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(Draft for Discussion)

Concept for Chemical, Biological, Radiological, and Nuclear (CBRN), Tight Fitting, Powered Air Purifying Respirator (PAPR)

1. Purpose

Develop a NIOSH, NPPTL, tight fitting, powered air-purifying respirator standard that address CBRN materials identified as inhalation and/or possible terrorist hazards for **emergency responders**. The respirator must meet the minimum requirements identified in the following paragraphs:

- Paragraph 3.0 Requirements specified in Title 42 CFR, Part 84 applicable paragraphs,
- Paragraph 4.0, Requirements based on existing standards,
- Paragraph 5.0, Special Requirements for CBRN.

In response to acts of terrorism and other natural disasters, air-purifying respirators are used to provide respiratory protection in work areas where the hazards are known, characterized and conditions of oxygen deficiency do not exist. Respirator use under these conditions must also be sufficient to provide for contingency use in the event of a secondary device or if additional unknown hazards are encountered exposing the responder to unexpected hazards. In these unexpected situations, the air-purifying respirator must be capable of delivering breathing protection as the responder escapes from the area.

This CBRN standard needs to be universal in defining performance based requirements that meet the widely varying needs of hazard protection, work rate and comfort. In terms of PAPR requirements and respirators in general these needs can represent competing performance requirements. For example, moderate to high to panic demand work rates have an influence on physical size and weight of the respirator, which can affect the filter size, weight and comfort. In addition, the hazard protection required can range from fully known and characterized conditions to the unknown and uncharacterized hazards of the unforeseen event requiring immediate escape.

This concept addresses major performance issues for flow, hazard protection, filter capacity and particulate efficiency. The concept addresses each of these respirator issues with performance-based requirements. The CBRN Tight Fitting PAPR concept specifies requirements for breathing performance based on the ability of the respirator to maintain a positive pressure in the breathing zone when tested with a breathing machine. The concept further allows for performance evaluation and approval at a moderate or high work rate. Breathing machines operating at 40 liters per minute (L/min) and 103 L/min volume work rates are used to establish conformance with the requirement. These breathing machine rates are well-recognized criteria used to evaluate self-contained breathing apparatus. Using this concept a CBRN Tight Fitting PAPR approval would be issued for either a moderate work rate of high work rate.

Filter hazard protection and capacity for the CBRN Tight Fitting PAPR concept follows a pattern similar to both the CBRN APR and CBRN APR Escape respirator standards. The concept provides for a minimum required performance consisting of: 99.97% particulate

efficiency and gas life with the 10 test representative agents (TRAs) defined in the existing CBRN respirator standards.

Canister capacity and particulate efficiency testing is done at flow rates determined by the maximum flow rate of the respirator. In addition to flow, canister capacity, work rate and particulate efficiency requirements the CBRN Tight Fitting PAPR concept also addresses CBRN required performance for Live Agent Testing (LAT) for Sarin (GB) and mustard (HD) and a Laboratory Respirator Protection Level (LRPL) test. Enhanced performance requirements for respirator field of view (FOV), communications, Durability Conditioning and battery performance are identified in the CBRN Tight Fitting PAPR concept.

2. Description

The CBRN Tight Fitting PAPR will use a blower to pass ambient air through an air-purifying canister(s) that will remove contaminants from the ambient air. They are to be designed for use in atmospheres where the concentrations of contaminants during use are not immediately dangerous to life and health and contain adequate oxygen to support life; in addition, they may be used to escape from hazardous atmospheres. The CBRN Tight Fitting PAPR will cover the eyes, nose and mouth, seal to the face or neck, and consist of a facepiece, helmet, hood, or a combination of these.

2.1 Respirator Use

A. Use Scenarios: Concentrations above acceptable exposure limits, but less than IDLH concentrations, to REL. Examples of use scenarios: sustained support operations; long-term use for decontamination, traffic control, rehabilitation, rescue and recovery; agent known, quantified, and controlled.

B. Crisis (Panic/Demand) Provision Mode: Egress and escape from above IDLH concentrations, high physiological (flow) demand possible; contingency for unforeseen factors such as secondary device or pockets of entrapped hazard.

C. The CBRN tight fitting PAPR canister(s) are single use and should be discarded after use.

D. CBRN respirators contaminated with liquid chemical warfare agents are to be disposed of after the use in which they have been contaminated.

