November 4, 2005

Concept Standard for Chemical, Biological, Radiological, and Nuclear (CBRN), Full Facepiece, Closed-Circuit, Self-Contained Breathing Apparatus (SCBA)

1.0 Purpose

The purpose of this standard is to specify minimum requirements to determine the effectiveness of a full facepiece, closed-circuit, self-contained breathing apparatus (CC-SCBA) used for entry into chemical, biological, radiological, and nuclear (CBRN) atmospheres that are Immediately Dangerous to Life or Health (IDLH). Currently, there is a NIOSH prohibition for entry into high radiant heat and open flame environments while wearing a pure oxygen, positive pressure CC-SCBA. Paragraph 4 of this standard specifies minimum requirements to ensure that the CC-SCBA possesses some features of high radiant heat and open flame resistance characteristics. These requirements are not meant to sanction its use in a firefighting situation. The CC-SCBA must meet the minimum requirements identified in the following paragraphs:

- Paragraph 2.0 Requirements specified in Title 42 Code of Federal Regulations (CFR) Part 84
- Paragraph 3.0 Special Requirements for CBRN Use
- Paragraph 4.0 High Radiant Heat and Open Flame Resistance Requirements
- Paragraph 5.0 Quality Assurance Requirements
- Paragraph 6.0 General Requirements

2.0 Title 42 Code of Federal Regulations (CFR) Part 84

The following paragraphs of 42 CFR Part 84 are applicable:

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 Requirements

2.2 42 CFR Part 84, Subpart H (Self-Contained Breathing Apparatus); the following paragraphs apply:

- 84.70 Self-contained breathing apparatus; description, paragraph (a)(1)
- 84.71 Self-contained breathing apparatus; required components
- 84.72 Breathing tubes; minimum requirements. Flexible breathing tubes used in conjunction with breathing apparatus shall be designed and constructed to prevent: (a) restriction of free head movement, (b) disturbance of the fit of facepieces and mouthpieces, (c) interference with the wearer's activities, and (d) shutoff of airflow due to kinking, or from chin or arm pressure
- 84.73 Harness; installation and construction; minimum requirements
- 84.74 Apparatus containers; minimum requirements
- 84.75 Half-mask facepiece, full facepiece, mouthpieces; fit; minimum requirements [full facepiece only] paragraphs (a), (b), and (d)

- 84.76 Facepiece; eyepieces; minimum requirements
- 84.77 Inhalation and exhalation valves; minimum requirements
- 84.78 Head harnesses; minimum requirements
- 84.79 Breathing gas; minimum requirements
- 84.80 Interchangeability of oxygen and air prohibited
- 84.81 Compressed breathing gas and liquefied breathing gas containers; minimum requirements
- 84.82 Gas pressure gages; minimum requirements
- 84.83 Timers; elapsed time indicators; remaining service life indicators; minimum requirements
- 84.84 Hand-operated valves; minimum requirements
- 84.85 Breathing bags; minimum requirements
- 84.86 Component parts exposed to oxygen pressures; minimum requirements
- 84.87 Compressed gas filters; minimum requirements
- 84.88 Breathing bag test
- 84.89 Weight requirement
- 84.90 Breathing resistance test; inhalation; paragraphs (a) and (c)
- 84.91 Breathing resistance test; exhalation; paragraph (e)
- 84.92 Exhalation valve leakage test
- 84.94 Gas flow test; closed-circuit apparatus
- 84.96 Service time test; closed-circuit apparatus
- 84.97 Test for carbon dioxide in inspired gas; open- and closed-circuit apparatus; maximum allowable limits; paragraph (b)
- 84.98 Tests during low temperature operation
- 84.99 Man tests; testing conditions; general requirements
- 84.100 Man tests 1, 2, 3, and 4; requirements
- 84.101 Man test 5; requirements
- 84.102 Man test 6; requirements
- 84.103 Man tests; performance requirements

