DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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October 8, 2003

LETTER TO ALL RESPIRATOR MANUFACTURERS

Subject: Voluntary Program for Acceptance of Applications for the Testing and Evaluation of Air-Purifying Escape Respirators and Self-Contained Escape Respirators for Use Against Chemical, Biological, Radiological and Nuclear (CBRN) Agents

It is imperative that the general working population be afforded effective respiratory protection in escaping from terrorist events involving possible chemical, biological, radiological and nuclear (CBRN) agents. Due to ongoing concern of a potential terrorist event and the need to provide the general working population with the best available respiratory protection as quickly as possible, the National Institute for Occupational Safety and Health (NIOSH) (or the Institute) is instituting this voluntary approval program on an expedited basis. The Institute will begin accepting applications on November 6, 2003, to test and evaluate air-purifying escape respirators for use against CBRN agents. The Institute will begin accepting applications on January 2, 2004, to test and evaluate self-contained escape respirators for use against CBRN agents. This letter informs manufacturers of voluntary requirements that air-purifying escape respirators and self-contained escape respirators must meet in order to obtain NIOSH approval. It also provides the procedures for the submission of applications for these approvals.

In April 2000, NIOSH entered into a Memorandum of Understanding with the National Institute for Standards and Technology (NIST), the Occupational Safety and Health Administration, and the National Fire Protection Association (NFPA) to work on the development of standards for all types of counter-terrorism respiratory protective equipment. NIOSH and NIST initiated Interagency Agreements with the U.S. Army Soldier and Biological Chemical Command (SBCCOM) for development of respiratory protection standards, test procedures and laboratory support. The new requirements for an air-purifying escape respirator and self-contained escape respirator certification have been developed under these agreements, and are responsive to public comments NIOSH received during three public meetings, numerous stakeholder meetings and to the NIOSH docket. NIOSH initiates this voluntary approval program pursuant to Title 42, *Code of Federal Regulations* (CFR), Part 84.60(b), 84.63(c), and 84.110(c). These sections provide NIOSH with the authority to issue approvals for respirators not specifically addressed in Part 84 and to develop additional requirements that the agency determines are "necessary to establish the

quality, effectiveness and safety of any respirator used as protection against hazardous atmospheres."

NIOSH will issue an approval and approval labels identifying the air-purifying escape respirators and self-contained escape respirators as appropriate for use against CBRN agents.

Requirements for Approval

To be approved for use in providing protection against CBRN agents, NIOSH has determined that an air-purifying escape respirator must be evaluated against the criteria defined in the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Air-Purifying Escape Respirator dated September 30, 2003. (Attachment A)

To be approved for use in providing protection against CBRN agents, NIOSH has determined that a self-contained escape respirator must be evaluated against the criteria defined in the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Self-Contained Escape Respirator dated September 30, 2003. (Attachment B)

Applications will be processed in the order in which they are received by the Institute. Priority of applications received on the same day will be based on a random selection from all applications received on that day. The applicant shall provide three complete respirator systems with the application. Two of the submitted units will be used for testing in accordance with Chemical Agent Penetration and permeation Resistance Against Distilled Sulfur Mustard (HD) and Sarin (GB) Agent Requirement and one will be used for general examination. The applicant will have eight weeks following notification of successful completion of the GB and HD tests, to complete the application with data from pretesting conducted by or for the applicant and remaining test equipment. See Attachment C, Guidelines for Identification of Test Configurations for Exposure to GB/HD and Part Number Change Guidelines for use in determining respirator configurations for test: Attachment D, Test Equipment and Test Data, Approval Labels and Markings contains information for providing test equipment, test data and approval labels and Attachment E, CBRN Escape Respirator Certification Costs, identifies test and evaluation fees and contains additional information about the application procedure.

Notification to Users and Regulatory Agencies

NIOSH will maintain and disseminate approval lists for respirators approved under this program. These lists will be entitled CBRN Air-Purifying Escape Respirators and CBRN Self-Contained Escape Respirators. The lists will contain the manufacturer, model, component parts, accessories, and rated duration. These lists will be maintained as a separate category within the NIOSH Certified Equipment List.

NIOSH will also disseminate the list of approved CBRN Air-Purifying Escape Respirators and CBRN Self-Contained Escape Respirators by maintaining the list on its website,

www.cdc.gov/niosh/homepage.html, and seek to have it placed on or linked to other appropriate websites that disseminate information regarding respiratory protection. In addition, NIOSH will supply the list to the Occupational Safety and Health Administration for dissemination to its district offices.

Respirator Identification / Labeling

In accordance with the requirements of paragraph 84.33 of Title 42, CFR, Subpart D, approval labels for the air-purifying escape respirator shall be marked with a CBRN Rating as determined by Paragraph 4.1, Duration Rating, of the Statement of Standard for Chemical, Biological, Radiological and Nuclear Air-Purifying Escape Respirator, dated September 30, 2003.

NIOSH will authorize the use of an additional approval label on the self-contained escape respirator that demonstrates compliance to the CBRN criteria. This label is to be placed in a visible location. The addition of this label will provide visible and easy identification of equipment for its appropriate use. In accordance with the requirements of paragraph 84.33 of Title 42, CFR, Subpart D, approval labels shall be marked with a CBRN rating as determined by Paragraph 4.1, Duration Rating, of the Statement of Standard for Chemical, Biological, Radiological and Nuclear Self-Contained Escape Respirator, dated September 30, 2003.

Cautions and Limitations for both types of escape respirators, Attachment F, must be incorporated as appropriate to type, into the manufacturers' instructions for use and canister label.

Standard Test Procedures that will be used to test and evaluate both types of escape respirators will be available on the NIOSH/NPPTL web site, http://www.cdc.gov/niosh/npptl/default.html.

If you need additional information, please contact: NIOSH at 412-386-4000 or e-mail at npptl@cdc.gov.

Sincerely yours,

for R J B

Roland J. Berry Ann
Branch Chief
Respirator Branch
National Personal Protective Technology Laboratory

Enclosures

September 30, 2003

Attachment A

Statement of Standard
For
Chemical, Biological, Radiological, and Nuclear (CBRN)
Air-Purifying Escape Respirator

1.0 Purpose:

The purpose of this standard is to specify minimum requirements to determine the effectiveness of air-purifying escape respirators that address CBRN materials identified as inhalation hazards from possible terrorist events for use by the general working population. The air-purifying escape 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

3.0 Requirements Based on Existing National and International Standards:

3.1 Breathing Resistance:

The resistance of airflow shall be measured at the breathing zone (nose cup or mouthpiece) of an air-purifying escape respirator mounted on a head form test apparatus operated at a continuous airflow rate of 85 Liters per minute (Lpm). The inhalation resistance shall not exceed 70 mm H_2O and the exhalation resistance shall not exceed 20 mm H_2O.

3.2 Field of View:

The air-purifying escape respirator shall obtain a Visual Field Score (VFS) of 70 or greater when tested in accordance with NIOSH Standard Test Procedure CET-APRS-STP-CBRN-0314. 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 Fogging:

The air-purifying escape respirator shall demonstrate an average Visual Acuity Score (VAS) of greater or equal to 70 points for all measurements for each individual. A minimum of two respirators shall be evaluated.