2.3 Hazards

NIOSH has been evaluating various lists of chemicals that could be deployed because of a terrorist incident. In earlier research during the development of the *Chemical Biological Radiological Nuclear (CBRN) Air-Purifying Respirator (APR) Standard*, NIOSH categorized potential respiratory hazards into families. Test representative agents identified for each family shall be the only agent tested for service life in that particular family, thus representing all the agents identified in the family. This effort was conducted in order to reduce the number of certification tests. Ten chemical

TRAs, plus one particulate TRA, were identified. Testing against these 11 TRAs ensures that the respirator provides protection for the 139 identified potential CBRN respiratory hazards."

3.0 Title 42 Code of Federal Regulations (CFR), Part 84

The following paragraphs of 42 CFR, Part 84 are applicable.

3.1 42 CFR, Part 84, Subparts A, B, D, E, F, and G

Subpart A.	General Provisions
Subpart B.	Application for Approval
Subpart D.	Approval and Disapproval
Subpart E.	Quality Control
Subpart F.	Classification of Approved Respirators: Scope of Approval Atmospheric Hazard Service Time
Subpart G.	General Construction and Performance Requirements

3.2 42 CFR, Part 84, Subpart KK

The following paragraphs apply:

84.1101	Definitions
84.1103	Approved Labels and Markings; Approval of Contents; use
84.1130 (b)	Respirators; description
84.1131	Respirators; Required Components
84.1132	Breathing Tubes; Minimum Requirements
84.1133	Harnesses; Installation and Construction
84.1134	Respirator Containers; Minimum Requirements
84.1135	Half-Mask Face pieces, Full Face pieces, Hoods, Helmets, and mouthpieces; fit; minimum requirements.
84.1136	Face pieces, Hoods, and Helmets; eyepieces; Minimum Requirements
84.1137	Inhalation and Exhalation Values, Minimum Requirements
84.1138	Head Harnesses; Minimum Requirements
84.1150	Exhalation Valve Leakage Test; Minimum Requirements
84.1154	Canister and Cartridge Requirements
84.1155	Filters used with Canisters and Cartridges; Location; Replacement

4.0 Requirements Based on Existing Standards

4.1 Respirator Containers; Minimum Requirements

4.1.1. 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.

4.1.2 The Minimum Packaging Configuration is the protective packaging configuration that the *end user shall store or maintain the CBRN Tight Fitting PAPR and the required components inside 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 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 the components when NIOSH performs the Durability Conditioning. The level of the Minimum Packaging Configuration, if any, is left to the discretion of the manufacturer. Examples of common Minimum Packaging Configurations are mask carriers, clamshell containers, drawl string plastic bags, hermetically sealed canister bags or nothing at all.

If over cases, 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.

4.2 Labels

In addition to the requirements of Paragraph 4.2, the following paragraphs apply:

4.2.1 The battery part number must be prominently displayed with the part number on the respirator battery pack or other suitable location.

4.2.2 Additional cautions and limitations appropriate to CBRN Tight Fitting PAPRs must be added as deemed necessary by NIOSH, such as "Observe low flow or pressure alarm indicators."

4.3 General Construction Requirements

4.3.1 Battery Requirements

4.3.1.1 User's Instructions: The user's instructions shall include the manufacturer's operational battery life for all battery options for the respirator in increments of 30 minutes. The manufacturer specified battery service life

will be used for Breathing Performance, Paragraph 4.4. The user's instructions will also include descriptive information regarding the distinct warning for low battery indication at the 15-minute warning and information regarding the operational battery life in typical climates. User instructions shall prominently list the operational battery life for all available battery options and provide adequate information on the function and operation of battery charge. The user instructions shall also provide the specific indicator location and method of indication in a manor that the user can understand.

4.3.1.2 Low Battery Indicator: Each CBRN Tight Fitting PAPR must contain an indicator to show the state of charge of the battery. The indicator may be passive such as a tamper proof device installed indicating a fully charged battery condition along with an identified date for expiration of the fully charged condition and an indicator, which alerts the user when 15 minutes of operational battery life remains. The indicator may also be an active indicator such as an illuminated light, which provides the same 15-minute remaining warning. The indicator must be capable of monitoring the battery conditions and signaling the user when the remaining operational battery life is sufficient to sustain the desired flow rate for at least 15 minutes but not more than 45 minutes when evaluated at room temperature (25 ± 5 ^{o}C). The indicator shall also be capable of alerting the user prior to a negative pressure condition at the manufacturer's lowest specified operating temperature; at this temperature, there is no minimum time limit or maximum time limit.

