Concept for CBRN Full Facepiece Air Purifying Respirator Standard

(1) Goal:

Develop a NIOSH, NPPTL, tight fitting, full facepiece, air purifying respirator standard that addresses CBRN materials identified as inhalation hazards and/or possible terrorist hazards using a minimum number of filters for emergency responders.

Target:

	Short Duration	**Long Duration**
Toxic Industrial Materials	**15 minutes***	**60 minutes***

*See paragraph (4)(4)(2) Service Life.

(2) Hazards:

NIOSH has been evaluating various lists of chemicals that could be deployed as a result of a terrorist incident. In an effort to reduce the number of certification tests necessary as part of a Chemical Biological Radiological Nuclear (CBRN) Air-Purifying Respirator (APR) standard, efforts have been underway to categorize potential respiratory hazards into families with a representative test agents identified for each family. The following information is a synopsis of this effort to date.

The current carbon technology used in canisters and cartridges were reviewed from existing certification standards. The current standards for gas masks in Europe and the U.S. (NIOSH) were reviewed. The military purchasing specification for ASZM-T carbon for C2A1 military canisters was also reviewed. The most common parameters identified from the review of the military specification and the certification standards were the middle range certification challenges. Some of the test chemicals were considered to be redundant, since other test chemicals would guarantee the carbon effectiveness against the chemicals in question (Chlorine, Hydrogen Chloride, Hydrogen Fluoride, Arsine, CS & CN Tear Gases). Cyclohexane is the representative chemical for organic vapors. Meeting the organic vapor test for a cartridge will provide protection for all organic vapors having vapor pressures less than that of cyclohexane. From the CWA /TIC list, approximately 61 organic chemicals are cover by this logic, including GB and HD. The acid gases (32 chemicals) are covered by cyanogen chloride, hydrogen cyanide, hydrogen sulfide, and sulfur dioxide. Ammonia represents the base gases, and covers another 4 chemicals on the list. Formaldehyde, phosgene, phosphine and nitrogen dioxide are considered special case chemicals. Phosphine is a hydride and must be removed catalytically (copper^{+2} and

silver impregnates on carbon). Therefore, 108 of the 151 respiratory inhalation hazards can be addressed through testing these 10 chemicals. Nine of the test chemicals are listed in ITF 25.

Particulate Biological Agents and Particulate Radiological/Nuclear Agents have also been considered as part of the development of test representative agents. Thirteen biological agents are addressed as part of the standard. They include Anthrax, Brucellosis, Glanders, Pneumonic Plague, Tularemia, Q Fever, Smallpox, Venezuelan Equine Encephalitis, Viral Hemorrhagic Fevers, T-2 Mycotoxins, Botulism, Ricin, and Staphylococcus Enterotoxin B. Sixteen radiological/nuclear agents addressed as part of the standard include Hydrogen 3, Carbon 14, Phosphorous 32, Cobalt 60, Nickel 63, Strontium 90, Technetium 99m, Iodine 131, Cesium 137, Promethium 147, Thallium 204, Radium 226, Thorium 232, Uranium 235 & 238, Plutonium 239, Americium 241. Three additional chemicals, adamsite, sodium azide, and sodium fluoroacetate, are addressed as part of the standard through particulate testing.

Chemicals		**Organization Using as Test Agent**
Ammonia		**NIOSH & EN**
Cyclohexane		**Organic Vapor- EN**
Cyanogen Chloride		**Military**
Formaldehyde		**NIOSH**
Hydrogen Cyanide		**NIOSH, EN & Military**
Hydrogen Sulfide		**NIOSH & EN**
Nitrogen Dioxide		**NIOSH & EN**
Phosgene		**Military**
Sulfur Dioxide		**NIOSH & EN**
Phosphine		**NIOSH**

(3) Respirator Use:

A. Warm Use: Less than IDLH concentrations, to REL; sustained warm zone support operations; long term use for decon, traffic control, rehabilitation, rescue and recovery; agent known & quantified.

B. Crisis Provision: Contingency use for short duration, above IDLH concentrations and high physiological (flow) demand possible; Contingency for unforeseen factors such as secondary device or pockets of entrapped hazard.