The respirator shall be donned by the test subject in an indoor ambient temperature of approximately 72 ± 2^0 F at 40±5% Relative Humidity (RH) and then shall enter into a simulated outdoor extreme temperature chamber where the visual acuity tests shall be administered. The air-purifying escape respirator shall be tested for fogging in the hot/humid condition of 90 ± 2^0F and 60±5% RH, and the cold condition of 13 ± 2^0F.

3.4 Breathing Gas:

Breathing gas criteria will be evaluated as a two-part requirement: 1) a dead-space carbon dioxide test performed with a breathing machine and 2) carbon dioxide and oxygen concentrations during human test subject exercises. The wearer shall not experience undue discomfort because of restrictions to breathing or other physical or chemical changes to the respirator. All trials shall be considered as part of the Practical Performance criteria of paragraph 4.8.

3.4.1 Breathing Machine

The maximum allowable average inhaled carbon dioxide concentration shall be less than or equal to 1 percent, measured at the mouth, while the air-purifying escape 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 that of the ambient room oxygen concentration. NIOSH Test Procedure RCT-APR-STP-0064 is used for carbon dioxide testing.

3.4.2 Human Subject 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 the limits as stated in Table 1.

Table 1.—Inspired carbon dioxide limits

Where the service time is	Maximum time-weighted fractional concentration of inspired carbon dioxide
15 min or 30 min	0.025 (or 2.5%)
45 min or 60 min	0.020 (or 2.0%)

The inhaled carbon dioxide concentration shall be as indicated in the above table. The inhaled fractional oxygen concentration shall be no less than 0.195 (or19.5%) 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. Table 2 gives face length and width criteria, which the subjects will be required to fill. Table 2 is applicable for 'one size fits all air-purifying escape respirator' or an air-purifying escape respirator with small, medium and large sizes. For other variations in air-purifying escape respirator size, test subjects will be determined to provide for panel range of Table 2.

Table 2.—Test design criteria

*LANL Boxes – 'Small'	*LANL Boxes – 'Medium'	*LANL Boxes – 'Large'
1, 2, 3, 4	**3, 4, 5, 6, 7, 8**	**7, 8, 9, 10**
Four subjects in 'Small' boxes. More than one subject possible in any box.	Four subjects in 'Medium' boxes. More than one subject possible in any box.	Four subjects in 'Large' boxes. More than one subject possible in any box.

*Adapted from the Los Alamos National Laboratory report respirator test panel

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, 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 4.8.

3.5 Flammability and Heat Resistance (applicable ONLY to respirators approved for carbon monoxide protection):

Air-purifying escape respirators submitted for approval for carbon monoxide protection shall be tested for Flammability and Heat Resistance using the test equipment specified in EN 136, Respiratory Protective Devices, Full Face Masks, Requirements, Testing, Marking, 1998 Edition, Class 1 facepiece. No component of the respirator shall have an after flame after 5 seconds. No component of the escape respirator shall drip, melt, or develop a visible hole.

The distance between the outer surface of the escape respirator and the burner shall be adjusted to 20 ± 2 mm. The pressure reducer shall be adjusted to $2.1 \pm .05$ psi. The temperature of the flame positioned above the burner tip shall be 800 ± 50^0 C at a point 20 ± 2 mm above the tip. The respirator shall be rotated once through the flame at a velocity of 6 ± 0.5 cm/s. Where components of the respirator such as valves, filters, etc. are arranged on the respirator, the test shall be repeated with these components at the appropriate height of 250 mm $\pm$ 6.4 mm.

3.6 Design Considerations:

3.6.1 Function:

The air-purifying escape respirator shall provide a barrier from ambient conditions for the wearer's entire head, eyes, and respiratory system. The air-purifying escape respirator shall not require the use of hands to maintain the respirator position to ensure proper function of the respirator when fully donned.

3.6.2 Hood Type Device:

The air-purifying escape respirator shall be designed as a hooded device. The hood shall include an area for field of vision. A hood is a respirator component which covers the wearer's head and neck, or head, neck, and shoulders, and is supplied with incoming respirable air for the wearer to breathe.

3.6.3 Respiratory Protection System:

The respiratory protection system may consist of an oral/nasal cup or mouthpiece. If a mouthpiece is employed, a method of preventing nasal breathing must be provided. An oral/nasal cup or a mouthpiece is not required provided all requirements of this standard are fulfilled by the air-purifying escape respirator.

4.0 Special CBRN Requirements:

4.1 Duration Rating:

Escape respirators will be rated for 15, 30, 45, or 60-minute duration as specified by the manufacturer. Only one duration rating can apply to any respirator.

4.2 Canister Test Challenge and Test Breakthrough Concentrations.

4.2.1 General Category

Escape respirators shall meet the gas/vapor test challenge concentrations in Table 3, when tested in accordance with 4.3 Gas Life requirements.

Table 3.—Gas/vapor test challenge concentrations

Agent	Test Challenge(ppm)	Breakthrough (ppm)
Ammonia	1250	25
Cyanogen Chloride	150	2
Cyclohexane	1300	10
Formaldehyde	250	10
Hydrogen Cyanide	470	10*
Hydrogen Sulfide	500	30
Nitrogen Dioxide	100	1 ppm NO2
Phosgene	125	1.25
Phosphine	150	0.5
Sulfur Dioxide	750	5

* Sum of HCN and C2N2

4.2.1.1 General Category Escape Respirator Multi Gas/Vapor/Particulate with Carbon Monoxide Requirements:

Escape respirators intended for use at the General category with carbon monoxide protection shall meet the requirements of paragraph 4.2.1 plus carbon monoxide.

For the general category, the test challenge concentration shall be 3600 ppm. The maximum allowable carbon monoxide penetration shall not exceed the values identified in the Table 4. The penetration of carbon monoxide shall not exceed a maximum peak excursion of 500 ppm at any point of the test.

Table 4.—Carbon monoxide penetration limits

Identified Service Life (Minutes)	Concentration-time(Ct) (ppm-minutes_
15	6037
30	12075
45	18111
60	24150

The respirators will be evaluated under the following test conditions:

a) Three respirators tested at 64+10 Lpm continuous airflow at 89 to 95% relative humidity, $25\pm3^{0}C$

b) Three respirators tested at 64+10 Lpm continuous airflow at 89 to 95% relative humidity, $0\pm2.5^{0}C$

4.2.1.1.1 Service Life Testing, High Flow, Carbon Monoxide:

The escape respirator shall provide a minimum duration of 5 minutes when tested at a flow rate of 100+10 Lpm, 89 to 95% relative humidity, 25±3°C, when tested at a challenge concentration of 3600 ppm. The penetration of carbon monoxide shall not exceed a maximum peak excursion of 500 ppm at any point of the test. The maximum allowable carbon monoxide penetration shall not exceed an overall Ct of 2013 ppm-minutes. Three respirators will be tested.

4.2.1.1.2 Inspired Air Temperature, Carbon Monoxide:

Three escape respirators mounted to a head form and connected to a breathing machine, cycling at 40Lpm, 36 respirations per minutes, 1.1 Liters tidal volume, will be tested with a challenge concentration of 1200 ppm (IDLH), at 89 to 95% relative humidity and 25±2.5°C. The inspired air temperature measured at the facepiece must always be less than or equal to 46°C (dry bulb) with less than or equal to 10 ppm CO for the entire test if the inspired air humidity is less than or equal to 50%. The inspired air temperature must be less than or equal to 41°C (dry bulb) with less than or equal to 10 ppm CO for the entire test if the inspired air relative humidity is greater than 50%. NIOSH test procedure RCT-APR-STP-0034 will be used.

