

Concept for Weapons of Mass Destruction (WMD) Capable Powered Air-Purifying Respirator (PAPR)

1.0. PURPOSE:

The purpose of this standard is to specify minimum requirements to determine the effectiveness of a WMD Capable, Powered Air-Purifying Respirator (PAPR) used as entry devices in atmospheres with low concentrations of chemical, biological, radiological and nuclear (CBRN) contaminants not immediately dangerous to life and health. The respirator must meet the minimum requirements identified in the following paragraphs:

- Paragraph 3.0 Requirements specified in Title 42 CFR, Part 84 applicable paragraphs
- Paragraph 4.0 Special Requirements for CBRN
- Paragraph 5.0, Special Requirements for Quality Assurance
- Paragraph 6.0, General Requirements
- Paragraph 7.0, Requirements for Cautions and Limitations

In response to acts of terrorism and other natural disasters, powered air purifying respirators are used to provide respiratory protection in work areas where the hazards are known, characterized, and conditions of oxygen deficiency do not exist. The WMD Capable PAPR will most likely be used by **first receivers** and others in atmospheres where the levels of CBRN contamination will be at low concentrations due to prior victim decontamination, minimal secondary contamination emitted from ambulatory victims or because of the extreme distance from the event. Respirators used under these conditions must be sufficient to provide protection against these anticipated low-level respiratory hazards. **The WMD Capable PAPR should not be used in traditional first responder activities (fire service or law enforcement service; emergency medical technicians) and should not be used for escape purposes.**

This concept addresses major performance issues of flow, hazard protection, filter capacity, particulate efficiency, and human factors. The concept addresses each of these respirator issues with performance-based requirements. The WMD Capable PAPR concept specifies requirements for breathing performance based on the ability of the respirator to maintain a positive pressure in the breathing zone.

Filter hazard protection and capacity for the WMD Capable PAPR concept provides for a minimum required performance consisting of: 99.97 percent particulate efficiency and gas life defined in the existing CBRN respirator standards.

Canister capacity and particulate efficiency testing is done at flow rates determined by the maximum flow rate of the respirator. In addition to flow, canister capacity, work rate, and particulate efficiency requirements, the WMD Capable PAPR concept also addresses CBRN

required performance for live agent testing (LAT) for sarin (GB) and mustard (HD) and a laboratory respirator protection level (LRPL) test. Enhanced performance requirements for respirator field of view (FOV), communications, and battery performance are identified in the WMD Capable PAPR concept.

2.0. DESCRIPTION:

The WMD Capable PAPR will use a blower to pass ambient air through an air-purifying filter cartridge(s) that will remove contaminants from the ambient air. They are designed for use in atmospheres where the concentrations of contaminants during use are not immediately dangerous to life and health and contain adequate oxygen to support life. They are not designed for use in atmospheres where escape from an unexpected IDLH condition could be necessary.

2.1 Respirator Use:

- (a) Cold Zone Use/ Potential Residual Hazard: Low concentrations due to prior victim decontamination or minimal secondary contamination emitted from ambulatory victims that potentially can be above acceptable exposure limits, but less than IDLH concentrations. Examples of use scenarios: sustained medical evaluation and treatment inside a medical facility, **agent unknown, quantified at low levels,** controlled **environment** with an expectation of no secondary devices and no liquid contamination present.
- (b) The **WMD Capable** PAPR filter cartridges are single use cartridges and it is required that **they remain sealed in the manufacturer's packaging until needed** and that they be disposed of after use.

2.2 Hazards:

NIOSH has evaluated various CBRN agents that could be deployed during a terrorist incident. In earlier research during the development of the *Chemical Biological Radiological Nuclear (CBRN) Air-Purifying Respirator (APR) Standard*, NIOSH categorized potential respiratory hazards into families. For the chemical threats, test representative agents identified for each family to be the only agents tested for service life in that particular family, thus representing all the agents identified in the family. This effort was conducted in order to reduce the number of certification tests. Based on the intended use for WMD Capable PAPR, the number of potential chemicals determined to be respiratory threats to a user of the WMD Capable PAPR **may be** reduced from the original assessment because of the anticipated absence or low toxicity of a specific chemical. **Additionally the concentrations of the test representative agents may be modified as well. This determination will be finalized as the hazard assessment is completed.**

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

The following paragraphs of 42 CFR, Part 84 are applicable.

