DRAFT

June 30, 2003

Part 1: Concept for CBRN Air-Purifying Escape Respirator Standard

(1) Goal:

Develop a NIOSH standard for escape only air-purifying respirators that addresses CBRN materials identified as inhalation hazards from possible terrorist events for use by the general working population.

(2) Hazard Categories:

Defining appropriate hazard levels for escape from a possible chemical, biological, radiological, and nuclear (CBRN) terrorist event is a complex problem. Analysis of possible escape scenarios indicates the range of possible hazard concentrations at and between levels typically identified by emergency responders as the Hot Zone and the Warm Zone. The Hot Zone is ground zero and can be characterized as the hazard levels associated with a likely terrorist event, "Most Credible Event" (MCE). MCE's for chemical warfare agents (CWA's) and toxic industrial materials (TIM's) expected at a terrorist event are determined using the Automated Decision Aid System for Hazardous Incidents (ADASHI) developed by the U.S. Army Soldier and Biological Chemical Command. This model considers several parameters associated with the potential event. These parameters include the means used to transport the CWA or TIM to the scene, the method of dissemination of the hazard, properties of the hazard, the quantity of the CWA or TIM used, the availability of the CWA or TIM, and physical characteristics of the area such as room size and the degree of ventilation present. Using this approach, challenge concentrations for sarin gas, GB, and sulfur mustard, HD were determined to be 2000 mg/m^3 for GB and 300 mg/m^3 for HD. Similar modeling techniques are currently being employed for TIM's that have also been identified as high threat possibilities.

Warm Zone analysis of the CWA's and TIM's are determined by the immediately dangerous to life or health, IDLH, concentrations or equivalent for the identified hazards. For GB and HD, the equivalent warm zone concentrations may be set at Acute Exposure Guideline Levels values at 30 minutes. Also, high concentrations of some Toxic Industrial Chemicals (TICs) will cause displacement of oxygen in the contaminated area, thus resulting in an IDLH condition where the oxygen content falls below 19.5%.

Based on the Hot Zone / Warm Zone GB and HD concentrations, it can be expected that respirator performance requirements for escape from the Hot Zone are different from those requirements for escape from or near Warm Zone concentrations. In addition, the characteristics of the diverse hazards and buildings or site characteristics vary significantly. No two are expected to be identical. Because of this, a wide range of strategies is expected.

Escape only air-purifying respirators designed for specific hazards at levels between the Hot and Warm Zones may be appropriate for specific escape scenarios but do not represent a universal escape respirator solution for protecting all or the majority of workers. Furthermore, requirements for acceptable escape respirator performance for a skyscraper are most likely different than acceptable escape respirator performance from a 3-level building. The threat for a

metropolitan area located near a major industrial complex, a chemical plant or oil refinery is not the same as the threat for metropolitan areas removed from industry.

The concept for escape respirator performance requirements to address the wide range of variables is segmented into three categories: **HIGH, SPECIFIC, and GENERAL**, and the categories are associated with a level of protection as follows:

HIGH: Self-Contained Escape Respirator for high concentrations, multipurpose use, and oxygen deficiency.

SPECIFIC: Air Purifying Escape Respirator for CWA's and TIM's, plus higher concentrations of specific TIC's .

GENERAL: Air Purifying Escape Respirator for CWA's and TIM's.

Part 1 of this concept paper addresses the **SPECIFIC** and **GENERAL** categories for air purifying escape respirators. The **HIGH** category, self-contained escape respirator, is addressed in Part 2 of the concept paper.

2(a) Category vs. Hazard vs. Escape Respirator Type:

Table: Escape Respirator Categories

Category	Hazard Description	Respirator Type
HIGH (Hot & Warm Zones)	CWA & TIM Hazard Threats and/or Oxygen Deficiency	Self Contained Escape Respirator
SPECIFIC (Hot & Warm Zones)	CWA & Multiple Hazard (TIM) Threats + Specific TIC Hazard Threats	Air Purifying Escape Respirator
GENERAL (Warm Zone)	CWA & Multiple Hazard (TIM) Threats	Air Purifying Escape Respirator

2(b) Escape Respirator Multi Gas/Vapor/Particulate Requirements GENERAL Category:

Multi Gas/Vapor/Particulate Escape respirators shall meet the gas/vapor test challenge concentrations as follows:

	Test Challenge	Breakthrough
Ammonia	**1250**	**12.5**
Cyanogen Chloride	**150**	**2**
Cyclohexane	**1300**	**10**
Formaldehyde	**250**	**10**
Hydrogen Cyanide	**470**	**10**[1]
Hydrogen Sulfide	**500**	**30**
Nitrogen Dioxide	**100**	**1 ppm NO2**
Phosgene	**125**	**1.25**
Phosphine	**150**	**0.5**
Sulfur Dioxide	**750**	**5**

(1) Sum of HCN and C2N2

2(c) Escape Respirator Multi Gas/Vapor/Particulate GENERAL Category with Carbon Monoxide Requirements:

Escape respirators intended for use at the GENERAL category with carbon monoxide protection shall meet the requirements of paragraph 2(b) plus carbon monoxide as follows: Test Concentration – 3600 ppm; Breakthrough Concentration – 350 ppm.

