

October 6, 2006

**Concept Standard for
Chemical, Biological, Radiological, and Nuclear (CBRN)
Type C and CE Positive Pressure, Pressure Demand Full Facepiece Supplied
Air Respirator (SAR)**

1.0. Purpose:

The purpose of this standard is to specify minimum performance requirements to determine the effectiveness of a full facepiece positive pressure, pressured demand Type C and Typed CE Supplied Air Respirator (SAR) used during entry into and escape from chemical, biological, radiological, and nuclear (CBRN) Immediately Dangerous to Life and Health (IDLH) atmospheres when worn in accordance with Occupational and Safety Health Administration Regulations.

The respirator must meet the minimum requirements for Type C Supplied Air Respirators identified in the following Paragraphs:

- Paragraph 2.0, Requirements Specified in Title 42 Code of Federal Regulations (CFR), Part 84 applicable paragraphs
- Paragraph 3.0, Requirements based on existing national and international standards
- Paragraph 4.0, Special requirements for CBRN use.
- Paragraph 5.0 Quality Assurance Requirements
- Paragraph 6.0 General Requirements

Additionally, the respirator must be equipped with a minimum of a 15 minute open circuit escape cylinder.

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

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2.2. 42 CFR, Part 84 Requirements for the SAR, Subpart J; the following paragraphs apply:

- 84.130 Supplied-air respirators; description.
- 84.131 Supplied-air respirators; required components.
- 84.132 Breathing tubes; minimum requirements.
- 84.133 Harnesses; installation and construction; minimum requirements.
- 84.134 Respirator containers; minimum requirements, paragraphs (a) and (c).
- 84.135 Half-mask facepieces, full facepieces, hoods, and helmets; fit; minimum requirements, [Full facepieces only].
- 84.136 Facepieces, hoods, and helmets; eyepieces; minimum requirements, [Full facepieces only].
- 84.137 Inhalation and exhalation valves; minimum requirements.
- 84.138 Head harnesses; minimum requirements, paragraphs (a) and (b).
- 84.139 Head and neck protection; supplied-air respirators, minimum requirements [(Optional) Head and neck protection].
- 84.141 Breathing gas; minimum requirements.
- 84.148 Type C supplied-air respirator, continuous flow class; minimum requirements.
- 84.149 Type C supplied-air respirator, demand and pressure demand class; minimum requirements.
- 84.150 Air-supply line tests; minimum requirements.
- 84.151 Harness test; minimum requirements.
- 84.152 Breathing tube test; minimum requirements.
- 84.155 Airflow resistance test, Type C supplied-air respirator, continuous flow class and Type CE supplied-air respirators; minimum requirements.
- 84.156 Airflow resistance test, Type C supplied-air respirator, demand class; minimum requirements.
- 84.157 Airflow resistance test, Type C supplied-air respirator, pressure-demand class; minimum requirements.
- 84.158 Exhalation valve leakage test.
- 84.159 Man tests for gases and vapors; supplied-air respirators; general performance requirements.
- 84.162 Man tests for gases and vapors; Type C respirators, continuous-flow class and Type CE supplied-air respirators; test requirements.
- 84.163 Man tests for gases and vapors; Type C supplied-air respirators, demand and pressure demand classes; test requirements.

3.0. Requirements Based on Existing National and International Standards:

3.1. Durability conditioning (Reference STP CBRN-0311)

3.1.1. Respirator containers; minimum requirements:

- 3.1.1.1. Required packaging configuration: (minimum packaging configuration):
The CBRN SAR and the required components shall be subjected to the

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environmental and transportation portions of the durability conditioning in the manufacturer specified minimum packaging configuration.

- 3.1.1.2. The minimum packaging configuration is the protective packaging configuration that the end user* shall store or maintain the SAR and the required components inside after it has been issued for immediate use. The user's instructions (UI) shall identify the minimum packaging configuration and shall direct the end user how to store or maintain the CBRN SAR and the required components inside the manufacturer specified minimum packaging configuration while in the possession of the end user. The same minimum packaging configuration identified in the UI shall encase the CBRN SAR and the components when NIOSH performs the durability conditioning. The type of the minimum packaging configuration, if any, is left to the discretion of the manufacturer. Examples of common minimum packaging configurations are respirator carriers, clamshell containers, draw string plastic bags, hermetically-sealed or nothing at all.

If over cases, packaging, or shipping containers are provided by the applicant over and above the minimum packaging configuration, these additional packaging levels may not be a substitute for the minimum packaging configuration and will not be used by NIOSH in the durability conditioning of the application

* End user: The definition of the end user is the person who will derive protection from the respirator by wearing it. It is assumed that the end user will store the respirator in a location where it will be available for immediate access and use during an emergency.