4.3.1.3 Battery Performance: The CBRN Tight Fitting PAPR shall be capable of maintaining positive pressure inside the breathing zone for greater than 40% of the manufacturer's operational battery life on average and no less than 35% for any unit. This test will be performed at the manufacturer's lowest specified operating temperature and in the same manner as the breathing performance test.

4.3.2 Low Flow Indicator

4.3.2.1 Users Instructions: User instructions shall provide adequate information on the function and operation of low flow and/or low-pressure indicators to insure proper use/attention/reaction to these indicators.

4.3.2.2 Low Flow Indicator: Each CBRN Tight Fitting PAPR shall have an indicator to alert the user when the airflow in the breathing zone reaches the applicant's identified acceptable minimum flow for the respirator to maintain positive pressure in the breathing zone. The indicator will be tested at the manufacturer's lowest specified operating temperature and 25 ^{o}C±2.5 ^{o}C. The CBRN Tight Fitting PAPR must be capable of maintaining positive pressure in the breathing zone until the low flow alarm signals the user. The low flow alarm may be audible, visual, or vibratory.

4.4 Breathing Performance:

4.4.1 Breathing Rate: Powered air-purifying respirators will be approved for breathing rate performance at either a moderate rate or a high rate as specified by the applicant.

4.4.2 Moderate Breathing Rate Performance: CBRN Tight Fitting PAPRs designated for the moderate breathing rate will be tested using a breathing machine operating at 24 respirations per minute while delivering a minute volume of 40 L/min flow. A breathing machine with a Silverman Cam (622 kg•m/min) will be used. The breathing machine is specified in 42 CFR, Part 84 subpart H, Paragraph 84.88.

4.4.3 High Breathing Rate Performance: PAPRs designated for the high breathing rate will be tested using a breathing machine operated at 30 respirations per minute while delivering a minute volume of 103 L/min. The breathing machine will be described in the supporting standard test procedure.

4.4.4 Breathing Performance Requirement: During operation of the breathing machine described in paragraphs 5.4.2 and 5.4.3, the PAPR shall be mounted on a manikin head equipped to continuously monitor pressure in the breathing zone of the respirator. During operation, the pressure shall be maintained greater than 0.0 and less than or equal to 3.5 inches water column pressure at all times for both inhalation and exhalation cycles of the breathing machine.

4.4.5 Breathing Performance Test Time: Breathing performance will be continuously recorded for the applicant specified operational battery life, plus 20 minutes.

4.5 Field of View

The CBRN Tight Fitting PAPR shall obtain a Visual Field Score (VFS) of 90 or greater. The VFS shall be obtained by using a medium size respirator or equivalent that is sized to fit the Head Form described in Figure 14 of EN 136, Respiratory protective devices – Full face masks – Requirements, testing marking; January 1998 or equivalent.

The VFS is determined by using a VFS grid (Dots on visual field) as defined in the *American Medical Association Guides to the Evaluation of Permanent Impairment, 5th Edition (2000)* that is overlaid on the diagram of the visual field plot obtained using the spherical shell of EN 136 aerometer or equivalent. The VFS score is the average of three fittings of the same respirator on the specified head form.

4.6 Respiratory Inlet Covering: Lens Material Haze, Luminous Transmittance and Abrasion Resistance

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

4.6.2 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.

4.6.3 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 a CS-10F Taber Calibrase wheel or equivalent at a minimum of 70 cycles 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 fro 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%.

4.6.4 Test Specimens: 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' dominant viewing area (Directly in front of the eyes) of the CBRN Tight Fitting 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. Six specimens shall be furnished to NIOSH for certification testing, three pre-abrasion specimens and three specimens after being tested for abrasion in accordance with ASTM D-1044-99.

