Concept: Proposed Industrial Powered, Air-Purifying Respirator (PAPR) Standard

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1. Scope
2. Definitions
3. Descriptions
4. Base Requirements – All PAPR will meet the following base requirements

    4.1 Non-respiratory

        4.1.1 Required components
        4.1.2 General construction
        4.1.3 Breathing tubes
        4.1.4 Body harnesses
        4.1.5 Head harness
        4.1.6 Respiratory inlet coverings
        4.1.7 Eyepieces/lens of respiratory inlet coverings
        4.1.8 Noise levels
        4.1.9 Low flow indicator
        4.1.10 Power indicator
        4.1.11 Battery life
        4.1.12 End of Service Life (ESLI) criteria
        4.1.13 Shelf life limitations
        4.1.14 Labeling requirements
        4.1.15 Failure Mode and Effects Analysis (FMEA)

    4.2 Respiratory

        4.2.1 Inhalation and exhalation valves
        4.2.2 Exhalation valve leakage
        4.2.3 Breathing resistance
        4.2.4 Air flow determination
        4.2.5 Breathing gas: Carbon dioxide (CO_2) machine tests
        4.2.6 Service time limitations
        4.2.7 Chemical cartridge/canister gas/vapor removing effectiveness
        4.2.8 PAPR P95 and PAPR P100 particulate filter efficiency level determination
        4.2.9 Breathing gas: Oxygen (O_2) and Carbon dioxide (CO_2) human subject generated
        4.2.10 Total Inward Leakage (TIL)

5. Application Specific Requirements - Performance requirements beyond base requirements that may be needed when respirators are designed for specific uses.

    5.1 CBRN Responder requirements
    5.2 LCBRN requirements
    5.3 Flammability resistance
    5.4 Hospital PAPR
    5.5 Clean Room PAPR
    5.6 Welding PAPR
    5.7 Multifunction PAPR
    5.8 Police/Special operations
    5.9 Additional requirements to assess new technology
    5.10 Eyepieces/lens of respiratory inlet coverings
    5.11 Air flow determination for maintaining positive pressure
    5.12 Extreme Cold Weather Use
    5.13 Field of view
    5.14 Low temperature fogging
    5.15 Hydration device (drink tube)
    5.16 Intrinsic Safety

1. Scope: Powered, Air-Purifying Respirators (PAPR) will be approved under this standard

1.1 To establish procedures and minimum requirements for issuing approvals and extensions of approval specifically to PAPR. PAPR will meet the applicable requirements of subparts A, B, F, and G of 42 CFR Part 84 plus this subpart.

1.2 Requirements are separated into two areas, Base and Application Specific. Base requirements are standards that all PAPR will meet for approval, Application Specific requirements are for testing specific to an application or hazard and additional testing that may be requesting by the manufacture.

1.3 Base requirements have been divided into two sections, non- respiratory and respiratory.

2. **Definitions**

2.1 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 and which maintains an air pressure above ambient as determined by pressure measurements during air flow testing described herein when measured in the area of the nose and mouth.

2.2 Tight-fitting PAPR - a PAPR which contains a respiratory inlet covering that seals to the face or neck.

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

2.3.1 Hood- a loose-fitting respiratory inlet covering that covers the head and neck and may cover portions of the shoulders.

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

2.3.3 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.

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

2.4 Gas Mask PAPR or Canister PAPR; 14G approval - A tight-fitting PAPR which contains an appropriate canister and may contain a PAPR95 or PAPR100 filter suitable for its intended use

and can be used for escape from atmospheres that may be Immediately Dangerous to Life or Health (IDLH). It may be designed to operate in a silent mode.

2.5 Chemical Cartridge PAPR or Filter PAPR; 23C approval - A tight-fitting PAPR which contains an appropriate cartridge and/or PAPR filter suitable for its intended use and not intended to be used for escape from atmospheres that may be IDLH.

2.6 CBRN Protection - Chemical, Biological, Radiological, and Nuclear. A detailed list of chemicals, including chemical warfare agents, biological agents and radiological agents that have been represented by testing against the 10 Test Representative Agents (TRA), dioctyl phalate (DOP) and Live Agent Testing (LAT).

2.7 LCBRN - Lower level Chemical, Biological, Radiological, and Nuclear. A loose-fitting PAPR that meets the additional minimum requirements defined herein for LCBRN protection.

2.8 Breath response PAPR - a tight-fitting PAPR which continuously monitors the user's air demand rate and adjusts air flow accordingly.

2.9 Respiratory inlet covering- A facepiece, hood, helmet or some combination of these that serves as a respiratory protective covering to the nose and mouth area.

2.10 End-of-Service-Life Indicator (ESLI) - A system which warns the respirator user that the chemical cartridge, canister, or filter has reached the end of its service life. It may be active or passive. An active ESLI is defined as an indicator that invokes a spontaneous warning signal such as a flashing light or an automatic ringing bell. A passive indicator requires monitoring by the wearer, such as a band that changes color to indicate cartridge or canister exhaustion.

2.11 Intrinsically safe - A PAPR that is intrinsically safe as determined by 30 CFR Part 18, Subpart D ' 18.82 or by a recognized independent laboratory.

2.12 Silent mode- A use mode of a tight-fitting PAPR wherein the PAPR is designed to offer respiratory protection when the blower is not operating.