4.2.2 Specific Category:

Escape respirators intended for use at the specific hazard threat category conditions shall meet the gas/vapor testing of paragraph 4.2.1. In addition to the test requirements of paragraph 4.2.1, test concentrations for additional specific test agent protections shall be as specified in Table 5.

Table 5.—Agent challenge concentrations

Agent	Test Challenge (ppm)
Ammonia	2500
Cyanogen Chloride	300
Cyclohexane	2600
Formaldehyde	500
Hydrogen Cyanide	940
Hydrogen Sulfide	1000
Nitrogen Dioxide	200
Phosgene	250
Phosphine	300
Sulfur Dioxide	1500

Additional specific test agent protections can be added to the minimum as specified by the applicant for any combination of the listed test agents. Test breakthrough concentrations for the specific category shall be the breakthrough concentrations identified in paragraph 4.2.1.

4.2.2.1 Specific Category Escape Respirator Multi Gas with Carbon Monoxide Requirements:

Escape respirators intended for use at the Specific category with carbon monoxide protection shall meet the requirements of paragraph 4.2.2 for the requested test agent protection, plus carbon monoxide.

For the specific category, the carbon monoxide test challenge concentration shall be 6000 ppm. The maximum allowable carbon monoxide penetration shall not exceed the values identified in paragraph 4.2.1.1 and Table 4.

4.2.2.1.1 Service Life Testing, High Flow, Carbon Monoxide:

The escape respirator shall provide a minimum duration of 5 minutes when tested at a flow rate of 100+10 Lpm, 89 to 95% relative humidity, 25±3°C, when tested at a challenge concentration of 6000 ppm. The penetration of carbon monoxide shall not exceed a maximum peak excursion of 500 ppm at any point of the test. The maximum allowable carbon monoxide penetration shall not exceed a Ct of 2013 ppm-minutes. Three respirators will be tested.

4.2.2.1.2 Inspired Air Temperature, Carbon Monoxide:

Three systems mounted to a head form and connected to a breathing machine, cycling at 40 Lpm, 36 respirations per minute, 1.1 Liters tidal volume, will be tested with a challenge concentration of 1200 ppm IDLH (IDLH) at 89 to 95% relative humidity and 25±2.5°C. The inspired air temperature measured at the facepiece must always be less than or equal to 46°C (dry bulb) and less than or equal to 10 ppm CO for the entire test if the inspired air humidity is less than or equal to 50%. The inspired air temperature must be less than or equal to 41°C (dry bulb) and less than or equal to 10 ppm CO for the entire test if the inspired air relative humidity is greater than 50%. NIOSH test procedure RCT-APR-STP-0034 will be used.

4.3 Gas Life:

Gas life tests are performed at room temperature, 25±5°C; 25±5 percent relative humidity, and 80±5 percent relative humidity. Three filters will be tested at each specified humidity with a flow rate of 64+10 Lpm, continuous flow. Tests will be conducted to minimum specified service time. Gas testing shall be performed following environmental conditioning and rough handling. The breakthrough concentration must be no greater than the specified breakthrough for each tested gas in Table 3. Testing is terminated after the applicant's specified service time is achieved.

4.4 Particulate/Aerosol Canister:

The canister shall meet the requirements of a P100 particulate filter in accordance with the following criteria of 42 CFR, Part 84.

1) Twenty filters for the air-purifying respirator shall be tested for filter efficiency against a dioctyl phthalate or equivalent liquid particulate aerosol.

2) Filters 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.

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

4) For air-purifying particulate respirators with a single filter, filters shall be tested at a continuous airflow rate of 85 $\pm$ 4 liters per minute. Where filters are to be used in pairs, the test-aerosol airflow rate shall be 42.5 $\pm$ 2 liters per minute through each filter.

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

6) The test shall continue until minimum efficiency is achieved or until an aerosol mass of at least 200 $\pm$ 5 mg has contacted the filter. If the filter efficiency is decreasing when the 200 $\pm$ 5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency.

7) The DOP aerosol shall have a particle size distribution with count median diameter of 0.185 $\pm$ 0.020 micrometer and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

8) The efficiency of the filter shall be monitored and recorded throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation.

9) The minimum efficiency for each of the 20 filters shall be determined and recorded and be equal to or greater than the filter efficiency criterion listed for the P100 filter: $\geq$99.97%.

4.5 Service Life Testing, High Flow:

Each escape respirator shall provide a minimum duration of 5 minutes when tested at a flow rate of 100$\pm$10 Lpm, 50$\pm$5 percent relative humidity and 25+5^{0}C for each of the gases/vapors identified in paragraphs 4.2.1 and 4.2.2.

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

The air-purifying escape 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 Lpm, 36 respirations per minute, 1.1 Liters tidal volume.

Test requirements for Distilled Sulfur Mustard (HD) are shown in Table 6.

Table 6.—Vapor-Liquid Sequential Challenge of Air-Purifying Escape Respirator with Distilled Sulfur Mustard (HD)

Agent	Challenge Concentration	Duration of Challenge (min)	Breathing Machine Airflow Rate (Lpm)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough (concentration integrated over minimum service life) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Test Time (hours)
HD-Vapor	50 mg/m^{3*}	15/30/45/60*,**					
HD-Liquid	0.43 to 0.86 ml†	15/30/45/60*,**	40	0.60‡	6.0§,‡‡	3	30/60/90/120††

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

†. Minimum volume is 0.43 ml based on the respirator and single canister. Liquid volume is applied as 25 drops of equal size.

‡ Three consecutive sequential test data points at or exceeding 0.6 mg/m^3 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.

** Duration of challenge is 15, 30, 45, or 60 minutes, equal to applicant's identified rated duration (para 4.1)

†† Minimum Test Life is 30, 60, 90, or 120 minutes, equal to twice the applicant's rated duration (para 4.1)

‡‡ Respirators will be monitored in the oral/nasal and ocular regions

Test requirements for Sarin (GB) agent are shown in Table 7.

Table 7.—Vapor Challenge of Air-Purifying Escape Respirator with Sarin (GB)

Challenge Concentration	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Breathing Machine Airflow Rate (Lpm)	Maximum Peak Excursion mg/m^3	Maximum Breakthrough (concentration integrated over minimum service life) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Test Time (hours)
GB	210	15/30/ 45/60*,**	40	0.087‡	0.9 for 15 and 30 minute devices 2.1 for 45 and 60 minute devices§,‡‡	3	30/60/ 90/120†,††

* 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.

‡ Three consecutive sequential test data points at or exceeding 0.087 mg/m^3 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. The breakthrough duration is based upon the applicant's identified duration.

** Duration of challenge is 15, 30, 45, or 60 minutes, equal to applicant's identified rated duration (para 4.1)

†† Minimum Test Life is 30, 60, 90, or 120 minutes, equal to twice the applicant's identified rated duration (para 4.1).

‡‡ Respirators will be monitored in the oral/nasal and ocular regions

4.7 Laboratory Respiratory Protection Level (LRPL) Test Requirement:

The measured laboratory respiratory protection level (LRPL) for each air-purifying escape respirator shall be 2000 or greater, for 95% of trials, sampled in the breathing zone of the respirator, and shall be 150, or greater, for 95% of trials, sampled outside the breathing zone (under the hood). Each trial must meet the breathing zone criteria and 'under the hood' criteria simultaneously for the trial to be considered passing. Test subject and replication numbers are outlined in Table 8.