3.1 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: Scope of Approval Atmospheric Hazard Service Time
- Subpart G. General Construction and Performance Requirements

3.2. 42 CFR, Part 84, Subpart KK:

- 84.1101 Definitions.
- 84.1103 Approved labels and markings; approval of contents; use.
- 84.1130 (b) Respirators; description.
- 84.1131 Respirators; required components.
- 84.1132 Breathing tubes; minimum requirements.
- 84.1133 Harnesses; installation and construction.
- 84.1134 Respirator containers; minimum requirements.
- 84.1135 Half-mask face pieces, full facepieces, hoods, helmets, and mouthpieces; fit; minimum requirements.
- 84.1136 Face pieces, hoods, and helmets; eyepieces; minimum requirements.
- 84.1137 Inhalation and exhalation values, minimum requirements.
- 84.1138 Head harnesses; minimum requirements.
- 84.1139 Air velocity and noise levels; hoods and helmets; minimum requirements.
- 84.1150 Exhalation valve leakage test; minimum requirements.
- 84.1154 Cartridge and cartridge requirements.
- 84.1155 Filters used with cartridges and cartridges; location; replacement.

4.0. Special CBRN Requirements

4.1. Labels: In addition to the requirements of Paragraph 3.2, the following paragraphs apply:

- 4.1.1. The battery part number must be prominently displayed with the part number on the respirator battery pack or other suitable location.
- 4.1.2. Additional cautions and limitations appropriate to WMD Capable PAPRs must be added as deemed necessary by NIOSH, such as “Observe low flow or pressure alarm indicators.”

4.2. Battery Requirements:

- 4.2.1. User’s Instructions: The user’s instructions shall include the manufacturer’s operational battery life for all battery options for the respirator in increments of 30 minutes. The manufacturer specified battery service life will be used for Breathing Performance, Paragraph 4.4. The user’s instructions will also include

descriptive information regarding the distinct warning for low battery indication at the 15-minute warning and information regarding the operational battery life in typical climates. User instructions shall prominently list the operational battery life for all available battery options and provide adequate information on the function and operation of battery charge. The user instructions shall also provide the specific indicator location and method of indication in a manner that the user can understand.

- 4.2.2. Low Battery Indicator: Each PAPR must contain an indicator to show the state of charge of the battery. The indicator may be passive such as a tamper proof device installed indicating a fully charged battery condition along with an identified date for expiration of the fully charged condition and an indicator, which alerts the user when 15 minutes of operational battery life remains. The indicator may also be an active indicator such as an illuminated light, which provides the same 15-minute remaining warning. The indicator must be capable of monitoring the battery conditions and signaling the user when the remaining operational battery life is sufficient to sustain the desired flow rate for at least 15 minutes but not more than 45 minutes when evaluated at room temperature (25 ± 5 °C).

4.3. Low Flow Indicator:

- 4.3.1. Users Instructions: User instructions shall provide adequate information on the function and operation of low flow and/or low-pressure indicators to insure proper use/attention/reaction to these indicators.
- 4.3.2. Low Flow Indicator: Each WMD Capable PAPR shall have an indicator to alert the user when the airflow in the breathing zone reaches the applicant's identified acceptable minimum flow for the respirator to maintain positive pressure in the breathing zone. The indicator will be tested at $25 \text{ }^{\circ}\text{C} \pm 2.5 \text{ }^{\circ}\text{C}$. The WMD Capable PAPR must be capable of maintaining positive pressure in the breathing zone until the low flow alarm signals the user. The low flow alarm may be audible, visual, or vibratory.

4.4. Breathing Performance:

- 4.4.1. Breathing Rate: WMD Capable PAPRs will be tested using a breathing machine operated at 30 respirations per minute while delivering a minute volume of 103 L/min. The breathing machine will be described in the supporting standard test procedure
- 4.4.5. Breathing Performance Test Time: Breathing performance will be continuously recorded for the applicant specified operational battery life.

4.5. Field of View:

The WMD Capable PAPR 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 aerometer or equivalent. The VFS score is the average of three fittings of the same respirator on the specified head form.

4.6. Carbon Dioxide:

4.6.1. Machine Test: The maximum allowable average inhaled carbon dioxide concentration shall be less than or equal to 1 percent **at the end of the breath stoke**, measured at the mouth, while the respirator is mounted on a dummy head operated by a breathing machine with the blower running. 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 $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$. A concentration of 5% carbon dioxide in air will be exhaled into the respiratory inlet covering.

4.6.2. Human Subject Breathing Gas testing: During the testing required by this section, the concentration of inspired carbon dioxide gas at the mouth will be continuously recorded, and the calculated maximum range concentration during the inhalation portion of the breathing cycle shall not exceed 0.02 (or 2.0%). The inhaled fractional oxygen concentration shall be no less than 0.195 (or 19.5%) when tested with human subjects at the following work rates: standing and walking at 3.5 miles per hour. Two tests (standing and walking at 3.5 miles per hour) shall be performed, each using 12 test subjects. Each exercise will be performed for 10 minutes. Carbon Dioxide and oxygen data will be considered for the last 5 minutes of each exercise. For each of these last 5 minutes, a minimum of the last 5 breaths will be considered.

For each group of 12 subjects, 95% of the total number of trials must meet the stated criteria. Should a group of test trials not pass the 95% of trials, one addition run of test trials consisting of 12 test subjects may be performed to increase the total number of trials; the total number of trials (total of 48) will be the sum of trials from the first and second run of subjects. All trials shall be considered in the Practical Performance requirement criteria of paragraph 4.13.

4.7. Cartridge Bench Tests; minimum requirements:

4.7.1. The gas/vapor test concentrations and maximum allowable penetration shown in Table 1 shall be used to establish the minimum service life.

- 4.7.2. Where two or more cartridges are used in parallel, the tests will be performed with the cartridges mounted on a blower assembly and the test requirements will apply to the combination rather than the individual cartridges.

Table 1.—Cartridge test concentrations and maximum allowable penetration[#]

TRA	Test Concentration (ppm)	Maximum allowable penetration (ppm)
Ammonia	2500	25
Cyanogen chloride	300	1
Cyclohexane	2600	10
Formaldehyde	500	1
Hydrogen cyanide	940	4.7 [*]
Hydrogen sulfide	1000	10
Nitrogen Dioxide	200	1 ppm NO ₂ or 25 ppm NO [†]
Phosgene	250	1.25
Phosphine	300	0.3
Sulfur dioxide	1500	2

^{*} Sum of HCN and C₂N₂.

[†] Nitrogen Dioxide breakthrough is monitored for both NO₂ and NO. The breakthrough is determined by which quantity, NO₂ or NO, reaches breakthrough first.

[#] Subject to modification following completion of hazard assessment

- 4.7.3. Bench tests will be performed at room temperature, (25 °C ± 2.5 °C); 25% ± 2.5% relative humidity; and 80% ± 2.5% relative humidity. Three cartridges will be tested at each specified humidity. The cartridges shall meet or exceed the 60 minute minimum service life time without exceeding the identified maximum allowable penetration in Table 1.

- 4.7.4. Flow rates for cartridge bench tests will be performed at flow rates determined by the flow output of the PAPR blower.

4.8.Canisters in Parallel Resistance

When two or more canisters are used in parallel, their resistance shall be uniform within the population when tested at 85 liters per minute continuous airflow. Canister uniformity will be required:

- 4.8.1 The canisters shall have an allowable resistance variation of $\pm 10\%$, which will be determined by one of the two following options:

4.8.1.1 Option 1: For canisters sold in Replacement Packs, (Replacement Packs will contain the appropriate number of canisters to complete a change out exhausted canisters) the average resistance of the canisters within a Replacement Packs will be determined.

4.8.1.2 Option 2: For canisters sold individually, Canister Uniformity will be based upon average resistance reported by the manufacturer as reported at the time of application.

4.8.2 System Service Test

The system manifold and canisters will be evaluated to allow design and canister resistance to effect service life. Service life testing will be performed using the following TRAs: Cyclohexane, Sulfur Dioxide and Cyanogen Chloride, and Phosphine. The manifold and canisters will be tested at be tested using complete systems at room temperature, $25\text{ }^{\circ}\text{C} \pm 2.5\text{ }^{\circ}\text{C}$; $50\% \pm 2.5\%$ relative humidity.

4.9. Particulate/Aerosol Cartridge:

The cartridge shall meet the requirements of 99.97% particulate filter efficiency in accordance with the following criteria.

4.9.1. Twenty (20) cartridges shall be tested for filter efficiency against a dioctyl phthalate or equivalent liquid particulate aerosol.

4.8.1.1. Additionally, six (6) cartridges from the cyclohexane gas life test of Paragraph 6.1 shall be tested for filter efficiency against dioctyl phthalate or equivalent liquid particulate aerosol.

4.9.2. Cartridges including holders and gaskets, when separable, shall be tested for filter efficiency level, as mounted on a test fixture in the manner as used on the respirator.

4.9.3. When the cartridges do not have separable holders and gaskets, the exhalation valves shall be blocked to ensure that leakage, if present, is not included in the filter efficiency level evaluation.

4.9.4. For PAPRs with a single cartridge element, the cartridge shall be tested at the [continuous airflow rate of the respirator](#). If multiple cartridges are used, the test-aerosol airflow rate shall be reduced in proportion to the number of cartridges. The twenty production filters shall be tested at 85 L/min flow to verify the effectiveness of the filter media to filter housing interface. If alternate testing procedures are used, media samples will be preconditioned with cyclohexane.

4.9.5. A neat cold-nebulized dioctyl phthalate (DOP) or equivalent aerosol at $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$ that has been neutralized to the Boltzmann equilibrium state shall be used in the test.. Each filter shall be challenged with a concentration not exceeding 200 mg/m^3 .

- 4.9.6. The test shall continue until minimum efficiency is achieved or until an aerosol mass of at least 200 mg ± 5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency.
- 4.9.7. The DOP aerosol shall have a particle size distribution with count median diameter of 0.185 μm ± 0.020 μm and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.
- 4.9.8. The efficiency of the filter shall be monitored throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation and recorded.
- 4.9.9. The minimum efficiency for each of the twenty filters shall be determined and recorded and be equal to or greater than 99.97%.

4.10. 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 with the blower operating. The distance between the listeners and speakers shall be 3 meters.

4.11. 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 airflow rate of 40 L/min, 36 respirations per minute, 1.1 liters tidal volume.

Penetration resistance performance and test requirements for distilled sulfur mustard (HD) are shown in Table 3:

Table 3.— Performance and Test Requirements for 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 test time) (mg-min/m ³)	Number of Systems Tested	Minimum Test Time (hours)
HD-Vapor	50 mg/m ³ *	30	40	0.30 [‡]	3.0 [§]	3	8 ^{††}

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

† 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 two (2) minutes.

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

†† The test period begins upon initial generation of vapor concentration and ends at eight (8) hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.

Penetration resistance performance and test requirements for Sarin (GB) agent are shown in Table 4:

Table 4.— Performance and Test Requirements for 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 test time) (mg-min/m ³)	Number of Systems Tested	Minimum Test Time (hours)
GB	210*	30	40	0.044 [‡]	1.05 [§]	3	8 [†]

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

† The test period begins upon initial generation of vapor concentration and ends at 8 hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.

‡ 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.

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

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

The measured laboratory respiratory protection level (LRPL) for each powered air-purifying respirator shall be 10,000 for ≥ 95% trials with the blower operating (Blower on mode). Should a group of test subjects result in LRPL trails where less than 95% of trials have passing results, one additional run of test subjects may be performed to increase the total number of trials: the total number of trials will be the sum of trials from the first and second run of subjects. All trials shall be considered in the Practical Performance criteria of paragraph 5.1.4. All sampling will be performed in the breathing zone of the respirator. The respirator is tested in an atmosphere containing 20–40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 µm. The LRPL shall be calculated using ten exercises: Normal Breathing, Deep Breathing, Turn Head Side to Side, Move Head Up and Down, Recite the Rainbow Reading Passage or equivalent, Reach for the Floor and Ceiling, On Hands and Knees – Look Side to Side, Facial Grimace, and Climb Stairs at a Regular Pace.

All sampling will be performed in the breathing zone of the respirator. The respirator is tested in an atmosphere containing 20–40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 μm. The atmosphere shall be maintained at normal operating conditions (ambient target) for LRPL Tests (70 °F, 50 % RH).

Test subject and replication numbers are indicated in Table 5 for a 3-size Configuration.

Table 5.— Anthropometric test criteria for a 3 size configuration

	Small	Medium	Large
Head Circumference*	Cell B	Cell E	Cell H
	N/A	N/A	378-451 mm
	Subjects = 0 Trials = 0	Subjects = 0 Trials = 0	Subjects = 10 Trials = 20
Neck Circumference*	Cell C	Cell F	Cell I
	306-378 mm	355-403 mm	378-451 mm
	Subjects = 10 Trials = 20	Subjects = 10 Trials = 20	Subjects = 10 Trials = 20

* If applicable to design of PAPR.

For each size category (Small, Medium, and Large), each cell corresponding to the anthropometric parameter will be tested. Cells can be either exclusively tested (if the test subjects only meet the requirements of a specific cell) or simultaneously tested (if the test subjects meet the requirements of more than one cell) tested for each size category.

User instructions must clearly and accurately explain how users choose appropriate size.