3.0 Special Requirements for CBRN Use

3.1 Operational Performance Requirement

When tested on the NIOSH Automated Breathing and Metabolic Simulator (ABMS) performing the protocol described in Table 2b, composed of the workloads in Table 2a, the CC-SCBA shall not exceed the ranges of stressor levels listed in Table 1. Any end-of-service-life alarms or monitoring systems present will be tested for functionality, as specified by the manufacturer, during all operational performance tests. The facepiece of the CC-SCBA being tested shall be mounted on the ABMS headform such that an initial pressure of 25.4 ± 2.5 mm, w.g. $(1.0 \pm 0.1$ in, w.g.) below ambient shall not decay by more than 5.1 mm, w.g. (0.2 in, w.g.) in 5 seconds. The remaining components shall be mounted on a manikin torso to simulate the wearing position during the test. The CC-SCBA shall be fully charged and ready to use as defined by the manufacturer's instructions. The CC-SCBA unit is not required to operate for the rated duration period established under 42 CFR 84.100 while following the protocol in Table 2b. This test is for functionality purposes and not a duration test. The CC-SCBA, including the

facepiece, shall be mounted on the headform and manikin torso in accordance with the manufacturer's specifications of the apparatus. Ambient test conditions of the operational performance test are as follows:

Ambient temperature: $22^{\circ}\text{C} \pm 3^{\circ}\text{C} (72^{\circ}\text{F} \pm 5^{\circ}\text{F})$

Relative humidity: $50\% \pm 25\%$

Barometric pressure: 725 + 50/-70 mm Hg (28.54 +1.97/-2.75 in. Hg)

Table 1—Performance requirements

Parameter	Requirement
CO₂ concentration of dry breathing gas during inhalation	≤ 4% by volume
O ₂ concentration of dry breathing gas during inhalation	≥ 15% by volume
Wet-bulb temperature of breathing gas during inhalation	≤ 50EC
Maximum breathing gas pressure	≤ 200 mm, w.g.
Minimum breathing gas pressure	≥ 0 mm, w.g.

Table 2—Test regimen

Table 2a—Parameters

Parameter	Work load A	Work load B
Ventilation rate, liters/min, at T _{lung} , P _{local} and 100% RH	100	40
Respiratory frequency, breaths/min	30.0	18.0
Oxygen consumption rate, liters/min, STPD	3.2	1.35
Carbon dioxide production rate, liters/min, STPD	3.4	1.15

Table 2b—Protocol

Rated duration as established by 42 CFR 84.100	Work load	Starting time (minutes)	Duration (minutes)
	А	0	12
Hour 1	В	12	43
	Α	55	5
	В	60	25
Hour 2	Α	85	5
	В	90	25
	Α	115	5
	В	120	25
Hour 3	Α	145	5
	В	150	30
Hour 4 and beyond	В	180	60

3.2 Environmental Temperature Operational Performance Requirement

- 3.2.1 The CC-SCBA shall be tested for environmental operational performance and meet the requirements in Section 3.1 except for the wet-bulb temperature breathing gas requirement in Table 1 during the hot and hot temperature shock conditions. The environmental sequence test conditions shall start with the first environmental condition listed at the top of Table 3, and end with the last test listed at the bottom of Table 3. After conducting the operational performance test in each environmental condition, the CC-SCBA shall be placed in an ambient environment of 22°C ± 3°C (72°F ± 5°F) with a relative humidity of 50 percent ± 25 percent for a minimum 12-hour dwell.
- 3.2.2 The manufacturer shall establish the cold temperature operational limit for their apparatus. EBM established by the manufacturer
- 3.2.3 After the 12-hour soak periods of the hot and cold temperature shock conditions and before the test initiation, the CO₂ absorbent material and coolant mechanisms will be replaced in accordance with the CC-SCBA manufacturer's instructions.
- 3.2.4 The facepiece of the CC-SCBA being tested shall be mounted on the ABMS headform and the other components shall be mounted on a manikin torso to simulate a typical wearing position, both of which shall be in the environmental chamber. The CC-SCBA, including the facepiece, shall be mounted on the headform and manikin torso in accordance with the manufacturer's specifications of the apparatus.

3.2.5 The dwell period between environmental test conditions shall be used for replacing those components or materials expended during normal CC-SCBA operation, and for visually inspecting the apparatus for any gross damage that could cause an unsafe test condition

Environment	Temperature	Test duration	Test procedure
Cold (EBM*)	EBM Temp ± 1°C	Cold soak for a	Perform test at
	(EBM Temp °F ± 2°F)	minimum of 12 hours	EBM Temp ± 1°C (EBM Temp °F ± 2°F)
Hot	71°C ± 1°C (160°F ± 2°F)	Hot soak for a minimum of 12 hours	Perform test at 71°C ± 5°C (160°F ± 10°F)
Cold temperature shock	71°C ± 1°C (160°F ± 2°F) transferred to EBM Temp ± 1°C (EBM Temp °F ± 2°F); Test temperature shall be EBM Temp ± 1°C (EBM Temp °F ± 2°F)	Hot soak for a minimum of 12 hours; initiate test within 3 minutes in cold chamber	Initiate test within 3 minutes after transferring apparatus to cold chamber
Hot temperature shock	EBM Temp ± 1°C (EBM Temp °F ± 2°F) transferred to 71°C ± 1°C (160°F ± 2°F); Test temperature shall be 71°C ± 5°C (160°F ± 10°F)	Cold soak for a minimum of 12 hours; initiate test within 3 minutes in hot chamber	Initiate test within 3 minutes after transferring apparatus to hot chamber

Table 3—Environmental test conditions

3.3 Vibration Endurance Requirement

The CC-SCBA shall meet the performance requirements in Section 3.1 after being 3.3.1 subjected to the vibration endurance testing. The vibration testing shall be conducted in accordance with NIOSH standard test procedure CBRN 6XX [To Be Developed (TBD)], that is, based on Section 8.3.5.3 of National Fire Protection Association (NFPA) 1981, Standard on Open-Circuit Self-Contained Breathing Apparatus for Fire Emergency Services, 2002 edition. The holding box shall be constructed with a minimum of one large compartment and one smaller compartment. The sides and base of the holding box shall be constructed of 6 mm (1/4 inch) stainless steel and the top of the compartments shall remain open. The compartment size shall not be less than that which would allow a minimum distance of 25.4 mm (1 inch) between the sidewall and any component of the test item and shall not exceed a maximum distance which would allow the test item to rotate from the original axis of intended orientation. The oxygen cylinder shall be empty during the vibration test. The SCBA facepiece and those components that attach directly to the facepiece, excluding regulators, shall be placed in the smaller compartment of the holding box unrestrained with the facepiece looking up. The SCBA, including the regulators and hoses, shall be placed in the larger compartment unrestrained with the SCBA backplate resting on the bottom of the holding box. The test shall be conducted with the specimens in smaller and larger compartments oriented in each of the following two positions: SCBA and facepiece axes perpendicular to the direction of tester

^{*}EBM - The cold temperature operational limit shall be established by the manufacturer

movement and SCBA and facepiece axes parallel to the direction of tester movement. The total test duration is 180 minutes consisting of two 90-minute periods for each orientation of the apparatus.

3.4 Accelerated Corrosion Resistance Requirement

- 3.4.1 The CC-SCBA shall be tested for accelerated corrosion; any corrosion must not prohibit the proper use and function as specified in the manufacturer's user instructions of any control or operating feature of the apparatus when tested for accelerated corrosion. In addition, the CC-SCBA shall meet the operational performance requirements described in Section 3.1 of this document.
- 1.0.0 The CC-SCBA and one set of consumable components, each in the stowed configuration according to the manufacturer's user instructions, shall be tested for accelerated corrosion in accordance with MIL-STD-810F, Environmental Test Methods, Method 509.4, Salt Fog.
- 1.0.0.0 The CC-SCBA and components shall be mounted on a test manikin to simulate a typical wearing position as specified by the manufacturer's user instructions. The manikin shall then be placed in the test chamber equalized at a temperature 35°C ± 2°C (95°F ± 3°F). The CC-SCBA mounted on the manikin shall be equalized to the test chamber for a minimum of two hours before initiating the salt fog.
- 2.0.0.0 The CC-SCBA and consumable components shall be exposed to a 5 percent \pm 1 percent salt fog for 24 hours. After the 24-hour salt fog exposure, the SCBA shall be removed from the salt fog chamber and be placed in a drying chamber set at 35°C \pm 2°C (95°F \pm 3°F) for 24 hours.
- 3.0.0.0 The CC-SCBA and consumable components shall then be exposed to a second 24-hour cycle of salt fog and drying period as previously described.
- 3.4.3 After the two 24-hour periods of salt fog exposure and drying periods, the CC-SCBA shall be made operationally ready to use and shall meet the accelerated corrosion resistance requirement described in Section 3.4.1.

