Dragon, Karen E.

From: Goran Berndtsson [goran@sea.com.au]

Sent: Friday, May 28, 2004 8:57 PM

To: NIOSH Docket Office; Boord, Leslie F.

Subject: Comments on the third Draft of the CBRN PAPR Standard

I hope you have not got this two times. The first e-mail was bounced by the computer so I hade to send it is two smaller loots.

There should be two altogether.

Regards Göran Berndtsson



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Att NIOSH Docket office; Draft CBRN PAPR Concept Paper.

The over all comments are that we are heading towards a functional standard for First responders.

Background statements such as "Filter capacity and particulate efficiency testing is done at flow rates determined by the maximum flow rate of the respirator." It is encouraging for the overall functionality of the standard.

In paragraph 3.2 Respirator Use: The statement in paragraph A, (Warm Zone/Cold Zone Use:) "Concentrations above acceptable exposure limits, but less than IDLH concentrations, to REL" and in paragraph 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", makes the RPD who complies with this standard functional for the First Responders.

If, during this situation the battery, the motor or other electronic failure occur, it should be possible to use the RPD as a negative pressure RPD. With other words I would suggest that the PAPR meets some minimum performance requirement with power off.

Paragraph 5.2.1- I believe that here we try to find a means to inform the user of the capacity (length the PAPR can be used limited by the battery). To make this useful we also need to inform the user of the consumption (ampere) at different work rates

Example; A test we recently performed in Sydney;

Power/Performance test

The purpose of the test is to ensure that unit does not change the performance due to battery discharging. The performance is measured by the units ability to maintain the positive pressure throughout the battery life time until the unit stops due to battery discharging. Also, this test allows comparing battery consumption in the same conditions.

The BM settings: 35 breaths per min, Tidal volume 1.46 liter.

SR500 (constant flow PAPR) Power supply test SR500 start

Dragon, Karen E.

From: Goran Berndtsson [goran@sea.com.au]

Sent: Saturday, May 29, 2004 8:06 AM

To: NIOSH Docket Office; Boord, Leslie F.

Subject: Comments on the third Draft of the CBRN PAPR Standard

This is the third time I try to send this e-mail. The two first times I got a message back as follow; **This Message was undeliverable due to the following reason:**

Your message is larger than the destination computer is willing to accept, so it was returned. The error message below indicates the size of your message and the maximum size allowed by the receiving E-mail system. You may be able to split your message into several smaller pieces and have them delivered separately.

Size of this message: 7960779 bytes Server maximum size: 7168000 bytes

The following recipients did not receive this message:

<niocindocket@cdc.gov> <zfx2@cdc.gov>

I hope it works this time. Unfortunately I hade to reduce the size resulting in deleting part of the original draft document, I hope it still make cense.

The original message below. The attachments are no longer zipped.

Hi,

There is two documents in the zipped folder, The PDF file are the same sent earlier, it is resent as we refer to this document in the comment of the third draft. The comments are from two people, GB comments are made by me and D comments by our project engineer in Sydney. If there is any questions please don't hesitate to contact me.

Regards Göran Berndtsson



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DRAFT CBRN PAPR Concept Paper April 1, 2004

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.

Comment: This is rely important to establish. In my last submission I talked about one way of establish this, please

POF

Att NIOSH Docket office PAPR1.2.pdf

Attached for your record.

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.

* End user:

If over cases, packaging, or shipping containers are provided by the applicant over

Comment: SEA's experience with customers, is that PAPR's we have supplied (New York State, Australian federal Government, Taiwan CDC) just to name a few. The PAPR's are not always stored with the end user, they are usually stored in some transportable storage unit such as a sea container or similar. This allows storage conditions to be suitable and sometimes controlled to suit the equipment stored. For example batteries need to be maintained and conditioned frequently. Also some of the electronic components such as transducers need to be in controlled environment to function ultimately when needed

We recommend NIOSH to consider Manufacturers instruction driven storage conditions. This will allow some flexibility for users. There is temperature and humidity limitations to certain electronic component used in advanced PAPR's. If the user need NO limitation to storage, they need to consider equipment not limited to certain storage conditions.

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.	Ĭ,
'	_

Demand PAPR's following the requirement of a user. This will change the performance time remaining to the end of battery dependant on the flow rate at the time. With other words if the user get a alarm 15 min to the end of battery (this is typically based on the flow/work rate at the time of alarm) and he start running out to change battery. Then he will use more air as he starts running resulting in a higher demand and a shorter lime to the end of service life of the battery. Equally if the user have worked hard digging in rubles for example and the alarm goes for end of service life for the battery. The user start to walk to a safe place to change battery, this walk is less intense than the digging, then the battery will last longer than the minimum requirement and could possible last longer than the maximum 25 minutes stipulated. The nature of batteries could make it difficult to fit such a narrow

Comment: The battery residual capacitance very difficult to estimate. It will depends on battery technology/ type, temperature, battery age

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 airfly achieved by a low flow indicator, or the breathing zone reaches the applicant's identified acceptable minimum activity measuring to see that positive 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.

