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January 3, 2008

LETTER TO ALL INTERESTED PARTIES

SUBJECT: Powered Air-Purifying Respirator (PAPR) Concept Paper

The National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory (NPPTL) is soliciting comments on a concept paper for PAPR performance requirements. The concept paper is provided as an attachment to this letter. Comments on this concept paper will be accepted through March 28, 2008. Reference Docket Number 008 for all submissions related to this topic. Interested persons or organizations are invited to participate in this process by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this concept paper.

Comments submitted by e-mail or mail should be addressed to the "NIOSH Docket Officer" and should identify the author(s), return address, and a phone number, in case clarification is needed. Comments can be submitted by e-mail to: niocindocket@cdc.gov. If submitting comments by e-mail, they may be provided as e-mail text or as a Word file attachment. Printed comments can be sent to the NIOSH Docket Office at: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, PAPR – Docket # 008, 4676 Columbia Parkway, Cincinnati, OH 45226.

All communications received on or before the closing date for comments will be fully considered. All comments submitted will be available for examination in the rule docket (a publicly available repository of the associated documents) both before and after the closing date for comments. NIOSH includes all comments received without change in the docket, including any personal information provided.

Sincerely yours,

Jonathan V. Szalajda
Chief, Policy and Standards Development Branch
National Personal Protective Technology Laboratory

Proposed Concept:
Powered Air-Purifying Respirator
(PAPR) Standard
Subpart P

December 21, 2007

1. Scope
2. Definitions
3. Descriptions
4. Base Requirements – All PAPR shall 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 pressure indicator
4.1.10 Power
4.1.11 Battery life
4.1.12 End of Service Life (ESLI) criteria
4.1.13 Shelf life limitations
4.1.14 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 removal effectiveness
4.2.8 PAPR P95 and PAPR P100 particulate filter efficiency level determination
4.2.9 Breathing gas concentrations determination: Oxygen (O_2) and Carbon dioxide (CO_2) human subject generated
4.2.10 Laboratory Respirator Protection Level (LRPL)

5. Enhanced Chemical, Biological, Radiological, Nuclear (CBRN) Requirements - Performance requirements beyond base requirements that may be desired by applicant for approval

    5.1 CBRN requirements
    5.2 Lower Level Chemical, Biological, Radiological, Nuclear (LCBRN) requirements

6. Additional Enhanced Requirements

    6.1 Flammability and Heat Resistance
    6.2 Silent Operation
    6.3 Operational Temperature Range
    6.4 Hydration device (drink tube)
    6.5 Intrinsic Safety

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

1.1 To establish procedures and minimum requirements for issuing approvals and extensions of approval specifically for PAPR. PAPR shall 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 Enhanced. Base requirements are standards that all PAPR shall meet for approval; Enhanced requirements are for unique hazards and performance characteristics beyond Base PAPR use.

1.3 Base requirements are described in two sections: respiratory and non-respiratory.

2. Definitions

2.1 Powered Air Purifying Respirator (PAPR) - a device equipped with a facepiece, hood or helmet, breathing tube, canister, cartridge, filter, canister with filter or cartridge with filter and a powered blower.

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

2.3 Loose-fitting PAPR - a 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 or loose fitting facepiece.

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 impact and penetration protection of the head as described herein.

2.3.3 Loose-fitting facepiece - a respiratory inlet covering which makes contact with but does not seal to the face. It may not cover the neck, the back of the head or shoulders.

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

2.4 Canister PAPR (Gas Mask PAPR) - A tight-fitting full facepiece PAPR which contains an appropriate canister and may contain a PAPR100 filter suitable for its intended use and can be used for escape from non-oxygen-deficient hazardous atmospheres. Additionally, a unit may be of intrinsically safe design. It may be designed to operate in a silent mode.

2.5 Chemical cartridge PAPR - A PAPR which contains an appropriate cartridge and/or filter suitable for its intended use and not intended to be used for escape from atmospheres that may be Immediately Dangerous to Life or Health Concentrations (IDLH).

2.6 CBRN Protection -. A PAPR that provides protection from 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 – defined in Table 9.), dioctyl phthalate (DOP) and Live Agent Testing (LAT).

