

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

1. Purpose

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

- Paragraph 4.0 Requirements specified in Title 42 CFR, Part 84 applicable paragraphs
- Paragraph 5.0, Requirements based on existing national and international standards
- Paragraph 6.0, 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. Respirators used under these conditions must be sufficient to provide for contingent 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 or 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 percent

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 designed for use in atmospheres where the concentrations of contaminants during use are not immediately dangerous to life and health (IDLH) 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 recommended exposure level (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 will 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 National and International 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 will be subjected to the environmental and transportation portions of the durability conditioning in the manufacturer specified MPC (MPC). The canisters will also be subjected to an additional rough handling drop test in its designated MPC.

- 4.1.2 The MPC is the protective packaging configuration that the *end user will 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) will identify the MPC and will direct the end user how to store or maintain the CBRN Tight Fitting PAPR and the required components inside the manufacturer specified MPC while in the possession of the end user. The same MPC identified in the UI will encase the CBRN Tight Fitting PAPR and the components when NIOSH performs the durability conditioning. The level of the MPC, if any, is left to the discretion of the manufacturer. Examples of common MPCs are mask carriers, clamshell containers, draw 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 MPC, these additional packaging levels may not be a substitute for the MPC 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 Instructions: The user instructions will include the manufacturer's operational battery life for all battery options for the respirator in increments of 30 minutes. The manufacturer's operational battery life will be used for breathing performance, Paragraph 4.4. The user 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 will provide adequate information on the function and operation of battery charge. The

user instructions will also provide the specific indicator location and method of indication in a manner 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 °C). The indicator will also be capable of alerting the user prior to a negative pressure condition at -30 °C ± 2.5 °C; at this temperature there is no minimum time limit or maximum time limit.

4.3.1.3 Battery Performance: The CBRN Tight Fitting PAPR will be capable of maintaining positive pressure inside the breathing zone for 40 percent of the manufacturer's operational battery life on average and no less than 35 percent for any unit. This test will be performed at -30 ± 2.5 °C and in the same manner as the breathing performance test.

4.3.2 Low Flow Indicator

4.3.2.1 User Instructions: User instructions will 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 will 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 -30 ± 2.5 °C and 25 °C ± 2.5 °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 operating at 30 respirations per minute while delivering a minute volume of 103 L/min. The breathing machine is specified in the *NFPA 1981, Open-Circuit Self-Contained Breathing Apparatus for Fire and Emergency Service*, 2002 Edition, Table 8.1.4.10.7(a) Lung Breathing Waveforms for 103 L/min Volume Work Rate.

4.4.4 Breathing Performance Requirement: During operation of the breathing machine described in paragraphs 5.4.2 and 5.4.3., the PAPR will be mounted on a mannequin head equipped to continuously monitor pressure in the breathing zone of the respirator. During operation, the pressure will 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 will obtain a Visual Field Score (VFS) of 90 or greater. The VFS will 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 will be 3 percent 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 will be 88 percent 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 will be determined in accordance with ASTM D 1003-00 before and after subjecting the lens material to the abrasion test. The abrasion test will 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, the residue will be removed 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 will not exhibit an increase of haze greater than 4 percent and a decrease of luminous transmittance greater than 4 percent.
- 4.6.4 Test Specimens: The test specimens will be the flat 4-inch (102 mm) square version as prescribed in ASTM D 1044-99 and will have the same nominal thickness and be 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 will be subjected to the same coating process, and any other processes, as the primary lens would be under normal production conditions. Six specimens will be furnished to NIOSH for certification testing. Three will be pre-abrasion specimens and three will be specimens that have been 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 will 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 $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$. A concentration of 5 percent carbon dioxide in air will be exhaled into the respiratory inlet covering. The minimum allowable oxygen concentration will be 19.5 percent.
- 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 will not exceed 0.02 (or 2.0 percent). The inhaled fractional oxygen concentration will be no less than 0.195 (or 19.5 percent) 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) will 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 five breaths will be considered.

For each group of 12 subjects, 95 percent of the total number of trials must meet the stated criteria. Should a group of test trials not pass the 95 percent of trials, one additional 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 will be considered in the practical performance requirement criteria of paragraph 5.14.

