DRAFT
CBRN PAPR Concept Paper
April 1, 2004

1.0 Background

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.

Work tasks associated with terrorism response can vary considerably based on the activity of the responder. Emergency Response procedures identify work zones at the site as Hot Zone, Warm Zone, and Cold Zone. Descriptions of these are:

Cold Zone: Area where the command post and support functions that are necessary to control the incident are located. (2000 Emergency Response Guidebook, U.S. Department of Transportation). This is also referred to as the clean zone, green zone or support zone in other documents (EPA Standard Operating Safety Guidelines, OSHA 29 CFR 1910.120, and NFPA 472).

Warm Zone: Area between hot and cold zones where personnel and equipment decontamination and hot zone support take place. It includes control points for the access corridor and thus assists in reducing the spread of contamination. (2000 Emergency Response Guidebook, U.S. Department of Transportation). It is also referred to as the contamination reduction corridor (CRC, contamination reduction zone (CRZ), yellow zone or limited access zone in other documents. (EPA Standard Operating Safety Guidelines, OSHA 29 CFR 1920.120, NFPA 472).

Hot Zone: Area immediately surrounding a dangerous goods incident, which extends far enough to prevent adverse effects from released dangerous goods to personnel outside the zone. (2000 Emergency Response Guidebook, U.S. Department of Transportation). This zone is also referred to exclusion zone, red zone or restricted zone in other documents (EPA Standard Operating Safety Guidelines, OSHA 29 CFR 1910.120, and NFPA 472).

Typical responder work activities in the Warm and Cold Zones where air-purifying respirators will be used may include but are not limited to: Decontamination (decon), perimeter control, material handling, rescue and recovery, clean-up and people management. Additional work activities are expected when the scope of response work is extended to first receivers at hospitals receiving victims from the terrorist event. These activities include patient care. The breathing demands of the respirator to meet the range of activities expected can vary considerably. For example, work tasks such as perimeter control, people management, some tasks associated with Decon and tasks performed by first receivers may be considered to require a low to moderate rate of work. Rescue and recovery tasks, clean up

and certain operations associated with decon (lifting and carrying) are considered a high and heavy work rate. In addition, the threat of secondary devices or unforeseen hazards can result in responder escape at high panic demand work rates.

Powered air-purifying respirators (PAPRs) offer distinct comfort advantages for responders and first receivers required to wear respiratory protection for extended periods of time. The chemical, biological, radiological and nuclear (CBRN) PAPR 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.

The CBRN PAPR 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 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 PAPR approval would be issued for either a moderate work rate of high work rate. The concept uses the same breathing machine performance requirement and test for both tight fitting and loose fitting face piece designs.

Filter hazard protection and capacity for the CBRN 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.

The minimum filter canister capacity is defined using a test time of 15 minutes at gas concentrations based on three times immediately dangerous to life or health (IDLH) concentration. The concept further allows stacking additional protection for one or more of the 10 TRAs tested for a test time of 30, 45, 60, 90 or 120 minutes. The additional specific TRAs are identified by the manufacturer. It is also possible to specify one, none or all 10 agent-families at the greater capacity of 30, 45, 60, 90 or 120 minutes test time.

Filter capacity and particulate efficiency testing is done at flow rates determined by the maximum flow rate of the respirator. The concept provision to stack specific hazard protection on top of the minimum protection is defined since responder use of the CBRN PAPR for extended periods is expected to be in known and characterized hazards.

In addition to flow, filter capacity, work rate and particulate efficiency requirements the CBRN 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 PAPR concept.

2.0 Purpose:

Develop a NIOSH, NPPTL, powered air-purifying respirator standard that address chemical biological radiological nuclear (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 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.

3.0 Description:

Powered air-purifying respirators use a powered mechanism to draw ambient air through an air-purifying filter elements(s) to 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 an unexpected IDLH condition provided there is adequate oxygen to support life.

3.1 Definitions:

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

(b) Tight fitting PAPR – a PAPR, which contains respiratory inlet covering that seals tightly to the face.

(c) Neck dam PAPR – a PAPR, which contains a hood or helmet and which covers and seals tightly around the neck area.

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

3.2 Respirator Use:

A. Warm Zone/Cold Zone Use: 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 devise or pockets of entrapped hazard.

C. The CBRN PAPR filter elements are single use filters 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.

3.3 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 provides protection for 139 potential respiratory hazards.