2.7 LCBRN -.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 electronically adjusts air flow by changing the blower speed 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 ESLI - A system that warns the respirator user that the chemical cartridge, canister, or filter is approaching 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 audible alarm. A passive indicator requires monitoring by the wearer, such as a band that changes color to indicate a cartridge or canister is approaching 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 which is designed to offer protection in a negative pressure operational mode with the blower intentionally turned off.

2.13 Work rating- A PAPR air flow rating. The three ratings are Low, Moderate or High, as designated by the manufacturer.

3. Descriptions

3.1 PAPR utilizes a powered mechanism to move 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 particulates (solid and/or liquid contaminants), gases and/or vapors or combination of gases, vapors and/or particulates where the concentrations during entry and use are not 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. It may be used for escape from IDLH atmospheres.

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

3.3 LCBRN PAPR is a loose-fitting PAPR meeting the additional minimum requirements for lower level CBRN as described herein. It is not acceptable for escape from IDLH atmospheres.

3.4 No Half-mask PAPR shall be approved for CBRN protection.

4. **Base Requirements** – All PAPRs shall meet base requirements. The base requirements are described in two sections, respiratory and non-respiratory.

4.1 Non-Respiratory requirements

4.1.1 Required Components. A PAPR shall, 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 pressure indicator
(8) 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 shall have a monitor to indicate the condition of the power source. It shall be readily detectable to the wearer during use without manipulation of the respirator and not affect protection and performance.

4.1.2.2 Each PAPR shall have an active indicator which alerts the user to low pressure in the breathing zone. It shall be readily detectable to the wearer during use without manipulation of the respirator and not affect protection and performance.

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

4.1.2.4 Each tight-fitting PAPR shall 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 shall be as per the ANSI Z88.7-2003 standard where applicable.

4.1.2.6 Where two or more cartridges, canisters or filters are used in parallel, their resistance to air flow shall be essentially equal when measured at 85 Lpm.

4.1.2.7 Where two or more cartridges, canisters or filters are used in parallel, the manifold system shall 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 shall be located on the inlet side of the cartridge or canister.

4.1.3 Breathing tubes. Flexible breathing tubes shall 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 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.

4.1.5 Head harnesses

4.1.5.1 Respiratory inlet covering head harnesses shall be adjustable and replaceable where necessary.

4.1.6 Respiratory inlet coverings

4.1.6.1 Half-mask facepieces and full facepieces shall 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 shall fit varying facial shapes and sizes

4.1.6.2 Common safety and/or corrective eyewear shall not interfere with the fit of half-mask facepieces.

4.1.6.3 Full facepieces shall provide for optional use of corrective eyewear, which shall not interfere with the sealing surface, pass between the sealing surfaces or reduce the respiratory protective qualities of the respirator.

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

4.1.6.5 Helmets designed for head protection shall meet the requirements of ANSI Z89.1-2003 Type I or Type II protective cap standards. Helmets not designed to provide head protection shall be prominently and permanently labeled to indicate that they are not impact and penetration resistant.

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

4.1.7 Eyepieces/lenses of respiratory inlet coverings

4.1.7.1 Respiratory inlet coverings shall be designed and constructed to provide adequate field of view.

4.1.7.1.1 Respiratory inlet coverings shall 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 shall be made using a head form that is best sized to the respiratory inlet covering.

4.1.7.2 Lenses of respiratory inlet coverings shall meet optical requirements of ANSI Z87.1-2003.

4.1.7.3 Lenses, including visors and shields, shall not fog as a result of low temperature operation as detailed in the Standard Test Procedure.

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

4.1.7.4 Lenses shall meet the requirements of the impact and penetration sections of ANSI Z87.1-2003 or the lenses shall be prominently and permanently labeled to indicate that they are not impact resistant.

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

4.1.9 Low pressure indicator

4.1.9.1 A low pressure indicator shall be present. It shall actively and readily indicate when pressure inside the respiratory inlet covering falls below ambient pressure during more than twelve consecutive breaths during blower operation.

4.1.9.2 Low pressure indicators shall be readily visible (via light) or detectable (via sound or vibration) to the user without manipulation of the respirator and shall not affect respirator protection and performance.

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

4.1.10 Power

4.1.10.1 Power for PAPR can be supplied by local battery or external power supply. PAPR using an external power supply that can be used for emergency escape must have a battery with a minimum life of 15 minutes. The switch from external power to emergency battery shall restore minimum required operating conditions within 15 seconds.