Table 8.—Anthropometric test criteria

	Small	Medium	Large
	Cell A	**Cell D**	**Cell G**
Face Length and Face Width	***Use LANL boxes 1, 2, 3, 4 (2 or 3 subjects each box, 2 trials per subject)**	***Use LANL boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 subjects each box, 2 trials per subject)**	***Use LANL boxes 7, 8, 9, 10; panel size 11 (2 or 3 subjects each box, 2 trials per subject)**
	Subjects= 10	Subjects= 17	Subjects= 11
	Trials= 20	Trials= 34	Trials= 22
	Cell B	**Cell E**	**Cell H**
Head Circumference	**N/A**	**N/A**	**570-603 mm**
	Subjects= 0	Subjects= 0	Subjects= 10
	Trials= 0	Trials= 0	Trials= 20
	Cell C	**Cell F**	**Cell I**
Neck Circumference	**306-378 mm**	**355-403 mm**	**378-451 mm**
	Subjects= 10	Subjects= 10	Subjects= 10
	Trials= 20	Trials= 20	Trials= 20

*Adapted from the Los Alamos National Laboratory report respirator test panel

The respirator is tested in an atmosphere containing 20-40 mg/m^3 corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers. Should a group of test subjects result in LRPL trials where less than 95% of trials have passing results, one addition run of test subjects that fills the entire anthropometric panel requirements 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 4.8. The LRPL shall be calculated using nine exercises: Normal Breathing, Deep Breathing, Turn Head Side to Side, Move Head Up and Down, Reach for the Floor and Ceiling, On Hands and Knees - Look Side to Side, Facial Grimace, Climb Stairs at a Regular Pace, and Normal Breathing.

For each size category (Small, Medium, and Large), each cell corresponding to the anthropometric parameter will be tested. Cells can be either consecutively 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) for each size category.

4.8 Practical Performance:

The Practical Performance of the air-purifying escape respirator shall be evaluated as part of the test procedures of paragraphs 3.4, Breathing Gas, and 4.7, Laboratory Respirator Protection Level. The Practical Performance of the respirator shall evaluate human

interface issues associated with the use of the escape respirator. As a minimum, contributing factors (if applicable based upon the respirator design) are: the use of mouth bits and nose clips; seal of the hood around the respirator wearer's neck; seating of inner masks; position of the hood on the respirator wearer's head; and strength required to don the respirator. Test subjects shall be trained on proper use of the escape respirator in accordance with the applicant's instructions identified in paragraph 8.0, Training. Inability of any test subject participating in the test procedures of paragraphs 3.4, Breathing Gas, and 4.8, Laboratory Respirator Protection Level, to complete the test procedures shall constitute a failure of the Practical Performance requirement for that trial.

Practical Performance trials shall be accumulated from the test procedures of paragraphs 3.4, Breathing Gas, and 4.7, Laboratory Respirator Protection Level. 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 be acceptable, one additional run of test trials consisting of either, or both, paragraph 3.4, Breathing Gas, or paragraph 4.8, Laboratory Respirator Protection Level, 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.

4.9 Donning:

The time to don the respirator from the ready-to-use configuration shall be no greater than 30 seconds. The ready to use configuration is the operational packaging state prior to use such that immediately upon opening allows the user to don the respirator.

4.10 Environmental Conditioning Requirements:

Environmental, vibration, and drop conditioning shall be performed on escape respirators in the ready-to-use configuration. The ready-to-use configuration is the operational packaging state prior to use, such that immediately upon opening allows the user to don the respirator. Respirators will be visually inspected following environmental conditioning to ensure no damage or deterioration has occurred that could negatively affect the intended use of the respirator.

Environmental conditioning shall be performed in accordance with Table 9.

Table 9.—Environmental Conditioning

Test	Test Method	Test Condition	Duration
Hot Constant	Mil-Std-810F; Method 501.4	71°C (160°F), Constant	5 Weeks
Cold Constant	Mil-Std-810F, Method 502.4	Basic Cold, -32°C (-24°F); Constant	3 Days
Humidity	Mil-Std-810E, 507.3;	Realistic, Natural Cycle Humidity Profiles in the U.S.	5 Days, "Quick Look" Mil-Std-810E Table 507.3-II
Transportation/Vibration	Mil-Std-810F, 514.5	US Roadway Vibration, Unrestrained	12 Hours/Axis, 3 Axis; Total Duration =36 Hours, equivalent to 12,000 miles
Drop	Standard Drop Test	Height of 3 feet	1 drop on each of the 3 Axes per Unit.

4.11 Test Sequence and Quantity:

Testing of the Escape Respirator shall follow Table 10.

Table 10.—Test Sequence and Quantity

Test Order	Resistance and Breathing Gas	Human Factors	Service Life, 100 Lpm	Service Life Testing, 64 Lpm flow	Penetration and Permeation Testing	Efficiency Particulate	LRPL Test†
Qty	24*	3-9	30	60	6 *	20	30-65
1	Inhalation Resistance Para 3.1	Donning Para 4.9	Hot Constant Para 4.10	Hot Constant Para 4.10	Hot Constant Para 4.10	Hot Constant Para 4.10	LRPL Para 4.7
2.	Exhalation Resistance Para 3.1	Fogging Para 3.3	Cold Constant Para 4.10	Cold Constant Para 4.10	Cold Constant Para 4.10	Cold Constant Para 4.10	Practical Performance Para 4.8
3.	CO_2 Machine Testing 84.63(b)(c)(d) Para.3.4.1	Field of View Para 3.2	Humidity Para 4.10	Humidity Para 4.10	Humidity Para 4.10	Humidity Para 4.10	
4.	Breathing Gas (Human Subjects) Para 3.4.2	Flammability and Heat Resistance Para 3.5	Transportation/ Vibration Para 4.10	Transportation/ Vibration Para 4.10	Transportation/ Vibration Para 4.10	Transportation/ Vibration Para 4.10	
5.	Practical Performance Para 4.8		Drop Para 4.10	Drop Para 4.10	Drop Para 4.10	Drop Para 4.10	
6.			Service Life 100 Lpm Para 4.3	Service Life 64 Lpm Para 4.2	System Testing Para 4.6	Filter Efficiency Para 4.4	

* 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. 4.10 Environmental Conditioning. Four systems tests, 2 GB and 2 HD, are performed after Para. 4.10 Environmental Conditioning.

† All tests in the Resistance and Breathing Gas and LRPL column are performed prior to Paragraph 4.10, Environmental Conditioning

5.0 Quality Assurance Requirements:

5.1 Quality Control Plan:

Respirators submitted for CBRN 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 air-purifying escape respirators demonstrating compliance with the gas life and particulate filter requirements of this standard.

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. Chemical Agent Penetration and Permeation Resistance against Distilled Sulfur Mustard (HD) and Sarin (GB) tests, Paragraph 4.6, are excluded from this requirement.

7.0 Useful Life and Maintenance:

The applicant will identify an initial useful life, not to exceed five (5) years, of the escape respirator. The "useful life" is defined as the length of time a unit can remain deployed in the 'ready to use' stowed condition. All applications for certification must specify useful service life with supporting data and rationale. Further, a rationale must be included for any sampling plan set forth in the user's manual which would extend the useful life of the

escape respirator beyond any initial useful life. However, extensions of useful life will be determined during the last year of the initial useful life.