Filter	Configuration	Long Duration Less Than IDLH	Crisis Panic Demand	Short Duration Less Than IDLH
Filter #1, TIMs	Full Facepiece (Mask); Back or Chest Mounted	60 Minutes(Min)	5 Minutes	
Filter #2, TIMs	Full Facepiece Mask Mounted		5 Minutes	45 Minutes(Max)

C. The CBRN APR filter is a single use filter. After one use the filter is to be discarded.

D. CBRN respirators contaminated with liquid chemical warfare agents are to be disposed of after use.

	Warm Zone	Crisis(1)
	Non IDLH (2)	Greater than IDLH (2)
64 lpm flow	X	
high flow 100 lpm		X
Environmentally challenged	X	X

(1) Crisis is a high use concentration at a high flow rate, 100 liters, per minute.

(2) Same test concentrations, different flow rates

4.0 Concept for Requirements: Draft For Discussion

4.1 Purpose:

The purpose is to identify minimum requirements to determine the effectiveness of full facepiece air purifying respirators (APR) used during entry into chemical, biological, radiological, and nuclear (CBRN) atmospheres not immediately dangerous to life or health. The respirator must meet the minimum requirements identified in the following sections:

- Section 4.2, Requirements Specified in Title 42 Code of Federal Regulations (CFR), Part 84 applicable sections,
- Section 4.3, Requirements based on existing national and international standards,
- Section 4.4, Special requirements for CBRN use.

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

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

4.2.1 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
Subpart G: General Construction and Performance

4.2.2 42 CFR, Part 84 Subpart I; the following paragraphs apply:

84.110 Gas Masks; description, paragraphs a(1), a(2), and (b)
84.111 Gas masks; required components
84.112 Canisters and cartridges in parallel; resistance requirements
84.113 Canisters and cartridges; color and markings; requirements
84.114 Filters used with canisters and cartridges; location; replacement
84.115 Breathing tubes; minimum requirements
84.116 Harnesses; installation and construction; minimum requirements
84.117 Gas mask containers; minimum requirements
84.118 Half-mask facepieces, full facepieces, and mouthpieces; fit; minimum requirements, paragraphs a(1), a(2), (b), and (e)
84.119 Facepieces; eyepieces; minimum requirements
84.120 Inhalation and exhalation valves; minimum requirements
84.121 Head harnesses; minimum requirements

84.123 Exhalation valve leakage test Discussion

4.2.3 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
84.181 Non-powered air purifying particulate filter efficiency

4.3 Requirements based on existing national and international standards:

4.3.1 Mechanical Connector:

The interface between the filter and the facepiece or respirator system shall use a standard thread in accordance with EN 148-1: 1999, Respirator Protective Devices - Threads for facepieces - Part 1: Standard Thread Connection. The filter shall be readily replaceable without use of special tools. A single interface connector thread shall be located on the facepiece. The interface connector on the facepiece shall be the female thread and gasket-sealing gland as identified in EN148.1. The filter shall use a male thread in accordance with EN148.1. For respirators where the filter canister is not directly attached to the facepiece, (i.e., not mask mounted) a female thread and gasket sealing gland connector complying with EN 148.1 must be securely attached to a harness system to provide strain relief between the filter and the remaining respirator system.

4.3.2 Gasket, Mechanical Connector:
The dimensions for the interface connector gasket shall be: outside diameter 37.5 mm minimum, inside diameter 28.5 mm maximum, thickness 2.0 + 0.5/ - 0 mm. The gasket material shall be ethylene propylene diene monomer, EPDM, with a hardness of 65 ±10 shore A durometer at room temperature.

4.3.3 Breathing Resistance, Facepiece:

In addition to the resistance to airflow determined by paragraph 3.5, the facepiece resistance to inhalation airflow without the filter canister shall be less than or equal to 10 mm water column when tested at 85 liters per minute continuous air flow.

4.3.4 Dimensions and Weight, Mask Mounted (Chin Style) Filter:

The maximum weight of a mask mounted (chin style) filter shall be 500 grams. The maximum size of a mask mounted (chin style) filter shall be such that the filter shall pass through a 5-inch diameter opening with the threaded connector perpendicular to the 5-inch diameter opening.

4.3.5 Breathing Resistance:

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

	Chin Style	Non Facepiece Mounted
Inhalation:		
Initial	65 mm H_2O	70 mm H_2O
Final [(1)]	80 mm H_2O	85 mm H_2O
Exhalation:	20 mm H_2O	20 mm H_2O

[(1)] Measured at end of service life

4.3.6 Field of View:

The full facepiece shall be designed so that the effective field of vision shall be not less than 70% related to the natural field of vision, and the overlapped field of vision related to the natural overlapped field of vision, shall not be less than 20%.