2(d) Escape Respirator Multi Gas/Vapor/Particulate SPECIFIC Category:

Escape respirators intended for use at the specific hazard threat category conditions shall meet the gas/vapor/particulate testing at identified conditions of paragraph 2(b) Escape Respirator MultiGas/Vapor Particulate Requirements GENERAL Category.

Additional specific test agent protections can be added to the minimum as specified by the applicant for: Ammonia, Cyclohexane, Cyanogen Chloride, Formaldehyde, Hydrogen Sulfide, Nitrogen Dioxide, Hydrogen Cyanide, Sulfur Dioxide, Phosgene, Phosphine, and Carbon Monoxide.

2(d) 1. Test Concentrations for Additional Agents, SPECIFIC Category:

In addition to the test requirements of paragraph 2(b) Escape Respirator Multi Gas/Vapor/Particulate Requirements (GENERAL) Category, test concentrations for additional specific test agent protections shall be as specified in the following table.

	Test Challenge
Ammonia	**2500**
Cyanogen Chloride	**300**
Cyclohexane	**2600**
Formaldehyde	**500**
Hydrogen Cyanide	**940**
Hydrogen Sulfide	**1000**
Nitrogen Dioxide	**200**
Phosgene	**250**
Phosphine	**300**
Sulfur Dioxide	**1500**
Carbon Monoxide	**6000**

2(d)2 Breakthrough Concentration for SPECIFIC Category: Test breakthrough concentrations for the specific category shall be Breakthrough concentrations identified in Section 2(b)

(3) Respirator Use:

3(a) Escape Only:

Escape respirators are intended to be one time use for escape only from terrorist events.

3(b) Panic Demand:

Each escape respirator shall provide a minimum duration of 5 minutes when tested at a flow rate of 100±10 liters per minute, 50±5 percent relative humidity and 25±5 ^{0}C for each of the gases/vapors identified in Section 2.

3(c) Duration Rating:

Escape respirators will be rated for 15, 30, 45 or 60 minute duration as specified by the manufacturer.

(4) Gas Life Test Requirements:

4(a) Test Duration:

Test duration will be 15, 30, 45 or 60 minutes as specified by the applicant.

4(b) Gas Life:

Gas life tests are performed at room temperature, 25 ± 5^0C; 25 ± 5 percent relative humidity, and 80 ± 5 percent relative humidity. Three filters will be tested at each of the specified humidities with a flow rate of 64 liters per minute, continuous flow. Tests will be conducted to minimum specified service time. Gas testing shall be performed following environmental conditioning and rough handling. Service Life testing is performed to the minimum specified service time. The breakthrough concentration must be no greater than the specified breakthrough for each tested gas. Testing is terminated after the applicant's specified service time is achieved.

4(c) Particulate Filtration:

The filter shall meet the requirements of a P100 particulate filter as described in 42 CFR, Part 84 paragraphs 84.170, 84.179, and 84.181

(5) Environmental Conditioning Requirements:

Environmental conditioning will be performed on escape respirators in the ready-to-use configuration. The ready-to-use configuration is the operational packaging state prior to use such that immediately upon opening allows the user to don the respirator.

Environmental conditioning shall be performed in accordance with the following Table:

Durability Test Matrix: Environmental, Transportation and Drop Tests

Test	Test Method	Test Condition	Duration
Hot Constant	MIL-STD-810F, 501.4	71 ^{0}C (160 ^{0}F), Constant	5 Weeks
Cold Constant	MIL-STD-810F, 502.4	Basic Cold, -32 ^{0}C (-24 ^{0}F), Constant	3 Days
Humidity	MIL-STD-810E, 507.3	Realistic, Natural Cycle Humidity Profiles in the U.S.	5 Days "quick look" Mil-Std-810E Table 507.3-II
Transportation Vibration	MIL-STD-810F, 514.5	U. S. Roadway Vibration, Unrestrained	12 hours/axis, 3 Axes; Total Duration = 36 hours = 12,000 miles
Drop	Adopted from NIOSH, CBRN APR Standard	Height of 3 Feet	1 Drop on each of the 3 Axes per Unit