The following guidelines should be included in the useful service life plans:

a. Useful life plans should be based upon reliability engineering methodology and describe the conditions for use for the unit. Each plan will be individually evaluated.

b. All respirator service actions are the responsibility of the applicant, or their authorized representative. The user/owner of the respirators should perform basic inspections as described in the instruction manual and/or as required by federal regulations.

c. In order for an escape respirator to receive an incremental useful life extension, some service action must be performed on each unit.

d. After the service action has been performed, the applicant, or their authorized representative, should collect a random sample of the serviced units and performance test these respirators to verify that they function as approved. The purpose of post-service sampling and performance testing is to identify unexpected problems caused by uncontrolled or unpredicted factors.

e. The applicant may define "performance testing" by specifying the following: test procedures, pass/fail standards, performance tolerances, sample size, etc.

f. An acceptable useful life plan is exemplified in Table 11.

Table 11.—Useful life plan timeline

Start	1st Service Date	2nd Service Date	3rd -- etc.	Stop
[--------I----------	---------I----------	---------I----------	---------I----------	-------I→
1st Service expiration date permanently visible on the unit	After a completed action on each unit stamp 2nd service date or terminal date	After a completed action on each unit stamp 3rd service date or terminal date	After a completed action, etc.	Terminal End of useful life

Note: The date on which the unit must be removed from service is to be permanently marked and clearly visible on the unit at the time of manufacture. If an incremental service life is granted, the applicant, or their authorized representative, must stamp the unit with a new date, as described by the time line model. The terminal date represents the final expiration date of the unit with no further extensions.

8.0 Training:

The applicant shall identify training requirements associated with their air-purifying escape respirator. As a minimum, the applicant shall include an instruction manual, which shall address donning procedures, respirator use, maintenance (care and useful life), and cautions and limitations. The applicant shall also provide for training aid systems, to include a training respirator that mimics the performance of the approved

respirator, such as inhalation and exhalation breathing resistance that will develop user proficiency in operation of the equipment, as well as identification of periodic refresher training requirements to maintain user proficiency. The applicants' training materials shall be used as the basis for preparing the human test subjects in the test procedures of paragraph 3.4, Breathing Gas, paragraph 4.7, Laboratory Respirator Protection Level, and paragraph 4.9, Donning.

9.0 Markings and Labels:

In accordance with the requirements of paragraph 84.33 of 42 CFR, Subpart D, approval labels shall be marked with a CBRN Rating as determined by paragraph 4.1 Duration Rating, of the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Air-Purifying Escape Respirator dated September 30, 2003. For example:

(a) Respirators receiving approval for a 30 minute duration rating are marked:

ESCAPE ONLY NIOSH CBRN 30.

(b) Respirators receiving approval for a 30 minute duration rating with carbon monoxide protections are marked:

ESCAPE ONLY NIOSH CBRN 30 with Carbon Monoxide

(c) Respirators receiving approval for a 30 minute duration rating with a specific category are marked:

ESCAPE ONLY NIOSH CBRN 30 with "chemical" Specific

(d) Respirators receiving approval for a 30 minute duration, with an specific category, and carbon monoxide are marked:

ESCAPE ONLY NIOSH CBRN 30 with "chemical" Specific and with Carbon Monoxide

September 30, 2003

Attachment B

Statement of Standard
For
Chemical, Biological, Radiological, and Nuclear (CBRN)
Self-Contained Escape Respirator

1.0 Purpose:

The purpose of this standard is to specify minimum requirements to determine the effectiveness of self-contained escape respirators that address CBRN materials identified as inhalation hazards from possible terrorist events for use by the general working population. 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 H:

Approval under Title 42, CFR, Part 84, Subpart H, for escape only, with a minimum service time of 15 minutes.

3.0 Requirements Based on Existing National and International Standards:

3.1 Field of View:

The CBRN self-contained escape respirator shall obtain a Visual Field Score (VFS) of 70 or greater when tested in accordance with NIOSH Standard Test Procedure CET-APRS-

STP-CBRN-0314. 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.

3.2 Fogging:

The CBRN self-contained escape respirator shall demonstrate an average Visual Acuity Score (VAS) of greater or equal to 70 points for all measurements for each individual. A minimum of two respirators shall be evaluated.

The respirator shall be donned by the test subject in an indoor ambient temperature of approximately 72±2°F at 40±5% Relative Humidity (RH) and then shall enter into a simulated outdoor extreme temperature chamber where the visual acuity tests shall be administered. The self-contained escape respirator shall be tested for fogging in the hot/humid condition of 90±2°F and 60±5% RH and the cold condition of 13±2°F.

3.3 Breathing Gas:

Breathing gas criteria will be evaluated as a two-part requirement: 1) a dead-space CO_2 test performed with a breathing machine and 2) carbon dioxide and oxygen concentrations during human test subject exercises. The wearer shall not experience undue discomfort because of restrictions to breathing or other physical or chemical changes to the respirator. All trials shall be considered as part of the Practical Performance criteria of paragraph 4.4.

3.3.1 Breathing Machine

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 that of the ambient room oxygen concentration. NIOSH Test Procedure RCT-APR-STP-0064 is used for carbon dioxide testing

3.3.2 Human Subject 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 the limits as stated in Table 1.

Table 1.—Inspired carbon dioxide limits

Where the service time is	Maximum time-weighted fractional concentration of inspired carbon dioxide
15 min or 30 min	0.025 (or 2.5%)
45 min or 60 min	0.020 (or 2.0%)

The inhaled carbon dioxide concentration shall be as indicated in the above table. The inhaled fractional oxygen concentration shall be no less than 0.195 (or19.5%) 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. Table 2 gives face length and width criteria, which the subjects will be required to fill. Table 2 is applicable for 'one size fits all air-purifying escape respirator' or an air-purifying escape respirator with small, medium and large sizes. For other variations in air-purifying escape respirator size, test subjects will be determined to provide for panel range of Table 2.

Table 2.—Test design criteria

*LANL Boxes – 'Small'	*LANL Boxes – 'Medium'	*LANL Boxes – 'Large'
1, 2, 3, 4	**3, 4, 5, 6, 7, 8**	**7, 8, 9, 10**
Four subjects in 'Small' boxes. More than one subject possible in any box.	Four subjects in 'Medium' boxes. More than one subject possible in any box.	Four subjects in 'Large' boxes. More than one subject possible in any box

*Adapted from the Los Alamos National Laboratory report respirator test panel

Each exercise will be performed for ten minutes. Carbon dioxide and oxygen data will be considered for the last five minutes of each exercise. For each of these last five minutes, the last five 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 4.4.

3.4 Flammability and Heat Resistance:

Self-contained escape respirators submitted for approval shall be tested for Flammability and Heat Resistance using the test equipment specified in EN 136, Respiratory Protective Devices, Full Face Masks, Requirements, testing, Marking, 1998 Edition, Class 1 facepiece. No component of the respirator shall have an after flame after 5 seconds. No component of the escape respirator shall drip, melt, or develop a visible hole.

The distance between the outer surface of the escape respirator and the burner shall be adjusted to 20 ± 2 mm. The pressure reducer shall be adjusted to 2.1 ± .05 psi. The temperature of the flame positioned above the burner tip shall be 800±500 C at a point 20+2 mm above the tip. The respirator shall be rotated once through the flame at a velocity of 6 ± 0.5 cm/s. Where components of the respirator such as valves, filters, etc. are arranged on the respirator, the test shall be repeated with these components at the appropriate height of 250 mm ± 6.4 mm.