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

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

4.1 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

4.2 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

5.0 Requirements Based on Existing National and International Standards:

5.1 Respirator Containers; Minimum Requirements:

5.1.1 CBRN PAPRs shall be equipped with a container bearing markings, which show the applicant's name and the type and commercial designation of the CBRN PAPR on all appropriate approval labels.

5.1.2 Containers for CBRN PAPRs shall be designed and constructed to permit easy removal of the respirator.

5.1.3. Required Packaging Configuration: Minimum packaging configuration: The 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.

The Minimum Packaging Configuration is the protective packaging configuration that the *end user shall store or maintain the 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 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 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 PAPR 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.

5.2 Labels:

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

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

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

5.3 General Construction Requirements:

5.3.1 Battery Requirements:

5.3.1.1 The user's instructions shall include the manufacturer's operational battery life for all battery options for the respirator. The manufacturer specified battery service life will be used for Breathing Performance, Paragraph 5.4. The user's instructions will also include descriptive information regarding the distinct warning for low battery indication at the 15-minute warning.

5.3.1.2 Each CBRN 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 25 minutes.

5.3.1.3 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.

5.3.2 Low Flow Indicator:

5.3.2.1 Each CBRN 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.

5.3.2.2 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.

5.3.3 Operational Controls:
CBRN PAPR units must be equipped with readily accessible switches and controls designed to prevent accidental shutoff.

5.4 Breathing Performance:

5.4.1 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.

5.4.2 Moderate Breathing Rate Performance:
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.

5.4.3 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 shall be as 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.

5.4.4 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.

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

5.5 Field of View:

The CBRN PAPR Respiratory inlet covering 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.

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

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

5.6.2 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.

5.6.3 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%.

5.6.4 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 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.

5.7 Carbon Dioxide:

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. The minimum allowable oxygen concentration shall be 19.5%.

5.8 Hydration:

For CBRN PAPR respirators equipped with a hydration facility, the CBRN PAPR respirator shall meet all requirements of the CBRN 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. The hydration facility leakage test will be developed and conducted based on the NIOSH Test Procedure RCT-APR-STP-0014.

5.9 Noise Levels:

Noise levels generated by the PAPR measured at each ear location shall not exceed 75 dBA. In the case of inlet coverings that cover the ear, the noise level will be measured inside the inlet covering.

6.0 Special CBRN Requirements:

6.1 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.

6.2 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 ± 5 °C; 25% ± 5% relative humidity; and 80% ± 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 (87% of 115 L/min) which ever is greater for the specified test time.	Tested at constant flow of blower or 261 L/min (87% of 300 L/min) which ever is greater for the specified test time.
	Moderate Breathing Rate Performance (reference Paragraph 5.4.2)	High Breathing Rate Performance (reference Paragraph 5.4.3)
Demand Responsive PAPR	Tested at a constant flow of 115 L/min	Tested at a constant flow of 300 L/min

Flow rates for Constant Flow PAPR system 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 6.9. For PAPRs with a single filter element, filters shall be tested at a continuous airflow rate determined as specified in this paragraph. Where multiple filter elements are used, the filter canister capacity airflow rate shall be reduced in proportion to the number of filter elements.

"Stacking" is allowed of one or more of the six chemical testing families. To be certified as "CBRN" all canisters will be tested to a minimum capacity with all 11 TRAs to a capacity # 1. In addition to this, as per manufacture request, additional family capacity can be stacked on top of the capacity # 1. To obtain this additional family capacity of #2, #3 or #4, the canister must pass the higher capacity of all of the TRAs for that testing family.

6.3 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.

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

6.3.1.1 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.

6.3.2 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.

6.3.3 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.

6.3.4 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. In lieu of efficiency tests at the determined flow rate, efficiency testing may be performed using test filters sized to produce an equivalent face velocity through the filter at a flow rate of 85 L/min. If efficiency testing with filters of reduced area is used, twenty test filters and twenty production filters are required. The twenty production filters will be tested at 85 L/min flow to verify the effectiveness of the filter media to filter housing interface. If alternate testing procedures are used, media samples will be preconditioned with cyclohexane.

6.3.5 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.

6.3.6 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.

6.3.7 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.

