

September 9, 1998

NIOSH Docket Office
Robert A. Taft Laboratories
M/S C34
4676 Columbia Parkway
Cincinnati, OH 45226

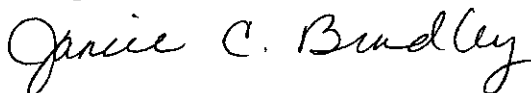
RE: Revision to the NIOSH Technical Module for Powered Air Purifying Respirators
(PAPR)

Dear Sir/Madam,

The ISEA is the leading national organization representing manufacturers of personal protective equipment. ISEA respirator manufacturers hold more than 95% of all NIOSH certifications.

We offer the following comments in response to the notice published in the May 16, 1996 *Federal Register* by the National Institute for Occupational Safety and Health (NIOSH).

Respectfully submitted,



Janice C. Bradley, CSP
Technical Director

cc: Richard Metzler, Chief
NIOSH, Certification and Quality Assurance Branch
Morgantown, WV

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Powered Air Purifying Respirators

1. Classification.

- A. Powered Air Purifying Respirators (PAPR) shall be classified as devices intended for low work levels or high work levels.
- B. PAPR respirator inlet coverings shall be classified as tight fitting half or full face piece coverings, or loose fitting facepiece coverings, or hoods or helmets.
- C. PAPR particulate filters shall be classified as P100 filters.
- D. PAPR chemical cartridges shall be classified as either high capacity or low capacity.
- E. PAPR chemical cartridges shall be further classified as to the chemical or groups of chemicals for which they are intended to be used.
- F. PAPR battery duration shall be specified as either 1, 4, or 8 hour duration or can be powered from a permanent power source.
- G. PAPR minimum air flow shall be specified.

2. Particulate Air Purifying elements.

- A. The P100 filters shall be labeled as in 84.179 (b)(3).
- B. Twenty filters of each powered air purifying respirator model shall be tested for filter efficiency.
- C. Filters, including attachment components, when separable shall be tested for filter efficiency, as mounted on a manufacturer-supplied test fixture in the manner as used on the respirator.
- D. For single filter PAPRs, filters shall be tested at a continuous airflow that is the effective airflow for the PAPR.
 - i. Effective airflow is the airflow rate delivered to the respiratory inlet covering after ten minutes of continuous running with unused filters and fully charged batteries.
 - ii. For PAPR with multiple filters used in parallel, filters shall be tested at a continuous airflow that is the effective airflow for the PAPR divided by the number of filters.
 - iii. For PAPR with multiple filters used in parallel, their resistance of airflow shall be within 10%.
- E. A neat, cold nebulized dioctyl phthalate (DOP) or equivalent aerosol at 25 ± 5 degrees 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 per cubic meter.
- F. The DOP aerosol shall have particle size distribution with count medial diameter of 0.185 ± 0.020 micrometer and a standard geometric deviation not exceeding 1.6 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.
- G. For PAPR with a single filter, the test shall continue until minimum efficiency is achieved or until an aerosol mass of at least 2000 mg has contacted the filter.
 - i. For PAPR with multiple filter used in parallel, the test shall continue until an aerosol mass of at least 2000 mg divided by the number filters has contacted the filter.
 - ii. If the filter efficiency is decreasing when the above mg challenge point is reached, the test shall be continued in 20 mg increments until there is no further decrease in efficiency.

- 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 99.97%.

3. Gas and Vapor Chemical Cartridges.

- A. Where two or more cartridges are used in parallel, their resistance to airflow shall be essentially equal.
- B. The color and markings of all cartridges or labels shall conform with the requirements of the American National Standards Institute, American National Standard for Identification of Air-Purifying Respirator Canisters and Cartridges, ANSI K13.1-1973.
- C. Cartridges shall be tested on an apparatus that allows the test atmosphere at 25 ± 3 degrees C to enter the cartridges continuously. Cartridges shall be tested at a continuous airflow that is the effective airflow for the PAPR.
- D. Three cartridges will be tested at $25 \pm 5\%$ relative humidity and three cartridges will be tested at $80 \pm 5\%$ relative humidity.
- E. Where two or more cartridges are used in parallel, the service life test will be performed with the cartridges arranged in parallel and the test requirements will apply to the combination of cartridges.
- F. Service life is defined as the time in minutes to when the test agent reaches the concentration specified in table 1 as the service life concentration.
- G. PAPR chemical cartridge respirators for respiratory protection against gases or vapors, which are not specifically listed, may be approved if the applicant submits a request for such approval, in writing, to the Institute. The Institute shall consider each such application and accept or reject the application after a review of the effects on the wearer's health and safety and in the light of any field experience in use of chemical cartridge respirators as protection against such hazards.
- H. Where a cartridge is designed for respiratory protection against more than one type of dissimilar gas or vapor, such as use for ammonia and chlorine, the minimum life shall be one half that shown for each type of gas or vapor. Where a respirator is designed for respiratory protection against more than one gas of a similar type, such as chlorine and sulfur dioxide, the minimal life shall apply.

Table 1
Cartridge Bench Tests

Test Agent	Service life concentration ppm	End of service life penetration ppm	High capacity end of service life time (min)	Low capacity end of service life time (min)
Ammonia	1000	50	50	25
Chlorine	500	5	35	17.5
Chlorine dioxide	500	0.1	30	15
Formaldehyde	100	1	50	25
Hydrogen chloride	500	5	50	25
Hydrogen fluoride	70	3	30	15
Hydrogen sulfide	1000	10	60	30
Mercury	21.5	0.05	480	240
Methylamine	1000	10	25	12.5
Organic vapor (carbon tetrachloride)	1000	5	50	25
Sulfur dioxide	500	5	30	15

4. **Combination Particulate elements and Gas and Vapor Cartridges.**
 - A. Particulate filters used in conjunction with a chemical cartridge shall be located on the inlet side of the cartridge.
 - B. Particulate air purifying elements shall meet the requirements of section 2.
 - C. Chemical cartridges shall meet the requirements of section 3.

5. **General Requirements.**

PAPR shall meet the requirements of 84.195 through 84.200.

6. **Noise level test.**
 - A. The respiratory shall be mounted on a head/torso form appropriately sized and operated with a fully charged battery.
 - B. The noise level shall not exceed 80 dba as measured with a sound level meter conforming, as a minimum, to ANSI S1.4-1983 Type S2a, with a remote microphone mounted at the ear of the headform.
 - C. Ambient noise levels in the test location shall not exceed 60 dbA.
 - D. Three PAPRs shall be tested.

7. **Simulated workplace test.**
 - A. A test chamber shall be used and shall be of sufficient size to permit the test subject to freely perform all the required exercises.
 - B. Test aerosol.
 - i. The test aerosol shall be of low toxicity in concentration of 15 to 25 mg per cubic meter.
 - ii. The test aerosol shall have a mass median aerodynamic diameter of 0.6 to 0.8 microns in diameter with a geometric standard deviation of less than or equal to 2.

- iii. The equipment generating the challenge atmosphere shall maintain the concentration of the challenge agent within a 20% variation for the duration of the test.
 - iv. The aerosol size and concentration shall be verified at the beginning of the test series and weekly thereafter while testing continues.
 - C. The measuring instrument shall be able to measure the real time penetration and capable of measuring a leakage of 0.002% or less.
 - D. The PAPR shall be equipped with a P100 filter and shall be modified to produce the minimum flow as specified by the manufacturer by restricting the filter or adjusting the voltage to the blower.
 - E. Test subjects shall be selected that are appropriately sized for the equipment being tested, be able to perform at the work levels specified in the exercise section and can readily perform the tests safely approved by a human subject review panel and qualified by a medical examination. The test subjects heart rate shall be monitored throughout the test. Eight test subjects shall be used.
 - F. Test exercises.
 - i. Treadmill.
 - a. Low work level PAPR.
 - 1. The treadmill speed and elevation shall be adjusted to elicit a 40% of maximum heart rate for the test subject. After the heart rate has stabilized for 3 minutes, the test shall begin and continue for 5 minutes.
 - 2. The test subject shall rest for 5 minutes.
 - b. High work level PAPR.
 - 1. The treadmill speed and elevation shall be adjusted to elicit a 80% of maximum heart rate for the test subject. After the heart rate has stabilized for 3 minutes, the test shall begin and continue for 5 minutes.
 - 2. The test subject shall rest for 5 minutes.
 - ii. Nail pounding.
 - a. The test subject will pick up a nail, pound it with a claw hammer into a board located on a vertical wall at eye level, then look back down for the next nail. Repeat this for 5 minutes.
 - b. The test subject will rest for 5 minutes.
 - iii. Grinding/polishing.
 - a. The test subject will move a buffing wheel across a metal surface that is three feet wide and four feet long. The motion used shall be a circular motion of six inch circles while traversing the metal surface from edge to edge, front to back.
 - b. The buffing wheel will not be running during this exercise so as to not generate aerosols.
 - c. The exercise shall continue for 5 minutes.
 - d. The test subject shall rest for 5 minutes.
 - iv. Step up and down.
 - a. The test subject shall step up onto and down from a seven inch high step.
 - b. The pace shall be 12 complete steps per minute in time with a metronome set at 48 beats per minute. The subject steps up with left

- foot on but number 1; right foot up on beat number 2; then town with let and right feel on beats number 3 and 4, respectively.
- c. The exercise shall continue for 5 minutes.
 - d. The test subject shall rest for 5 minutes.
- v. Block move.
- a. The test subject, at his/her own pace, shall stack and move a pile of 27-7.5 x 7.5 x 1.5 inch, 26 ± 3 pound concrete blocks arranged in a pile of three blocks high.
 - b. The blocks will be lifted one at a time to waist height and moved a distance of 3 feet and restacked.
 - c. The exercise shall continue for 5 minutes.
 - d. The test subject shall rest for 5 minutes.
- vi. Shovel gravel.
- a. The test subject, at his/her own pace, shall moved oiled (to reduce aerosol generation) gravel from one bin to the other at a distance of three feet with a short-handled shovel.
 - b. The exercise shall continue for 5 minutes.
 - c. The test subject shall rest for 5 minutes.
- vii. Bolting, unbolting, flange.
- a. The test subject, at his/her own pace, shall bolt and unbolt flanges from a test frame with flanges at heights of 2, 3, 4 and 5 with six one-inch bolts for each flange arranged in a circle and tighten with a torque wrench to 20 foot pounds.
 - b. The exercise shall continue for 5 minutes.
- G. Record leakages only during the exercise. Measure the integrated (average) leakage for each exercise.
- H. The integrated (average) leakage for each exercise shall not exceed the value found in table 2 for the style of respiratory inlet covering tested.

Table 2
Maximum total inward leakage

Respiratory inlet covering type	Maximum percent leakage
Loose fitting facepiece	0.4
Half mask	0.2
Full facepiece	0.01
Hood/Helmet	0.01

8. Low flow measuring device.

- A. A low flow measuring device shall be made available.
- B. The manufacturers shall specify the minimum flow at which the device will perform.
- C. The device shall be accurate to +20, -0% of the specified minimum flow.

9. Low flow warning device (optional).

- A. The use of a low flow warning device is optional.
- B. If the device is present, it shall provide its warning at +20, -0% of the specified minimum flow.

10. Battery Duration.

- A. The manufacturer shall specify a battery duration of 1, 4, or 8 hours.
- B. A fully charged batter with a new filter shall maintain a flow in excess of the specified minimum at the specified battery duration time.
- C. Three batteries shall be tested.