4.1.10.2 Each PAPR shall have an indicator to monitor the condition and source (battery or external, if applicable) of the power.

4.1.10.3 Each PAPR equipped with a local battery shall have an active low power warning. This warning indicator shall signal 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. A PAPR with emergency battery power only does not require a low battery warning indicator.

4.1.10.4 All power indicators shall be readily visible (via light) or detectable (via sound or vibration) to the user without manipulation of the respirator and without affecting protection and performance.

4.1.10.5 As long as the blower is in the operational mode, the low power indicator must not be configured to be switched off.

4.1.11 Battery life

4.1.11.1 Battery life time increments, for which batteries shall be approved, shall be in one hour increments (example - 1-hours, 2-hours, 3-hours, etc.) with a minimum rating of one hour except for emergency escape batteries.

4.1.11.2 Battery life times shall be such that batteries shall perform properly and meet testing requirements for the entire stated battery operational service time at the lowest recommended operating temperature specified by the applicant.

4.1.11.3 The battery shall be tested in a fully charged state as per the manufacturer's instructions.

4.1.11.4 The PAPR system shall be operated fully assembled on a headform using a breathing machine as described in section 4.2. The breathing machine shall be set at the manufacturer's requested work rate and the pressure shall remain above ambient when measured in the nose/mouth area.

4.1.12 ESLI criteria

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

4.1.12.1.1 Demonstration that the ESLI is at its end point (e.g., color change is complete, warning signal activates, etc.), when the cartridge or canister has at least 10% of its service life remaining.

4.1.12.1.2 Desorption of any impregnating agents used in the indicator.

4.1.12.1.3 Chemicals or other interferences that could cause the ESLI to malfunction, if they are commonly found in workplaces where it is anticipated that a given ESLI shall be used.

4.1.12.1.4 Any potentially hazardous exposures resulting from the reaction of the ESLI and the gases and/or vapors the air purifying element is designed to remove.

4.1.12.1.5 The shelf (storage) life of the ESLI, if any, and permissible storage conditions, e.g., temperature, humidity, etc.

4.1.12.1.6 Flow-temperature results at minimum and maximum recommended flows and temperatures of the PAPR system, at 25% and 80% relative humidity (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 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.

4.1.12.2.2 If the passive ESLI relies on color change, the change shall 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 shall be placed adjacent to the indicator.

4.1.12.3 General ESLI requirements

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

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

4.1.12.3.3 If the ESLI is mask mounted, it shall not significantly interfere with required lines of sight.

4.1.12.3.4 Any ESLI that is not discarded with the cartridge or canister shall withstand cleaning.

4.1.12.3.5 Replaceable ESLI shall be designed to be easily removed and replaced without special tools.

4.1.12.3.6 PAPR with an ESLI shall be labeled appropriately to adequately inform the user of use conditions and of any situations that could cause the ESLI to fail to respond properly to the contaminant(s) for which it shall be used or to improperly respond to the presence of chemicals for which its use is not intended.

4.1.12.3.7 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 the ESLI to fail to respond properly to the contaminant(s) for which it is intended to be used or to improperly respond to the presence of chemicals for which its use is not intended.

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

4.1.13 Shelf life limitations

4.1.13.1 Shelf (storage) life requirements for filters, cartridges, canisters, batteries and any other applicable components shall be addressed in the User's Instructions if applicable.

4.1.14 FMEA

4.1.14.1 Manufacturers shall demonstrate that reliability is assessed and controlled by conducting a system FMEA on their device or component.

4.1.14.2 The manufacturer shall provide a written declaration that the FMEA was completed.

4.1.14.3 The manufacturer shall maintain a copy of the FMEA in their records.

4.2 Respiratory requirements

4.2.1 Inhalation and exhalation valves

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

4.2.1.2 Inhalation valves shall 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 shall 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 shall be subjected to a suction of 25 mm water column height while in any orientation.

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

4.2.3 Breathing resistance

4.2.3.1 For all PAPR, exhalation breathing resistance shall 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 63.5 mm (2.5") water column height above ambient at any flow rate with the respirator operating while properly mounted on a headform connected to a breathing machine as described in 4.2.4.