4.8 Hydration

For CBRN Tight Fitting PAPR respirators equipped with a hydration facility, the CBRN Tight Fitting PAPR respirator will 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 rate of 75 mm water column height while in a normal operating position. Leakage between the valve and the valve seat will not exceed 30 mL/min. The hydration facility leakage test will be developed and conducted based on the NIOSH test procedure RCT-APR-STP-0014.

4.9 Noise Levels

Noise levels generated by the CBRN Tight Fitting PAPR measured at each ear location will 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 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 C₂N₂.

† Nitrogen Dioxide breakthrough is monitored for both NO₂ and NO. The breakthrough is determined by which quantity, NO₂ or NO, reaches breakthrough first.

5.2 Canister Capacity

The applicant will 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 °C ± 5 °C; 25 percent ± 5 percent relative humidity; and 80 percent ± 5 percent 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 will meet or exceed the specified test times without exceeding

the identified breakthrough concentrations in Table 1. Canister capacity testing will be performed following durability conditioning described in paragraph 6.9. For systems with a single filter element, filters will be tested at a continuous airflow rate determined as specified in this paragraph. Where multiple canisters are used, the canister capacity airflow rate will be divided by the number of canister elements used on the CBRN Tight Fitting PAPR.

5.3 Particulate/Aerosol Canister

The canister will meet the requirements of 99.97 percent particulate filter efficiency in accordance with the following criteria. Particulate filter efficiency testing will be performed following the durability conditioning.

- 5.3.1 Twenty (20) canisters will be tested for filter efficiency against a dioctyl phthalate or equivalent liquid particulate aerosol.
 - 5.3.1.1 Additionally, 6 canisters from the cyclohexane gas life test of Paragraph 6.1 will be tested for filter efficiency against dioctyl phthalate or equivalent liquid particulate aerosol.
- 5.3.2 Canisters including holders and gaskets, when separable, will 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 will 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 will 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 will be reduced in proportion to the number of canisters. The 20 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 $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$ that has been neutralized to the Boltzmann equilibrium state will be used. Each filter will be challenged with a concentration not exceeding $200 \text{ mg}/\text{m}^3$.
- 5.3.6 The test will continue until minimum efficiency is achieved or until an aerosol mass of at least $200 \text{ mg} \pm 5 \text{ mg}$ challenge point is reached, the test will be continued until there is no further decrease in efficiency.
- 5.3.7 The DOP aerosol will have a particle size distribution with count median diameter of $0.185 \mu\text{m} \pm 0.020 \mu\text{m}$ 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 will 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 20 filters will be determined and recorded and be equal to or greater than 99.97 percent.

5.4 Crisis (Panic Demand) Provision

Constant Flow PAPR and Pressure Demand PAPR canister capacity will be evaluated using a method to be determined. The canisters will not exceed the breakthrough times identified in Paragraph 5.1.

5.5 Canisters in Parallel Resistance

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

5.6 Breathing Resistance:

Resistance to air flow will be measured in the facepiece of a CBRN PAPR mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute both before and after each gas service life bench test. The maximum allowable air resistance to airflow is as follows:

	PAPR
Inhalation:	
Initial	50 mm H ₂ O
Final ⁽¹⁾	70 mm H ₂ O
Exhalation:	20 mm H ₂ O

(1) Measured at end of service life.

5.7 Low Temperature/Fogging

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

5.8 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 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 will be activated to produce a level of 60 dBA + 3dBA. The distance between the listeners and speakers will be 3 meters..

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

The CBRN Tight Fitting PAPR, with the blower 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. The evaluation will include testing on an upper-torso mannequin 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-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/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.

** Liquid agent is applied to respirator at hour 6 of the vapor test cycle.

†† 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.

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-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/m³ 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.

5.10 Laboratory Respiratory Protection Level (LRPL) Test Requirement

The measured laboratory respiratory protection level (LRPL) for each powered air-purifying respirator will be 2,000 for ≥ 95 percent trials with the blower operating (blower on mode) and 500 for ≥ 95 percent of trials with the blower not operating (blower off mode). Should a group of test subjects result in LRPL trails where less than 95 percent 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 will be considered in the practical performance criteria of paragraph 5.1.4. 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 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
- 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
- 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 will be maintained at normal operating conditions (ambient target) for LRPL Tests (70 °F, 50 percent RH).