The applicant shall provide test data demonstrating compliance with the Field of View requirement when tested in accordance with EN 136: 1998, Respiratory Protective Devices-Full facemasks-Requirements, testing, marking, paragraph 8.17 Field of Vision.

4.3.7 Haze (Lens Abrasion):

Specimen CBRN APR facepiece lenses shall be tested for abrasion resistance and the average value of the tested specimens shall not exhibit a delta haze greater than 14%.

The applicant shall provide test data demonstrating compliance with the Haze requirement when tested in accordance with NFPA 1981 Standard on Open-Circuit Self-Contained Breathing Apparatus for Fire and Emergency Services, 2002 edition, section 8.9, Facepiece Lens Abrasion Test.

4.3.8 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. 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 $\pm$ 5 ^{o}C. A concentration of 5 percent carbon dioxide in air will be exhaled into the facepiece. The minimum allowable oxygen concentration shall be 19.5 percent.

4.3.9 Hydration:

For CBRN APR respirators equipped with a hydration facility, the CBRN APR respirator shall meet all requirements of the CBRN APR standard with the hydration facility in place. In addition, dry drinking tube valves, valve seats, or seals will be subjected to a suction of 75mm water column height while in a normal operating position. Leakage between the valve and the valve seat shall not exceed 30 milliliters per minute.

4.3.10 Tolerance Analysis:

The applicant shall provide a tolerance analysis of the mechanical connector, filter thread and gasket identified in sections 4.3.1 Mechanical Connector and 4.3.2 Gasket, Mechanical Connector demonstrating the applicant's filter design will contact and seal on the gasket surface area defined by the 37.5 mm minimum outside diameter and the 28.5 maximum inside diameter under all tolerance conditions.

4.3.11 Practical Performance:

A modified laboratory protection level test (LRPL) shall be performed using masks fitted with a filter weighted to 500 grams and sized to the maximum permissible dimensions of Section 3.4 Dimensions and Weight, Mask Mounted (Chin Style) Filter. A minimum of eight masks shall be tested to full-fill the small, medium and large designations of facial size, 2 small. 4 medium and 2 large. The measured laboratory respiratory protection level (LRPL) for each full facepiece, air purifying respirator shall be 2000, when the APR facepiece is tested in a negative pressure mode 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.

During the test the respirator shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:

a). Vision, i.e. restrictions vision field and distortion,
b). Security of fastenings and couplings,
c). Harness donning and removal, adjustability, security and comfort,
d). Any other comment reported by the wearer on request.

4.4 Special CBRN Requirements:

4.4.1 Filter Canister Test Challenge, Breakthrough Concentrations, and Filter Efficiency:

The gas/vapor test challenges and breakthrough concentrations shown in Table 1: Filter Canister Challenge, Breakthrough concentrations, and Filter Efficiency shall be used to establish the filter service life:

Table 1: Filter Canister Test Challenge, Breakthrough Concentrations, and Efficiency

	Test Concentration (ppm) Draft	**Breakthrough Concentration (ppm) Draft**
Ammonia	2500	12.5
Cyanogen Chloride	300	2
Cyclohexane	3900	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

* 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.
** Sum of HCN and C_2N_2

4.4.2 Service Life:

The applicant shall identify as part of the application for certification a specified rating period for the filter. Short Duration filter applications shall be identified in 15-minute intervals (15 minutes, 30 minutes, 45 minutes). Long Duration filter applications shall be identified in 30-minute intervals (60 minutes, 90 minutes, 120 minutes). Gas life tests are performed at room temperature, 25 ±5 ºC; 25 ±5 percent relative humidity, and 80 ± 5 percent relative humidity. Three filters will be tested at each specified humidity with a flow rate of 64 liters per minute, continuous flow. Tests will be conducted to the 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 minimum specified service time is achieved

4.4.3 Particulate / Aerosol Filter:

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. In addition to the 20 filters required by 42 CFR, Part 84, paragraph 84.181, six (6) additional filters shall be environmentally conditioned as specified in section 4.4.9 Environmental Conditioning, tested for cyclohexane service life as specified in section 4.4.2 Service Life and tested for filter efficiency as specified in 42 CFR, Part 84, paragraph 84.181 as illustrated in section 4.10 Test Sequence.

4.4.4 Service Life Testing, High Flow:

Each filter shall provide a minimum service life of 5 minutes when tested at a flow rate of 100±10 liters per minute, 50±5 percent relative humidity and 25 ±5 ºC for each of the gases/vapors identified in section 4.4.1 Filter Canister Test Challenge, Breakthrough Concentrations, and Filter Efficiency.