4.2.4 Breathing Rate Verification of Low, Moderate, and/or High work rates

4.2.4.1 The manufacturer shall specify the highest work rate from Table 1 for the intended use of the PAPR system. The PAPR must maintain pressure above ambient in the face area and/or the hood area around the neck during the manufacturer's minimum battery life time while breathing at each of the rates desired while properly mounted on a headform.

Table 1: NIOSH Approved Work Rates

Work Rate	Minute Volume	Tidal Volume and Respirations
Low	25 Lpm	1.30 liters @19.2 respirations per minute
Moderate	40 Lpm	1.67 liters @ 24 respirations per minute
High	57 Lpm	1.95 liters @ 29.1 respirations per minute

4.2.4.1.1 Air pressure shall be measured in the area of the nose and mouth, inside the respiratory inlet covering of the completely assembled PAPR on a headform.

4.2.4.1.2 A breathing machine shall be used to meet the work rates as described in Table 1.

4.2.4.2 Pressure shall 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.

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 shall be measured at the mouth of a headform while the respiratory inlet covering is properly mounted on a headform connected to a breathing machine.

4.2.5.2 This test shall be conducted with the PAPR blower operating at the minimum air flow rate specified by the manufacturer for units with multiple power settings and, for silent mode PAPR, with the blower not operating. Single speed PAPR not designed for silent mode operation shall be tested at the airflow specified by the manufacturer.

4.2.5.3 A NIOSH sedentary breathing machine cam shall be used with a breathing rate of 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 shall 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 shall be exhaled into the respiratory inlet covering through the mouth port of the headform.

4.2.5.5 The respirator shall 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 shall be continuously recorded and the average concentration measured during the inhalation portion of the breathing cycle for each of three donnings shall be recorded.

4.2.5.7 A minimum of three respiratory inlet coverings, or one of each size, whichever number is greater, shall be tested. For example - three of a single size device, one small/medium and two medium/large for a two 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, determined by subtracting the blank run average CO_2 level measured during the inhalation phase from the average CO_2 level measured during the inhalation phase with the respirator properly mounted on the headform, shall not exceed 1.0 % for one of the three donnings.

4.2.6 Service time limitations

4.2.6.1 Service time recommendations for batteries and any other applicable components shall be listed in the User's Instructions.

4.2.7 Chemical cartridge/canister gas/vapor removal effectiveness

4.2.7.1 PAPR cartridges and canisters shall be tested as received and shall meet the minimum requirements set forth in Tables 3 or 4 of this subpart using the constant flow rate set forth in Table 2.

4.2.7.1.1 PAPR dual cartridge/canisters shall first be tested as received and shall meet the minimum requirements set forth in table 3 of this subpart for each gas/vapor for which approval is sought using the constant required flow rate set forth in Table 2. Each tested dual cartridge/canister element shall then be stored in an air-tight enclosure. After no less than eight and not more than twenty four

hours, the same dual cartridge/canisters shall then be tested at the same humidity and temperature as the initial test and meet the requirements set forth in Table 4 of this subpart for the corresponding gas/vapor using the constant required flow rate set forth in Table 2.

4.2.7.2 Three PAPR cartridges or canisters shall be tested at 25 ± 2.5°C and 25 ± 5% RH, and three PAPR cartridges or canisters shall 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 Continuous airflow rates required for testing are given in Table 2 depending on the type of respirator and the work rating of the respirator. For PAPR with two or more canisters, canister tests shall be performed at the required flow divided by the number of canisters.

4.2.7.3.1 Manifold testing may be performed based on an engineering analysis of system.

Table 2: PAPR Bench Test Constant Airflow Requirements

Respirator Type	Low Work Rate	Moderate Work Rate	High Work Rate
Tight-fitting	Not Applicable	115 Lpm	170 Lpm
Loose-fitting	115 Lpm	170 Lpm	235 Lpm

Table 3: 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 4: 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 Chloride	5000	5	6@85% RH 12@25% RH
Hydrogen Cyanide	940	4.7	60
Hydrogen Fluoride	1000	3	60
Hydrogen Sulfide	5000	5	60
Methylamine	5000	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: Systems containing canisters and cartridges meeting cyclohexane and PAPR P100 requirements may be approved for tear gases chloroacetophenone and o-chlorobenzylidene malononitrile 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 be listed as effective against additional gases and vapors that are not specifically listed in Table 3 or 4 , as determined by NIOSH, where:

4.2.7.5.1 The cartridges or canisters have been approved for gases or vapors in the same class or family as those listed in Table 3 or 4.