2.13 Flow rating- A PAPR air flow rating of Low, Moderate, or High designated by the manufacturer and determined in *Air Pressure Determination for Maintaining Positive Pressure.*

3. **Descriptions**

3.1 PAPR utilizes a powered mechanism to force ambient air through an air-purifying element(s) to remove contaminants from the ambient air. It is 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 dangerous to

life or health (IDLH). All are considered as positive pressure when tested by air flow testing described herein.

3.2 Gas Mask PAPR is a tight-fitting full facepiece PAPR equipped with appropriate canisters. May also contain PAPR100 filters and be designed to operate in a silent mode as defined herein. They may be used for escape from hazardous atmospheres containing a minimum of 19.5% oxygen to support life.

3.2.1 CBRN PAPR is a tight-fitting full facepiece PAPR meeting the additional requirements for CBRN protection.

3.2.2 LCBRN PAPR is a loose-fitting PAPR meeting lower level CBRN additional requirements described herein.

3.2.3 Half-mask PAPR will not be approved for CBRN protection.

4. **Base Requirements** – All PAPR will meet base requirements. The base requirements are in two sections, respiratory, and non respiratory.

4.1 Non-Respiratory requirements

4.1.1 Required Components. PAPR will, where its design requires, contain the following component parts:

(1) Respiratory inlet covering
(2) Cartridge(s), canister(s) 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 power indicator
(9) Operation switch

4.1.2 General construction. In addition to Subpart G of 42 CFR Part 84:

4.1.2.1 Each PAPR will have an indicator to indicate when the power is full and low. It will be readily detectable to the wearer during use without manipulation of the respirator.

4.1.2.2 Each PAPR will 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 will be readily detectable to the wearer during use without manipulation of the respirator.

4.1.2.3 Each PAPR will have readily accessible switches and controls designed to prevent accidental shutoff.

4.1.2.4 Each tight-fitting PAPR will be designed to prevent unpurified air from entering the system if the blower function stops.

4.1.2.5 Color coding of cartridges and canisters will be per the ANSI Z88.7 -2003 (or most recent version) where applicable.

4.1.2.6 Where two or more cartridges, canisters or filters are used in parallel, their resistance to air flow will be within ± 10% when measured at 85 Lpm.

4.1.2.7 Where two or more cartridges, canisters or filters are used in parallel, the manifold system will be designed for essentially equal air flow through each cartridge, canister or filter.

4.1.2.8 Particulate filters used in conjunction with cartridges or canisters will be located on the inlet side of the cartridge or canister.

4.1.2.9 Filters will be incorporated in or firmly attached to the cartridge or canister and each filter assembly will, were applicable, be designed to permit its easy removal and replacement on the cartridge or canister.

4.1.3 Breathing tubes. Flexible breathing tubes will be designed and constructed to prevent

4.1.3.1 Restriction of free head movement

4.1.3.2 Disturbance of the fit of the respiratory inlet covering

4.1.3.3 Interference with the wearer's activities

4.1.3.4 Shutoff of airflow due to kinking, or from chin or arm pressure.

4.1.4 Body harnesses

4.1.4.1 Each respirator will, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearers' body.

4.1.4.2 Where harnesses are provided for holding the respiratory inlet covering, they will be designed and constructed to hold a respiratory inlet covering in the ready position when not in use.

4.1.5 Head harnesses

4.1.5.1 All respiratory inlet coverings will 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 head or face.

4.1.5.2 Respiratory inlet covering head harnesses will be adjustable and replaceable where necessary.

4.1.6 Respiratory inlet coverings

4.1.6.1 Half-mask facepieces and full facepieces will be designed and constructed to fit persons with various facial shapes and sizes either:

4.1.6.1.1 By providing more than one facepiece size.

4.1.6.1.2 By providing one facepiece size which will fit varying facial shapes and sizes.

4.1.6.2 Half-mask facepieces will not interfere with the fit of common safety and/or corrective eyeglasses.

4.1.6.3 Full facepieces will provide for optional use of eyeglasses or lenses, which will not interfere with the sealing surface or reduce the respiratory protective qualities of the respirator.

4.1.6.4 Hoods, helmets, and loose-fitting facepieces will be designed and constructed to fit persons with various head sizes, allow for the optional use of corrective eyeglasses or lenses, and insure against any restriction of movement or vision by the wearer.

4.1.6.5 Neck seal designs will provide a seal around the neck without causing discomfort to the user and permit easy donning and doffing.

4.1.7 Eyepieces/lens of respiratory inlet coverings

4.1.7.1 Respiratory inlet coverings will be designed and constructed to provide adequate vision.

4.1.7.2 Lenses of respiratory inlet coverings will not distort vision.

4.1.7.3 Lenses, including visors and shields, will not fog as a result of normal operation.

4.1.7.4 Nonflexible lenses will meet the requirements of ANSI Z87.1-2003 (or most current version) or the lenses will be prominently and permanently labeled to indicate that they are not impact resistant.

4.1.8 Noise levels generated by any PAPR will be measured at each ear location, at the maximum average constant airflow specified by the manufacturer, and will not exceed 80 dBA.

4.1.9 Low flow indicator

4.1.9.1 A low flow or pressure indicator will be present. It will actively and readily indicate when pressure inside the respiratory inlet covering falls to ambient pressure during blower operation.

4.1.9.2 Low pressure indicators will be readily visible or detectable (via sound or vibration) to the user without manipulation of the respirator.

4.1.9.3 Low pressure indicators will be configured so that they may not be de-energized when the blower is energized.

4.1.10 Power indicator

4.1.10.1 Power for PAPR can be supplied by local battery or external power supply. PAPR using external power supply that can be used for emergency escape must have a 15 minute battery attached.