4.4.5 Fogging:

Two persons with a visual acuity of 20/70 or better will perform the tests described in paragraphs (a) and (b) of this section. The respirator shall meet the requirements of paragraph (c) of this section.

(a). The respirator shall be cold soaked in an environmental chamber at minus 21ºC (- 6ºF) for 4 hours.

At the start of each cold temperature wear trial a test participant shall enter the test chamber (maintained at -21ºC) and sit quietly for five minutes. Once the five minute rest period transpires, subjects shall self-don their assigned respirator.

A visual acuity test shall then be administered to quantify the impact of any lens fogging on vision.
The test participant shall then complete a 12-minute work-rest-work regimen comprised of five minutes of exercise, 2 minutes of rest, and an additional five minutes of exercise with the exercise periods consisting of treadmill walking at 4.8 km/hr (3 mph) on a level grade.

Visual acuity tests shall be repeated at the end of each walk period (i.e., after five minutes of walking and at the end of the 12 minute period immediately following the treadmill walk).

(b). The respirator shall be conditioned in an environmental chamber at 15.5ºC (60ºF), 75% RH for 4 hours.

At the start of each cool/humid temperature wear trial a test participant shall enter the test chamber (maintained at 15.5 C) and sit quietly for five minutes. Once the five minute rest period transpires, subjects shall self-don their assigned respirator.

A visual acuity test shall then be administered to quantify the impact of any lens fogging on vision.

The test participant shall then complete a 12-minute work-rest-work regimen comprised of five minutes of exercise, 2 minutes of rest, and an additional five minutes of exercise with the exercise periods consisting of treadmill walking at 4.8 km/hr (3 mph) on a level grade.

(c). Visual acuity tests shall be repeated at the end of each walk period.

(c) 1. The respirator shall function satisfactory for both tests. The wearer shall not experience undue discomfort because of restrictions to breathing or other physical or chemical changes to the respirator.

(c) 2. Visual acuity scores obtained during each environmental test with the respirator shall be divided by a subject's visual acuity score obtained with the mask prior to testing to calculate a performance rating using the following equation:

$$\text{Performance Rating (\%)} = VA_{CHAMBEREX} / VA_{INITIAL} \text{ X } 100 \quad (1)$$

where $VA_{chamber\ x}$ = visual acuity score during chamber test at time x and VA_{intial} = visual acuity score obtained with the mask prior to testing.
Visual acuity performance ratings calculated from measurements taken post-donning

and at the end of each treadmill walk shall be averaged for each individual subject to obtain an average visual acuity performance rating for each subject based on the environmental condition.
Average *performance rating* for each test participant shall be greater than or equal to 70% for both tests.

(d). The wearer shall not experience undue discomfort because of restrictions to breathing or other physical or chemical changes to the respirator.

4.4.6 Communications:

The respirator shall be tested for speech intelligibility/communications using a panel of five speakers and three listeners in accordance with paragraphs a) and b) of this section. The respirator shall meet the requirements of paragraph c) of this section.

a). Speech intelligibility/communications testing shall be performed through the use of the Modified Rhyme Test (MRT), to evaluate a listener's ability to comprehend single words from a speaker wearing the respirator and provides an indication of speech transmission of the selected words. The MRT consists of multiple lists of 50 monosyllabic, phonetically balanced words.

Three test listeners (two males and one female) comprise the subject test panel. All participants shall be tested for "normal" hearing prior to testing by a qualified individual.

Five test subjects (four males and one female) without obvious speech defects or strong regional accents serve as MRT speakers.

All test subjects shall be trained in the donning and usage of the respirator per manufacturer's instructions and all shall pass a qualitative facepiece-to-face fit check according to the manufacturer's instructions.

b). The three test listeners shall be seated opposite a single test speaker for each MRT trial at a distance of 2 meters (6 ft). The listeners and speaker shall be facing one another. Each listener shall be given a multiple choice answer sheet or positioned before a computer and monitor that will be used to input responses.

Data for the MRT will be collected with a steady background noise of 60 dBA consisting of a broadband "pink" noise. A Brüel and Kjaer Type 1405 Noise Generator or equivalent will be used to produce the background noise. Background noise levels will be monitored at a position near the listening panel using a Type 2 digital sound level meter and recorded at the beginning, middle, and end of each MRT session

Speakers will be instructed and trained to maintain a constant output volume at 75 dBA to 85

dBA for all presented words. A Type 2 digital sound level meter will be positioned in front of the speaker within his or her sight to provide feedback concerning the loudness of their voice during testing. Speaker output levels will be recorded at the beginning, middle, and end of each MRT session for verification.