3.5 Particulate Resistance Requirement

1.0.0 The CC-SCBA shall meet the operational performance requirements described in Section 3.1 of this document while being exposed to dust and sand in accordance with MIL-STD-810F, Method 510.4, Procedure I – Blowing Dust. The particulate resistance testing shall be conducted in accordance with NIOSH STP CBRN 6XX (To Be Developed (TBD)). When testing the CC-SCBA for the particulate resistance requirement, the apparatus and components shall be mounted on a test manikin in a manner typical of a user configuration that is integrated with the NIOSH ABMS, in accordance with the ABMS instruction manual. The CC-SCBA facepiece shall be mounted on a test headform in accordance with the CC-SCBA's user instructions that shall be connected to the test

manikin.

- 2.0.0 The simulator shall be operated at work load B as defined in Table 2. The test duration shall be one hour, and the ABMS shall be in operation throughout the entire test.
- 3.5.3 The particulate resistance requirement shall be tested in accordance with MIL-STD-810F, Method 510.4, Procedure I Blowing Dust, at the following conditions:

• Air velocity: $533.4 \text{ m/min} \pm 76.2 \text{ m/min} (1750 \text{ ft/min} \pm 250 \text{ ft/min})$

• Temperature: $23^{\circ}\text{C} \pm 3^{\circ}\text{C} (72^{\circ}\text{F} \pm 5^{\circ}\text{F})$

3.6 Facepiece Lens Haze, Luminous Transmittance, and Abrasion Resistance Requirement

3.6.1 The SCBA primary facepiece lens specimens shall not exhibit an average increase in haze greater than 14 percent when tested in accordance with NIOSH STP 6XX that is based on the test procedures prescribed in NFPA 1981, 2002 edition, for the facepiece lens abrasion resistance performance requirement.

3.7 Communications Performance Requirement

1.0.0 The SCBA shall have an average calculated value of not less than 72 when tested in accordance with NIOSH STP 6XX, which is based on the communication performance test procedure prescribed in Section 8.10 of NFPA 1981, 2002 edition.

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

3.8.1 The SCBA, 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 the NIOSH ABMS operating at a breathing rate of 30 L/min (VO2 = 1.35 L/min; 18 breaths per minute). The test requirements and test conditions for HD are shown in Table 4 and Table 5 for GB. The apparatus shall meet the operational performance requirements of Table 1 in Section 3.1, and the end-of-service-life alarms or monitoring systems shall function as designed by the apparatus manufacturer. During this test, the functionality of end-of-service-life alarms or monitoring systems will be tested. After the apparatus meets the rated duration period identified by the applicant that was established under 42 CFR 84.100, O₂ and CO₂ concentrations in the breathing gas will not be monitored; however, all other requirements in Table 1 shall be met.

Table 4—Simultaneous liquid and vapor challenge of SCBA with distilled sulfur mustard (HD)

Agent	Challenge concentration	Duration of challenge (min)	Breathing machine airflow rate (L/min)	Maximum peak excursion (mg/m³)	Maximum breakthrough (concentration integrated over minimum service life) (mg-min/m³)	Number of systems tested	Minimum service life (hours)
HD- Vapor	$300 \text{ mg/m}^3 \dagger \dagger$	30*	30 L/min (STPD) §§	0.60‡	6.0§	3	† ‡‡
HD- Liquid	0.86 mL	Minimum service life					

^{*} Vapor challenge generation will start immediately after the liquid drops have been applied and the test chamber has been sealed

[†] The test period begins upon the start of initial vapor generation

Three consecutive sequential test data points at or exceeding 0.6 mg/m³ will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes

[§] The cumulative C_t, including all peak data points, must not be exceeded for the duration of the minimum service life

^{**} Minimum service life is equal to applicant's identified duration plus one hour

^{††} Decay rate of vapor challenge will follow the same profile as the decay rate of the NIOSH CBRN Standard for an Open-Circuit SCBA

^{§§} Standard temperature 0°C and Pressure Dry 760 mm HG (STPD)

Agent	Vapor challenge concentration (mg/m³)	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-min/m³)	Number of systems tested	Minimum service life (hours)
GB	2,000 mg/m ³ ††	30*	30 L/min	0.087^{\ddagger}	2.1 [§]	3	‡‡ †
			(STPD) §§				

^{*}The vapor challenge generation will be initiated immediately after test chamber has been sealed

3.9 Laboratory Respiratory Protection Level (LRPL) Test Requirement

- 3.9.1 The measured LRPL for each CC-SCBA system, when worn by a human test volunteer in the operational mode in accordance with the manufacturer's user instructions, shall be greater than or equal to 10,000 in an atmosphere containing 20 to 40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 μ m. A minimum of eight CC-SCBA systems shall be tested to fulfill the small, medium, and large designations of facial size -2 small, 4 medium, and 2 large.
- 3.9.2 The measured LRPL for the CC-SCBA facepiece shall be greater than or equal to 500 when the facepiece is worn by a human test volunteer in accordance with the manufacturer's user instructions in an atmosphere containing 20 to 40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 µm. Applicants shall provide enough facepieces (approximately 11-25 facpieces) and adapters that contain a P100 filter to meet the LRPL requirements of the NIOSH CBRN Standard for Open-Circuit Self-Contained Breathing Apparatus, December 2001.

1.0 Firefighter Protection Requirements

4.1 Fabric Flame Resistance Requirement

4.1.1 The fabric used to secure the CC-SCBA to the wearer shall have an average char length of no more than 4.0 inches (101.6 mm), an average after-flame of no more than 2

[†] The test period begins upon initial generation of vapor concentration

[‡] Three consecutive sequential test data points at or exceeding 0.087 mg/m³ will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes

[§] The cumulative C_t including all peak data points must not be exceeded for the duration of the Minimum Service Life

[†] Minimum service life is equal to applicant's identified duration plus one hour

^{††} Decay rate of vapor challenge will follow the same profile as the decay rate of the NIOSH CBRN Standard for an Open-Circuit SCBA

^{§§} Standard Temperature 0°C and Pressure Dry 760 mm HG (STPD)

seconds, and shall not melt or drip when testing specimens in accordance with the American Society for Testing and Materials (ASTM) D 6413, Standard Test Method for Flame Resistance of Textiles (Vertical Test). A wire lattice test frame specified in Section 8.4.8.2 of the NFPA 1981, 2002 edition or in NIOSH STP 6XX shall be used to hold test specimens that do not comply with Section 4.1.3 of this standard.

- 1.0.0 Five specimens of each fabric component of the apparatus shall be tested for fabric flame resistance. Prior to testing, the specimens of each fabric component of the apparatus shall first be conditioned by five washing and drying cycles in accordance with procedures specified in Machine Cycle 1, Wash Temperature V, Drying Procedure Ai, of AATCC 135, Dimensional Changes in Automatic Home Laundering of Woven and Knit Fabrics.
- 2.0.0 The test specimens shall be a minimum of 12 inches in length (305 mm) and 3 inches (75mm) in width.

4.2 Fabric Heat Resistance Requirement

The fabric used to secure the CC-SCBA to the wearer shall not melt or ignite when tested for heat resistance in accordance with NIOSH STP 6XX, which is based on NFPA 1981, 2002 edition, Section 8.5, Fabric Heat Tests.

4.3 Thread Heat Resistance Requirement

The thread used in the components of the CC-SCBA shall not melt or ignite when thread specimens are tested in accordance with NIOSH STP 6XX, which is based on NFPA 1981, 2002 edition, Section 8.6, Thread Heat Tests.