- 3.1.2. Environmental conditioning shall be performed in accordance with Table 1:

Table 1: Environmental Conditioning

Test	Test Method	Test Condition	Duration
Hot Diurnal	Mil-Std-810F; Method 501.4; Table 501.4-II; Hot-Induced Conditions	Diurnal Cycle, 35°C (95°F) -71°C (160°F);	3 Weeks
Cold Constant	Mil-Std-810F, Method 502.4;	Basic Cold (C1), -32°C (-95°F); Constant	3 Days
Humidity	Mil-Std-810E, 507.3; Method 507.3; Table 507.3-II	Natural Cycle, Cycle 1, Diurnal Cycle, 31°C (88°F) RH 88% -41°C (105°F) RH 59%	5 Days, Quick Look
Vibration	Mil-Std-810F, 514.5	US Highway Vibration, Unrestrained Figure 514.5C-1	12 Hours/Axis, 3 Axis; Total Duration =36 Hours, equivalent to 12,000 miles
Drop	3 foot drop onto bare concrete surface	Inside the minimum packaging configuration	1 drop/SAR on one of the 3 axes.

3.2. Field of View:

The CBRN SAR shall obtain a Visual Field Score (VFS) of 90 or greater. The VFS shall be obtained by using a medium size respirator or equivalent that is sized to fit the Head Form described in Figure 14 of EN 136, Respiratory protective devices – Full face masks – Requirements, testing, marking; January 1998 or equivalent.

The VFS is determined by using a VFS grid (Dots on visual field) as defined in the American Medical Association *Guides to the Evaluation of Permanent Impairment*, 5th Edition (2000) that is overlaid on the diagram of the visual field plot obtained using the spherical shell of EN 136 apertometer or equivalent. The VFS score is the average of three fittings of the same respirator on the specified head form.

3.3. Lens Material Haze, Luminous Transmittance and Abrasion Resistance:

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

3.3.2. Luminous Transmittance: The luminous transmittance value of the primary lens material shall be 88% or greater when tested in accordance with ASTM D 1003-00.

3.3.2. Abrasion Resistance: The haze and luminous transmittance of the primary lens material shall be determined in accordance with ASTM D 1003-00 before and after subjecting the lens material to the abrasion test. The abrasion test shall be conducted in accordance with ASTM D 1044-99 using a CS10F calibrase wheel at a minimum of 70 revolutions under a 500-gram weight. After subjecting the

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lens material to the abrasion test, remove the residue from the test specimens in accordance with ASTM D 1044-99 or by using a cleaning method recommended by the applicant. After the residue is removed from the test specimens, the test specimens shall not exhibit an increase of haze greater than 4% and a decrease of luminous transmittance greater than 4%.

- 3.3.3. The test specimens shall be the flat four (4) inch (102mm) square version as prescribed in ASTM D 1044-99 and shall have the same nominal thickness and within the tolerance range as the primary lens of the CBRN SAR. The test specimens shall be subjected to the same coating process and any other processes, as the primary lens would be under normal production conditions. A total of 6 specimens shall be furnished to NIOSH for certification testing, three pre-abrasion specimens and three specimens after being tested for abrasion in accordance with ASTM D-1044-99.

3.4. 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 $25 \pm 5^{\circ}\text{C}$. 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. NIOSH Test Procedure RCT-APR-STP-0064 is used for Carbon Dioxide Testing.

3.5. Hydration:

For CBRN SAR equipped with a hydration facility, the CBRN SAR shall meet all requirements of the CBRN SAR standard with the hydration facility in place. 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. NIOSH Test Procedure RCT-APR-STP-0014 is used for hydration facility leakage.

3.6. Low Temperature/Fogging:

The respirator shall demonstrate an average Visual Acuity Score (VAS) of greater or equal to 75 points for all measurements of acuity. The respirator shall be cold soaked and tested in an environmental chamber at minus 21°C for four (4) hours. The wearer shall not experience undue discomfort because of restrictions to breathing or other physical or chemical changes to the respirator.

3.7. Communications:

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

4.0 Special CBRN Requirements:

4.1. Chemical Agent Permeation and Penetration Resistance Against Distilled Sulfur Mustard (HD) and Sarin (GB) Agent Requirement:

The Supplied Air Respirator 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.

4.1.1. Test requirements for distilled sulfur mustard (HD) are shown in Table 2.

Table 2: Simultaneous Liquid and Vapor Challenge of SAR with 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-min/m ³)	Number of Systems Tested	Minimum Service Life (hours)
HD-Vapor	300 mg/m ³	30 ⁽¹⁾	40	0.60 ⁽³⁾	6.0 ⁽⁴⁾	3	6 ⁽²⁾
HD-Liquid	0.86 ml	360					

⁽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/m³ 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.

4.1.2. Test requirements for sarin (GB) agent are shown in Table 3.

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Table 3: Vapor Challenge of SCBA 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-min/m ³)	Number of Systems Tested	Minimum Service Life (hours)
GB	2,000 mg/m ³	30 ⁽¹⁾	40	0.087 ⁽³⁾	2.1 ⁽⁴⁾	3	6 ⁽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/m³ 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.

4.2. Laboratory Respiratory Protection Level (LRPL) Test Requirement:

The measured laboratory respiratory protection level (LRPL) for each SAR shall be 2000, when the respirator is tested in an atmosphere containing 20-40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers.

5.0 Quality Assurance Requirements:

5.1 Quality Control Plan:

Respirators submitted for CBRN SAR 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.

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- c). Final performance quality control tests on the respirator and accessories to include but not limited to air supply hose, air supply valve, orifice, or regulators, and detachable couplings.

6.0 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. Paragraph 4.1 Systems Tests are excluded from this requirement.