4.1.10.2 Each PAPR will contain an indicator to show when the power is full.

4.1.10.3 Each PAPR equipped with a local battery will contain a low battery indicator. This indicator will signal that the battery is full and 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 attainable with the highest resistance combination of cartridges/canisters/filters. A PAPR with emergency battery power only does not require a low battery indicator.

4.1.10.4 Low power indicators will be readily visible or detectable (via sound or vibration) to

the user without manipulation of the respirator.

4.1.10.5 Low power indicators will be configured so that they may not be de-energized when the blower is energized

4.1.11 Battery life

4.1.11.1 The battery will be tested in a fully charged state per the manufacturers' instructions.

4.1.11.2 The PAPR system will be operated fully assembled on a headform with the lowest resistance filtering elements.

4.1.11.3 For Breath Response PAPR, a breathing machine as described in this part will be used.

4.1.11.4 The PAPR system will operate for the stated battery life plus 15 minutes at the lowest recommended operating temperature specified by the applicant.

4.1.11.5 At no time will the pressure, when measured in the nose/mouth, drop below ambient during testing when connected to a breathing machine.

4.1.12 End-of-Service-Life (ESLI) criteria

4.1.12.1 Approval for PAPR which utilize cartridges or canisters with an ESLI will provide the following data:

4.1.12.1.1 Demonstration that the ESLI fully indicates cartridge or canister end of service life at less than or equal to 90% of the service life.

4.1.12.1.2 Adsorption of any impregnating agents used in the indicator.

4.1.12.1.3 Effects of industrial interferences which are commonly found in workplaces where it is anticipated that a given respirator will be used.

4.1.12.1.4 Any reaction products produced in the reaction between the sorbent and the contaminant gases and/or vapors against which it is designed to protect.

4.1.12.1.5 The shelf (storage) life of the indicator.

4.1.12.1.6 The data will include flow-temperature results at minimum and maximum recommended flows and temperatures of the PAPR system, at

25% and 80% RH, and at two contaminant levels.

4.1.12.2 Additional requirements for approval for PAPR which utilize cartridges or canisters with a passive ESLI.

4.1.12.2.1 ESLI will be situated on the respirator so that it is readily visible by the wearer without manipulation of either the respirator or the indicator.

4.1.12.2.2 If the passive ESLI utilizes color change, the change will be detectable to people with physical impairments such as color blindness (Example- light color to dark color).

4.1.12.2.3 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 will be placed adjacent to the indicator.

4.1.12.3 General ESLI requirements

4.1.12.3.1 The ESLI will not interfere with the effectiveness of the face seal.

4.1.12.3.2 The ESLI will not change the weight distribution of the respirator to the detriment of fit.

4.1.12.3.3 The ESLI will not interfere with required lines of sight.

4.1.12.3.4 Any ESLI that is permanently installed will withstand cleaning and a drop from a 2 meter height onto concrete.

4.1.12.3.5 Replaceable ESLI will be designed to be easily removed and replaced.

4.1.12.3.6 PAPR with an ESLI will be labeled appropriately to adequately inform the user of use conditions and of any situations that could cause false positive and negative ESLI responses.

4.1.12.3.7 PAPR with an ESLI will contain adequate information in the User instructions to fully explain the operation, use conditions, and of any situations that could cause false positive and negative ESLI responses.

4.1.12.3.8 The ESLI will not create any hazard to the wearers' health or safety.

4.1.13 Shelf life limitations

4.1.13.1 Special shelf (storage) life requirements for filters, cartridges, canisters, batteries, and any other applicable components will be addressed in the user instructions if applicable.

4.1.14 Labeling requirements – TBD

4.1.15 Failure Mode and Effects Analysis (FMEA)

4.1.15.1 Manufacturers will conduct a system failure modes and effect analysis (FMEA) on each respirator protection system or components that have been developed and submitted for approval. The FMEA is an important tool for the development of a reliable product that conforms to intended standards and consistently performs to its design specifications. The manufacturer has the greatest knowledge and experience of the product to perform a FMEA. At a minimum the FMEA process will include the following: the probability that the occurrence will occur; the potential severity of the occurrence; the ability to detect the occurrence, and specific instructions including cautions, limitations, and restrictions of use to assure product reliability.

4.1.15.2 Manufacturers will provide a (copy) summary of the documented FMEA process results to the approval authority to demonstrate that a prudent systematic engineering process was employed to provide the highest confidence that product meets the standard and has minimal risk of failure when used in accordance with manufacturers' instructions. Annex X contains guidance on the FMEA process.

4.2 Respiratory requirements

4.2.1 Inhalation and exhalation valves

4.2.1.1 Inhalation valves will be provided as necessary and protected against damage, distortion and external influences.

4.2.1.2 Inhalation valves will be designed, constructed, and provided where necessary to prevent exhaled air from adversely affecting cartridges, canisters, and/or filters.

4.2.1.3 Exhalation valves will be protected against damage, distortion, and external influence.

4.2.1.4 Exhalation valves are to be designed and constructed to prevent inward leakage of contaminated air.

4.2.2 Exhalation valve leakage

4.2.2.1 Dry exhalation valves and valve seats will be subjected to a suction of 25 mm water column height while in a normal operating position.

4.2.2.2 Leakage between the valve and valve seat will not exceed 30 milliliters per minute.

4.2.3 Breathing resistance

4.2.3.1 For all PAPR, exhalation breathing resistance will be measured in the nose/mouth area of the respiratory inlet covering with the blower operating.

