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 ± 2^0F 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 ± 2^0F and 60 ± 5% RH and the cold condition of 13 ± 2^oF.

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
Face Length and Face Width	**Cell A** **Use LANL boxes 1, 2, 3, 4 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 10 Trials= 20	**Cell D** **Use LANL boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 17 Trials= 34	**Cell G** **Use LANL boxes 7, 8, 9, 10; panel size 11 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 11 Trials= 22
Head Circumference	**Cell B** **N/A** Subjects= 0 Trials= 0	**Cell E** **N/A** Subjects= 0 Trials= 0	**Cell H** **570-603 mm** Subjects= 10 Trials= 20
Neck Circumference	**Cell C** **306-378 mm** Subjects= 10 Trials= 20	**Cell F** **355-403 mm** Subjects= 10 Trials= 20	**Cell I** **378-451 mm** Subjects= 10 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	71^0C (160^0F), Constant	5 Weeks
Cold Constant	Mil-Std-810F, Method 502.4	Basic Cold, -32^0C (-24^0F); 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.

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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
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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.