The test speaker shall present each stimulus word using the carrier phrase "The word is _____." Listeners will select the word that was perceived to be spoken from a list of six response words. Listeners shall then provide a visual signal such as a hand gesture to the speaker to cue the speaker to say the next word. Each speaker will present a total of 50 stimulus words to complete one MRT trial. A different speaker shall then be used to present the next MRT trial. Speakers will continue to rotate among the speaker test panel until all trials have been complete. Data will be obtained without the respirator and with the respirator worn and operated per the manufacturer's instructions by both speakers and listeners. All conditions shall be randomly assigned and a different word list shall be used for each test. A sample test matrix is provided in Table 2: Sample MRT Test Matrix.

Table 2: Sample MRT Test Matrix

Speaker	Speaker Condition	Listener Condition	Word List
1	No Mask	No Mask	1
2	No Mask	No Mask	3
3	Masked	Masked	5
4	Masked	Masked	7
5	No Mask	No Mask	9
2	Masked	Masked	2
4	No Mask	No Mask	4
1	Masked	Masked	6
5	Masked	Masked	8
3	No Mask	No Mask	10

A total of 10 MRT trials shall be performed with a total of 15 MRT scores (five per listener) for the unworn mask condition and 15 scores for the worn condition.

c). Listener performance on the MRT shall be scored in terms of the percentage of words correctly identified using the equation: %correct = (number correct - (number incorrect/5)) * 2

The calculation accounts for chance or guessing made possible by the multiple-choice form of the answer sheet (*Human Engineering Guide to Equipment Design,* American Institutes for Research, Washington, DC, 1972).

Individual listeners' scores for the unworn and worn respirator conditions shall be averaged for each condition. Each individual listener's average score with respirator shall be divided by their average unmasked MRT score to calculate a performance rating as follows:

$$\text{Performance rating (\%)} = \left\{(\text{MRT \%correct with respirator}) \div (\text{MRT \%correct without respirator})\right\} * 100$$

Since listening subjects serve as their own controls, the performance rating allows the effect of the respirator condition to be isolated from the effect of the individual. The speech intelligibility/communications requirement is met if the overall average performance rating is greater than or equal to 70% where the overall average performance is calculated as:

$$\text{Overall Average Performance} = \left\{(\text{Performance Rating})_{L1} + (\text{Performance Rating})_{L2} + (\text{Performance Rating})_{L3}\right\} \div 3$$

4.4.7 Chemical Agent Permeation and Penetration Resistance Against Distilled 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 air flow rate of 40 liters per minute (L/min), 36 respirations per minute, 1.1 liters tidal volume.

Test requirements for distilled sulfur mustard (HD) are shown in Table 3: Simultaneous Liquid and Vapor Challenge of APR with Distilled Sulfur Mustard (HD)

Table 3: Simultaneous Liquid and Vapor Challenge of APR with Distilled Sulfur Mustard (HD)

Agent	Challenge[1] Concentration	Duration of Chal-lenge (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 (hours)
HD-Vapor	300 mg/m^3	30					
HD-Liquid	0.43 to 0.86 ml[2]	720	40	0.30 [3]	3.0 [4]	3	12

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

[2] Liquid volume dependent on accessories used with the respirator. Minimum volume is 0 .43 ml based on
mask and single mask mounted filter/canister

[3] 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 2 minutes.

[4] The cumulative Ct including all peak data points must not be exceeded for the duration of the test.

Test requirements for Sarin (GB) agent are shown in Table 4: Vapor Challenge of APR with Sarin (GB).

Table 4: Vapor Challenge of APR 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 (hours)
GB	210	30 [(1)]	40	0.044 [(3)]	0.75 [(4)]	3	12 [(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 0.044 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.

4.4.8 Laboratory Respiratory Protection Level (LRPL) Test Requirement:

The measured laboratory respiratory protection level (LRPL) for each full facepiece, air purifying respirator shall be 2000, when the APR facepiece is tested in a negative pressure mode 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.

4.4.9 Environmental Conditioning (transportability, temperature range, survivability):

Environmental conditioning shall be performed in accordance with the Table 5: Environmental Conditioning requirements as indicated in Section 4.4.10, Test Sequence.

Table 5: Environmental Conditioning

Test	**Test Method**	**Test Condition**	**Duration**
Hot Diurnal	Mil-Std-810F, 501.4	71 ^{0}C max, cyclical	3 Weeks
Cold Constant	Mil-Std-810F, 502.4	Basic Cold, -32 ^{0}C	3 Days
Humidity	Mil-Std-810E, 507.3	Table 507.3-II, Natural Cycle, Cycle 1	5 Days, Quick Look
Vibration	Mil-Std-810F, 514.5	US Highway Vibration, Unrestrained Figure 514.5C-1	12 Hours / Axis,3 Axis 36 Hours Total (12,000 miles)
Drop	3 foot drop onto bare concrete surface	Filter Only, In package 3 Axis	N/A

4.4.10 Test Sequence:

Testing of the CBRN APR system and filters shall follow Table 6: Test Sequence.

Table 6: Test Sequence.

Test Order	42 CFR Testing	Human Factors Tests, Certified Data & Analysis	Service Life 100 lpm	Service Life Testing, 64 lpm flow	Particulate Filter Degredation	Penetration and Permeation Testing	Efficiency Particulate Filter	LRPL Test
	3 APR systems	APR Systems (12 APR systems per test)	30 canister units	60 canister units	6 canister Units	6 APR systems (3 - GB and 3 - HD)	20 canisters	25 to 29 systems
1.	Canister in Parallel Resistance 84.112	Communications Sect. 4.4.6	Hot Diurnal Sect. 4.4.9	Hot Diurnal Sect. 4.4.9	Hot Diurnal Sect. 4.4.9	Hot Diurnal Sect. 4.4.9	Filter Efficiency 84.181	LRPL Sect. 4.4.8
2.	Breathing Tube, 84.115	Fogging Sect. 4.4.5	Cold Constant Sect. 4.4.9	Cold Constant Sect. 4.4.9	Cold Constant Sect. 4.4.9	Cold Constant Sect. 4.4.9	Cold Constant Sect. 4.4.9	Pract. Perf. Test Sect. 4.3.11
3.	Facepieces; eyepieces minimum requirement 84.119	Facepiece Resistance Sect. 4.3.3	Humidity Sect. 4.4.9	Humidity Sect.4. 4.9	Humidity Sect. 4.4.9	Humidity Sect. 4.4.9	Humidity Sect. 4.4.9	
4.	Exhalation valve leakage test, 84.123	Field of View Sect.4.3.6	Transpor-tation/ vibration Sect. 4.4.9	Transpor-tation/ vibration Sect. 4.4.9	Transpor-tation/ vibration Sect. 4.4.9	Transpor-tation/ vibration Sect. 4.4.9	Transpor-tation/ vibration Sect. 4.4.9	
5.	Determine CO_2 levels Sect. 4.3.8	Haze Sect. 4.3.7	Drop Sect. 4.4.9	Drop Sect. 4.4.9	Drop Sect. 4.4.9	System testing Sect. 4.4.7	System testing Sect. 4.4.7	
6.	Hydration Sect. 4.3.9	Tolerance Analysis Sect. 4.3.10	Service Life, 100 Lpm Sect. 4.4.4	Initial breathing resistance, Sect. 4.3.5	Initial breathing resistance, Sect. 4.3.5		Filter Efficiency 84.181	
7.				Service Life Testing, 64 LPM Sect. 4.4.2	Service Life Cyclohexane Sect. 4.4.2			
8.				Final breathing resistance, Sect. 4.3.5	DOP Testing, 84.181			
9.					Final breathing resistance, Sect. 4.3.5			

5.0 Quality Assurance Requirements:

5.1 Quality Control Plan:

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

5.2 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.
d. Conformance with mechanical dimensions of respirator to filter connecting thread.
e. Conformance with mechanical dimensions of respirator to filter sealing gland including length of threads, gasket seating dimensions and configuration.
f. Conformance with material, dimensional and hardness requirements of the respirator to filter gasket.

6.0 CBRN APR Cautions and Limitations for Use:

The following Caution and Limitation statements shall be prominently displayed in the respirator operation manual:

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

Not for use in atmospheres immediately dangerous to life or health.

Do not exceed maximum use concentrations established by regulatory standards.

When used at maximum use concentrations the rated service time can not be exceeded. Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.

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

Follow the manufacturer's User's Instructions for changing cartridges, canisters and/or filters.

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

Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the applicable regulations.

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

This respirator has been tested for operation at minus 21^0 C (-6^0 F). For use at low temperatures consult manufacturer's User's Instructions.

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

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

Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard.

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

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

The respirator should not be used beyond 12 hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation.