-5 Quantitative fit testing; minimum requirements.

- (a) Respirators designed for use against particulates having a time-weighted average (TWA) not less than 0.05 milligrams per cubic meter shall have a mean penetration value of less than 10 percent.
- (b) Respirators designed for use against particulates having a time-weighted average (TWA) of less than 0.05 milligrams per cubic meter shall have a mean penetration value of less than one percent.

- (c) Powered air purifying respirators shall have a mean penetration value of less than 0.03 percent.

11.135 Particulate filter respirators; airflow resistance testing, minimum requirements.

- (a) Resistance to airflow will be measured in the respiratory inlet covering of a particulate filter respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute, both before and after each test conducted in accordance with paragraphs 11.136 through 11.136-3.
- (b) Maximum initial inhalation resistance shall be three millibar (30 mm water column height).
- (c) Maximum final inhalation resistance shall be five millibar (50 mm water column height).
- (d) Maximum exhalation resistance (both initial and final) shall be two millibar (20 mm water column height).

11.136 Particulate filter tests, general; airflow requirements.

- (a) Particulate filter respirators equipped with exhalation and inhalation valves to prevent exhaled breath from contacting the filter element shall be tested against the appropriate aerosol by drawing a continuous airflow of 32 liters per minute through the filtration element.
- (b) Particulate filter respirators which allow the exhaled breath to contact the filter element shall be tested against the appropriate aerosol using a cyclical airflow rate.
 - (i) Air shall be cycled through the respirator at the rate of 24 respirations per minute with a minute volume of 40 liters.
 - (ii) A breathing machine cam having a work rate of 622 kilogram-meters squared per minute shall be used.
 - (iii) Air exhaled through the respirator shall be conditioned to $35^{\circ} \pm 2^{\circ} \text{C}$ and $94\% \pm 3\%$ relative humidity.
- (c) Powered air purifying respirators equipped with tight-fitting respiratory inlet coverings shall be evaluated against the appropriate aerosols while in the normal operational mode.
 - (i) A minimum airflow rate of 115 liters per minute, both before and after each applicable aerosol test, shall be required.
 - (ii) Airflow rates shall be measured with the respirator mounted on a suitable head-form.

- (d) Powered air purifying respirators equipped with loose-fitting respiratory inlet coverings shall be evaluated against the appropriate aerosols while in the normal operational mode.
 - (i) A minimum airflow rate of 170 liters per minute, both before and after each applicable aerosol test, shall be required.
 - (ii) Airflow rates shall be measured with the respirator mounted on a suitable mannequin.

11.136-1 Silica dust test; minimum requirements.

- (a) Three respirators will be evaluated.
 - (i) Non-powered air purifying respirators will be exposed to the test aerosol for a period of 90 minutes.
 - (ii) Powered air purifying respirators will be exposed to the test aerosol for a period of four hours.
- (b) The test aerosol in the chamber will consist of 55 ± 5 milligrams per cubic meter flint (99+ percent free silica).
- (c) The particle size distribution of the test aerosol will have a geometric mean diameter of 0.4 to 0.6 micrometer, and the standard geometric deviation will be 1.8 ± 0.2 .
- (d) Chamber concentration shall not fluctuate more than plus or minus ten percent during the performance of any test.
- (e) The relative humidity in the test chamber will be 45 to 55 percent, and the chamber temperature will be $23 \pm 2^\circ \text{C}$.
- (f) The total amount of test aerosol not retained by the respirator filter during the initial thirty minutes of the test, and during the entire test period shall be monitored.
 - (i) The maximum amount of leakage for standard efficiency filters shall be as follows:
 1. Maximum initial leakage (30 minutes) for non-powered air purifying respirators equipped with inhalation and exhalation valves shall be 0.5 milligrams, and the total cumulative leakage shall not exceed 1.5 milligrams.
 2. Maximum initial leakage (30 minutes) for non-powered air purifying respirators without valves shall be 0.6 milligrams, and the total cumulative leakage shall not exceed 1.8 milligrams.
 3. Maximum initial leakage (30 minutes) for powered air purifying respirators equipped with tight-fitting respirator inlet coverings shall be 1.8 milligrams, and the total cumulative leakage shall not exceed 14.4 milligrams.

4. Maximum initial leakage (30 minutes) for powered air purifying respirators equipped with loose-fitting respiratory inlet coverings shall be 2.66 milligrams, and the total cumulative leakage shall not exceed 21.3 milligrams.

(ii) High efficiency filters approved for dusts must comply with paragraph 11.137 in addition to the silica dust tests herein specified.

11.135-2 Silica mist test; minimum requirements.

(a) Three respirators will be evaluated.

(i) Non-powered air purifying respirators will be exposed to the test aerosol for a period of 312 minutes.

(ii) Powered air purifying respirators will be exposed to the test aerosol for a period of four hours.

(b) The test aerosol in the test chamber will not be less than 20 nor more than 25 milligrams per cubic meter of air when dried and weighed as silica dust.

(c) Mist will be produced by spraying an aqueous suspension of flint (99+ percent free silica), and the flint shall be ground to pass 99 percent through a 325-mesh sieve (U.S. Series).

(d) Chamber concentration shall not fluctuate more than plus or minus ten percent during the performance of any test.

(e) The chamber temperature will be maintained at 23°+2° C.

(f) The total amount of test aerosol, weighed as silica dust, not retained by the respirator filter during the initial thirty minutes of the test, and during the entire test period shall be monitored.

(i) The maximum amount of leakage for standard efficiency filters shall be as follows:

1. Maximum initial leakage (30 minutes) for non-powered air purifying respirators equipped with inhalation and exhalation valves shall be 0.25 milligrams, and the total cumulative leakage shall not exceed 2.5 milligrams.

2. Maximum initial leakage (30 minutes) for non-powered air purifying respirators without valves shall be 0.3 milligrams, and the total cumulative leakage shall not exceed 3.0 milligrams.

3. Maximum initial leakage (30 minutes) for powered air purifying respirators equipped with tight-fitting respiratory inlet coverings shall be 0.85 milligrams, and the total cumulative leakage shall not exceed 6.9 milligrams.

4. Maximum initial leakage (30 minutes) for powered air purifying respirators equipped with loose-fitting respiratory inlet coverings shall be 1.28 milligrams, and the total cumulative leakage shall not exceed 10.2 milligrams.

(ii) High efficiency filters approved for mists must comply with paragraph 11.137 in addition to the silica mist tests herein specified.

11.136-3 Lead fume test, minimum requirements.

(a) Three respirators will be evaluated.

(i) Non-powered air purifying respirators will be exposed to the test aerosol for a period of 312 minutes.

(ii) Powered air purifying respirators will be exposed to the test aerosol for a period of four hours.

(b) The test aerosol in the test chamber will not be less than 15 nor more than 20 milligrams of freshly generated lead-oxide fume, calculated as lead, per cubic meter of air.

(c) The fume will be generated by impinging an oxygen-gas flame on molten lead.

(d) Chamber concentration shall not fluctuate more than plus or minus ten percent during the performance of any test.

(e) The relative humidity in the test chamber will be 40 to 60 percent, and the room temperature will be $23 \pm 2^{\circ}\text{C}$.

(f) The total amount of test aerosol, which is analyzed and calculated as lead, not retained by the respirator filter during the initial thirty minutes of the test, and during the entire test period shall be monitored.

(1) The maximum amount of leakage for standard efficiency filters shall be as follows:

1. Maximum initial leakage (30 minutes) for non-powered air purifying respirators equipped with inhalation and exhalation valves shall be 0.15 milligrams, and the total cumulative leakage shall not exceed 1.5 milligrams.

2. Maximum initial leakage (30 minutes) for non-powered air purifying respirators without valves shall be 0.18 milligrams, and the total cumulative leakage shall not exceed 1.8 milligrams.

3. Maximum initial leakage (30 minutes) for powered air purifying respirators equipped with tight-fitting respiratory inlet coverings shall be 0.40 milligrams, and the total cumulative leakage shall not exceed 4.2 milligrams.
4. Maximum initial leakage (30 minutes) for powered air purifying respirators equipped with loose-fitting respiratory inlet coverings shall be 0.60 milligrams, and the total cumulative leakage shall not exceed 6.2 milligrams.

(ii) High efficiency filters approved for fumes must comply with paragraph 11.137 in addition to the lead fume tests herein specified.

11.137 DOP filter test; respirators designed as respiratory protection against particulates having a time-weighted average (TWA) less than 0.05 milligrams per cubic meter, and radionuclides; minimum requirements.

- (a) All single air-purifying respirator filter elements will be tested against a 0.3 micrometer mono-dispersed, thermally-generated aerosol of DOP having a concentration of 90 to 110 micrograms per liter of air.
- (b) Filter elements shall be evaluated at the following flowrates:
 - (i) Where the respirator design employs a single filter element, a continuous flowrate of 85 liters per minute will be used.
 - (ii) Where the respirator design employs filter elements in pairs, the flowrate will be 42.5 liters per minute through each filter.
- (c) Filters will be evaluated for a time period of five to ten seconds.
- (d) The total leakage for the filter shall not exceed 0.03 percent of the ambient DOP concentration.

11.138 Tests for respirators designed for respiratory protection against more than one type of particulate; minimum requirements.

- (a) Respirators designed as respiratory protection against more than one type of particulate hazard (dust, fume, mist, etc.) shall comply with all the requirements of this part, with respect to each of the specific hazards involved.