4.7 Carbon Dioxide

4.7.1 Machine Test: The maximum allowable average inhaled carbon dioxide concentration shall be less than or equal to 1 percent, measured at the mouth, while the respirator is mounted on a dummy head operated by a breathing machine with the blower running. The breathing rate will be 14.5 respirations per minute with a minute volume of 10.5 liters. Tests will be conducted at ambient temperature of 25ºC ± 5ºC. A concentration of 5% carbon dioxide in air will be exhaled into the respiratory inlet covering.

4.7.2 Human Subject Breathing Gas testing: During the testing required by this section, the concentration of inspired carbon dioxide gas at the mouth will be continuously recorded, and the calculated maximum range concentration during the inhalation portion of the breathing cycle shall not exceed 0.02 (or 2.0%). The inhaled fractional oxygen concentration shall be no less than 0.195 (or 19.5%) when tested with human subjects at the following work rates: standing and walking at 3.5 miles per hour. Two tests (standing and walking at 3.5 miles per hour) shall be performed, each using 12 test subjects. Each exercise will be performed for 10 minutes. Carbon Dioxide and oxygen

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

For each group of 12 subjects, 95% of the total number of trials must meet the stated criteria. Should a group of test trials not pass the 95% of trials, one addition run of test trials consisting of 12 test subjects may be performed to increase the total number of trials; the total number of trials (total of 48) will be the sum of trials from the first and second run of subjects. All trials shall be considered in the Practical Performance requirement criteria of paragraph 5.13.

4.8 Hydration

For CBRN Tight Fitting PAPR respirators equipped with a hydration facility, the CBRN Tight Fitting PAPR respirator shall meet all requirements of the CBRN Tight Fitting PAPR standard with the hydration facility in place. Dry drinking tube valves, valve seats, or seals will be subjected to a suction of 75 mm water column height while in a normal operating position. Leakage between the valve and the valve seat shall not exceed 30 mL/min.

4.9 Noise Levels

Noise levels generated by the CBRN Tight Fitting PAPR measured at each ear location shall not exceed 80 dBA. In the case of inlet coverings that cover the ear, the noise level will be measured inside the inlet covering.

5.0 Special CBRN Requirements

5.1 Canister Test Challenge and Test Breakthrough Concentrations

The gas/vapor test challenges and breakthrough concentrations shown in Table 1: Canister Challenge, Breakthrough Concentrations, and Canister Efficiency shall 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.

5.2 Canister Capacity

The applicant shall specify the canister capacity as indicated in Table 2:

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

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 specified humidity. Canister capacity testing will be performed at flow rates determined by the flow output of the PAPR blower as determined by Table 3:

Table 3.—Constant flow PAPR and demand responsive PAPR flow rates

	Moderate Breathing Rate Performance (reference Paragraph 5.4.2)	High Breathing Rate Performance (reference Paragraph 5.4.3)
Constant Flow PAPR	Tested at constant flow of blower or 100 L/min which ever is greater for the specified test time.	Tested at constant flow of blower or 261 L/min which ever is greater for the specified test time.
Demand Responsive PAPR	Tested at a constant flow of 115 L/min	Tested at a constant flow of 300 L/min

Flow rates for CBRN Tight Fitting PAPR systems will be established using a test procedure developed and conducted based on the existing procedure RCT-APR-STP-0012. The canisters shall meet or exceed the specified test times without exceeding the identified breakthrough concentrations in Table 1. Canister capacity testing shall be performed following Durability Conditioning described in paragraph 5.10. For systems with a single filter element, filters shall be tested at a continuous airflow rate determined as specified in this paragraph. Where multiple canisters are used, the canister capacity airflow rate shall be divided by the number of canister elements used on the CBRN Tight Fitting PAPR.

5.3 Particulate/Aerosol Canister

The canister shall meet the requirements of 99.97% particulate filter efficiency in accordance with the following criteria. Particulate filter efficiency testing shall be performed following the Durability Conditioning.

5.3.1 Twenty (20) canisters shall be tested for filter efficiency against a dioctyl phthalate or equivalent liquid particulate aerosol.

5.3.1.1 Additionally, six (6) canisters from the cyclohexane gas life test of Paragraph 6.1 shall be tested for filter efficiency against dioctyl phthalate or equivalent liquid particulate aerosol.

5.3.2 Canisters including holders and gaskets, when separable, shall be tested for filter efficiency level, as mounted on a test fixture in the manner as used on the respirator.

