

Concept for Industrial Powered Air-Purifying Respirator (PAPR) Standard

5/30/05

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§84.300 Scope: Powered, Air-purifying Respirators (PAPR) will be approved under this subpart

The purpose of Subpart P is to establish procedures and requirements for issuing approvals and extensions of approval specifically to Powered, Air-purifying Respirators (PAPR). PAPR must meet the applicable requirements of subparts A through G of Part 84 plus this subpart. This subpart replaces Subpart KK and all other applicable requirements for PAPR.

§84.301 Definitions

(a) Powered, Air-Purifying Respirator (PAPR) - an air-purifying respirator that uses a powered mechanism (blower) to pass ambient air through an air-purifying element to a respiratory inlet covering.

(b) Tight-fitting PAPR - a PAPR which contains a respiratory inlet covering that seals tightly to the face or neck. The sealing surface of the respiratory inlet covering may consist of a face mask or a neck seal.

(1) Positive Pressure PAPR- a tight-fitting PAPR which continuously maintains a pressure above ambient air pressure during operation and testing at all times inside the respiratory inlet covering measured in the area of the nose and mouth during operation. A positive pressure PAPR may be approved for low flow, moderate flow, or high flow.

(2) Breath response PAPR- a positive pressure tight-fitting PAPR which continuously monitors the user's air demand rate and adjusts air flow accordingly. A breath response PAPR must be of a positive pressure design.

(c) Loose fitting PAPR- a PAPR which contains a respiratory inlet covering that does not seal tightly to the face or neck. It may consist of a hood, helmet or non-tight sealing facepiece or neck dam.

(1) Hood - a loose-fitting respiratory inlet covering that covers the head and neck and may cover portions of the shoulders

(2) Helmet - a loose-fitting non-flexible respiratory inlet covering that is designed to offer some degree of impact and penetration protection of the head

(3) Loose-fitting facepiece - a loose fitting respiratory inlet covering which makes contact with but does not seal to the face. It does not cover the neck or shoulders

(4) Loose-fitting neck dam - a loose fitting respiratory inlet covering which makes contact with but does not seal to the neck

(d) Respiratory inlet covering - A facepiece, hood, helmet or some combination of these which serves as the covering to the nose and mouth area and ensures that only purified air reach the respiratory system.

(e) End-of-Service-Life-Indicator (ESLI) - An indicator which indicates to the user that the chemical cartridge or canister is exhausted. It may be active or passive. An active ESLI is defined as an indicator which invokes a spontaneous warning signal (e.g., flashing lights, ringing bells, etc.) which is automatic. A passive indicator requires monitoring by the wearer, such as a band which changes color to indicate cartridge or canister exhaustion.

(f) Intrinsically safe - A PAPR which is intrinsically safe as determined by 30 CFR Part 18, Subpart D. §18.82 or by a recognized independent laboratory

§84.302 Description

(a) Powered, air-purifying respirators utilize a powered mechanism to draw ambient air through an air-purifying element(s) to remove contaminants from the ambient air. They are designed for use as respiratory protection against atmospheres with solid and liquid contaminants (e.g., dusts, fumes and/or mists), gases, and/or vapors where the concentrations during entry and use are not immediately

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dangerous to life or health and the atmosphere contains adequate oxygen to support life. They may or may not be further classified as positive pressure.

§84.303 Required components

(a) Powered, air-purifying particulate respirators shall, where its design requires, contain the following component parts:

- (1) Respiratory inlet covering
- (2) Cartridge, canister and/or filter unit(s)
- (3) Harness assembly
- (4) Blower
- (5) Breathing tube
- (6) Battery and/or power cord
- (7) Low flow/pressure indicator
- (8) Low and full battery charge indicator
- (9) Operation switch

§84.304 General construction requirements

In addition to Subpart G:

(a) Each PAPR shall have an indicator to indicate when the battery is fully charged and at low charge. It must be readily detectable to the wearer during use without manipulation of the respirator