4.2.3.2 Exhalation breathing resistance may not exceed 25.4 mm (1") water gauge above static at any flow rate with the respirator operating on a headform and the static reference point being between inhalation and exhalation breaths.

4.2.4 Air flow determination, blowers speed are Low, Moderate, and High work rates.

4.2.4.1 Single power blower units. These are blower units that have a single "On/Off" switch and use one maintained blower speed. All single power blower units will be Moderate work rate approvals.

4.2.4.1.1 Tight-fitting PAPR must maintain an average airflow of 115 Lpm during the manufacturer minimum service life time while breathing at a simulated rate of 40 Lpm (1.667 Liters @ 24 Respirations per minute) on headform.

4.2.4.1.2 Loose-fitting PAPR must maintain an average airflow of 170 Lpm during the manufacturer minimum service life time while breathing at a simulated rate of 40 Lpm (1.667 Liters @ 24 Respirations per minute) on headform.

4.2.4.2 Variable power blower units. These are PAPR units with blowers that have multiple settings for blower speed or have a mechanism to adjust the blower speed to respond to a user's variable breathing pattern.

4.2.4.2.1 Units that have specific settings for airflow must be marked as Low and/or Moderate and/or High.

4.2.4.2.2 Tight-fitting PAPR Low flow rating will not be allowed.

4.2.4.2.3 Tight-fitting PAPR Moderate flow rating must maintain an average airflow of 115 Lpm during the manufacturer minimum service life time while breathing at a simulated rate of 40 Lpm (1.667 Liters @ 24

respirations/min) on a headform.

4.2.4.2.4 Tight-fitting PAPR High flow rating must maintain an average of 250 Lpm during the manufacturer minimum service life time while breathing at a simulated rate of 86 Lpm (2.867 Liters @ 30 respirations/min) on headform.

4.2.4.2.5 Breath responsive Tight-fitting PAPR must maintain positive pressure in the facepiece during the manufacturer minimum service life while breathing at either Moderate or Moderate and High rates, depending on desired rating.

4.2.4.2.6 Loose-fitting PAPR Low flow rating must maintain an average of 100 Lpm during the manufacturer minimum service life time while breathing at a simulated rate of 21 Lpm (1.2 Liters @ 17.5 respirations/min) on a headform.

4.2.4.2.7 Loose-fitting PAPR Moderate flow rating must maintain an average of 170 Lpm during the manufacturer minimum service life time while breathing at a simulated rate of 40 Lpm (1.667 Liters @ 24 respirations/min) on a headform.

4.2.4.2.8 Loose-fitting PAPR High flow rating must maintain an average of 370 Lpm during the manufacturer minimum service life time while breathing at a simulated rate of 86 Lpm (2.867 Liters @ 30 respirations/min) on a headform.

4.2.4.2.9 Breath response Loose-fitting PAPR must maintain positive pressure in both the face area and the hood area around the neck during the manufacturer's minimum service life time while breathing at each of the rates desired while on a headform.

4.2.5 Breathing gas: Carbon dioxide (CO_2) machine tests

4.2.5.1 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 connected to a breathing machine.

4.2.5.2 This test will be conducted with the PAPR blower operating at the minimum air flow rate specified by the manufacturer and, for silent mode PAPR, with the blower not operating.

4.2.5.3 A sedentary breathing machine cam will be used with the breathing rate at 14.5 respirations per minute generating 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.

4.2.5.4 A concentration of 5% carbon dioxide in air will be exhaled into the respiratory inlet covering through the mouth/nose port of the headform.

4.2.5.5 The respirator will be tested at a temperature of 25 ± 5°C.

4.2.5.6 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 will be recorded. The test will be performed until the carbon dioxide concentration stabilizes.

4.2.5.7 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.

4.2.5.8 The maximum allowable average carbon dioxide concentration, during the inhalation cycle, will not exceed 1.0 %.

4.2.6 Service time limitations

4.2.6.1 Service time recommendations for batteries and any other applicable components will be listed in the user instructions.

4.2.6.2 Battery service life time increments for which batteries will be approved will be in one hour increments (example - 2-hours, 3-hours, 4-hours, etc.) with a minimum rating of two hours.

4.2.6.3 Battery service times will be such that batteries will perform properly and meet testing requirements for the entire stated battery operational service time at the lowest recommended operating temperature specified by the applicant and with the highest resistance combination of cartridges, canisters and/or filters.

4.2.7 Chemical cartridge/canister gas/vapor removing effectiveness

4.2.7.1 PAPR cartridges and canisters will be tested as received and will meet the minimum requirements set forth in Tables 1 and 2 of this subpart using the maximum average constant flow rate specified by the manufacturer.

4.2.7.2 Three PAPR cartridges or canisters will be tested at 25 ± 2.5°C and 25 ± 5% RH, and three PAPR cartridges or canisters will be tested at 25 ± 2.5°C and 80 ± 5% RH for each gas and vapor for which approval is sought.

4.2.7.3 Airflow required for testing is given in table 1.1 depending on the type of respirator and the work rating of the respirator. For PAPR with two or more canisters, canisters will be tests will be performed at the required flow divided by the number of canisters.

Type respirator	Constant Flow: Low Work Rate	Constant Flow: Moderate Work Rate	Constant Flow: High	Breath response Low / Moderate / High Work Rate
Tight-fitting	Not Applicable	115 Lpm	270 Lpm	Average Flow at Highest Work Rate Requested
Loose-fitting	100 Lpm	170 Lpm	325 Lpm	Average Flow at Highest Work Rate Requested

TABLE 1-PAPR CARTRIDGE GAS/VAPOR BENCH TESTS AND REQUIREMENTS

Gas/vapor	Test Concentration (ppm)	Maximum Break Through (ppm)	Minimum allowable service life(min)
Ammonia	1000	12.5	50
Chlorine	500	5	35
Chlorine Dioxide	500	0.1	30
Cyclohexane	1000	5	50
Formaldehyde	100	1	50
Hydrogen Chloride	500	5	50
Hydrogen Fluoride	70	3	30
Hydrogen Sulfide	1000	10	30
Methylamine	1000	10	25
Sulfur dioxide	500	5	30

TABLE 2-PAPR CANISTER GAS/VAPOR BENCH TESTS AND REQUIREMENTS

Gas/vapor	Test Concentration (ppm)	Maximum Break Through (ppm)	Minimum allowable service life(min)
Ammonia	2500	12.5	24
Chlorine	2500	5	24
Chlorine Dioxide	1000	0.1	60
Cyanogen Chloride	300	2	60
Cyclohexane	2600	10	60
Ethylene Oxide	5000	1	60
Formaldehyde	500	1	60
Hydrogen Cyanide	940	4.7	60
Hydrogen Sulfide	5000	5	60
Methylamine	1000	10	12
Nitrogen dioxide	200	1 NO_2 or 25 NO	60

Phosgene	250	1.25	60
Phosphine	300	0.3	60
Sulfur dioxide	1500	5	60

Note: Canisters and cartridges meeting cyclohexane and PAPR P100 requirements may be approved for tear gases chloroacetophenone and o-chlorobenzylidene malonitrile if desired by the applicant without additional testing when used on full facepiece tight-fitting respirators.

4.2.7.4 Carbon monoxide testing – TBD

4.2.7.5 Chemical cartridges and canisters may listed as effective against additional gases and vapors that are not specifically listed in Table 1 or 2 , as determined by NIOSH, where

4.2.7.5.1 The cartridges or canister have been approved for gases or vapors in the same class or family as those listed in Table 1 or 2.

4.2.7.5.2 The cartridge or canister has been demonstrated to be effective against removing these additional gases or vapors.

4.2.7.6 Manufacturers may further request approval of chemical cartridges and canisters for gases or vapors that are not listed in Table 1 or 2 and, as determined by NIOSH, are not effective at removing the gas or vapor in the same class or family as those listed in Table 1 or 2.

4.2.7.7 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.

4.2.7.8 Cartridge test concentration calculations will be determined using the following priority list:

4.2.7.8.1 Established IDLH (if a respiratory hazard) times 1.5

4.2.7.8.2 The NIOSH recommended exposure limit (REL) multiplied by the highest assigned protection factor (APF) of the system on which it will be used multiplied by a safety factor of 5

4.2.7.8.3 If a REL does not exist, other exposure limit will be used as selected by NIOSH.

4.2.7.8.4 Where these values are not achievable or cannot be done safely in the laboratory, time and concentrations may be proportionally adjusted.

4.2.7.8.5 Test time for cartridges for which approval is sought under this paragraph (d) will generally be set at 50 minutes. Where this is not achievable or can not be done safely in the laboratory, time and concentrations may be proportionally adjusted.

4.2.7.9 Canister test concentration calculations will be determined using the following priority list:

4.2.7.9.1 Established IDLH (if a respiratory hazard value) times 1.5

4.2.7.9.2 The NIOSH recommended exposure limit (REL) multiplied by the highest assigned protection factor (APF) of the system on which it will be used multiplied by a safety factor of 5

4.2.7.9.3 If a REL does not exist, another exposure limit will be used as selected by NIOSH.

4.2.7.9.4 Where these values are not achievable or cannot be done safely in the laboratory, time and concentrations may be proportionally adjusted.

4.2.7.9.5 Test time for canisters for which approval is sought under this paragraph (d) will generally be set at 60 minutes. Where this is not achievable or can not be done safely in the laboratory, time and concentrations may be proportionally adjusted.

4.2.7.9.6 Allowable breakthrough concentrations for all testing for which approval is sought will based on the NIOSH REL (recommended exposure limit) or OSHA PEL (permissible exposure limit) in effect at the time of testing, whichever is lower. Where this is not achievable or can not be readily detected in the laboratory the concentrations may be proportionally adjusted.

4.2.7.10 Three PAPR cartridges or canisters will be tested at 25 ± 2.5^{o}C and 25 ± 5% RH, and three PAPR cartridges or canisters will be tested at 25 ± 2.5^{o}C and 80 ± 5% RH for each gas and vapor for which approval is sought.

4.2.7.11 Testing airflow used will be established using table 1.1. Individual canisters can be tested at the listed airflow divided by the number of canisters per system.

4.2.8 PAPR P95 and PAPR P100 particulate filter efficiency level determination

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

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

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

4.2.8.4 For non-separable filters, the respirator will be mounted on a test fixture that is designed to simulate the manner in which the respirator is used and will expose all parts of the respirator to the test aerosol that would be exposed during use.

4.2.8.5 Particulate filters will be tested at the maximum average constant flow rate specified by the manufacturer

4.2.8.6 Filter efficiency test aerosols will be as follows:

4.2.8.6.1 A neat, cold-nebulized dioctyl phthalate (DOP) or equivalent aerosol at $25 \pm 5\ ^{o}C$ that has been neutralized to the Boltzmann equilibrium state will be used. Each PAPR100 and PAPR95 filter will be challenged with a concentration not exceeding 200 mg/m^3.