5.3.3 When the canisters do not have separable holders and gaskets, the exhalation valves shall be blocked to ensure that leakage, if present, is not included in the filter efficiency level evaluation.

5.3.4 For PAPRs with a single canister element, the canister shall be tested at a continuous airflow rate determined as specified in Paragraph 6.2, *Canister Capacity*. Where multiple canisters are used, the test-aerosol airflow rate shall

be reduced in proportion to the number of canisters. The twenty production canisters will be tested at 85 L/min flow to verify the effectiveness of the filter media to filter housing interface.

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

5.3.6 The test shall continue until minimum efficiency is achieved or until an aerosol mass of at least 200 mg ± 5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency.

5.3.7 The DOP aerosol shall have a particle size distribution with count median diameter of 0.185 µm ± 0.020 µm and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

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

5.3.9 The minimum efficiency for each of the twenty filters shall be determined and recorded and be equal to or greater than 99.97%.

5.4 Crisis (Panic Demand) Provision

Constant Flow PAPR and Pressure Demand PAPR canister capacity shall be evaluated using a method to be determined. The canisters shall not exceed the breakthrough times identified in Paragraph 5.1. There are two methods being considered: (a) Evaluating the canisters using a high, constant flow in the range of 100-135 L/min, for a five minute exposure, or (b) Evaluating the canisters using a breathing machine with a sinusoidal breathing pattern with a V_e of 114 L/min and a peak flow rate of 360 L/min.

5.5 Canisters in Parallel Resistance

When two or more canisters are used in parallel, their resistance shall be uniform within the population when tested at 85 liters per minute continuous airflow. Canister uniformity will be required:

5.5.1 The canisters shall have an allowable resistance variation of ±10%, which will be determined by one of the two following options:

5.5.1.1 Option 1: For canisters sold in Replacement Packs, (Replacement Packs will contain the appropriate number of canisters to complete a

change out exhausted canisters) the average resistance of the canisters within a Replacement Packs will be determined.

5.5.1.2 Option 2: For canisters sold individually, Canister Uniformity will based upon average resistance reported by the manufacture as reported at the time of application.

5.5.2 System Service Test

The system manifold and canisters will be evaluated to allow design and canister resistance to effect service life. Service life testing will be performed using the following TRAs: Cyclohexane, Sulfur Dioxide and Cyanogen Chloride, and Phosphine. The manifold and canisters will be tested at be tested using complete systems at room temperature, 25 ºC ± 2.5 °C; 50% ± 2.5% relative humidity.

5.6 Low Temperature/Fogging

The CBRN tight fitting PAPR respiratory inlet covering shall demonstrate and average Visual Acuity Score (VAS) of greater or equal to 75 points for all measurements of acuity with the blower operating. The respirator shall be cold soaked for 4 hours and then worn in an environmental chamber maintained at minus 21°C.

5.7 Communications

Communication requirements are based upon speech conveyance and intelligibility performance using a Modified Rhyme Test (MRT). The communication requirement is met if the overall performance rating is greater than or equal to seventy (70) percent. The MRT will be performed with a minimum steady background noise of 60 dBA consisting of noise generated by the operating blowers worn by test subjects. If the blowers do not generate a noise level of 60 dBA, then the noise generator that produces a broadband “pink” noise shall be activated to produce a level of 60 dBA + 3dBA. The distance between the listeners and speakers shall be 3 meters..

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

The CBRN Tight Fitting PAPR, while the blower is running, and including all components and accessories, shall 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:

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.
[@] For Pressure Demand systems, the airflow rate will be increased to 60L/min at minutes 15 – 30 of each hour of the test.
[‡] 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.

Test requirements for Sarin (GB) agent are shown in Table 5:

Table 5.—Vapor challenge with Sarin (GB)

Challenge Concentration	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	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)
GB	210[*)]	30	40[@]	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.

5.9 Laboratory Respiratory Protection Level (LRPL) Test Requirement

The measured laboratory respiratory protection level (LRPL) for each powered air-purifying respirator shall be 10,000 for ≥ 95% trials with the blower operating (Blower on mode) . Should a group of test subjects result in LRPL trails where less than 95% of trials have passing results, one additional run of test subjects may be performed to increase the total number of trials: the total number of trials will be the sum of trials from the first and second run of subjects. All trials shall be considered in the Practical Performance criteria of paragraph 5.13. All sampling will be performed in the breathing zone of the respirator. The respirator is tested in an atmosphere containing 20–40 mg/m3 corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 µm. The LRPL shall be calculated using eleven exercises: Normal Breathing, Deep Breathing, Turn Head Side to Side, Move Head Up and Down, Recite the Rainbow Reading Passage or equivalent, Sight a Mock Rifle, Reach for the Floor and Ceiling, On Hands and Knees – Look Side to Side, Facial Grimace, Climb Stairs at a Regular Pace, and Normal Breathing.

All sampling will be performed in the breathing zone of the respirator. The respirator is tested in an atmosphere containing 20–40 mg/m3 corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 µm. The atmosphere shall be maintained at normal operating conditions (ambient target) for LRPL Tests (70 ^{o}F, 50 % RH).

5.10 Durability Conditioning

Durability Conditioning shall be performed in accordance with Table 7.

Table 7.— Durability conditioning

Test	Test Method	Test Condition	Duration
Hot Diurnal	Mil-Std-810F; Method 501.4; Table 501.4-II; Hot-Induced Conditions	Diurnal Cycle, 35° C (95° F) to 71° C (160° F)	3 Weeks
Cold Constant	Mil-Std-801F, Method 502.4;	Basic Cold (C1), -32° C -25.6° F); Constant	72 Hours
Humidity	Mil-Std-810E, 507.3; Method 507.3; Table 507.3-II	Natural Cycle, Cycle 1, Diurnal Cycle, 31° C (87.8°F) RH 88% to 41° C (105.8° F) RH 59%	5 Days, Quick Look
Vibration	Mil-Std-810F,	U.S. Highway Vibration,	12 Hours/Axis, 3

	514.5	Unrestrained Figure 514.5C-1	Axis; Total Duration = 36 Hours, equivalent to 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.

Notes:
(1) Extra batteries (not subjected to the Durability Conditioning) are required for certification testing.
(2) Batteries may be recharged after conditioning if used for certification testing.

5.11 Test Sequence

Order	Bench Testing	Human Factors	Service Life Testing, Panic Mode	Service Life Testing	Particulate Canister Degradation	Penetration and Permeation Testing	Efficiency Particulate Canister	LRPL Test
Qty	3 PAPR systems; 3 exhalation valve assy.	9 PAPR Systems, 6 lens samples	30 sets of canisters	54 sets of canisters	6 sets of canisters	6 PAPR systems (1)	20 sets of canisters	25 to 38 systems
1.	42 CFR, Part 84 Requirements,	Low Temperature Fogging	Hot Diurnal,	Hot Diurnal,	Hot Diurnal,	Hot Diurnal,	Hot Diurnal,	Human subject Breathing Gas Test
2.	Breathing Performance,	Field of View,	Cold Constant,	Cold Constant,	Cold Constant,	Cold Constant,	Cold Constant,	LRPL
3.	Determination of Airflow	Haze, Transmittance, Abrasion,	Humidity,	Humidity,	Humidity,	Humidity,	Humidity,	Practical Performance Test
4.	Battery Requirements,	Noise levels	Transportation/ Vibration,	Transportation/ Vibration,	Transportation/ Vibration,	Transportation/ Vibration,	Transportation/ Vibration,	Commo,
5.	Low Flow Indicator,		Drop,	Drop,	Drop,	Drop,	Drop,	
6.	Determine CO_2 levels,		Canisters in parallel resistance	Canisters in parallel resistance	Canisters in parallel resistance	System Testing,	Particulate/ Aerosol Canister,	
7.	Hydration,		Service Life	Service Life Testing, Less Cyclohexane(1)	Service Life Testing, Less Cyclohexane(1)			

(1) Results from Determination of Airflow, section 5.2 are needed to perform these tests

5.12 Quality Assurance Requirements

5.12.1 Quality Control Plan

Respirators submitted for CBRN powered air-purifying respirator approvals shall be accompanied by a complete quality control plan meeting the requirements of Subpart E of Title 42, *Code of Federal Regulations* (CFR), Part 84.

5.12.2 Sampling/Test/Inspection Plan

The applicant shall specify a sampling/test/inspection plan for respirator parts and materials to ensure the construction and performance requirements of this standard are established through the manufacturing process. As a minimum, specific attributes to be addressed are:

a). Materials of construction used for respirator parts that form a barrier between the user and ambient air.

b). Integrity of mechanical seals that comprise a barrier between the user and ambient air.

c). Final performance quality control tests on complete filter canisters demonstrating compliance with the gas life and particulate filter requirements of this standard.

5.13 Practical Performance

The Practical Performance of the powered air-purifying respirator shall be evaluated as part of the test procedures of paragraph 5.9, Laboratory Respirator Protection Level, and paragraph 4.7.2, Human Subject Breathing Gas. The Practical Performance of the respirator shall evaluate human interface issues associated with the use of the respirator. As a minimum, factors which will be evaluated (if applicable based upon the respirator design) are: the inability for the user to accidentally turn the power switch off; and the inability for hoses and electrical wires to tangle, causing the respirator position on the wearer to move to an improper position, such as the respirator facepiece or hood being removed from the wearer's head. Test subjects shall be trained on proper use of the respirator in accordance with the applicant’s user instructions.

Practical Performance trials shall be accumulated from the test procedure of paragraph 5.9, Laboratory Respirator Protection Level, and paragraph 4.7.2, Human Subject Breathing Gas . For the total of these accumulated trials, 95% of these trials shall exhibit acceptable Practical Performance. Should 95% of the Practical Performance test trials not be acceptable, one additional run of test trials of paragraph 5.9 or paragraph 4.7.2 , may be performed to increase the total number of trials. The

total number of trials will be the sum of trials from the first and second run of subjects.

5.14 Failure Modes and Effects Analysis:

Failure Modes and Effects Analysis (FMEA) is methodology for analyzing potential reliability problems early in the development cycle where it is easier to take actions to overcome these issues, thereby enhancing reliability through design. FMEA is used to identify potential failure modes, determine their effect on the operation of the product, and identify actions to mitigate the failures. The FMEA is required to demonstrate that when all manufacturer specified maintenance, use, and pre-use procedures are followed, there shall be no potential failure modes during normal use.

The early and consistent use of FMEAs in the design process allows the manufacturer to design out failures and produce reliable, safe, and customer pleasing products. FMEAs should always be done whenever failures would mean potential harm or injury to the user of the end item being designed.

Respirators submitted for CBRN Non-Tight Fitting PAPR approval shall include a design FMEA that accompanies the quality control plan meeting the requirements of Subpart E of Title 42, *Code of Federal Regulations* (CFR), Part 84. The design FMEA shall include identifying the design characteristics that contributes to failures and how they were addressed in product design. It will also address how the failure modes effects were minimized as well as addressing problem prevention and actions taken to reduce risk.

5.15 General Requirements

In addition to the requirements of Title 42, *Code of Federal Regulations* (CFR), Subpart G – General Construction and Performance Requirements, the following requirements apply:

Prior to making or filing any application for approval or modification of approval, the applicant shall conduct, or cause to be conducted, examinations, inspections, and tests of respirator performance, which are equal to or exceed the severity of those prescribed in the standard. Paragraph 5.8 tests are excluded from this requirement.

5.16 Cautions and Limitations

- Not for use in atmospheres containing less than 19.5 percent oxygen.

- Failure to properly use and maintain this product could result in injury or death

- Follow the manufacturer's User’s Instructions for changing canisters

- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations

-Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

- Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

- Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.

- Direct contact with CBRN agents requires proper handling of the respirator after each use and between multiple entries during the same use. Decontamination and disposal procedures must be followed. If contaminated with liquid chemical warfare agents dispose of the respirator after decontamination.

- Not for entry into atmospheres immediately dangerous to life and health or where hazards have not been fully characterized.

-Use replacement parts in the configuration as specified by the applicable regulations and guidance.

- Consult manufacturer's User Instructions for information on the use, storage, and maintenance of these respirators.

- This respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. Procedures for monitoring radiation exposure and full radiation protection must be followed.

- If during use, an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforeseen hazard, immediately leave the area for clean air.

- Follow established canister change out schedules or observe End of Service Life Indicators to ensure that canisters are replaced before breakthrough occurs.

- Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. Failure to do so may result in personal injury even when the respirator is properly fitted, used, and maintained.

- The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours.