Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CRBN) Full Facepiece Air Purifying Respirator (APR)

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Fig. 1 Updated; January 30, 2004

1.0 Purpose:

The purpose of this standard is to specify 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 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.

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

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

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

3.0 Requirements Based on Existing National and International Standards:

3.1 Mechanical Connector:

The interface between the canister and the facepiece or respirator system shall use a standard Rd 40 X 1/7 thread in accordance with Figure 1 (NIOSH CBRN Full Facepiece APR Mechanical Connector and Gasket). The canister shall be readily replaceable without the use of special tools. For respirators where the canister is attached directly to the facepiece, i.e. respirator mounted, a single interface connector thread shall be located on the facepiece. The interface connector on the facepiece shall be the internal thread and gasket sealing gland. The canister shall use the external thread.

For respirators where the canister is not directly attached to the facepiece, i.e. not respirator mounted, an internal thread and gasket sealing gland connector complying with Figure 1 must be securely attached to a harness system to provide strain relief between the canister and the remaining respirator system. For respirator systems where the canister is not respirator mounted, multiple canister assemblies are permitted.

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, minimum thickness 1.55 mm as illustrated in Figure 1. The gasket material shall be ethylene propylene diene monomer, EPDM, or equivalent meeting the physical and chemical properties of Table 1 (Rubber Gasket Physical and Chemical Properties) when tested in accordance with Table 2 (Gasket Tests, Specimens and Test Methods). The manufacturer is required to provide data indicating compliance with the requirements of Table 1 and 2. Agent permeation data is not required for EPDM gasket material meeting all other properties of Table 1. For gasket material other than EPDM material samples must be tested to the agent permeation requirements.

3.3 Breathing Resistance, Canister:

In addition to the resistance to airflow determined by paragraph 3.5, Breathing Resistance, the canister resistance to inhalation airflow shall be less than or equal to 50 mm water column when tested at 85 liters per minute continuous air flow.

Table 1: Rubber Gasket Physical and Chemical Properties

Property	Units	Unaged Minimum	Unaged Maximum	Aged Minimum	Aged Maximum
Tensile Strength	Mpa (psi)	8.3 (1200)	---	6.9 (1000)	---
Ultimate elongation	Percent (%)	350	---	300	---
Tensile set at 300% elongation	Percent (%)	---	25	---	25
Tensile stress at 200% elongation	Mpa (psi)	3.4 (500)	---	3.4(500)	---
Tear resistance Either Die B or Die C (1)	kN/m (lbf/in)	21.9 (125)	---	21.9 (125)	---
Durometer hardness (Shore "A")	---	55	75	---	---
Compression set 22 hrs. at 68° C	Percent (%)	---	25	---	---
Impact resilience	Percent (%)	35	---	---	---
Agent permeation HD, Mustard & GB, Sarin (2)	Minutes Minutes	360 360	---	---	---
Low temperature brittleness at minus 51° C	---	Pass	---	---	---

(1) Test specimens shall be cut from Die B or Die C. Test specimens shall not be a mixture of Die specimens. See Table 2: Tear Resistance Method ASTM 624 D.

(2) The applicant shall submit agent permeation data on materials that are not classified as EPDM. Rubber material formulations that are 51% or greater in EPDM classifies the material as EPDM.

Table 2: Gasket Tests, Specimens and Test Methods

Property	Specimen			Total	Method
	Unaged	Heat Aged (1)	Oxygen aged (2)		
Tensile strength Ultimate elongation Tensile stress at 200% elongation	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	9	ASTM D 412
Tensile set at 300% elongation	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	9	ASTM D 412
Tear resistance, Either Die B or Die C	Cut one specimen from each of three	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	9	ASTM D 624

	slabs/buttons.				
Low temperature Brittleness at –51°	Cut one specimen from each of five slabs.	None	None	5	ASTM D 746
Durometer hardness (Shore “A”)	Cut one specimen from each of three slabs.	None	None	3	ASTM D 2240
Compression set (3)	Three test buttons.	None	None	3	ASTM D 395
Impact resilience (3)	Three test buttons.	None	None	3	ASTM D 2632
Agent permeation (4) (5) Sarin (GB) and Sulfur Mustard (HD)	Cut two specimens from each of six test slabs. Six specimens per agent.	None	None	12	MIL-STD-282 Method 208 Method 209

(1) Heat Aging. The specimens selected for heat aging shall be aged in an air oven at a temperature of 158° F +/-7°F (70°C -/+ 2°C) for a continuous period of 24 hours as prescribed in ASTM D 573.

(2) Oxygen Aging. Specimens shall be aged in an oxygen environment in accordance with ASTM D 572 for 72 hours.

(3) Same test buttons shall be used for impact resilience and compression set in that order.

(4) If gasket material is not EPDM, applicant shall submit permeation test data for gasket material along with six test slabs for Agent Permeation Test.

(5) Test specimens shall be fabricated in accordance with ASTM D 3182 from material of the same formulation that will be used during regular production of the respirator. The test specimens shall have a cure equivalent to that of the regular production gaskets. The thickness of the test specimens shall be the minimum gasket thickness specified by the applicants design specification. Any finish or treatment, applied to the finished gasket, shall be applied to the test specimens.

3.4 Dimensions and Weight, Respirator Mounted (Chin Style) Canister:

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

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 air 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.

3.6 Field of View:

The full facepiece CBRN APR 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.

3.7 Lens Material Haze, Luminous Transmittance and Abrasion Resistance:

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

3.7.2 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.

3.7.3 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 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%.

3.7.4 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 APR. 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

3.8 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 ± 5°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.

3.9 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. 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.

3.10 Tolerance Analysis:

The applicant shall provide a tolerance analysis of the mechanical connector, canister thread and gasket identified in Paragraphs 3.1 Mechanical Connector and 3.2 Gasket, Mechanical Connector demonstrating the applicant's canister design will contact and seal on the gasket surface area defined by the 37.5mm minimum outside diameter and the 28.5 maximum inside diameter under all tolerance conditions.

3.11 Practical Performance (Modified Laboratory Protection Level Test):

A modified laboratory protection level test (LRPL) shall be performed using respirators fitted with a canister weighted to 500 grams and sized to the maximum permissible dimensions of Paragraph 3.4 Dimensions and Weight, Respirator Mounted (Chin Style) Canister. A minimum of eight respirators shall be tested to fulfill 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 an atmosphere containing 20-40 mg/m3 corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers.

4.0 Special CBRN Requirements:

4.1 Canister Test Challenge and Test Breakthrough Concentrations:

The gas/vapor test challenges and breakthrough concentrations shown in Table 3: Canister Challenge, Breakthrough Concentrations, and Canister Efficiency shall be used to establish the canister service life:

Table 3: Canister Test Challenge and Test Breakthrough Concentrations

	Test Concentration (ppm)	Breakthrough Concentration (ppm)
Ammonia	2500	12.5
Cyanogen Chloride	300	2
Cyclohexane	2600	10
Formaldehyde	500	1
Hydrogen Cyanide	940	4.7(1)
Hydrogen Sulfide	1000	5.0
Nitrogen Dioxide	200	1 ppm NO_2 or 25 ppm NO(2)
Phosgene	250	1.25
Phosphine	300	0.3
Sulfur Dioxide	1500	5

(1) Sum of HCN and C2N2.

(2) Nitrogen Dioxide breakthrough is monitored for both NO2 and NO. The breakthrough is determined by which quantity, NO2 or NO, reaches breakthrough first.

4.2 Service Life:

The applicant shall specify a minimum service life as part of the application for certification. For less than a 60 minute service life, applications shall be identified in 15-minute intervals (15 minutes, 30 minutes, 45 minutes). For a service life of 60 minutes or greater, applications shall be identified in 30-minute intervals (60 minutes, 90 minutes, 120 minutes). Gas life tests are performed at room temperature, 25±5° C; 25±5 percent relative humidity; and 80 + 5 percent relative humidity. Three canisters 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. The canisters shall meet or exceed the specified service times without exceeding the identified breakthrough concentrations in Table 3. Gas testing shall be performed following environmental conditioning and rough handling.

4.3 Particulate/Aerosol Canister:

The canister shall meet the requirements of a P100 particulate filter in accordance with 42 CFR, Part 84, paragraphs 84.170, 84.179, and 84.181.

4.4 Service Life Testing, High Flow:

Each canister shall provide a minimum service life of 5 minutes when tested at a flow rate of 100 liters per minute, 50±5 percent relative humidity and 25±5° C for each of the gases/vapors identified in Paragraph 4.1, Canister Test Challenge and Test Breakthrough Concentrations.

4.5 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.

4.6 Communications:

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.

4.7 Chemical Agent Permeation and Penetration Resistance Against Distilled Sulfur 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 4:

Table 4: Vapor-Liquid Sequential Challenge of APR 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 (hours)
HD-Vapor	50 mg/m^3 (1)	30	40	0.30 (3)	3.0 (4)	3	8 (6)
HD-Liquid	0.43 to 0.86 ml (1)(2)(5)	120	40	0.30 (3)	3.0 (4)	3	2

(1) Vapor challenge concentration will start immediately after the test chamber has been sealed. Minimum Service Life for liquid exposure starts after the first liquid drop is applied.

(2) Liquid volume dependent on accessories used with the respirator. Minimum volume is 0.43 ml based on the respirator and single respirator mounted canister.

(3) Three consecutive sequential test data points at or exceeding 0.3 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 maximum peak excursion data points must not be exceeded for the duration of the test.

(5) Liquid agent is applied to respirator at hour 6 of the test cycle.

(6) The test period begins upon initial generation of vapor concentration and ends at 8 hours.

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

Table 5: Vapor Challenge of APR with Sarin (GB)

Challenge Concentration	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/m3)	Number of Systems Tested	Minimum Service Life (hours)
GB	210(1)	30	40	0.044(3)	1.05(4)	3	8(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 and ends at 8 hours.

(3) Three consecutive sequential test data points at or exceeding 0.044 mg/m3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.

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

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 an atmosphere containing 20-40 mg/m3 corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers.

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

Environmental conditioning shall be performed in accordance with Table 6:

Table 6: Environmental Conditioning

Test	Test Method	Test Condition	Duration
Hot Diurnal	Mil-Std-81°F; Method 501.4; Table 501.4-II;Hot-Induced Conditions	Diurnal Cycle, 35°C (950F) - 71°C (160°F);	3 Weeks
Cold Constant	Mil-Std-81°F, 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 (880F) 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	Canister only; In individual canister packaging container	1 drop/filter on one of the 3 axes.

4.10 Test Sequence and Quantity:

Testing of the CBRN APR system and canisters shall follow Table 7:

Table 7: Test Sequence and Quantity

Test Order	42 CFR Testing	Human Factors	Service Life, 100 lpm	Service Life Testing, 64 lpm flow	Particulate Canister Degradation	Penetration and Permeation Testing	Efficiency Particulate Canister	LRPL Test
Qty	3 APR systems; 3 exhalation valve assy.	9 APR Systems, 6 lens samples	30 canisters	54 canisters	6 canisters	6 APR systems (1)	20 canisters	25 to 38 systems
1.	Breathing Tube, 84.115 Para.2.2	Commo. Para. 4.6	Hot Diurnal Para. 4.9	Hot Diurnal Para. 4.9	Hot Diurnal Para. 4.9	Hot Diurnal Para. 4.9	Filter Efficiency 84.181	LRPL Para. 4.8
2.	Facepieces; eyepieces minimum requirement, 84.119 Para.2.2	Low Temperature Fogging Para. 4.5	Cold Constant Para. 4.9	Cold Constant Para. 4.9	Cold Constant Para. 4.9	Cold Constant Para. 4.9	Cold Constant Para. 4.9	Practical Performance Test Para.3.11
3.	Canister in Parallel Resistance, 84.112 /.122 Para.2.2	Facepiece Resistance Para. 3.3	Humidity Para. 4.9	Humidity Para. 4.9	Humidity Para. 4.9	Humidity Para. 4.9	Humidity Para. 4.9	Humidity Para. 4.9

4.	Exhalation valve leakage test, 84.123 Para.2.2	Field of View Para. 3.6	Transportation/ Vibration Para. 4.9	Transportation/ Vibration Para. 4.9	Transportation/ Vibration Para. 4.9	Transportation/ Vibration Para. 4.9	Transportation/ Vibration Para. 4.9	
5.	Hydration 84.63(a)(c)(d) Para.3.9	Haze, Transmittance, Abrasion Para. 3.7	Drop Para. 4.9(2)	Drop Para. 4.9(2)	Drop Para. 4.9(2)	Drop Para. 4.9(2)	Drop Para. 4.9(2)	
6.	Determine CO2 levels 84.63(b)(c)(d) Para.3.8	Tolerance Analysis Para. 3.10	Service Life 100 lpm Para. 4.4	Initial Breathing Resistance Para. 3.5	Canister Breathing Resistance Para. 3.3	System Testing Para. 4.7	Filter Efficiency 84.181	
7.				Service Life Testing, Less Cyclohexane, 64 lpm Para. 4.2	Service Life Cyclohexane Para. 4.2			
8.				Final Breathing Resistance Para. 3.5	DOP Testing 84.181			
9.					Final Breathing Resistance Para. 3.5			

(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 Para. 4.9 Environmental Conditioning. Four systems tests, 2 GB and 2 HD, are performed after Para. 4.9 Environmental Conditioning.

(2) The Drop Test is performed on the canister only, in the minimum manufacturer's recommended packaging.

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 canisters demonstrating compliance with the gas life and particulate filter requirements of this standard.
d). Conformance with mechanical dimensions of respirator to canister connecting thread.
e). Conformance with mechanical dimensions of respirator to canister sealing gland including length of threads, gasket seating dimensions, and configuration.
f). Conformance with material properties, dimensional and hardness requirements of the respirator to canister gasket.

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 4.7 Systems Tests are excluded from this requirement. NIOSH CBRN Full Facepiece APR Mechanical Connector and Gasket Drawing from Revision 3 (April 3, 2007) to Revision 4 (August 30, 2007).