3.5 Design Considerations:

3.5.1 Function:

The self-contained escape respirator shall provide a barrier from ambient conditions for the wearer's entire head, eyes, and respiratory system. The self-contained escape respirator shall not require the use of hands to maintain the respirator position to ensure proper function of the respirator when fully donned.

3.5.2 Hood Type Devices:

The self-contained escape respirator shall be designed as a hooded device. The hood shall include an area for field of vision. A hood is a respirator component which covers the wearer's head and neck, or head, neck and shoulders, and is supplied with incoming respirable air for the wearer to breathe.

3.5.3 Respiratory Protection System:

The respiratory protection system may consist of an oral/nasal cup or mouthpiece. If a mouthpiece is employed, a method of preventing nasal breathing must be provided. An oral/nasal cup or a mouthpiece is not required provided all requirements of this standard are fulfilled by the self-contained escape respirator.

4.0 Special CBRN Requirements:

4.1 Duration/Service Life:

The self-contained escape respirator shall have a minimum service life of 15 minutes.

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

The self-contained escape 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. For closed circuit devices, they will be connected to a metabolic breathing simulator, using the following protocol:

For a mean VO2 = 1.67 L/min for 30 minutes (aggregate VO2 = 50 L/minTime)

Min	VO2 L/min, STPD	VCO2 L/min, STPD	Minute Ventilation L/min, STPD	Resp.rate b/min
0-5	3.0	3.2	65	25
6-20	2.0	1.8	44	20
21-30	0.5	0.4	20	12

For open circuit devices, a breathing machine will be used, operating at an air flow rate of 19.5 Lpm,18 respirations per minute, 1.1 Liters tidal volume.

Test requirements for Distilled Sulfur Mustard (HD) are shown in Table 3.

Table 3.—Vapor-Liquid Sequential Challenge of Self-contained Escape Respirator with Distilled Sulfur Mustard (HD)

Agent	Challenge Concentration	Duration of Challenge (min)	Breathing Machine Airflow Rate (Lpm)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough (concentration integrated over minimum service life) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Service Life (hours)
HD-Vapor	300 mg/m^3*	Stated Duration*,**					
HD-Liquid	0.50 ml†	Stated Duration**	19.5	0.60‡	6.0§,‡‡	3	Stated Duration††

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

†Liquid volume is applied as 25 drops of equal size.

‡ Three consecutive sequential test data points at or exceeding 0.6 mg/m^3 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.

** Duration of challenge is equal to applicant's identified duration

†† Minimum Service Life is equal to twice the applicant's identified duration.

‡‡ Respirators will be monitored in the oral/nasal and ocular regions

Test requirements for Sarin (GB) agent are shown in Table 4.

Table 4.—Vapor Challenge of Self-contained Escape Respirator with Sarin (GB)

Challenge Concentration	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Breathing Machine Airflow Rate (Lpm)	Maximum Peak Excursion mg/m^3	Maximum Breakthrough (concentration integrated over minimum service life) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Service Life (hours)
GB	Total CT of 10,000$mg\text{-}m^3$ $	Stated Duration*, **	19.5	0.087‡	0.9 for durations less than 30 minutes 2.1 for durations greater than 30 minutes§,‡‡	3	Stated Duration†, ††

* 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.

‡ Three consecutive sequential test data points at or exceeding 0.087 mg/m^3 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.

** Duration of challenge is equal to applicant's identified duration

†† Minimum Service Life is equal to the applicant's identified duration.

‡‡ Respirators will be monitored in the oral/nasal and ocular regions

$ Exposure will include at least two minutes at a concentration of 2000 $mg\text{-}m^3$

4.3 Laboratory Respiratory Protection Level (LRPL) Test Requirement:

The measured laboratory respiratory protection level (LRPL) for each air purifying escape respirator shall be 3000 or greater, for 95% of trials, sampled in the breathing zone of the respirator, and shall be 150, or greater, for 95% of trials, sampled outside the breathing zone (under the hood). Each trial must meet the breathing zone criteria and 'under the hood' criteria simultaneously for the trial to be considered passing. Test subject and replication numbers are outlined in Table 5.

Table 5.—Anthropometric test criteria

	Small	Medium	Large
	Cell A	Cell D	Cell G
Face Length and Face Width	Use LANL boxes 1, 2, 3, 4 (2 or 3 subjects each box, 2 trials per subject)	Use LANL boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 subjects each box, 2 trials per subject)	Use LANL boxes 7, 8, 9, 10; panel size 11 (2 or 3 subjects each box, 2 trials per subject)
	Subjects= 10	Subjects= 17	Subjects= 11
	Trials= 20	Trials= 34	Trials= 22
	Cell B	Cell E	Cell H
Head Circumference	N/A	N/A	570-603 mm
	Subjects= 0	Subjects= 0	Subjects= 10
	Trials= 0	Trials= 0	Trials= 20
	Cell C	Cell F	Cell I
Neck Circumference	306-378 mm	355-403 mm	378-451 mm
	Subjects= 10	Subjects= 10	Subjects= 10
	Trials= 20	Trials= 20	Trials= 20

The respirator is tested in an atmosphere containing 20-40 mg/m^3 corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers. Should a group of test subjects result in LRPL trials where less than 95% of trials have passing results, one addition run of test subjects that fills the entire anthropometric panel requirements 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 requirement criteria of paragraph 4.4. The LRPL shall be calculated using nine exercises: Normal Breathing, Deep Breathing, Turn Head Side to Side, Move Head Up and Down, Reach for the Floor and Ceiling, On Hands and Knees - Look Side to Side, Facial Grimace, Climb Stairs at a Regular Pace, and Normal Breathing.

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

4.4 Practical Performance:

The Practical Performance of the air-purifying escape respirator shall be evaluated as part of the test procedures of paragraphs 3.4, Breathing Gas, and 4.7, Laboratory Respirator Protection Level. The Practical Performance of the respirator shall evaluate human

interface issues associated with the use of the escape respirator. As a minimum, contributing factors (if applicable based upon the respirator design) are: the use of mouth bits and nose clips; seal of the hood around the respirator wearer's neck; seating of inner masks; position of the hood on the respirator wearer's head; and strength required to don the respirator. Test subjects shall be trained on proper use of the escape respirator in accordance with the applicant's instructions identified in paragraph 8.0, Training. Inability of any test subject participating in the test procedures of paragraphs 3.3, Breathing Gas, and 4.3, Laboratory Respirator Protection Level, to complete the test procedures shall constitute a failure of the Practical Performance requirement for that trial.

Practical Performance trials shall be accumulated from the test procedures of paragraphs 3.3, Breathing Gas, and 4.3, Laboratory Respirator Protection Level. 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 be acceptable, one additional run of test trials consisting of either, or both, paragraph 3.3, Breathing Gas, or paragraph 4.3, Laboratory Respirator Protection Level, 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.

4.5 Donning:

The time to don the self-contained escape respirator from the ready-to-use configuration shall be no greater than 30 seconds. The ready to use configuration is the operational packaging state prior to use such that immediately upon opening allows the user to don the respirator.

4.6 Environmental Conditioning Requirements:

Environmental, vibration, and drop conditioning shall be performed on the self-contained escape respirators in the ready-to-use configuration. The ready-to-use configuration is the operational packaging state prior to use, such that immediately upon opening allows the user to don the respirator. Respirators will be visually inspected following environmental conditioning to ensure no damage or deterioration has occurred that could negatively affect the intended use of the respirator.