1.0 Heat and Flame Resistance Performance Requirement

The CC-SCBA and its accessories shall meet the following heat and flame resistance requirements when tested in accordance with the procedure prescribed in NIOSH STP 6XX, which is based on Section 8.11.5 of NFPA 1981, 2002 edition, and meet the minimum and maximum breathing gas pressure requirements in Table 1 of Section 3.1.

- 4.4.1 The components of either the SCBA or its accessories shall have an after-flame that is not greater than 2.2 seconds.
- 1.0.0 No components of either the SCBA or its accessories shall separate or fail in such a manner that would cause the SCBA to be worn and used in a position not specified by the manufacturer's user instructions.
- 2.0.0 The facepiece lens shall not obscure vision below the 20/100 vision criteria when tested in accordance with NIOSH STP 6XX, which is based on NFPA 1981, 2002 edition, Section 8.11.5.21.
- 3.0.0 When the CC-SCBA and its accessories are tested for heat and flame resistance performance, any end-of-service-life alarms or monitoring systems shall function as designed by the apparatus manufacturer and will be tested for functionality.

2.0 Quality Assurance Requirements

5.1 Quality Control Plan

Respirators submitted for CBRN closed-circuit, self-contained breathing apparatus 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 that the construction and performance requirements of this standard are established through the manufacturing process. As a minimum, specific attributes to be addressed are:

- Materials of construction used for respirator parts that form a barrier between the user and ambient air
- Integrity of mechanical seals that comprise a barrier between the user and ambient air

1.0 Test Sequence and Quantity

Testing of the CC-SCBA shall follow Table 6

Table 6—Required Sequence and Standard Test Procedure for CBRN CC-SCBA Concept

Test Order	SCBA #1 Initial	SCBA #2	SCBA #3	SCBA #4 Initial	SCBA #5	SCBA #6	SCBA #s 7, 8, 9, 10,	Component Tests* (As required by test
	Qualifier			Qualifier			11 and 12	procedures)
		Cold	Cold		Communication Pe	rformance		Fabric Flame Resistance
1.		Para. 3.2.	Para. 3.2.		Para. 3.7			Para. 4.1.
		STP-611	STP-0611		STP-0613			ASTM F1891
								AATCC 135
		Hot	Hot		Laboratory Respira	tor Protection Lev	el	Fabric Heat Resistance
2.		Para. 3.2.	Para. 3.2.		Para. 3.9			Para. 4.2
		STP-0611	STP-0611		Requires an Ad	lditional 11-25 Fac	cepieces and	NFPA 1981, 2002, Sec 85
					adapters with o	nly P100 Filters		AATCC 135
		Cold Shock	Cold Shock		Corrosion	Heat and		Thread Heat Resistance
3.		Para. 3.2.	Para. 3.2.		Para. 3.4	Flame	Return to	Para. 4.3
		STP-0611	STP-0611		STP-0612	Para. 4.4	Manufacturer	ASTM D 276
						STP- 0615		
		Hot Shock	Hot Shock		Particulate			Facepiece Lens
4.		Para. 3.2.	Para. 3.2.		Para. 3.5			Para. 3.6 Test based on
		STP-0611	STP-0611		STP-0613			NFPA 1981, 2002, Sec 10.5
		Vibration	Vibration		Operational			
5.		Para. 3.3	Para. 3.3		Performance			
		STP-0611	STP-0611		Para. 3.1.			
					STP-06??			
		Operational	Operational					
6.		Performance	Performance					
		Para. 3.1.	Para. 3.1.					
		STP-06??	STP-06??					
7.	. HD Chemical Agent GB Chemical Ager					Return to		
	Para. 3.8 Table 4		Para. 3.8 Table 5				Manufacturer	
	STP-0652		STP-0650					

^{*}Different specimens required for each test

6.0 General Requirements

In addition to the requirements of Title 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 Agent Penetration and Permeation Resistance Against Distilled Sulfur Mustard (HD) and Sarin (GB) tests, Paragraph 3.8, are excluded from this requirement.