(b) Each non-positive pressure PAPR shall have an active indicator which alarms the user, via a readily visible light or other means, when the airflow in the breathing zone drops to the minimum air flow requirement. It must be readily detectable to the wearer during use without manipulation of the respirator

(c) Each positive pressure PAPR shall have an active indicator which alarms the user, via a readily visible light or other means, when the air pressure inside the respiratory inlet covering is not above ambient. It must be readily detectable to the wearer during use without manipulation of the respirator

(d) PAPR units must have readily accessible switches and controls designed to prevent accidental shutoff

(e) Tight fitting PAPR units must be designed to prevent unpurified air from entering the system if the blower function stops

(f) Color coding of cartridges and canisters shall be per the most recent version of ANSI K13.1. where applicable

(g) Where two or more cartridges, canisters or filters are used in parallel, their resistance to air flow shall be within +/- 10% when measured at 85 lpm

§84.305 Breathing tubes; minimum requirements

Flexible breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:

- (a) Restriction of free head movement

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- (b) Disturbance of the fit of the respiratory inlet covering
- (c) Interference with the wearer's activities; and
- (d) Shutoff of airflow due to kinking, or from chin or arm pressure

§84.306 Harnesses; installation and construction; minimum requirements

- (a) Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body
- (b) Harnesses shall be designed and constructed to permit easy removal and replacement of respirator parts, and where applicable, provide for holding a respiratory inlet covering in the ready position when not in use

§84.307 Head harnesses; minimum requirements

- (a) All respiratory inlet coverings shall be equipped with a head harness designed and constructed to hold the unit properly in place, provide adequate tension during use, and provide even distribution of pressure over the entire area in contact with the face
- (b) Respiratory inlet covering head harnesses shall be adjustable and replaceable where necessary

§84.308 Respirator Containers; minimum requirements

- (a) All containers shall be designed and constructed to permit easy donning of the unit
- (b) PAPR shall be equipped with a container bearing markings which show the applicant's name and all appropriate approval labels
- (c) Containers shall prominently list the battery duration(s) and battery part number(s) of the unit

§84.309 Respiratory inlet coverings for PAPRS, fit; minimum requirements

- (a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either:
 - (1) By providing more than one facepiece size; or
 - (2) By providing one facepiece size which will fit varying facial shapes and sizes
- (b) Half-mask facepieces shall not interfere with the fit of common industrial safety and/or corrective spectacles
- (c) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the respirator
- (d) Hoods, helmets, and loose fitting facepieces shall be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer
- (e) Neck seal designs must provide a tight seal around the neck without causing discomfort to the user and permit easy donning and doffing.

§84.310 Respiratory inlet coverings, eyepieces; minimum requirements

- (a) Respiratory inlet coverings shall be designed and constructed to provide adequate vision which is not distorted by the eyepieces
- (b) Lenses, including visors and shields, shall not fog as a result of normal operation
- (c) Lenses must be impact resistant as per ANSI Z87.1- 1986 or latest version or the lense must be prominently and permanently labeled to indicate that it is not impact resistant
- (d) Helmets shall be impact resistant per ANSI Z89.1-1986 or latest version or the helmet shall be prominently and permanently labeled to indicate that it is not impact resistant
- (e) Respiratory inlet coverings with eyepieces shall be designed to prevent eyepiece fogging

§84.311 Inhalation and exhalation valves; minimum requirements

- (a) Inhalation and exhalation valves shall be
 - (1) Protected against damage or distortion
 - (2) Designed, constructed, and provided where necessary to prevent exhaled air from adversely affecting cartridges, canisters, and/or filters
- (c) Exhalation valves shall be:
 - (1) Protected against damage, distortion, and external influence; and
 - (2) Designed and constructed to prevent inward leakage of contaminated air

§84.312 Low Pressure indicator; minimum requirements

- (a) For positive pressure PAPR, a low pressure indicator must actively and readily indicate when pressure inside the respiratory inlet covering falls to ambient pressure
- (b) Low pressure indicators must be readily visible or detectable (via sound or vibration) to the user without manipulation of the respirator

§84.313 Low flow indicators; minimum requirements

- (a) For non-positive pressure PAPR, a low flow indicator must actively and readily indicate if the airflow inside the respiratory inlet covering drops to the minimum specified flow rate in this subpart.
- (b) Low flow indicators must be readily visible or detectable (via sound or vibration) to the user without manipulation of the respirator

§84.314 Full and low battery power indicator, minimum requirements

- (a) Each PAPR equipped with a battery must contain an indicator to show when the battery is fully charged
- (b) Each PAPR equipped with a battery must contain a low battery indicator and must indicate when or before when the battery can no longer provide the unit with 15 minutes of additional adequate power to properly power the unit at the lowest recommended operating temperature and at the highest flow demand with the highest resistance combination of cartridges/canisters/filters
- (c) Low battery indicators must be readily visible or detectable (via sound or vibration) to the user without manipulation of the respirator

§84.315 Airflow, positive pressure PAPR; minimum requirements

- (a) PAPR specified by the applicant as being positive pressure units must maintain a positive pressure above ambient during testing
- (b) Air pressure will be measured in the area of the nose and mouth, inside the respiratory inlet covering of the completely assembled PAPR on a headform
- (c) Airflow will be measured with the most restrictive filter/cartridge/canister combination for which approval is sought
- (d) A breathing machine shall be used with breathing rates as follows:
 - Low flow rating
 - ≥ 14.5 res./min @ 10.5 L/min. vol.
 - Moderate flow rating
 - ≥ 24 res./min. @ 40 L/min
 - High flow rating
 - ≥ 30 res./min. @ 86 L/min + 30 res./min @ 103 L/min for the last 10 minutes of rated operational time (see note)
- (e) Pressure must remain above-ambient at all times during testing
- (f) Static pressure may not exceed 3.5" of water column height for any PAPR

Note: Positive pressure high flow units must remain above ambient when tested at 30 res./min. @ 86 L/min up until the last 10 minutes of the rated operational service time followed by testing at 30 res./min. @ 103 L/min for the last 10 minutes of the rated operational service time followed by 30 res./min. @ 86 L/min for 15 minutes beyond the rated operational service time.

§84.316 Airflow: non-positive pressure PAPRS; minimum requirements

- (a) Airflow will be measured in the area of the nose and mouth, inside the respiratory inlet covering of the completely assembled PAPR on a headform
- (b) Airflow will be measured with the most restrictive filter/cartridge/canister combination for which approval is sought
- (c) Minimum flow rates shall be CONSTANT FLOW
 - Light flow (work) rating
 - Tight fit ≥ 85 lpm
 - Loose fit ≥ 115 lpm
 - Moderate flow rating
 - Tight fit ≥ 115 lpm
 - Loose fit ≥ 170 lpm
 - High flow rating
 - Tight fit ≥ 261 lpm for the last 10 minutes of rated operation time. (See note)
 - Loose fit ≥ 350 lpm for the last 10 minutes of rated operation time (See note)

Note: Constant flow units must meet minimum flow requirements when tested at moderate flow rates up until the last 10 minutes of the rated operational service time followed by testing at high flow rates for the last 10 minutes of the rated operational service time followed by moderate flow rates for 15 minutes beyond the rated operational service time.

§84.317 Noise levels

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Noise levels generated by any PAPR which covers or come in contact with the wearer's ears will be measured inside the respiratory inlet covering, at each ear location, at the maximum airflow obtainable, and shall not exceed 80 dba.

§84.318 Service time limitations: batteries and other components; minimum requirements

(a) Service time recommendations for batteries and any other applicable components must be listed in the user's instructions

(b) Battery service life time increments for which batteries will be approved must be in one hour increments (example - 1- Hour, 2-Hours, 3-Hours, etc.)

(c) Battery service times shall be such that batteries will perform properly and meet testing requirements for the entire stated battery operational service time + 15 minutes at the lowest recommended operating temperature specified by the applicant

§84.319 Powered,air-purifying respirators; shelf life limitations; minimum requirements

(a) Special shelf (storage) life requirements for filters, cartridges, canisters, batteries, and any other applicable components must be addressed in the user's instructions, if applicable

§84.320 PAPR-100 and PAPR-95 particulate filter efficiency level determination

(a) Twenty filters or filter assemblies of each powered air-purifying particulate respirator model shall be tested for filter efficiency against a dioctyl phthalate (DOP) or equivalent liquid particle aerosol deemed to meet the requirements of this section

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

(c) 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

(d) Particulate filters shall be tested at a continuous airflow rate equal to the highest attainable flow rate through the filter of any PAPR system on which that filter will be used. For multiple unit filters, each filter may be tested at the continuous airflow rate equal to the highest flow rate of any PAPR system on which that filter will be used divided by the number of filters

(e) Filter efficiency test aerosols

(1) A neat, cold-nebulized dioctyl phthalate or equivalent aerosol at 25 ± 5 degrees C that has been neutralized to the Boltzmann equilibrium state shall be used. Each PAPR 100 and PAPR 95 filter shall be challenged with a concentration not exceeding 200 mg/m^3

(2) The PAPR 100 test shall continue until minimum efficiency is achieved or until an aerosol mass of $200 \pm 50 \text{ mg}$ has contacted each filter

(3) Each PAPR 95 filter shall be challenged with a concentration not exceeding 200 mg/m^3 to determine initial penetration only

(f) The DOP aerosol shall have a particle size distribution with a 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

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

(h) The minimum filter efficiency for each of the twenty tested filters shall be determined and

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recorded and be equal to or greater than the filter efficiency criterion listed for each level as follows:
PAPR 100, Efficiency $\geq 99.97\%$
PAPR 95, Efficiency $\geq 95\%$

§84.321 Exhalation valve leakage, test; minimum requirements

- (a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm water column height while in a normal operating position
- (b) Leakage between the valve and valve seat shall not exceed 30 milliliters per minute

§84.322 Breathing gas Carbon dioxide (CO₂), machine test; minimum requirements

- (a) The concentration of carbon dioxide in inspired gas in a PAPR will be measured at the mouth of a headform while the respiratory inlet covering is mounted on a headform which is connected to a breathing machine
- (b) This test will be conducted with the PAPR blower operating
- (c) A sedentary breathing machine cam will be used;
- (d) The breathing rate will be 14.5 respirations per minute with a minute volume of 10.5 liters.

Note: If a nose cup is specified as being an optional component by the manufacturer, this test will be conducted with and without it. The nose cup is not to be sealed to the headform

- (e) A concentration of 5% carbon dioxide in air will be exhaled into the respiratory inlet covering through the mouth/nose port of the headform
- (f) The respirator will be tested at a temperature of 25 ± 5 degrees C
- (g) During testing, the concentration of carbon dioxide in the inspired gas at the mouth will be continuously recorded and the maximum average concentration during the inhalation portion of the breathing cycle shall be recorded. The test will be performed until the carbon dioxide concentration stabilizes.
- (h) A minimum of three respiratory inlet coverings, or one of each size, whichever number is greater, will be tested. For example - three of a single size device or one each of a three-size device
- (i) The maximum allowable average carbon dioxide concentration, during the inhalation cycle, shall not exceed 0.5%

§84.323 Breathing gas Oxygen (O₂) and Carbon dioxide (CO₂), human subject test; minimum requirements

- (a) The concentration of carbon dioxide and oxygen in inspired gas in a PAPR will be measured at the mouth of a test subject
- (b) This test will be conducted with the PAPR blower operating.
- (c) Twelve human subjects (equally distributed for each size) shall perform the test at the following work rates:
 - (1) Standing and
 - (2) Walking at 3.5 miles per hour
- (d) Each exercise will be performed for 10 minutes
- (e) Carbon Dioxide and oxygen data will be considered for the last 5 minutes of each exercise
- (f) For each of these last five minutes, a minimum of the last five breaths will be considered
- (g) The calculated maximum range concentration for carbon dioxide during the inhalation

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portion of the breathing cycle shall not exceed 0.02 (or 2.0%)

- (h) The inhaled fractional oxygen concentration shall be no less than 0.195 (or 19.5%)
- (i) The respirator will be tested at a temperature of 25 ± 5 degrees C
- (j) The respirator must meet these criteria for 11 of 12 subjects

§84.324 Battery life test; minimum requirements

- (a) The battery shall be tested in a fully charged state per the manufacturer's instructions
- (b) The PAPR system shall be operated fully assembled on a headform with the most restrictive component configuration (i.e. - most restrictive combination of cartridges, canisters, filters, respiratory inlet covering, etc.)
- (c) For Breath Response PAPR, a breathing machine as described in this part shall be used
- (d) The PAPR system must operate for the stated battery life + 15 minutes at the lowest recommended operating temperature specified by the applicant
- (e) For non-positive PAPR, at no time shall the air flow fall below the minimum air flow rate as stated in this part
- (f) For Positive Pressure PAPR, at no time shall the airflow drop to ambient when connected to a breathing machine

§84.325 Laboratory Respiratory Protection Level (LRPL) Test Requirement

- (a) The LRPL will be determined for each PAPR design and shall be $\geq 10,000$ for $> 95\%$ trials with the blower operating
- (b) Sampling shall be performed in the breathing zone of the respirator
- (c) The test atmosphere shall contain 20–40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 μm
- (d) The test atmosphere shall be maintained at normal operating conditions of $70^{\circ} \pm 5$ F and 50 ± 10 % RH)
- (e) The LRPL shall be calculated using eleven exercises: Normal Breathing, Deep Breathing, Turn Head Side to Side, Move Head Up and Down, Recite the Rainbow Reading Passage or equivalent, Sight a Mock Rifle, Reach for the Floor and Ceiling, On Hands and Knees – Look Side to Side, Facial Grimace, Climb Stairs at a Regular Pace, and Normal Breathing
- (f) Practical performance will also be evaluated in this test. The Practical Performance of the respirator shall evaluate human interface issues associated with the use of the respirator. As a minimum, factors which will be evaluated (if applicable based upon the respirator design) are: the likelihood for the user to accidentally turn the power switch off, the likelihood for hoses and electrical wires to tangle causing the respirator position on the wearer to move to an improper position, and ease of use. Test subjects shall be trained on proper use of the respirator in accordance with the applicant's user instructions.

§84.326 Chemical cartridge/canister bench tests; minimum requirements

- (a) PAPR cartridges and canisters will be tested unconditioned and shall meet the minimum

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requirements set forth in Table 1 of this subpart

(b) Testing of the cartridge or canister shall be performed at the highest flow rate of respirator system on which cartridges or canisters will be used divided by number of cartridges or canisters

(c) Chemical cartridges and canisters for gases and vapors which are not specifically listed may be approved if the applicant submits a request for such approval. NIOSH may accept or reject the request after a review of the effects on the wearer's safety and health and with consideration of field experience and resources.

(1) Concentration calculation shall be determined as the permissible exposure limit (PEL) X the highest Assigned protection factor (APF) of the system on which it will be used X safety factor of 10. Where this is not achievable in the laboratory, time and concentrations may be proportionally adjusted.

(d) Three PAPR cartridges will be tested at 25+- 2.5°C and 25% RH and three PAPR cartridges will be tested at 25+- 2.5°C and 80% RH for each gas and vapor for which approval is sought

TABLE 1-PAPR CARTRIDGE/CANISTER BENCH TESTS AND REQUIREMENTS

Gas/Vapor	Test Concentration ppm	Maximum Break Through ppm
Ammonia	2500	25
Cyanogen Chl.	300	1
Cyclohexane	2600	10
Formaldehyde	500	1
Hyd. Cyanide	940	4.7
Hyd Sulfide	1000	10
Nitrogen Dio	200	1NO2, 25 NO
Phosgene	250	1.25
Phosphine	300	0.3
Sulfur Dio	1500	5
Carbon Mon.	18000	35
Ethylene Oxi.	5000	1
Methyl Amine	5000	10

Canisters meeting Cyclohexane and PAPR100 requirements may be approved for tear gas (Chloroacetophenone and o-Chlorobenzylidene Malonitrile) if desired by the applicant without additional testing.

§84.327 End-of-Service-Life (ESLI) criteria; minimum requirements

Manufacturers seeking approval for PAPR which utilize cartridges or canisters with an ESLI must provide the following:

(a) Data:

(1) Demonstrating that the ESLI is a reliable indicator of sorbent depletion (the ESLI fully indicates cartridge or canister exhaustion at less than or equal to 90% of the exhaustion point)

(2) On adsorption of any impregnating agents used in the indicator

(3) On the effects of industrial interferences which are commonly found in workplaces where it is anticipated that a given respirator will be used

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- (4) On any reaction products produced in the reaction between the sorbent and the contaminant gases and a vapor against which it is designed to protect.
- (5) The shelf (storage) life of the indicator

The data shall include flow-temperature results at minimum and maximum recommended flows and temperatures of the PAPR system, at 25% and 85% RH, and at two contaminant levels.

(b) Passive ESLI additional requirements

In addition to the foregoing, all passive ESLI shall meet the following criteria:

- (1) A passive ESLI shall be situated on the respirator so that it is readily visible by the wearer without manipulation of either the respirator or the indicator
- (2) If the passive ESLI utilizes color change, the change shall be detectable to people with physical impairments such as color blindness (Example- light color to dark color)
- (3) If the passive indicator utilizes color change, reference colors for the initial color of the indicator and the final (end point) color of the indicator shall be placed adjacent to the indicator

(c) General ESLI requirements

All ESLI shall meet the following requirements:

- (1) The ESLI shall not interfere with the effectiveness of the face seal
- (2) The ESLI shall not change the weight distribution of the respirator to the detriment of fit
- (3) The ESLI shall not interfere with required lines of sight
- (4) Any ESLI that is permanently installed shall withstand cleaning and a drop from a 6-foot height
- (5) Replaceable ESLI must be able to be easily removed and replaced
- (6) PAPR with an ESLI shall be labeled appropriately to adequately inform the user of use conditions and of any situations that could cause false positive and negative ESLI responses.
- (7) PAPR with an ESLI shall contain adequate information in the user's instructions to fully explain the operation, use conditions, and of any situations that could cause false positive and negative ESLI responses
- (8) The ESLI shall not create any hazard to the wearer's health or safety

§84.328 Low temperature fogging; minimum requirements

(a) The respiratory inlet covering shall demonstrate and average Visual Acuity Score (VAS) of greater or equal to 75 points for all measurements of acuity with the blower operating. The respirator shall be cold soaked for 4 hours and then worn in an environmental chamber maintained at the minimum operating temperature specified by the applicant.

§84.329 Failure Modes and Effects Analysis (FMEA); minimum requirements

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To be approved, the respirator shall have undergone a FMEA to insure that no component of the blower system or indicators will fail under use. A report with findings shall accompany the application for approval. The FMEA is required to demonstrate that when all manufacturer-specified maintenance, use, and pre-use procedures are followed, there shall be no potential failure modes during normal use.

§84.330 Intrinsic Safety; minimum requirements, optional

To be approved as intrinsically safe, the respirator shall meet the requirements for permissibility and intrinsic safety set forth in 30 CFR Part 18, Subpart D §18.82 or it may be approved by a recognized independent laboratory per standards accepted by NIOSH.

§84.331 Hydration Device (Drink tube); minimum requirements, optional

To be approved, dry drinking tube valves, valve seats, or seals will be subjected to a suction of 75 mm of water column height while in a ready for use position (not in a hose retainer) and with any manual or automatic flow valve in a non-drinking position. Leakage between through the tube shall not exceed 30 mL/min.

§84.332 Labels

- (a) The battery service life and part number must be prominently displayed on the respirator battery pack, and if not readily visible on the battery pack, on another visible location on the unit
- (b) The protections for which approval is being sought shall be clearly and legibly displayed on the cartridge/canister/filter
- (c) Additional cautions and limitations appropriate to PAPR must be added as deemed necessary by NIOSH