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

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

6.4 <u>Crisis (Panic Demand) Provision:</u>

Constant Flow PAPR and Pressure Demand PAPR canister capacity shall be evaluated using a constant flow rate of 430 L/min for 5 minutes. The canisters shall not exceed the breakthrough times identified in Paragraph 6.1.

6.5 Low Temperature/Fogging:

The CBRN 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.

6.6 Communications:

Communication requirements are based upon performance using a Modified Rhyme Test (MRT). The communications requirement is met if the overall performance rating is greater than or equal to seventy (70) percent. The MRT will be performed with a steady background noise of 60 dBA consisting of a broadband "pink" noise with the blower operating. The distance between the listeners and speakers shall be 3 meters.

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

The air-purifying respirator system, 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 of PAPR with distilled sulfur mustard (HD)

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

[*] Vapor challenge concentration will start immediately after the test chamber has been sealed. Minimum test time for liquid exposure starts after the first liquid drop is applied.
[†] Liquid Volume dependent on accessories used with the respirator. Minimum volume is 0.43 ml based on the respirator only.
[‡] Three consecutive sequential test data points at or exceeding 0.3 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately two (2) minutes.

[§] The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.
[**] Liquid agent is applied to respirator at hour six (6) of the vapor test cycle.
[††] The test period begins upon initial generation of vapor concentration and ends at eight (8) hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.

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

Table 5.—Vapor challenge of APR 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.
[†] 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.

6.8 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% of trials with the blower operating. 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.

Test subject and replication numbers are outlined in Table 6 for a 3-size Configuration.

Table 6.— Anthropometric test criteria for a 3 size configuration

	Small	Medium	Large
Face Length and Face Width	**Cell A** **Use LANL boxes 1, 2, 3, 4 (2 or 3 subjects each box, 2 trials per subject)** Subjects = 10 Trials = 20	**Cell D** **Use LANL boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 subjects each box, 2 trials per subject)** Subjects = 17 Trials=34	**Cell G** **Use LANL boxes 7, 8, 9, 10; panel size 11 (2 or 3 subjects each box, 2 trials per subject)** Subjects = 11 Trials = 22
Head Circumference*	**Cell B** **N/A** Subjects = 0 Trials = 0	**Cell E** **N/A** Subjects = 0 Trials = 0	**Cell H** **378-451 mm** Subjects = 10 Trials = 20
Neck Circumference*	**Cell C** **306-378 mm** Subjects = 10 Trials = 20	**Cell F** **355-403 mm** Subjects = 10 Trials = 20	**Cell I** **378-451 mm** Subjects = 10 Trials = 20

* If applicable to design of PAPR.

For each size category (Small, Medium, and Large), each cell corresponding to the anthropometric parameter will be tested. Cells can be either exclusively tested (if the test subjects only meet the requirements of a specific cell) or simultaneously tested (if the test subjects meet the requirements of more than one cell) tested for each size category.

Example: For the 'Large' category, eleven (11) subjects are needed for the 'Face Length and Width' category (cell G). If ten (10) of these eleven (11) subjects also meet the measurement range for the 'Large Head Circumference' category (cell H), then the number of subjects required for cell H is simultaneously met. If only six (6) of the eleven (11) subjects needed for the 'Large Face Length and Width' category (cell G) meet the measurement range for the 'Large Head Circumference' category (cell H), then an additional four (4) subjects will need to be tested in cell H.

User instructions must clearly and accurately explain how users choose appropriate size.

6.9 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, 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:
Extra batteries (not subjected to the Durability Conditioning) are required for certification testing.

Batteries may be recharged after conditioning if used for certification testing.

Batteries Exposed to Durability Conditioning must not render the PAPR in-operable and must result in self –reporting of functionality

6.10 Test Sequence:

To Be Determined.

6.11 Quality Assurance Requirements:

6.11.1 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.

6.11.2 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.

6.12 Practical Performance:

The Practical Performance of the powered air-purifying respirator shall be evaluated as part of the test procedures of paragraph 6.8, Laboratory Respirator Protection Level. 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 6.8, Laboratory Respirator Protection Level. 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 6.8, Laboratory Respirator Protection Level, 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.

6.13 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 6.7 Systems Tests are excluded from this requirement.

6.14 Cautions and Limitations:

To Be Determined