Operational Controls:

inhalation resistance with a PAPR. CBRN PAPR units must be equipped with readily accessible switches and contro. designed to prevent accidental shutoff.

Breathing Performance:

5.4

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.

Breathing Performance Requirement: During operation of the breathing 5.4.4 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.

Breathing Performance Test Time: Breathing performance will be 5.4.5 continuously recorded for the applicant specified

Comment: I don't understand the logic with the extra 20 minutes. If the requirement is 2 or 4 hour why do we need an extra 20 minutes? We are requiring a battery warning 15 min before end of battery life, this gives the warning to the user. Why don't we require 2 hour and 20 minute or 4 hour and 20 minuets.

Can someone explain the logic?

Comment: Low Flow Indicator: The reason must be to warn if Positive Pressure is not maintained. If this is

pressure is maintained in the inner mask

the end result is achieved without limiting

Comment: Silverman; He reported a

mean flow rate of 44.8 L/min at 622kg·m/min with no inhalation resistance. We would expect no

should not matter. I suggest that the positive pressure method be added. alternatively rewrite the requirement so

the way how to achieve it.

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.
- 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 tens 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.

Comment: Note to paragraph 5.4.5 (20 minutes statement). I believe here we should mention that battery should be freshly charged and conditioned or other defined battery status.

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 $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$. 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 Breakthrough Concentration (ppm) Concentration (ppm)

Ammonia 2500 12.5

Cyanogen chloride 300 Cyclohexane 2600

Formaldehyde 500 1 Hydrogen cyanide 940 Hydrogen sulfide 1000

Nitrogen Dioxide	200	1	ppm NO	2 or 25	ppm NO [†]
Phosgene	250		Sec.	1.25	
Phosphine	300			0.3	
Sulfur dioxide	1500	76 F	\$ C.	5	

^{*} Sum of HCN and C2N2.

6.2 Canister Capacity:

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

-Canister capacity Table 2.

Filter Capacity Test Time (min)	Filter Capacity (ppm-min)
Capacity # 1	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% ± 5% confusing foe everyone as we tried to relative humidity, and 80% ± 5% relative humidity. Three canisters will be tested at eac establish Test Concentration times specified humidity. Canister capacity testing will be performed at flow rates determined Concentration" X 15. I believe that the X the flow output of the PAPR blower as determined by Table 3:

Comment: The Table 2 was very 15, X 30 etc is confusing and should be removed as Test time is already specified in the table.

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

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

Moderate Breathing Rate High Breathing Rate Performance (reference Performance (reference Paragraph 5.4.2) Paragraph 5.4.3) Constant Flow PAPR Tested at constant flow of Tested at constant flow of

blower or 100 L/min (87% of 115 L/min) which ever is greater for the specified test time.

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)
Tested at a constant flow of

115 L/min

High Breathing Rate Performance (reference Paragraph 5.4.3) Tested at a constant flow of

300 L/min

Demand Responsive PAPR

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.

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.
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Comment: I think if you will be able to implement the highlighted changes at page 2, this paragraph (Table 3, demand Responsive PAPR, which is tested a constant flow of 300l/min) should be changed accordingly

- 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.
- 1. 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.
- 2. 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 25°C ± 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/m³.
 - 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 μ m \pm 0.020 μ 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.
 - 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 Crisis (Panic Demand) Provision:

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.

Comment: This requirement do not make sense, unless we require tight fitting human interfaces.

We should require tight fitting human interfaces.

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:

Communications:

Communication requirements are based upon performance using a Modified Rhyme Te (MRT). The communications requirement is met if the overall performance rating is greathan or equal to seventy (70) percent. The MRT will be performed with a steady backgr 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.

Chemical Agent Permeation and Penetration Resistance against Distilled Sulfur

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

distance between the listeners and speakers shall be 3 meters.

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	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Machine	Maximum Peak Excursion (mg/m ³)	Maximum Breakthrough (concentration integrated over minimum test time) (mg-min/m³)	Number Of Systems Tested	Minim um Test Time (hours)
HD-	50 mg/m ^{3*}	30	40	0.30^{\ddagger}	3.0§	3	8 ^{††}
Vapor 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 agent is applied to respirator at hour six (6) of the vapor test cycle.