4.2.7.5.2 The cartridges or canisters have 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 3 or 4 and, as determined by NIOSH, where these cartridges and canisters are not effective at removing the gas or vapor in the same class or family as those listed in Table 3 or 4.

4.2.7.6.1 NIOSH may accept or reject this request after a review of the effects on the wearers' safety and health and with consideration of field experience and resources.

4.2.7.7 Cartridge test conditions shall be determined as follows:

4.2.7.7.1 The test concentration for cartridges shall be the IDLH multiplied by four (4).

4.2.7.7.2 If an IDLH does not exist, another exposure limit shall be used as selected by NIOSH.

4.2.7.7.3 Test time for cartridges for which approval is sought under this paragraph shall be 60 minutes.

4.2.7.7.4 The maximum breakthrough concentration shall be the NIOSH recommended exposure limit (REL).

4.2.7.7.5 If the REL does not exist, another exposure limit shall be used as selected by NIOSH.

4.2.7.7.6 Values that are not achievable or cannot be done safely in the laboratory shall be adjusted.

4.2.7.8 Canister test conditions shall be determined as follows:

4.2.7.8.1 The test concentration for canisters shall be 5000ppm.

4.2.7.8.2 Test time for canisters for which approval is sought under this paragraph shall be 12 minutes

4.2.7.8.3 The maximum breakthrough concentration shall be 10ppm.

4.2.7.8.4 Values that are not achievable or cannot be done safely in the laboratory shall be adjusted.

4.2.8 PAPR95 and PAPR100 particulate filter efficiency level determination

4.2.8.1 Twenty filters or filter assemblies of each powered air-purifying particulate respirator model shall be tested for filter efficiency against a 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 shall 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 shall 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 shall be mounted on a test fixture that is designed to simulate the manner in which the respirator is used and shall expose all parts of the respirator to the test aerosol that would be exposed during use.

4.2.8.5 Particulate filters shall be tested at the maximum work rate specified by the manufacturer using the appropriate flow rate from Table 2 divided by the number of filtering elements on the system.

4.2.8.6 Filter efficiency test aerosols shall be as follows:

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

4.2.8.6.2 The PAPR100 test shall 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 shall be challenged with a concentration not exceeding 200 mg/m^3 to determine initial penetration only.

4.2.8.6.4 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.

4.2.8.6.5 The efficiency of the filter shall 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 shall be determined and recorded and be equal to or greater than the filter efficiency criterion listed for each level as follows:

PAPR100, Efficiency ≥ 99.97%
PAPR95, Efficiency ≥ 95%

4.2.9 Breathing gas concentration determinations: O_2 and CO_2 human subject generated

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

4.2.9.2 This test shall 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) shall 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 shall be performed for 10 minutes.

4.2.9.4 CO_2 and O_2 data shall 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 shall be considered.

4.2.9.6 The inhaled fractional CO_2 concentration during the inhalation portion of the breathing cycle shall not exceed 0.02 (or 2.0%).

4.2.9.7 The inhaled fractional O_2 concentration shall be no less than 0.195 (or 19.5%).

4.2.9.8 The respirator shall be tested at a temperature of $25 \pm 5^{o}C$.

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

4.2.10 Laboratory Respirator Protection Level (LRPL)

4.2.10.1 The measured LRPL shall be determined for each PAPR. Required LRPL values are listed in Table 5.

Table 5: LRPL Values

Type of PAPR	LRPL - Minimum Value (%)
Half-mask	100
Loose-fitting Facepiece	10,000
Tight-fitting Facepiece Including Hoods and Helmets	10,000
Tight-fitting Facepiece Including	2000

Hoods and Helmets with Blower Off (Silent Operation)	
Note: The protection offered by a given respirator is contingent upon (1) the user adhering to complete respirator program requirements (2) use in an approved configuration, and (3) individual fit testing. This data may be used in an applicant's request to OSHA for assignment of an assigned protection factor.	