5.11 Durability Conditioning

Durability Conditioning will 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 percent to 41° C (105.8° F) RH 59 percent	5 Days, Quick Look
Vibration	Mil-Std-810F, 514.5	U.S. Highway Vibration, Unrestrained Figure 514.5C-1	12 Hours/Axis, 3 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.
- (3) After durability conditioning the battery must be able to supply power to the PAPR indicators

5.12 Test Sequence

October 30, 2004
(Draft for Discussion)

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, section 3.0	Low Temperature Fogging, section 5.7	Hot Diurnal, Section 5.11	Hot Diurnal, Section 5.11	Hot Diurnal, Section 5.11	Hot Diurnal, Section 5.11	Hot Diurnal, Section 5.11	Human subject Breathing Gas Test, section 4.7
2.	Breathing Performance, section 4.4	Field of View, section 4.5	Cold Constant, Section 5.11	Cold Constant, Section 5.11	Cold Constant, Section 5.11	Cold Constant, Section 5.11	Cold Constant, Section 5.11	LRPL, section 5.10
3.	Determination of Airflow, section 5.2	Haze, Transmittance, Abrasion, section 4.6	Humidity, Section 5.11	Humidity, Section 5.11	Humidity, Section 5.11	Humidity, Section 5.11	Humidity, Section 5.11	Practical Performance Test, section 5.13
4.	Battery Requirements, section 4.3.1	Noise levels, section 4.9	Transportation/ Vibration, Section 5.10	Transportation/ Vibration, Section 5.10	Transportation/ Vibration, Section 5.10	Transportation/ Vibration, Section 5.10	Transportation/ Vibration, Section 5.10	Commo, section 5.8
5.	Low Flow Indicator, section 4.3.2		Drop, Section 5.11	Drop, Section 5.11	Drop, Section 5.11	Drop, Section 5.11	Drop, Section 5.11	
6.	Determine CO ₂ levels, section 4.7		Canisters in parallel resistance section 5.5	Canisters in parallel resistance section 5.5	Canisters in parallel resistance section 5.5	System Testing, Section 5.9	Particulate/ Aerosol Canister, section 5.3	
7.	Hydration, section 4.8		Initial breathing resistance, section 5.6	Initial breathing resistance, section 5.6	Initial breathing resistance, section 5.6			
8.			Service Life section 5.4	Service Life Testing, Less Cyclohexane ⁽¹⁾	Service Life Cyclohexane ⁽¹⁾			
9.			Final breathing resistance, section 5.6	Final breathing resistance, section 5.6	Final breathing resistance, section 5.6			
10.					Particulate/ Aerosol Canister, section 5.3			

(1) Results from determination of airflow, section 5.2 are needed to perform these tests

5.13 Quality Assurance Requirements

5.13.1 Quality Control Plan

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

5.13.2 Sampling/Test/Inspection Plan

The applicant will 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

5.14 **Practical Performance**

The practical performance of the powered air-purifying respirator will be evaluated as part of the test procedures of paragraph 5.10, Laboratory Respirator Protection Level, and paragraph 4.7.2, Human Subject Breathing Gas. The practical performance of the respirator will evaluate human interface issues associated with the use of the respirator. As a minimum, factors that will be evaluated (if applicable based upon the respirator design) are:

- the inability for the user to accidentally turn the power switch off
- 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 will be trained on proper use of the respirator in accordance with the applicant's user instructions.

Practical performance trials will be accumulated from the test procedure of paragraph 5.10, Laboratory Respirator Protection Level, and paragraph 4.7.2, Human Subject Breathing Gas. For the total of these accumulated trials, 95 percent of these trials will exhibit acceptable practical performance. Should 95 percent of the practical performance test trials not be acceptable, one additional run of test trials of paragraph 5.10 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.

5.15 General Requirements

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

Prior to making or filing any application for approval or modification of approval, the applicant will 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 5.9 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 will 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 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 2 hours.