4.2.8.6.2 The PAPR100 test will continue until minimum efficiency is achieved or until an aerosol mass of 1000 ± 50 mg has contacted each filter.

4.2.8.6.3 Each PAPR95 filter will be challenged with a concentration not exceeding 200 mg/m^3 to determine initial penetration only.

4.2.8.6.4 The DOP aerosol will 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.

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

4.2.8.6.6 The minimum filter efficiency for each of the twenty tested filters will be determined and recorded and be equal to or greater than the filter

efficiency criterion listed for each level as follows:

PAPR P100, Efficiency >= 99.97%
PAPR P95, Efficiency >= 95%

4.2.9 Breathing gas: Oxygen (O_2) and Carbon dioxide (CO_2) human subject generated

4.2.9.1 The concentration of carbon dioxide and oxygen in inspired air in a PAPR will be measured at the nose/mouth area of a test subject.

4.2.9.2 This test will be conducted with the PAPR blower operating and, for silent mode PAPR, with the blower not operating.

4.2.9.3 Twelve human subjects (equally distributed for each respiratory inlet covering size) will perform the test at the following work rates:

4.2.9.3.1 Standing

4.2.9.3.2 Walking at 3.5 miles per hour

4.2.9.3.3 Each exercise will be performed for 10 minutes

4.2.9.4 Carbon Dioxide and oxygen data will be considered for the last 5 minutes of each exercise.

4.2.9.5 For each of these last 5 minutes, a minimum of the last 5 breaths will be considered.

4.2.9.6 The calculated maximum range concentration for carbon dioxide during the inhalation portion of the breathing cycle will not exceed 0.02 (or 2.0%).

4.2.9.7 The inhaled fractional oxygen concentration will be no less than 0.195 (or 19.5%).

4.2.9.8 The respirator will be tested at a temperature of 25 ± 5 ^{o}C.

4.2.9.9 The respirator will meet these criteria for 11 of 12 subjects.

4.2.10 Total Inward Leakage (TIL)

4.2.10.1 The measured Total Inward Leakage (TIL) will be determined for each PAPR design equipped with the heaviest available cartridges, canisters, and accessories. TIL values are listed in Table 5.

Type of PAPR	TIL Minimum value
Half-mask	100
Loose-fitting Facepiece	250
Tight-fitting Facepiece	10,000

Table 5: TIL Values

4.2.10.2 Sampling will be performed in the breathing zone of the respirator.

4.2.10.3 The test atmosphere will contain 20 - 40 mg/m^3corn oil aerosol of a mass median aerodynamic diameter of 0.4 - 0.6 μm.

4.2.10.4 The test atmosphere will be maintained at normal operating conditions of $70^o \pm 5^o$ F and 50 % ± 10 % RH.

4.2.10.5 The LRPL will 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, 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.

4.2.10.6 Practical performance will also be evaluated in this test. The practical performance of the respirator will evaluate human interface issues associated with the use of the respirator. At 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 breathing tubes and electrical wires to tangle causing the respirator position on the wearer to move to an improper position, continued clear and unobstructed visibility with turning of the head or looking up or down, and ease of use. Test subjects will be trained on proper use of the respirator in accordance with the applicant's user instructions.

5. Application-specific Requirements - Performance requirements beyond base requirements that may be needed when respirators are designed for specific uses.

5.1 CBRN Responder requirements. Respirators used for responding to CBRN events must have the following requirements:

5.1.1 CBRN Responder PAPR will meet the following conditioning requirements prior to testing. The PAPR must meet all testing requirements after conditioning. All components must perform as intended following conditioning. Rechargeable batteries may be recharged prior to testing.

Test	Test Method	Test Conditions	Duration
Hot Diurnal	Mil-Std-810F 501.4	35°C to 71°C, 24 Hour cycle	3 Weeks Diurnal Cycle
Cold Constant	Mil-Std-810F 502.4	Basic Cold, -32°C, Constant	3 Days
Humidity	Mil-Std-810E 507.3	Realistic, Natural Cycle Humidity Profiles in the U.S. (range 88°F @ 88%RH to 5°F @ 59%RH, 24 hr period)	5 Days "quick look" Mil-Std-810E Table 507.3-II
Transportation Vibration	Mil-Std-810F 514.5	U. S. Roadway Vibration, Unrestrained	12 hours/axis, 3 Axes Total duration = 36 hours = 12,000 miles
Drop	3 foot drop onto bare concrete surface	Canister only; In individual canister packaging container	1 drop/filter on one of the 3 axes.

5.1.2 Tight-fitting full facepiece respirator with impact resistant and scratch resistant lenses that meet the requirements of ANSI Z87.1- 2003.

5.1.3 Field of view, described in paragraph 5.13.

5.1.4 Chemical Agent Permeation and Penetration Resistance against Distilled Sulfur Mustard (HD) and Sarin (GB) Agent Requirement

5.1.4.1 The PAPR, while the blower is running, and including all components and accessories, will resist the permeation and penetration of distilled sulfur mustard (HD) and Sarin (GB) chemical agents when tested on an upper-torso manikin connected to a breathing machine operating at an airflow rate of 40 L/min, 36 respirations per minute, 1.1 liters tidal volume. Test requirements for distilled sulfur mustard (HD) are shown in Table 4. Test requirements for Sarin (GB) agent are shown in Table 5.

Table 4.—Vapor-liquid sequential challenge with distilled sulfur mustard (HD)

Agent	Challenge Concentration	Duration Of Challenge (min)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough (concentration integrated over minimum test time) ($mg\text{-}min/m^3$)	Number Of Systems Tested	Minimum Test Time (hours)
HD-Vapor	50 mg/m^{3*}	30	40	0.30[‡]	3.0[§]	3	8[††]
HD-Liquid	0.43 to 0.86 ml[*,†,**]	120	40	0.30[‡]	3.0[‡]	3	2

[*] Vapor challenge concentration will start immediately after the test chamber has been sealed. Minimum test time for liquid exposure starts after the first liquid drop is applied.
[†] Liquid Volume dependent on accessories used with the respirator. Minimum volume is 0.43 ml based on the respirator only.
[‡] Three consecutive sequential test data points at or exceeding 0.3 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately two (2) minutes.
[§] The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.
[**] Liquid agent is applied to respirator at hour six (6) of the vapor test cycle.
[††] The test period begins upon initial generation of vapor concentration and ends at eight (8) hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.

Table 5.—Vapor challenge with Sarin (GB)

Challenge Concentration	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Maximum Peak Excursion mg/m^3	Maximum Breakthrough (concentration integrated over minimum test time) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Test Time (hours)
GB	210[*)]	30	0.044[‡]	1.05[§]	3	8[†]

[*] The vapor challenge concentration generation will be initiated immediately after test chamber has been sealed.
[@] For Pressure Demand systems, the airflow rate will be increased to 60L/min at minutes 15 – 30 of each hour of the

test.
† The test period begins upon initial generation of vapor concentration and ends at 8 hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.
‡ Three consecutive sequential test data points at or exceeding 0.044 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.
§ The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.

5.1.5 Low temperature fogging, testing described in paragraph 5.14.

5.1.6 Canister Test Challenge and Test Breakthrough Concentrations

5.1.6.1 The gas/vapor test challenges and breakthrough concentrations shown in Table 1: Canister Challenge, Breakthrough Concentrations, and Canister Efficiency will be used to establish the canister service life.

Table 1.—Canister test challenge and test breakthrough concentrations

	Test Concentration (ppm)	Breakthrough Concentration (ppm)
Ammonia	2500	12.5
Cyanogen chloride	300	2
Cyclohexane	2600	10
Formaldehyde	500	1
Hydrogen cyanide	940	4.7*
Hydrogen sulfide	1000	5.0
Nitrogen Dioxide	200	1 ppm NO_2 or 25 ppm NO†
Phosgene	250	1.25
Phosphine	300	0.3
Sulfur dioxide	1500	5

* Sum of HCN and C_2N_2.
† Nitrogen Dioxide breakthrough is monitored for both NO_2 and NO. The breakthrough is determined by which quantity, NO_2 or NO, reaches breakthrough first.

5.1.6.2 Canister Capacity. The applicant will specify the canister capacity as indicated in Table 2. Canister capacity tests will be performed at room temperature, 25 ºC ± 2.5 °C; 25% ± 2.5% relative humidity; and 80% ± 2.5% relative humidity. Three canisters will be tested at each humidity specified.

Table 2.—Canister capacity

Filter Capacity	Test Time (min)	Filter Capacity (ppm-min)
Capacity # 1	15	Test Concentration X 15
Capacity # 2	30	Test Concentration X 30
Capacity # 3	45	Test Concentration X 45
Capacity # 4	60	Test Concentration X 60
Capacity # 5	90	Test Concentration X 90
Capacity # 6	120	Test Concentration X 120

5.2 LCBRN Receiver requirements. Respirators used for lower level CBRN event:

5.2.1 Lenses will meet the requirements of ANSI Z87.1- 2003 (or latest version) or the lenses will be prominently and permanently labeled to indicate that they are not impact resistant.

5.2.2 All respirators must obtain of TIL value of >= 10,000 for > 95% trials with the blower operating.

5.2.3 **Chemical Agent Permeation and Penetration Resistance against Distilled Sulfur Mustard (HD) and Sarin (GB) Agent Requirement**

5.2.3.1 The PAPR, while the blower is running, and including all components and accessories, will resist the permeation and penetration of distilled sulfur mustard (HD) and Sarin (GB) chemical agents when tested on an upper-torso manikin connected to a breathing machine operating at an airflow rate of 40 L/min, 36 respirations per minute, 1.1 liters tidal volume. Test requirements for distilled sulfur mustard (HD) and Sarin (GB) are shown in Table 4.

Table 4.—Vapor challenge with chemical warfare agent

Agent	Challenge Concentration	Duration Of Challenge (min)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough (concentration integrated over minimum test time) ($mg\text{-}min/m^3$)	Number Of Systems Tested	Minimum Test Time (hours)
Sarin	210 mg/m^{3*}	30	0.044‡	1.05§	3	8††
Distilled Mustard	50 mg/m^{3*}	30	0.30‡	3.0§	3	8††

*Vapor challenge concentration will start immediately after the test chamber has been sealed.
*Minimum test time for liquid exposure starts after the first liquid drop is applied.
‡Three consecutive sequential test data points at or exceeding 0.3 mg/m3 will collectively constitute a failure where each test value is based on a detector sample time of approximately two (2) minutes.
§The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.
††The test period begins upon initial generation of vapor concentration and ends at eight (8) hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.

5.2.4 Cartridge Test Challenge and Test Breakthrough Concentrations

5.2.4.1 The gas/vapor test challenges and breakthrough concentrations shown in Table 1: Cartridge Challenge, Breakthrough Concentrations, and Canister Efficiency will be used to establish the canister service life.

Table 1.—Canister test challenge and test breakthrough concentrations

	Test Concentration (ppm)	Breakthrough Concentration (ppm)
Ammonia	1250	12.5
Cyanogen chloride	150	2
Cyclohexane	1300	10
Formaldehyde	250	1
Hydrogen cyanide	470	4.7*
Hydrogen sulfide	500	5.0
Nitrogen Dioxide	100	1 ppm NO_2 or 25 ppm NO†
Phosgene	125	1.25
Phosphine	150	0.3
Sulfur dioxide	750	5

* Sum of HCN and C_2N_2.
† Nitrogen Dioxide breakthrough is monitored for both NO_2 and NO. The breakthrough is determined by which quantity, NO_2 or NO, reaches breakthrough first.

5.2.5 Cartridge capacity. Minimum cartridge capacity is 15 minutes. Cartridge capacity tests will be performed at room temperature, 25 ºC ± 2.5 °C; 25% ± 2.5% relative humidity; and 80% ± 2.5% relative humidity. Three canisters will be tested at each humidity specified.

5.3 Flammability and Heat Resistance

5.3.1 Respirators submitted for approval for flammability and heat resistance using the test

equipment specified in EN 136, Respiratory Protective Devices, Full Face Masks, Requirements, Testing, Marking, 1998 Edition, Class 1 facepiece. No component of the respirator will have an after flame after 5 seconds. No component of the escape respirator will drip, melt, or develop a visible hole.

5.3.2 The distance between the outer surface of the respirator component and the burner will be adjusted to 20 ± 2 mm. The pressure reducer will be adjusted to 2.1 ± .05 psi. The temperature of the flame positioned above the burner tip will be 800 ± 50° C at a point 20 ± 2 mm above the tip. The respirator will be rotated once through the flame at a velocity of 6 ± 0.5 cm/s. Each components of the respirator such as valves, filters, hoses, batteries, etc. on the respirator will be tested

5.4 Hospital PAPR – TBD

5.5 Clean Room – TBD

5.6 Welding – TBD

5.7 Multifunction – TBD

5.8 Police/Special operations

5.8.1 Tight-fitting full facepiece PAPR may optionally meet and be granted approval for use in silent (non-powered) as well as normal (powered) mode.

5.8.2 For approval in a silent mode, initial resistance to airflow will additionally be measured inside the respiratory inlet covering of a completely assembled PAPR with the blower not operating and with the highest resistance cartridges, canisters, and/or filters.

5.8.3 For approval in a silent mode, the maximum allowable resistance requirements with the blower not operating, mounted on a test fixture, and air flowing at a continuous rate of 85 liters per minute, are as follows:

Type of Protection	Initial Inhalation Resistance	Initial Exhalation Resistance
Particulate Only	35 mm H_20	20 mm H_20
Gas/Vapor cartridge Only	40 mm H_20	20 mm H_20
Gas/vapor cartridge/ particulate	50 mm H_20	20 mm H_20
Gas/vapor canister Only	40 mm H_20	20 mm H_20
Gas/vapor canister/ particulate	65 mm H_20	20 mm H_20

5.9 Requirements for assessing new technology

5.10 Eyepieces / Lens of respiratory inlet covering – TBD

5.11 Air flow determination for maintaining positive pressure

5.11.1 Positive pressure PAPR will maintain a pressure above ambient inside the facepiece during operation.

5.11.2 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.

5.11.3 Units will meet the minimum requirements with the most restrictive (highest resistance) filter/cartridge/canister combination for which approval is sought at the Low, Moderate, and/or High Flow Rating(s) as for which approval is sought.

5.11.4 A breathing machine will be used with breathing rates as follows:

5.11.4.1 Low flow rating – 21 Lpm minute volume: 0.724 Liters @ 14.5 respirations/min.

5.11.4.2 Moderate flow rating - 40 Lpm minute volume: 1.667 Liters @ 24 respirations/min.

5.11.4.3 High flow rating - 86 Lpm minute volume: 2.867 Liters @ 30 respirations/min. Units will remain above ambient when tested at 30 res./min. @ 86 L/min up until the last 5 minutes of the rated operational service time. During the last 5 minutes of rated operational service time, the unit will be tested at 37 res./min. @ 103 L/min for. Then, the unit will continue to perform at 30 res./min. @ 86 L/min for 15 minutes beyond the rated operational service time.

5.11.5 Pressure will remain above ambient at all times during testing. Static pressure relative to external pressure may not exceed 2" of water column height for any PAPR during testing.

5.12 Extreme Cold Weather Use – TBD

5.13 Field of View

5.13.1 Respiratory inlet coverings will obtain an average Visual Field Score (VFS) of 90 or greater following the VFS method described by the American Medical Association (AMA). Where multiple sizes are offered, the determination will be made using a head

form that is best sized to the respiratory inlet covering.

5.14 Low Temperature Fogging

5.14.1 The respiratory inlet covering will demonstrate an average Visual Acuity Score (VAS) of greater or equal to 75 points following the VFS method described by the American Medical Association for all measurements of acuity with the blower operating, and for silent mode PAPR, with the blower not operating. The respirator will be cold soaked for 4 hours and then worn in an environmental chamber maintained at the minimum operating temperature specified by the applicant.

5.15 Hydration Device – TBD

5.16 Intrinsic Safety - TBD