4.2.10.2 Practical performance shall also be evaluated in this test. The practical performance of the respirator shall evaluate human interface issues associated with the use of the respirator. At a minimum, factors which shall 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 shall be trained on proper use of the respirator in accordance with the applicant's User's instructions.

5. **Enhanced CBRN Requirements -** Performance requirements beyond base requirements that may be desired by applicant for approval.

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

5.1.1 Respirator containers; minimum requirements

5.1.1.1 Required packaging configuration: (minimum packaging configuration): The CBRN tight-fitting PAPR and the required components shall be subjected to the environmental and transportation portions of the durability conditioning in the manufacturer specified minimum packaging configuration. The canisters shall also be subjected to an additional rough handling drop test in its designated minimum packaging configuration.

5.1.1.2 The minimum packaging configuration is the protective packaging configuration in which the end user* shall store or maintain the CBRN tight-fitting PAPR and the required components after it has been issued for immediate use. The user's instructions (UI) shall identify the minimum packaging configuration and shall direct the end user how to store or maintain the CBRN tight-fitting PAPR and the required components inside of the manufacturer specified minimum packaging configuration while in the possession of the end user. The same minimum packaging configuration identified in the UI shall encase the CBRN tight-fitting PAPR and its components when NIOSH performs the durability conditioning. The type of

minimum packaging configuration, if any, is left to the discretion of the manufacturer. Examples of common minimum packaging configurations are mask carriers, clamshell containers, draw string plastic bags, hermetically-sealed canister bags or nothing at all.

If packaging or shipping containers are provided by the applicant over and above the minimum packaging configuration, these additional packaging levels may not be a substitute for the minimum packaging configuration and will not be used by NIOSH in the durability conditioning of the application.

* End user: The definition of the end user is the person who will derive protection from the respirator by wearing it. It is assumed that the end user will store the respirator in a location where it will be available for immediate access and use during an emergency.

5.1.2 CBRN PAPR shall meet the conditioning requirements in Table 6 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.

Table 6: Conditioning Requirements

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

5.1.3 Tight-fitting Full Facepiece Respirator Lens Material Haze, Luminous Transmittance and Abrasion Resistance:

5.1.3.1 Haze**:** The haze value of the primary lens material shall be 3% or less when tested in accordance with ASTM D 1003-00.

5.1.3.2 Luminous Transmittance: The luminous transmittance value of the primary lens material shall be 88% or greater when tested in accordance with ASTM D 1003-00.

5.1.3.3 Abrasion Resistance: The haze and luminous transmittance of the primary lens material shall be determined in accordance with ASTM D 1003-00 before and after subjecting the lens material to the abrasion test. The abrasion test shall be conducted in accordance with ASTM D 1044-99 using CS10F (Type IV) abrasive wheels at a minimum of 70 revolutions under a 500-gram weight. After subjecting the lens material to the abrasion test, remove the residue from the test specimens in accordance with ASTM D 1044-99 or by using a cleaning method recommended by the applicant. After the residue is removed from the test specimens, the test specimens shall not exhibit an increase of haze greater than 4% and a decrease of luminous transmittance greater than 4%.

5.1.3.4 The test specimens shall be the flat 4-inch (102-mm) square version as prescribed in ASTM D 1044-99 and shall have the same nominal thickness and within the tolerance range as the primary lens of the CBRN PAPR. The test specimens shall be subjected to the same coating process and any other processes, as the primary lens would be under normal production conditions. A total of 6 specimens shall be furnished to NIOSH for certification testing, three un-abraded specimens and three specimens abraded in accordance with ASTM D-1044-99.

5.1.4 Chemical Agent Permeation and Penetration Resistance against HD and GB Requirement

5.1.4.1 The PAPR, while the blower is running, and including all components and accessories, shall resist the permeation and penetration of HD and 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 HD are shown in Table 7. Test requirements for GB agent are shown in Table 8. The Ct used as a criterion in these tables is defined as the agent concentration integrated over the minimum service life time.

Table 7: Vapor-Liquid Sequential Challenge with HD

Agent	Challenge Concentration	Duration of Challenge (min)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough-Ct ($mg\text{-}min/m^3$)	Number of Systems Tested	Min. Test Time (hours)
HD-	50 mg/m^{3*}	30	40	0.30[‡]	3.0[§]	3	8[††]

Vapor							
HD-Liquid	0.43 to 0.86 ml[*,†,**]	120	40	0.30[‡]	3.0[‡]	3	2

[*] Vapor challenge concentration shall 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 shall 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 8: Vapor challenge with GB

Challenge Agent	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Maximum Peak Excursion mg/m^3	Maximum Breakthrough-Ct (mg-min/m^3)	Number of Systems Tested	Min. Test Time (hours)
GB	210[*]	30	0.044[‡]	1.05[§]	3	8[†]

[*] The vapor challenge concentration generation shall be initiated immediately after the test chamber has been sealed.
[@] For Pressure Demand systems, the airflow rate shall 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 shall 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 Canister Test Challenge and Test Breakthrough Concentrations

5.1.5.1 The gas/vapor test challenges and breakthrough concentrations shown in Table 9 shall be used to establish the canister service life.

Table 9: Canister Test Challenge And Test Breakthrough Concentrations

Challenge Agent	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 andC_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.		

5.1.5.2 Canister Capacity. The applicant shall specify the canister capacity as indicated in Table 10. Canister capacity tests shall be performed at room temperature, 25 ºC ± 2.5 °C; 25% ± 2.5% relative humidity and 80% ± 2.5% relative humidity. Three canisters shall be tested at each humidity specified.

Table 10: Canister Capacity

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

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

5.2.1 All respirators must obtain LRPL value of ≥ 10,000 for > 95% of the trials with the blower operating. This exceeds the general requirement for a loose-fitting PAPR.

5.2.2 Chemical Agent Permeation and Penetration Resistance against HD and GB Agent Requirement

5.2.2.1 The PAPR, while the blower is running, and including all components and accessories, shall resist the permeation and penetration of HD and 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 HD and GB are shown in Table 11.

Table 11: Vapor Challenge with Chemical Warfare Agent

Challenge Concentration	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough -Ct ($mg\text{-}min/m^3$)	Number of Systems Tested	Min. Test Time (hours)
GB	210*	30	0.044‡	1.05§	3	8†
HD	50	30	0.30‡	3.0§	3	8††

* The vapor challenge concentration generation shall be initiated immediately after the test chamber has been sealed.
@ For Pressure Demand systems, the airflow rate shall 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 shall 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.

5.2.3 Cartridge Test Challenge and Test Breakthrough Concentrations

5.2.3.1 The gas/vapor test challenges and breakthrough concentrations shown in Table 12 shall be used to establish the cartridge service life.

Table 12: Cartridge Test Challenge and Test Breakthrough Concentrations

Challenge Agent	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.

5.2.4 Cartridge capacity. The applicant shall specify the canister capacity as indicated in Table 9. Cartridge capacity tests shall be performed at room temperature, 25 ºC ± 2.5 °C; 25% ± 2.5% relative humidity; and 80% ± 2.5% relative humidity. Three canisters shall be tested at each humidity specified.

6. Additional Enhanced Requirements

6.1 Flammability and Heat Resistance

6.2 Silent Operation

6.2.1 Tight-fitting full facepiece CBRN respirators shall meet and the CBRN air-purifying respirator (APR) to be granted approval for use in silent (non-powered) as well as normal (powered) mode.

6.2.2 For approval in a silent mode, initial resistance to airflow shall additionally be measured inside the respiratory inlet covering of a completely assembled PAPR with the blower not operating.

6.2.3 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:

Table 13: Maximum Allowable Resistance for Silent Mode PAPR Operation

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

6.3 Operational Temperature Range – NIOSH may conduct an additional evaluation to assure the respirator functions within the applicant's specified operational temperature range.

6.4 Hydration Device – TBD

6.5 Intrinsic Safety

6.5.1 Units to be identified as intrinsically safe on NIOSH-approved labels must be certified as intrinsically safe prior to submission to NIOSH. Certification must be through a recognized authority such as the National Fire Protection Agency (NFPA), Factory Mutual (FM), Underwriters Laboratories (UL) or the Mine Safety and Health Administration (MSHA).

6.5.2 The hazardous locations for which a PAPR is to be certified must be provided with submittal to NIOSH and included on product label. Hazardous location information should be as defined in the NFPA 70, National Electrical Code (NEC). Class, Division, Group and Temperature Code information should be specified.