4.13. Practical Performance:

The Practical Performance of the powered air-purifying respirator shall be evaluated as part of the test procedures of paragraph 4.12, Laboratory Respirator Protection Level, and paragraph 4.6.2, Human Subject Breathing Gas. The Practical Performance of the respirator shall evaluate human interface issues associated with the use of the respirator. As a minimum, factors which will be evaluated (if applicable based upon the respirator design) are: the inability for the user to accidentally turn the power switch off; and the inability for hoses and electrical wires to tangle, causing the respirator position on the wearer to move to an improper position, such as the respirator facepiece or hood being removed from the wearer's head. Test subjects shall be trained on proper use of the respirator in accordance with the applicant's user instructions.

Practical Performance trials shall be accumulated from the test procedure of paragraph 4.12, Laboratory Respirator Protection Level, and paragraph 4.6.2, Human Subject Breathing Gas. For the total of these accumulated trials, 95% of these trials shall exhibit acceptable Practical Performance. Should 95% of the Practical Performance test trials not

Draft For Discussion
April 1, 2005

be acceptable, one additional run of test trials of paragraph 4.12 or paragraph 4.6.2, may be performed to increase the total number of trials. The total number of trials will be the sum of trials from the first and second run of subjects.

4.14 Failure Modes and Effects Analysis:

Failure Modes and Effects Analysis (FMEA) is methodology for analyzing potential reliability problems early in the development cycle where it is easier to take actions to overcome these issues, thereby enhancing reliability through design. FMEA is used to identify potential failure modes, determine their effect on the operation of the product, and identify actions to mitigate the failures. The FMEA is required to demonstrate that when all manufacturer specified maintenance, use, and pre-use procedures are followed, there shall be no potential failure modes during normal use.

The early and consistent use of FMEAs in the design process allows the manufacturer to design out failures and produce reliable, safe, and customer pleasing products. FMEAs should always be done whenever failures would mean potential harm or injury to the user of the end item being designed.

Respirators submitted for WMD Capable PAPR approval shall include a design FMEA that accompanies the quality control plan meeting the requirements of Subpart E of Title 42, *Code of Federal Regulations* (CFR), Part 84. The design FMEA shall include identifying the design characteristics that contributes to failures and how they were addressed in product design. It will also address how the failure modes effects were minimized as well as addressing problem prevention and actions taken to reduce risk.

4.15 Test Sequence:

Test Order	42 CFR Testing	Human Factors	Service Life Testing	Particulate Cartridge Degradation	Penetration and Permeation Testing	Efficiency Particulate Cartridge	LRPL Test
Qty	3 PAPR systems; 3 exhalation valve assy.	9 PAPR Systems, 6 lens samples	60 sets of cartridges (estimated)	6 sets of cartridges	6 PAPR systems	20 sets of cartridges	25 to 38 systems
1.	Breathing Tube	Commo.	Initial Breathing Resistance	Initial Breathing Resistance	System Testing	Filter Efficiency	LRPL
2.	Facepieces; eyepieces minimum requirement	Field of View	Service Life Testing, Less Cyclohexane,	Service Life Cyclohexane			Practical Performance Test
3.	Cartridge in Parallel Resistance	Practical Perform. Test	Final Breathing Resistance	Final Breathing Resistance			
4.	Exhalation valve leakage			DOP Testing			

	Test						
5.	Determine CO ₂ levels						

5.0. Quality Assurance Requirements:

5.1. Quality Control Plan: Respirators submitted for approval shall be accompanied by a complete quality control plan meeting the requirements of Subpart E of Title 42, *Code of Federal Regulations* (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 cartridges demonstrating compliance with the gas life and particulate filter requirements of this standard.

6.0. General Requirements:

In addition to the requirements of Title 42, *Code of Federal Regulations* (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 4.11 Systems Tests are excluded from this requirement.

7.0 Cautions and Limitations:

- Not for use in atmospheres containing less than 19.5 percent oxygen, and atmospheres that have a potential for liquid chemical warfare agent contamination.
- Failure to properly use and maintain this product could result in injury or death.
- Follow the manufacturer's User's Instructions for changing canisters.
- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.

Draft For Discussion
April 1, 2005

- Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.
- 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.
- Not for entry into atmospheres immediately dangerous to life and health or where hazards have not been fully characterized.
- Use replacement parts in the configuration as specified by the applicable regulations and guidance.
- Consult manufacturer's User Instructions for information on the use, storage, and maintenance of these respirators.
- This respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. Procedures for monitoring radiation exposure and full radiation protection must be followed.
- If during use, an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforeseen hazard, immediately leave the area for clean air.
- Follow established canister change out schedules or observe End of Service Life Indicators to ensure that canisters are replaced before breakthrough occurs.
- Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. Failure to do so may result in personal injury even when the respirator is properly fitted, used, and maintained.
- The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If exposed to liquid chemical warfare agents during use, exit immediately for decontamination and respirator disposal.