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5 (a) Test Sequence and Quantity:

Testing of the Escape Respirator shall follow the following table

Test Sequence and Quantity

Test Order	Resistance and Breathing Gas	Human Factors	Service Life, 100 lpm	Service Life Testing, 64 lpm flow	Penetration and Permeation Testing	Efficiency Particulate	LRPL Test
Qty	12	3 - 9	30	60	6 systems [1]	20	30 - 65
1.	Inhalation Resistance	Field of View	Hot Constant	Hot Constant	Hot Constant	Hot Constant	Donning
2.	Exhalation Resistance	Fogging	Cold Constant	Cold Constant	Cold Constant	Cold Constant	LRPL
3.	Breathing Gas	Flammability and Heat Resistance	Humidity	Humidity	Humidity	Humidity	
4.			Transportation/ Vibration	Transportation/ Vibration	Transportation/ Vibration	Transportation/ Vibration	
5.			Drop	Drop	Drop	Drop	
6.			Service Life 100 lpm	Service Life 64lpm	System Testing	Filter Efficiency 84.170 84.179 84.181	

[1] A total six systems tests are performed, 3 GB and 3 HD. Two systems tests, 1 GB and 1 HD, are performed prior to Environmental Conditioning. Four systems tests, 2 GB and 2 HD, are performed after Environmental Conditioning.

(6) Performance Requirements:

Escape respirator performance requirements considered will include the following:

6(a) Chemical Agent Permeation and Penetration Resistance Against Distilled Mustard (HD) Agent Requirement, GENERAL and SPECIFIC Category:

The escape respirator system 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 air flow rate of 40 liters per minute (L/min), 36 respirations per minute, 1.1 liters tidal volume.

Test requirements for distilled mustard (HD) are shown in the following Table:

Table: Simultaneous Liquid and Vapor Challenge of Escape Respirator with Distilled Sulfur Mustard (HD)

Agent	Challenge(1) Concentration	Duration of Challenge (minutes)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough Concentration Integrated Over Minimum Service Life ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Service Life (minutes)
HD-Vapor	50 mg/m^3	15/30/45/60 (1,5)					
HD-Liquid	0.43 to 0.86 ml (2)	15/30/45/60 (1,5)	40	0.60(3)	6.0(4)	3	30/60/ 90/120(6)

(1) Vapor challenge concentration will start immediately after the liquid drops have been applied and the test chamber has been sealed.
(2) Liquid volume applied as 25 drops of equal size..
(3) Three consecutive sequential test data points at or exceeding 0.6 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.
(4) The cumulative Ct including all peak data points must not be exceeded for the duration of the test.
(5) 15, 30, 45 or 60 minutes, equal to the tested duration.
(6) 30, 60, 90 or 120 minutes, twice the tested duration.

6(b) Chemical Agent Permeation and Penetration Resistance Against Sarin Agent (GB) Requirement, GENERAL and SPECIFIC Category:

Table: Vapor Challenge of Escape Respirator with Sarin (GB)

Challenge Agent	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 Service Life ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Service Life (minutes)
GB	210	15/30/45/60 (1,5)	40	0.087(3)	2.1(4)	3	30/60/ 90/120(2,6)

(1) The vapor challenge concentration generation will be initiated immediately after test chamber has been sealed.
(2) The test period begins upon initial generation of vapor concentration.
(3) Three consecutive sequential test data points at or exceeding 0.087 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.
(4) The cumulative Ct including all peak data points must not be exceeded for the duration of the test.

(5) 15, 30, 45 or 60 minutes, equal to the tested duration.
(6) 30, 60, 90 or 120 minutes, twice the tested duration.

6(c) Breathing Resistance:

The resistance of airflow shall be measured at the breathing zone (nosecup or mouthpiece) of a hood mounted on a head form test apparatus operated at a continuous airflow rate of 85 liters per minute. The inhalation resistance shall not exceed 70 mm H_2O and the exhalation resistance shall not exceed 20 mm H_2O.

6(d) Breathing Gas:

During the testing required by this section, the concentration of carbon dioxide in inspired gas in the mouth will be continuously recorded, and the maximum average concentration during the inhalation portion of the breathing cycle shall not exceed the following limits:

Where the service time is	Maximum allowable average concentration of carbon dioxide inspired air percent by volume
Not more that 30 minutes	2.5
1 hour	2.0

The inhaled carbon dioxide concentration shall be as indicated in the above table, and the oxygen concentration shall be greater than 19.5% when tested with human subjects at the following work rates: standing, walking at 2.5 miles per hour, and walking at 3.5 miles per hour. The test shall be performed with two test subjects, one weighing 60 kg or less, and one weighing 80 kg or more. The test shall be performed for the rated duration of the respirator at each work rate.

6(e) Field of View:

The CBRN AP Escape Respirator shall obtain a Visual Field Score (VFS) of 70 or greater when tested in accordance with NIOSH Standard Test Procedure CET-APRS-STP-CBRN-0314. 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 apertometer or equivalent. The VFS score is the average of three fittings of the same respirator on the specified head form.

6(f) Donning:

The time to fully don the respirator from the ready-to-use configuration shall be no greater than 30 seconds. The ready-to-use configuration is the operational packaging state prior to use such that immediately upon opening allows the user to don the respirator.

6(g) Fogging:

The AP Escape Respirator shall demonstrate an average Visual Acuity Score (VAS) of greater or equal to 70 points for all measurements for each individual. The wearer shall not experience undue discomfort because of restrictions to breathing or other physical or chemical changes to the respirator.

The respirator shall be donned by the test subject in an indoor ambient temperature of approximately 72^0F +/- 2 F at 30% RH +/- 5% and then shall enter into a simulated outdoor extreme temperature chamber where the visual acuity tests shall be administered. The APR Escape Respirator shall be tested for fogging in the hot/humid condition of 90 ^{0}F/ 60% RH and the cold condition of 13.1^0F.

6(h) Flammability and Heat Resistance (ONLY applicable to respirators approved for carbon monoxide protection):

GENERAL and SPECIFIC Category Escape Respirator shall be tested for Flammability and Heat Resistance using the test equipment specified in EN 136, Respiratory Protective Devices, Full Face Masks, Requirements, testing, Marking, 1998 Edition. No component of the respirator shall have an afterflame after 5 seconds. No component of the escape respirator shall drip, melt, or develop a visible hole or damaged in any manner that compromises the breathing protection provided by the respirator.

The distance between the outer surface of the escape respirator and the burner shall be adjusted to 250 mm ± 6.4 mm. The pressure reducer shall be adjusted to 2.1 bar ± .05 psi. The temperature of the flame positioned 250 mm ± 6.4 mm above the burner tip shall be 800 ^{0} C ± 50^0 C. The respirator shall be rotated once through the flame at a velocity of 6 ± 0.5 cm/s. Where components of the respirator such as valves, filters, etc. are arranged on the respirator, the test shall be repeated with these components at the appropriate height of 250 mm ± 6.4 mm.

6(i) Laboratory Respirator Protection Level:

The measured laboratory respirator protection level (LRPL) for each air purifying escape respirator shall be 2000, sampled in the breathing zone of the respirator, and 150, sampled outside the breathing zone (under the hood), when the respirator is tested in an atmosphere containing 20-40 mg/m^3 corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers. The LRPL shall be calculated using nine exercises: Normal Breathing; Deep Breathing; Turn Head Side to Side; Move Head Up and Down; Reach for the Floor and Ceiling; On Hands and Knees, Look Side to Side; Facial Grimace; Climb Stairs at Regular Pace; and Normal Breathing.

For each size category (Small, Medium, and Large) each cell corresponding to the anthropometric parameter will be tested. Cells can either be uniquely or simultaneously tested for each size category.

Example: For the 'Large' category, 11 subjects are needed for the 'Face Length and Width' category (cell G). If 10 of these 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 6 of the 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 4 subjects will need to be tested in cell H.

	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 **568-594 mm** Subjects= 10 Trials= 20
Neck Circumference	Cell C **292-332 mm** Subjects= 10 Trials= 20	Cell F **333-373 mm** Subjects= 10 Trials= 20	Cell I **374-413 mm** Subjects= 10 Trials= 20

6 (j) Practical Performance:

The Practical Performance of the escape respirator shall be evaluated as part of 6(i) Laboratory Respirator Protection Level. The Practical Performance of the respirator shall evaluate human interface issues associated with the use of the escape respirator. Factors to be evaluated (if applicable based on the respirator design); are the use of mouth bits and nose clips; Seal of the hood around the respirator wearer's neck; seating of inner masks; position of the hood on the respirator's wearer's head; and the strength to don the respirator.

(7) Design Considerations:

The following design features will be considered:

7(a) Function:

The escape respirator shall provide a barrier from ambient conditions for the wearer's entire head, eyes, and respiratory system. The escape respirator shall not require the use of hands to maintain the respirator position to ensure proper function of the respirator when fully donned.

7(b) Hood Type Device:

The escape respirator shall be designed as a hooded device. The hood shall include an area for field of vision.

7(c) Respiratory Protection System:

The respiratory protection system may consist of an oral/nasal cup or mouthpiece. If a mouthpiece is employed, a method of preventing nasal breathing must be provided.

(8) 42 CFR Applicable Sections:

The following sections of 42 CFR, Part 84 are applicable:

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
Subpart G: General Construction and Performance

42 CFR, Part 84, Subpart K; the following paragraphs apply:

84.170 Non-powered air purifying particulate respirators; description
84.179 Non-powered air purifying particulate respirators; filter identification
84.180 Non-powered air purifying particulate filter efficiency

(9) Service and Maintenance:

The applicant will identify an initial useful life, not to exceed five (5) years, of the escape respirator. The "useful life" is defined as the length of time a unit can remain in service. All applications for certification must specify useful service life with supporting data and rationale. Further, a rationale must be included for any sampling plan set forth in the user's manual which would extend the useful life of the escape respirator beyond any initial useful life.

The following guidelines should be included in the useful service life plans:

a. Service life plans should be based upon reliability engineering methodology and describe the conditions for use for the unit. Each plan will be individually evaluated

b. All respirator service actions are the responsibility of the applicant, or their authorized representative. The user/owner of the respirators should perform basic inspections as described in the instruction manual and/or as required by federal regulations.

c. In order for an escape respirator to receive an incremental service life extension, some service action must be performed on each unit.

d. After the service action has been performed, the applicant, or their authorized representative, should collect a random sample of the serviced units and performance test these respirators to verify that they function as approved. The purpose of post-service sampling and performance testing is to identify unexpected problems caused by uncontrolled or unpredicted factors.

e. The applicant may define "performance testing" by specifying the following: test procedures, pass/fail standards, performance tolerances, sample size, etc.

f. The following timeline exemplifies an acceptable service life plan:

Start	1st Service Date	2nd Service Date	3rd -- etc.	Stop
[----------I	----------I	----------I	----------I	----------I→
1st Service expiration date permanently visible on the unit	After a completed action on each unit stamp 2nd service date or terminal date	After a completed action on each unit stamp 3rd service date or terminal date	After a completed action, etc..	Terminal End of service life

Note: The date on which the unit must be removed from service is to be permanently visible on the unit at the time of manufacture. If an incremental service life is granted, the applicant, or their authorized representative, must stamp the unit with a new date, as described by the time line model. The terminal date represents the final expiration date of the unit with no further extensions.

(10) Training:

The applicant will identify training requirements associated with their equipment. As a minimum, the applicant shall include an instruction manual, which will address donning procedures, system use, maintenance (care and shelf life), and cautions and limitations. The applicant shall also provide for training aid systems to develop user proficiency in operation of the equipment, as well as identification of periodic refresher training requirements to maintain user proficiency.

(11) Cautions and Limitations:

The following Cautions and Limitations statements shall be prominently displayed in the respirator user instructions:

1. Not for use in atmospheres containing less than 19.5 percent oxygen.
2. Failure to properly use and maintain this product could result in injury or death.
3. All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
4. Refer to User's Instructions and/or maintenance manuals for information on use and maintenance of these respirators.
5. Consult manufacturer's User's Instructions for information on the use, storage, and maintenance of these respirators at various temperatures.
6. This respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. This respirator provides limited dermal protection to the head area and eyes.
7. Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.
8. Direct contact with CBRN agents requires proper handling of the respirator after use. Correct disposal procedures must be followed.

These limitations are not all inclusive. The respirator manufacturer may also identify further cautions and limitations for their respirators. In addition, regulatory agencies may also place a limit on the use of respirators in their standards.

(12) Quality Assurance Provisions:

12.1 Quality Control Plan:

Respirators submitted for CBRN approval shall be accompanied by a complete quality control plan meeting the requirements of Subpart E of 42 CFR, Part 84.

12.2 Sampling/Test/Inspection Plan:

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

a). Materials of construction used for respirator parts that form a barrier between the user and ambient air.
b). Integrity of mechanical seals that comprise a barrier between the user and ambient air.
c). Final performance quality control tests on complete canisters demonstrating compliance with the gas life and particulate filter requirements of this standard.

12.3 General Requirements:

In addition to the requirements of 42 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. Chemical Warfare Agent tests (section 6.a and 6.b are excluded from this requirement.

June 30, 2003

Part 2: Concept for CBRN Self-Contained Escape Respirator Standard

(1) General:

The concept for escape respirator performance requirements to address the wide range of variables is segmented into three categories: **HIGH, SPECIFIC,** and **GENERAL**. The categories are associated with a level of protection as follows:

HIGH: Self-Contained Escape Respirator for unknown conditions and oxygen deficiency.

SPECIFIC: Air Purifying Escape Respirator for high concentrations of CWA's and specific TIM's.

GENERAL: Air Purifying Escape Respirator for low concentrations of CWA's and TIM's.

The standard discussed in Part 2 of this concept paper addresses the **HIGH** category for self-contained escape respirators. The **SPECIFIC** and **GENERAL** Categories are discussed in Part 1 of the Escape Respirator Concept.

(2) Requirements for the **HIGH** Category Self-Contained Escape respirator are identified as a three tier set of requirements:

- 42 CFR, Part 84, Subpart H Escape Respirator Approval,
- Enhanced Escape Respirator Performance Requirements,
- CBRN Requirements.

(3) 42 CFR, Part 84, Subpart H Approval:

The **HIGH** Category Escape Respirator must be NIOSH approved as a self-contained escape respirator in accordance with the requirements of 42 CFR, Part 84, Subpart H.

(4) Enhanced Escape Respirator Performance Requirements:

(4.1) Environmental Conditioning:

Environmental conditioning will be performed on escape respirators in the ready-to-use configuration. The ready-to-use configuration is the operational packaging state prior to use such that immediately upon opening allows the user to don the respirator.

Environmental conditioning shall be performed in accordance with the following Table:

Durability Test Matrix: Environmental, Transportation and Drop Tests

Test	Test Method	Test Condition	Duration
Hot Constant	MIL-STD-810F, 501.4	71 ^{0}C (160 ^{0}F), Constant	5 Weeks
Cold Constant	MIL-STD-810F, 502.4	Basic Cold, -32 ^{0}C (-24 ^{0}F), Constant	3 Days
Humidity	MIL-STD-810E, 507.3	Realistic, Natural Cycle Humidity Profiles in the U.S.	5 Days "quick look" Mil-Std-810E Table 507.3-II
Transportation Vibration	MIL-STD-810F, 514.5	U. S. Roadway Vibration, Unrestrained	12 hours/axis, 3 Axes; Total Duration = 36 hours = 12,000 miles
Drop	Adopted from NIOSH, CBRN APR Standard	Height of 3 Feet	1 Drop on each of the 3 Axes per Unit

(4.2) Hood:

The escape respirator shall be designed as a hooded device. The hood shall include an area for field of vision

(4.3) Respiratory Protection System:

The respiratory protection system may consist of an oral/nasal cup or mouthpiece. If a mouthpiece is employed a method of preventing nasal breathing must be provided.

(4.4) Donning Time:

The HIGH Category Escape Respirator shall be fully donned and activated from its stored configuration in less than 30 seconds.

(4.5) Flammability and Heat Resistance:

HIGH Category Escape Respirator shall be tested for Flammability and Heat Resistance using the test equipment specified in EN 136, Respiratory Protective Devices, Full Face Masks, Requirements, testing, Marking, 1998 Edition. No component of the respirator shall have an afterflame after 5 seconds. No component of the escape respirator shall drip, melt, or develop a visible hole or damaged in any manner that compromises the breathing protection provided by the respirator.

The distance between the outer surface of the escape respirator and the burner tips shall be adjusted to 250 mm ± 6.4 mm. The pressure reducer shall be adjusted to 2.1 bar ± .05 psi. The temperature of the flame positioned 250 mm ± 6.4 mm above the burner tip shall be 800 ^{0} C ± 50^0 C. The respirator shall be rotated once through the flame at a velocity of 6 ± 0.5 cm/s. Where components of the respirator such as valves, filters, etc. are arranged on the respirator, the test shall be repeated with these

components at the appropriate height of 250 mm ± 6.4 mm. If compressed oxygen is used in the escape respirator this requirement will be tested using a surrogate oxygen pressure vessel.

(4.6) Field of View:

The CBRN Self Contained Escape Respirator shall obtain a Visual Field Score (VFS) of 70 or greater when tested in accordance with NIOSH Standard Test Procedure CET-APRS-STP-CBRN-0314. 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 apertometer or equivalent. The VFS score is the average of three fittings of the same respirator on the specified head form.

(4.7) Fogging:

The CBRN Self Contained Escape Respirator shall demonstrate an average Visual Acuity Score (VAS) of greater or equal to 70 points for all measurements for each individual. The wearer shall not experience undue discomfort because of restrictions to breathing or other physical or chemical changes to the respirator.

The respirator shall be donned by the test subject in an indoor ambient temperature of approximately 72^0F +/- 2 F at 30% RH +/- 5% and then shall enter into a simulated outdoor extreme temperature chamber where the visual acuity tests shall be administered. The APR Escape Respirator shall be tested for fogging in the hot/humid condition of 90 ^{0}F/ 60% RH and the cold condition of 13.1^0F.

(4.8) Breathing Gas Concentrations:

During the testing required by this section, the concentration of carbon dioxide in inspired gas in the mouth will be continuously recorded, and the maximum average concentration during the inhalation portion of the breathing cycle shall not exceed the following limits:

Where the service time is	Maximum allowable average concentration of carbon dioxide inspired air percent by volume
Not more that 30 minutes	2.5
1 hour	2.0

The inhaled carbon dioxide concentration shall be as indicated in the above table, and the oxygen concentration shall be greater than 19.5% when tested with human subjects at the following work rates: standing, walking at 2.5 miles per hour, and walking at 3.5 miles per hour. The test shall

be performed with two test subjects, one weighing 60 kg or less, and one weighing 80 kg or more. The test shall be performed for the rated duration of the respirator at each work rate.

(4.9) Test Sequence and Quantity:

Testing of the Self Contained Escape Respirator shall follow the following table

Test Sequence and Quantity

Test Order	Breathing Gas	Human Factors	Penetration and Permeation Testing	LRPL Test
Qty	12	5 - 11	6 systems [1]	30 - 65
1.	Breathing Gas	Fogging	Hot Constant	Donning
2.		Field of View	Cold Constant	LRPL
3.		Flammability and Heat Resistance	Humidity	
4.			Transportation/ Vibration	
5.			Drop	
6.			System Testing	

[1] A total six systems tests are performed, 3 GB and 3 HD. Two systems tests, 1 GB and 1 HD, are performed prior to Environmental Conditioning. Four systems tests, 2 GB and 2 HD, are performed after Environmental Conditioning.

(5.0) CBRN Requirements:

(5.1) Laboratory Respiratory Protection Level (LRPL):

The measured laboratory respirator protection level (LRPL) for each air purifying escape respirator shall be 2000, sampled in the breathing zone of the respirator, and 150, sampled outside the breathing zone (under the hood), when the respirator is tested in an atmosphere containing 20-40 mg/m^3 corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers. The LRPL shall be calculated using nine exercises: Normal Breathing; Deep Breathing; Turn Head Side to Side; Move Head Up and Down; Reach for the Floor and Ceiling; On Hands and Knees, Look Side to Side; Facial Grimace; Climb Stairs at Regular Pace; and Normal Breathing.

For each size category (Small, Medium, and Large) each cell corresponding to the anthropometric parameter will be tested. Cells can either be uniquely or simultaneously tested for each size category.

Example: For the 'Large' category, 11 subjects are needed for the 'Face Length and Width' category (cell G). If 10 of these 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 6 of the 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 4 subjects will need to be tested in cell H.

	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 **568-594 mm** Subjects= 10 Trials= 20
Neck Circumference	Cell C **292-332 mm** Subjects= 10 Trials= 20	Cell F **333-373 mm** Subjects= 10 Trials= 20	Cell I **374-413 mm** Subjects= 10 Trials= 20

5.2) Live Agent Test:

(1). Chemical Agent Permeation and Penetration Resistance Against Distilled Mustard (HD) and Sarin (GB) Agent Test Requirement

Self Container Escape Respirators, 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 an automated breathing machine operating at an air flow rate of 19.5 liters per minute (L/min), 1.3 liters tidal volume.

Test requirements for distilled sulfur mustard (HD) are shown in Table 1.

Table 1: Simultaneous Liquid and Vapor Challenge of Self Contained Escape Respirator 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 Service Life) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Service Life (min)
HD-Vapor	300 mg/m^3	Stated duration (1,5)	40	0.60 (3)	6.0 (4)	3	Stated duration (2)
HD-Liquid	0.43 to 0.86 ml	Stated duration (5)					

(1) Vapor challenge concentration will start immediately after the liquid drops have been applied and the test chamber has been sealed.

(2) The test period begins upon start of initial vapor generation.

(3) Three consecutive sequential test data points at or exceeding 0.6 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.

(4) The cumulative Ct including all peak data points must not be exceeded for the duration of the 6-hour test.

(5) For a duration period equal to the stated duration life.

Test requirements for sarin (GB) agent are shown in Table 2.

Table 2: Vapor Challenge of Self Contained Escape Respirator with Sarin (GB)

Challenge Agent	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 Service Life) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Service Life (min)
GB	(6)Total CT of 10,000mg-m^3	Stated duration (1,5)	40	0.087 (3)	2.1 (4)	3	Stated duration (2)

(1) The vapor challenge concentration generation will be initiated immediately after test chamber has been sealed.

(2) The test period begins upon initial generation of vapor concentration.

(3) Three consecutive sequential test data points at or exceeding 0.087 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.

(4) The cumulative Ct including all peak data points must not be exceeded for the duration of the 6-hour test.

(5) For a duration period equal to the stated duration life.

(6) Exposure will include at least two minutes at a concentration of 2000 mg-m^3

5.3 Practical Performance:

The Practical Performance of the escape respirator shall be evaluated as part of 5.1 Laboratory Respirator Protection Level. The Practical Performance of the respirator shall evaluate human interface issues associated with the use of the escape respirator. Factors to be evaluated (if applicable based on the respirator design); are the use of mouth bits and nose clips; Seal of the hood around the respirator wearer's neck; seating of inner masks; position of the hood on the respirator's wearer's head; and the strength to don the respirator.

(6) Service and Maintenance:

The applicant will identify a useful life, not to exceed five (5) years, of the escape respirator. The "useful life" is defined as the length of time a unit can remain in service. All applications for certification must specify useful service life with supporting data and rationale. Further, a rationale must be included for any sampling plan set forth in the user's manual which would extend the useful life of the escape respirator beyond any initial useful life.

The following guidelines should be included in the useful service life plans:

a. Service life plans should be based upon reliability engineering methodology and describe the conditions for use for the unit. Each plan will be individually evaluated

b. All respirator service actions are the responsibility of the applicant, or their authorized representative. The user/owner of the respirators should perform basic inspections as described in the instruction manual and/or as required by federal regulations.

c. In order for an escape respirator to receive an incremental service life extension, some service action must be performed on each unit.

d. After the service action has been performed, the applicant, or their authorized representative, should collect a random sample of the serviced units and performance test these respirators to verify that they function as approved. The purpose of post-service sampling and performance testing is to identify unexpected problems caused by uncontrolled or unpredicted factors.

e. The applicant may define "performance testing" by specifying the following: test procedures, pass/fail standards, performance tolerances, sample size, etc.

f. The following timeline exemplifies an acceptable service life plan:

Start	1st Service Date	2nd Service Date	3rd -- etc.	Stop
[----------I	----------I	----------I	----------I	----------I→
1st Service expiration date permanently visible on the unit	After a completed action on each unit stamp 2nd service date or terminal date	After a completed action on each unit stamp 3rd service date or terminal date	After a completed action, etc..	Terminal End of service life

Note: The date on which the unit must be removed from service is to be permanently visible on the unit at the time of manufacture. If an incremental service life is granted, the applicant, or their authorized representative, must stamp the unit with a new date, as described by the time line model. The terminal date represents the final expiration date of the unit with no further extensions.

(7) Training:

The applicant will identify training requirements associated with their equipment. As a minimum, the applicant shall include an instruction manual, which will address donning procedures, system use, maintenance (care and shelf life), and cautions and limitations. The applicant shall also provide for training aid systems to develop user proficiency in operation of the equipment, as well as identification of periodic refresher training requirements to maintain user proficiency.

(8) Cautions and Limitations:

The following Cautions and Limitations statements shall be prominently displayed in the respirator user instructions:

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

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

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

4. Consult manufacturer's User's Instructions for information on the use, storage, and maintenance of these respirators at various temperatures.

5. This respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. This respirator provides limited dermal protection to the head area and eyes

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

7. Direct contact with CBRN agents requires proper handling of the respirator after use. Correct disposal procedures must be followed.

These limitations are not all inclusive. The respirator manufacturer may also identify further cautions and limitations for their respirators. In addition, regulatory agencies may also place a limit on the use of respirators in their standards.

(9) Quality Assurance Provisions:

9.1 Quality Control Plan:

Respirators submitted for CBRN approval shall be accompanied by a complete quality control plan meeting the requirements of Subpart E of 42 CFR,
Part 84.

9.2 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.

9.3 General Requirements:

In addition to the requirements of 42 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. Systems Tests are excluded from this requirement.