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

Comment: There is two different opinions. It would be nice to specify or develop the method or strategy how the liquid will be applied. It will simplify the development process. Hoverer from other side it'll force developers to evaluate and consider all possible risks during development.

Comment: This method makes it difficult to foresee all different possibilities, unfortunately (I don't have a solution to the problem) it comes down to luck or unlucky in some cases, it seems to be difficult for the test lab repeatedly test the same way. The human error has to much to do with this.

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 will collectively constitute a failure where each test value is based on a detector sample time of approximately two (2) minutes.

^{&#}x27;The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.

The test period begins upon initial generation of vapor concentration and ends at eight (8) hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.

Table 5.—Vapor challenge of APR with Sarin (GB)

Challenge Concentration	Vapor Concentration (mg/m ³)	Vapor Challenge Time (minutes)	Breathing Machine Airflow Rate	Maximum Peak Excursion mg/m ³	Maximum Breakthrough (concentration integrated	Number of Systems Tested	Minim um Test Time
		(minute	es) Rate (L/mir	mg/m²	integrated over	Tested	Tii (hoi
					minimum test time) (mg-min/m³	5	
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

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 \geq 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 ar Comment: LRPL testing; When testing

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.

PAPR's it has been established that certain designs are less simple to test Quantitative with the power on. For example, a Portacount instrument are to sensitive and will identify as a leakage, particles coming of the motor, equally there is some similar difficulties with com oil.

Electric motors with bearings will sometimes relies some of the oil greasing the bearings, this will be identified as leakage by the test instruments used for LRPL. This can be handled by a dry LRPL test to establish the background levels prior to final test. This must be performed with all test samples and all test subjects for the entire test period. The will result in two tests instead of one, whoever this is required as we are looking for very high performance levels. Of course the level of background is dependent on the design of the PAPR, for high performance PAPR it is necessary to use bearings in the design and technically difficult to avoid background noise. Any friction will potentially release particulars.

[†] 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.

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

Small Medium Large Face Length and Cell A Cell D Cell G Face Width

	Use LANL boxes 1, 2, 3, 4 (2 or 3 subjects each box, 2 trials per subject)	Use LANL boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 subjects each box, 2 trials per subject)	Use LANL boxes 7, 8, 9, 10; panel size 11 (2 or 3 subjects each box, 2 trials per subject)
	Subjects $= 10$		
	Trials = 20	Subjects = 17	Subjects = 11
		Trials=34	Trials = 22
Head	Cell B	Cell E	Cell H
Circumference*			
	N/A	N/A	378-451 mm
	Sa.		
	Subjects = 0	Subjects = 0	Subjects = 10
	Trials = 0	Trials = 0	Trials = 20
Neck	Cell C	Cell F	Cell I
Circumference*	306-378 mm	355-403 mm	378-451 mm
	Subjects = 10	Subjects = 10	Subjects = 10
Age of the second	Trials = 20	Trials = 20	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. Passing/not passing.

Table 7.— Durability conditioning

Test	Test Method	Test Condition	Duration
Hot Diurnal	Mil-Std-810F;	Diurnal Cycle, 35° C	3 Weeks
	Method 501.4;	(95° F) to 71° C (160° F)	
	Table 501.4-II;		
	Hot-Induced		
	Conditions		

Comment: What are we looking for as a failure here?

Are we expecting all electronics to pass this durability test with no failure. What I think is reasonable is to require some self test/simple test to establish normal performance. If the test recognize a fault it should be corrected then tested. What I recommend to be Pass/Failure is the capability to warn the user if the PAPR is not performing as expected. Things can break and it will break, what's really important is that when someone are going to use any type of RPD he/she must have a way to know if the RPD is functional as intended. If the RPD for whatever reason has been damaged, the user shall have a simple way of identify this (in particular with a RPD providing this level of protection), it is as important as if the RPD would not maintain positive pressure in the

breathing zone.

The simple self test has to give a acknowledgement of the condition of the PAPR. Is the PAPR performing as intended or is it broken, if this information is not working, it is a failure even if the PAPR start. The logic for this is that the user cant without this help, determine the performance status of the PAPR

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	Comment: The last box 1 drop/filter on one of the 3 axes. Not clear the test
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	method all filters should be dropped the same, chose one of 3 axis? Or on different defined axis? Or may be randomly?
Drop	3 foot drop onto bare concrete surface	Canister only; In individual canister packaging container	1 drop/filter on one of the 3 axes.	Comment: Below: "Battery Exposed to Durability" It is really difficult, almost impossible to detect battery capacitance without performing charging-discharging tests a few times.

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

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