Environmental conditioning shall be performed in accordance with Table 6.

Table 6.—Environmental Conditioning

Test	Test Method	Test Condition	Duration
Hot Constant	Mil-Std-810F; Method 501.4	71°C (160°F), Constant	5 Weeks
Cold Constant	Mil-Std-810F, Method 502.4	Basic Cold, -32°C (-24°F); Constant	3 Days
Humidity	Mil-Std-810E, 507.3;	Realistic, Natural Cycle Humidity Profiles in the U.S.	5 Days, "Quick Look" Mil-Std-810E Table 507.3-II
Transportation/Vibration	Mil-Std-810F, 514.5	US Roadway Vibration, Unrestrained	12 Hours/Axis, 3 Axis; Total Duration =36 Hours, equivalent to 12,000 miles
Drop	Standard Drop Test	Height of 3 feet	1 drop on each of the 3 Axes per Unit.

4.7 Test Sequence and Quantity:

Testing of the self-contained escape respirator shall follow Table 7.

Table 7.—Test Sequence and Quantity

Test Order	Breathing Gas†	Human Factors	Penetration and Permeation Testing	LRPL Test †
Qty	24.	5-11	6 systems *	30-65
1.	Breathing Gas Para 3.3	Donning Para 4.5	Hot Constant Para 4.6	LRPL Para 4.3
2	Practical Performance Para 4.4	Fogging Para 3.2	Cold Constant Para 4.6	Practical Performance Para 4.4
3		Field of View Para 3.1	Humidity Para 4.6	
4		Flammability and Heat Resistance Para 3.4	Transportation/ Vibration Para 4.6	
5			Drop Para 4.6	
6			System Testing Para 4.2	

* 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. 4.6 Environmental Conditioning. Four systems tests, 2 GB and 2 HD, are performed after Para. 4.6 Environmental Conditioning.

† Breathing Gas and LRPL are performed prior to Paragraph 4.6, Environmental Conditioning

5.0 Quality Assurance Requirements:

5.1 Quality Control Plan:

Respirators submitted for CBRN approval shall be accompanied by a complete quality control plan meeting the requirements of Subpart E of Title 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.

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 4.2, are excluded from this requirement.

7.0 Useful Life and Maintenance:

The applicant will identify an initial useful life, not to exceed five (5) years, of the escape respirator. The "useful life" is defined as the length of time a unit can remain deployed in the 'ready to use' stowed condition. All applications for certification must specify useful service life with supporting data and rationale. Further, a rationale must be included for any sampling plan set forth in the user's manual which would extend the useful life of the escape respirator beyond any initial useful life. However, extensions of useful life will be determined during the last year of the initial useful life.

The following guidelines should be included in the useful service life plans:

a. Useful life plans should be based upon reliability engineering methodology and describe the conditions for use for the unit. Each plan will be individually evaluated.

b. All respirator service actions are the responsibility of the applicant, or their authorized representative. The user/owner of the respirators should perform basic inspections as described in the instruction manual and/or as required by federal regulations.

c. In order for an escape respirator to receive an incremental useful life extension, some service action must be performed on each unit.

d. After the service action has been performed, the applicant, or their authorized representative, should collect a random sample of the serviced units and performance test these respirators to verify that they function as approved. The purpose of post-service sampling and performance testing is to identify unexpected problems caused by uncontrolled or unpredicted factors.

e. The applicant may define "performance testing" by specifying the following: test procedures, pass/fail standards, performance tolerances, sample size, etc.

f. An acceptable useful life plan is exemplified in Table 8.

Table 8.—Useful life plan timeline

Start	1st Service Date	2nd Service Date	3rd -- etc.	Stop
[--------I----------	---------I----------	---------I----------	---------I----------	-------I→
1st Service expiration date permanently visible on the unit	After a completed action on each unit stamp 2nd service date or terminal date	After a completed action on each unit stamp 3rd service date or terminal date	After a completed action, etc.	Terminal End of service life

Note: The date on which the unit must be removed from service is to be permanently marked and clearly visible on the unit at the time of manufacture. If an incremental service life is granted, the applicant, or their authorized representative, must stamp the unit with a new date, as described by the time line model. The terminal date represents the final expiration date of the unit with no further extensions.

8.0 Training:

The applicant shall identify training requirements associated with their air-purifying escape respirator. As a minimum, the applicant shall include an instruction manual, which shall address donning procedures, respirator use, maintenance (care and useful life), and cautions and limitations. The applicant shall also provide for training aid systems, to include a training respirator that mimics the performance of the approved respirator, such as inhalation and exhalation breathing resistance that will develop user proficiency in operation of the equipment, as well as identification of periodic refresher training requirements to maintain user proficiency. The applicants' training materials shall be used as the basis for preparing the human test subjects in the test procedures of paragraph 3.3, Breathing Gas, paragraph 4.3, Laboratory Respirator Protection Level, and paragraph 4.5, Donning.

9.0 Markings and Labels:

NIOSH will authorize the use of an additional approval label on the self-contained escape respirator that demonstrates compliance to the CBRN criteria. This label is to be placed in a visible location. The addition of this label will provide visible and easy identification of equipment for its appropriate use. In accordance with the requirements of paragraph 84.33 of 42 CFR, Subpart D, approval labels shall be marked with a CBRN Rating as determined by paragraph 4.1 Duration/Service Life Rating. For example, respirators tested for 15 minutes are marked ESCAPE ONLY NIOSH CBRN 15.

September 30, 2003

Attachment C

Guidelines for Identification of Test Configurations for Exposure to GB/HD
And Part Number Change Guidelines

Guidelines for Identification of Test Configurations for Exposure to GB/HD

Guidelines for determining respirator configurations that need to be tested for agent resistance in accordance with sarin (GB) and mustard (HD) agent test provisions of the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Air-Purifying Escape Respirator and the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Self-Contained Escape Respirator are:

A. Unique parts, components and/or materials that form a pressure boundary between the breathing gas and the ambient environment need to be tested. For respirators that use a neck dam, if the neck dam is visible after the respirator has been properly mounted on the SMARTMAN apparatus during testing, the neck dam will be challenged with liquid HD exposure.

B. Unique parts, components and/or materials that have a direct effect on the ability of the respirator to provide respiratory protection, such as a facepiece head-harness, need to be tested.

Warfare agents, sarin (GB) and distilled sulfur mustard (HD), are aggressive penetrating and permeating substances. In order to ensure the integrity of the respirator is maintained during and after exposure to these agents, all parts that form a boundary between the breathing gas and ambient conditions need to be tested. Pressure boundary parts identical in configuration but made from different materials need to be individually tested as separate respirator configurations. For example, the same facepiece made from two different materials, natural rubber and EPDM, must be tested as separate respirator configurations.

Test agents can also attack materials causing them to deteriorate and fail. A facepiece headharness that fails during use could affect the user to facepiece seal. Consequently, head harnesses manufactured from different materials must be individually tested as separate respirator configurations.

Part Number Change Guidelines:

Design changes to components or parts that have a direct effect on the ability of the respirator to provide respiratory protection need to be evaluated to determine the need for a part number change. The evaluation needs to consider the forward and backward compatibility of the part or component both before and after the design change. If the part or component is not forward and backward compatible before and after the change, a new part number is required for the part or component and the NIOSH approved subassembly in which it is used.

September 30, 2003
Rev. 1, October 2, 2003

Attachment D

Test Equipment and Pre-approval Test Data, Approval Labels and Markings

Test Equipment and Pre-approval Test Data:

The applicant shall provide three complete respirator assemblies for testing in accordance with Paragraph 4.6, Chemical Agent Permeation and Penetration Resistance Against Distilled Mustard (HD) and Sarin (GB) Agent Requirement of the Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Respirator OR Paragraph 4.2, Chemical Agent Permeation and Penetration Resistance Against Distilled Mustard (HD) and Sarin (GB) Agent Requirement of the Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Self-contained Escape Respirator.

Following successful completion of one GB and one HD test, the applicant will be instructed to complete the application and send all additional test equipment and pre-approval test data. The additional test equipment and data must be provided within eight weeks of notification to complete the application. Additional equipment submitted must include the following estimated numbers of respirator assemblies for a new respirator certification that requires all tests:

Air-Purifying Respirator Assemblies

Number of Sizes	Maxium Number of Respirator Assemblies for Each Size		
Three (3) Sizes	32 (Small)	164 (Medium)	43 (Large)
Two (2) Sizes	62 (Small/Medium)	190 (Medium/Large)	Not Applicable
One (1), 'One-Size-Fits-All'	234 (One Size)	Not Applicable	Not Applicable

Self-Contained Respirator Assemblies

Number of Sizes	Maxium Number of Respirator Assemblies for Each Size		
Three (3) Sizes	31 (Small)	47 (Medium)	42 (Large)
Two (2) Sizes	62 (Small/Medium)	71 (Medium/Large)	Not Applicable
One (1), 'One-Size-Fits-All'	115 (One Size)	Not Applicable	Not Applicable

Approval Labels and Markings:

In accordance with the requirements of paragraph 84.33 of Title 42, CFR, Subpart D, approval labels for the air-purifying escape respirator shall be marked with a CBRN Rating as determined by Paragraph 4.1, Duration Rating, of the Statement of Standard for Chemical, Biological, Radiological and Nuclear Air-Purifying Escape Respirator, dated September 30, 2003. For example:

(a) Respirators receiving approval for a 30 minute duration rating are marked:
ESCAPE ONLY NIOSH CBRN 30

(b) Respirators receiving approval for a 30 minute duration rating with carbon monoxide protections are marked: ESCAPE ONLY NIOSH CBRN 30 with Carbon Monoxide

(c) Respirators receiving approval for a 30 minute duration rating with a specific category are marked: ESCAPE ONLY NIOSH CBRN 30 with "chemical" Specific

(d) Respirators receiving approval for a 30 minute duration, with an specific category, and carbon monoxide are marked: ESCAPE ONLY NIOSH CBRN 30 with "chemical" Specific and with Carbon Monoxide

NIOSH will authorize the use of an additional approval label on the self-contained escape respirator that demonstrates compliance to the CBRN criteria. This label is to be placed in a visible location. The addition of this label will provide visible and easy identification of equipment for its appropriate use. In accordance with the requirements of paragraph 84.33 of 42 CFR, Subpart D, approval labels shall be marked with a CBRN rating as determined by Paragraph 4.1, Duration Rating, of the Statement of Standard for Chemical, Biological, Radiological and Nuclear Self-Contained Escape Respirator, dated September 30, 2003. For example, respirators tested for 15 minutes shall be marked ESCAPE ONLY NIOSH CBRN 15.

September 30, 2003

Attachment E

CBRN Air-Purifying Escape Respirator
CBRN Self-Contained Escape Respirator
Inspection and Certification Fees

The following fees will be charged for examination, inspection, and testing of the CBRN Air-Purifying Escape Respirator and CBRN Self-Contained Escape Respirator:

CBRN Air-Purifying Escape Respirator	$ 97,950
CBRN Self-Contained Escape Respirator	$103,600

Itemized testing fees are as follows:

Environmental Conditioning	$ 32,300
Laboratory Respirator Protection Level (LRPL)	$ 15,000
P100 Particulate	$ 1,750
Service Life Test	$ 6,600
Systems Agent Test (SMARTMAN)	$ 27,800
Bench Tests (Resistance, Valve Leakage, CO_2)	$ 10,850
Fogging	$ 2,700
Field of View	$ 950
	$ 97,950

Flammability & Heat Resistance (if required)	$14,000

Self-Contained Escape Respirator

Itemized testing fees are as follows:

Environmental Conditioning	$32,300
Laboratory Respirator Protection Level (LRPL)	$15,000
Systems Agent Test (SMARTMAN)	$27,800
Flammability & Heat Resistance	$14,000
Bench Tests (Resistance, Valve Leakage, CO_2)	$10,850
Fogging	$ 2,700
Field of View	$ 950
	$103,600

September 30, 2003

Attachment F

Cautions and Limitations – Air-Purifying Escape Respirators:

The following Cautions and Limitations statements shall be prominently displayed in the respirator user instructions:

1. This respirator is to be used for escape only and will protect against the inhalation of certain respiratory hazards.
2. Not for use in atmospheres containing less than 19.5 percent oxygen.
3. Failure to properly use and maintain this product could result in injury or death.
4. All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
5. Refer to User's Instructions and/or maintenance manuals for information on use and maintenance of these respirators.
6. Consult manufacturer's User's Instructions for information on the use, storage, and maintenance of these respirators at various temperatures.
7. This respirator provides respiratory protection against inhalation of certain gas and vapor chemical agents, biological particulates, and radiological and nuclear dust particles. This respirator provides limited dermal (skin) protection to the head area and eyes.
8. Eye irritation may be experienced based upon the CBRN agent and exposure (concentration and duration)
9. Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.
10. CBRN Agents, depending on how they are used, may provide disabling effects as a result of skin exposure
11. Direct contact with CBRN agents requires proper handling of the respirator after use. Correct disposal procedures must be followed.

For air-purifying escape respirators that include carbon monoxide protections:

12. This respirator provides protection from certain inhalation hazards associated with fire.

These limitations are not all inclusive. The respirator manufacturer may also identify further cautions and limitations for their respirators. In addition, regulatory agencies may also place a limit on the use of respirators in their standards.

Cautions and Limitations – Self-Contained Escape Respirators:

The following Cautions and Limitations statements shall be prominently displayed in the respirator user instructions:

1. This respirator is to be used for escape only and will protect against the inhalation of certain respiratory hazards.
2. Failure to properly use and maintain this product could result in injury or death.
3. All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
4. Refer to User's Instructions and/or maintenance manuals for information on use and maintenance of these respirators.
5. Consult manufacturer's User's Instructions for information on the use, storage, and maintenance of these respirators at various temperatures.
6. This respirator provides respiratory protection against inhalation of certain gas and vapor chemical agents, biological particulates, and radiological and nuclear dust particles. This respirator provides limited dermal (skin) protection to the head area and eyes.
7. Eye irritation may be experienced based upon the CBRN agent and exposure (concentration and duration)
8. Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.
9. CBRN Agents, depending on how they are used, may provide disabling effects as a result of skin exposure
10. Direct contact with CBRN agents requires proper handling of the respirator after use. Correct disposal procedures must be followed.
11. This respirator provides protection from certain inhalation hazards associated with fire.

These limitations are not all inclusive. The respirator manufacturer may also identify further cautions and limitations for their respirators. In addition, regulatory agencies may also place a limit on the use of respirators in their standards.