National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236		
Procedure No. CET-APRS-STP-CBRN-0456	Revision: 1.1	Date: 22 December 2005

DETERMINATION OF PRACTICAL PERFORMANCE LEVEL FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) AIR-PURIFYING ESCAPE RESPIRATOR AND SELF-CONTAINED ESCAPE RESPIRATOR (SCER) STANDARD TEST PROCEDURE (STP)

1. PURPOSE

1.1. This test establishes procedures for evaluating the practical performance level requirements provided by the chemical, biological, radiological, and nuclear (CBRN) air-purifying escape respirator (APER) and self-contained escape respirator (SCER) submitted for new approval, extension of approval, or examined during certified product audits, meets the minimum certification standards set forth in this standard test procedure (STP) as prescribed in *42 CFR, Part 84, Subpart G, Section 84.63(a)(c)&(d)* and *Federal Register*, Volume 60, Number 110, June 8, 1995.

1.2. The purpose of this STP is to describe the procedures to test and certify civilian manufacturer submitted CBRN APER and SCER certification applications for NIOSH approval. A CBRN APER or SCER is a complete system including a tight-fitting hooded respiratory device including: 1) the proper designations required by NIOSH and the manufacturer's unique components and 2) a compatible negative pressure air-purifying device or self-contained breathing gas supply that is installed per the manufacturer's current user instructions.

1.3. This STP is used to evaluate the practical performance level of CBRN APER and SCER when human subjects attempt to successfully don, wear, complete test exercises, and doff the unit as described in the following four NIOSH standard test procedures:

1.3.1. *Determination of Laboratory Respirator Protection Level (LRPL) Quantitative, Medium Flow, Deep Probe, Corn Oil, Fit Factor Performance Test for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator Standard Testing Procedure (STP) (CET-APRS-STP-CBRN-0452).*

1.3.2. *Determination of Laboratory Respirator Protection Level (LRPL) Quantitative, Medium Flow, Deep Probe, Corn Oil, Fit Factor Performance Test for Chemical, Biological, Radiological, and Nuclear (CBRN) Self-Contained Escape Respirator (SCER) Standard Testing Procedure (STP) (CET-CBRN-ESCAPE-STP-0453).*

Approvals:	1st Level	2nd Level	3rd Level

1.3.3. *Determination of Human Subject Breathing Gas (HSBG) Concentrations (Carbon Dioxide and Oxygen) for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator Standard Testing Procedure (STP) (CET-APRS-STP-CBRN-0454).*

1.3.4 *Determination of Human Subject Breathing Gas (HSBG) Concentrations (Carbon Dioxide and Oxygen) for Chemical, Biological, Radiological, and Nuclear (CBRN) Self-Contained Escape Respirator (SCER) Standard Testing Procedure (STP) (CET-CBRN-ESCAPE-STP-0455).*

1.4. Procedures in this STP will be used each time a subject attempts to successfully don, wear, complete test exercises, and doff the unit when participating in exercises of any of the NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP for partial fulfillment of requirements for CBRN approval.

1.5. The practical performance level as described in this STP will be used to verify that all CBRN APER and SCER, seeking NIOSH CBRN approval, have:

1.5.1. Good self-donning, self-doffing, and fitting characteristics that can accommodate a wide variety of facial sizes and shapes, neck circumferences, and head circumferences.

1.5.2. User instructions for donning, wearing, and doffing that are easily understood, applicable to all components, both visual and written, and current.

1.5.3. Achieved a pass or fail result based on the practical performance level testing requirements described in the STP.

1.5.4. Been evaluated on subjects having facial sizes and shapes, neck circumferences, and head circumferences, which approximate the distribution of these anthropometric parameters of the user population applicable to the currently approved versions of the *Statements of Standard for CBRN APER and SCER Escape Respirators.*

2. GENERAL

2.1. This document describes procedures for determining the practical performance level for the CBRN APER and SCER in sufficient detail that a team of persons knowledgeable in the appropriate technical field can evaluate individual subject test trials on a practical performance level pass or fail basis.

2.2. Practical performance level factors which shall be evaluated on a pass or fail basis (as applicable based upon respirator design) are:

2.2.1. The ability to use mouth bits and nose clips.
2.2.2. Tightness of seal of the hood around the respirator wearer's neck.
2.2.3. Proper seating of inner masks.
2.2.4. Proper position of the hood on the respirator wearer's head.

2.2.5. The ability to self don and doff the respirator.
2.2.6. The ability to complete the test exercise.

2.3. This test is considered a human factors test that requires participation of human subjects. The quantity and selection criteria of human subjects are specified within the relevant NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

2.4. This STP shall be used to test different types of CBRN APER and SCER for meeting the minimum requirements of the practical performance level. The CBRN APER is an escape only, hooded, air-purifying respiratory protective device. The CBRN SCER is an escape only, hooded, self-contained breathing apparatus (open circuit or closed circuit).

3. EQUIPMENT AND MATERIALS

3.1. Test Equipment and Test Items. The list of necessary test equipment and test items to be used are specified within the relevant NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

3.2. Human Subjects. The quantity and selection criteria of human subjects are specified within the relevant NIOSH STPs identified in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

3.2.1. When evaluating the practical performance level of APER during the laboratory respirator protection level (LRPL) test (*CET-CBRN-ESCAPE-STP-0452)* and evaluating the practical performance level of SCER during the LRPL test (CET-CBRN-ESCAPE-STP-0453), all procedures and requirements specified in the NIOSH Human Subject Review Board (HSRB) Protocol *HSRB-03-NPPTL-04XP*, dated July 31, 2003, entitled, "*Determination of Laboratory Respirator Protection Level (LRPL) for Respiratory Protective Devices (RPD)*" shall be followed and met. Informed consent will be obtained from each volunteer upon completion of the Volunteer Agreement Affidavit and Volunteer Agreement Affidavit Explanation contained in Protocol *HSRB-03-NPPTL-04XP*. The test subjects shall be required to complete a health history questionnaire as part of the Volunteer Agreement Affidavit Explanation contained in Protocol *HSRB-03-NPPTL-04XP*. As specified in this protocol, the test subjects shall be subjected to facial, neck, and head measurements. The electronic or manual caliper and measuring tape shall be used to determine facial, neckhead size and panel placement prior to each test subject donning an APER or SCER.

3.2.2. When evaluating the practical performance level of APER and SCER during the HSBG tests, all procedures and requirements specified in the HSRB Protocol (*HSBG) Concentrations (Carbon Dioxide and Oxygen) for Chemical, Biological, Radiological And Nuclear (CBRN) Self-Contained Escape Respirator (SCER) and Air-purifying Escape Respirator (APER) Submitted for NIOSH Certification* shall be followed and met. For practical performance level determination of APER and SCER evaluated during the HSBG test, informed consent will be obtained from each volunteer upon completion of the designated forms within the referenced HSRB protocol.

3.2.3. Test Administrator(s). Shall have successfully completed the Centers for Disease Control and Prevention (CDC)/ Agency for Toxic Substances and Disease Registry (ATSDR) *Scientific Ethics Training,* the Department of Health and Human Services (DHHS)/National Institutes of Health (NIH) *Human Participant Protections Education for Research Teams* or an equivalent NIOSH sanctioned course. Note: The NIOSH Human Subject Review Board will determine if specific courses not stated above are equivalent.

4. TESTING REQUIREMENTS AND CONDITIONS

Note: Review the manufacturer's operation and maintenance manuals of laboratory test equipment for calibration instructions, operational use, and maintenance procedures prior to commencing this STP.

4.1. Any laboratory using this procedure to supply certification test data to NIOSH will be subject to the provisions of the NIOSH Supplier Qualifications Program (SQP). This program is based on the tenets of *ISO/IEC 17025*, the *NIOSH Manual of Analytical Methods* and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the program. Additional details of the program and its requirements can be obtained directly from the Institute.

4.2. Precision and accuracy (P&A) must be determined for each instrument in accordance with laboratory procedures and NIOSH/NPPTL guidance. Sound practice requires, under *NIOSH Manual of Analytical Methods*, demonstrating a tolerance range of expected data performance of a plus or minus 25% of a 95% confidence interval of the stated standard requirement. NIOSH/NPPTL P&A tolerance can be higher but not lower.

4.3. Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with the manufacturer's calibration procedure and schedule. At a minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months using a method traceable to the National Institute of Standards and Technology (NIST).

4.3.1. Calibration: The calibration criteria of test equipment are specified within the relevant NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

4.4. Safety. Normal laboratory safety practices must be observed. This includes safety precautions described in the current *Centers for Disease Control and Prevention (CDC) General Laboratory Health and Safety Manual* or site-specific procedures that are applicable to health and safety requirements.

4.5. Certification Inventory. The certification inventory criteria are specified within the relevant NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

4.6. User Instructions. The practical performance level evaluation will be performed each time a subject attempts to successfully don, wear, complete test exercises, and doff the

unit when participating in exercises of any of the NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP for partial fulfillment of requirements for CBRN approval. Prior to attempting to don the APER or SCER, the user's instructions provided with the test equipment shall be reviewed by the test facility personnel and the test subjects. Test subjects will be taught by the principal investigator or a facility representative on the areas of manufacturer's size selection, donning, fit check, doffing, and other fitting procedures for the APER or SCER, in order to represent any training prescribed or offered by the manufacturer's instructions. Any clarifications or supplemental instructions provided by manufacturer representatives at the time of certification inventory, during the test, or after the test, must be NIOSH reviewed prior to incorporation into revised user instructions before final NIOSH approval is granted.

5. PROCEDURE

5.1. General

5.1.1. This procedure describes the practical performance level test for ensuring that the level of respiratory protection provided by the CBRN APER and SCER meets or exceeds the requirements defined in the currently approved versions of the statements of standards for the CBRN APER or SCER being tested for approval. Practical performance level factors which shall be evaluated on a pass or fail basis (as applicable based upon respirator design) are identified in Paragraph 2.3. of this STP.

5.1.2. This procedure describes the required subject sample size, test equipment and test items, data collection methods, human use protocol requirements, and the specific practical performance level requirements for the APER or SCER being tested.

5.2. Number of Test Samples

5.2.1. The quantities of test samples (CBRN APER or SCER) are specified within the relevant NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

5.2.2. All CBRN APER and SCER shall be individually numbered with an indelible pen or tagged in a sequence such that the number can be correlated to the NIOSH application number (TN), manufacturer, and tracked throughout the relevant NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

5.2.3. The administrative sequence numbers are to be replicated in the test summary data sheets to indicate product performance per the stated requirement.

5.3. Test Equipment Set-Up

5.3.1. Test equipment set-up requirements are specified within the relevant NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

5.4. Conducting the Practical Performance Test

5.4.1. Panels. The quantity and selection criteria of human subjects are specified within the relevant NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP.

5.4.2. Training. Prior to attempting to don the APER and SCER, the user's instructions provided with the test equipment shall be reviewed by the test facility personnel and the test subjects. Test subjects will be taught by the principal investigator or a facility representative on the areas of manufacturer's size selection, donning, fit check, doffing, and other fitting procedures for the APER or SCER, in order to represent any training prescribed or offered by the manufacturer's instructions. Any clarifications or supplemental instructions provided by manufacturer representatives at the time of certification inventory, during the test, or after the test must be NIOSH reviewed prior to incorporation into revised user instructions before final NIOSH approval is granted.

5.4.3. Self Donning and Doffing. Each test subject shall perform an unassisted donning and doffing of the APER or SCER in accordance with the manufacturer's user instructions. Prior to beginning test activities, each test subject will conduct self-donning under the supervision of the principal investigator or a test facility representative and is permitted time to make the appropriate adjustments to the unit until they are satisfied that they are wearing the unit in compliance with the manufacturer's user's instructions. Self-donning and doffing rely on the clarity of the user instructions to address (if applicable based on the respirator's design) head harness pull-tab sequence, unit orientation, and other APER or SCER component orientations. If the human test subject cannot doff the escape respirator efficiently or exhibits emergency concerns requiring immediate removal of the APER or SCER, laboratory personnel are authorized to remove the respirator from the subject. Each wearer is not subjected to any undue discomfort or encumbrance because of the donning or doffing of the respirator during certification testing period.

5.4.4. Data Sheets. Practical performance level determination is performed during the NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP. Practical performance level data will be recorded in the Practical Performance Level Observation Data Sheet located in Appendix A.

6. PASS OR FAIL CRITERIA

6.1. Procedures in this STP will be used each time a subject attempts to successfully don, wear, complete test exercises, and doff an APER or SCER when participating in exercises of any of the NIOSH standard test procedures stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP. A practical performance failure does not count against the pass or fail determination of the individual performance criteria of the NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP. A chart demonstrating the relationship of the practical performance level to the NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP is included in Appendix B.

6.2. Each trial testing of the NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP will be assessed on a pass or fail basis of practical performance. The specific practical performance assessment factors are identified in para 2.3 of this STP.

6.3. Pass or fail data from practical performance trials shall be accumulated from all trials of the NIOSH STPs stated in para 1.3.1., 1.3.2., 1.3.3., and 1.3.4. of this STP. For the total of these accumulated trials, ≥95% of these trials shall exhibit acceptable (passing) practical performance. Should <95% of the practical performance test trials be acceptable (passing), one additional run of test trials consisting of either human subject breathing gas and laboratory respirator protection level, or both, may be performed to increase the total number of practical performance level trials. The total number of trials will be the sum of trials from the first and second run of subjects.

7. ADDITIONAL REQUIREMENTS

7.1. In addition to the stated requirements, NIOSH/NPPTL reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous CBRN atmospheres.

7.2. Where it is determined after receipt of an application that additional requirements are necessary for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

8. RECORDS AND TEST DATA SHEETS

8.1. Data Sheets. Practical performance level determination is performed during the NIOSH STPs stated in para 1.3.1, 1.3.2, 1.3.3, and 1.3.4 of this STP. Practical performance level data will be recorded in the Practical Performance Level Observation Data Sheet located in Appendix A.

8.2. All videotapes and photographs of the actual test being performed and of the tested equipment shall be maintained in the task file as part of the permanent record.

8.3. All equipment failing any portion of this test will be handled as follows:

8.3.1. If the failure occurs on a new certification application, or extension of approval application, the Test Facility Manager (Principal Investigator or designee) will send a test report to the NIOSH Certification Evaluation and Testing (CET) Section Team Leader and prepare the hardware for return to the manufacturer.

8.3.2. If the failure occurs on hardware examined under an off-the-shelf audit, the hardware will be examined by a laboratory technician and the CET Section Team Leader for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the CET Section Team Leader or his designee, following the standard

operating procedures outlined in *Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-005-00*.

8.3.3. If a APER or SCER fails the criteria specified in Section 6.0 of this STP, ensure all measures are taken to ascertain the reason or cause for failure, conduct all post test inspections in accordance with this STP that support the accuracy of the reported failure and provide NIOSH with written Test Incident Reports (TIR)s, digital photos of assessment and recommendations as required.

APPENDIX A
Practical Performance Level Observation Data Sheet (Page 1 of 8)

Task No.: **STP No.:** 0456

Manufacturer:

Test Date:

Model Number / Trade Name:

APER / SCER Actual Ready to Use Device Part Number:
APER / SCER Training Device Part Number:
Is this a retest under the same TN number?

NIOSH	Approval Numbers

If yes, what are the original test dates?

For which CBRN STP is Practical Performance being evaluated? (enter one choice only)

CET-APRS-STP-CBRN-0452 (APER LRPL)
CET-APRS-STP-CBRN-0453 (SCER LRPL)
CET-APRS-STP-CBRN-0454 (APER HSBG)
CET-APRS-STP-CBRN-0455 (SCER HSBG)

APPENDIX A

Practical Performance Level Observation Data Sheet (Page 2 of 8)

Task No.: **STP No.:** 0456

Manufacturer: **Reference No.:** 42 CFR 84.63 (a)(c)(d)

Test:
Determination of Practical Performance Level for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER)Standard Testing Procedure (STP)

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

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

Test Subject No.	Test Subject Identification	Assigned Hood Size	Practical Performance (Pass/Fail) Trial 1	Practical Performance (Pass/Fail) Trial 2	Reason for Practical Performance Failure
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					

APPENDIX A
Practical Performance Level Observation Data Sheet (Page 3 of 8)

Task No.:

STP No.: 0456

Manufacturer:

Reference No.: 42 CFR 84.63 (a)(c)(d)

Test:

Determination of Practical Performance Level for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER)Standard Testing Procedure (STP)

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

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

Test Subject No.	Test Subject Identification	Assigned Hood Size	Practical Performance (Pass/Fail) Trial 1	Practical Performance (Pass/Fail) Trial 2	Reason for Practical Performance Failure
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					
38					
39					
40					
41					
42					
43					

APPENDIX A
Practical Performance Level Observation Data Sheet (Page 4 of 8)

Task No.:

STP No.: 0456

Manufacturer:

Reference No.: 42 CFR 84.63 (a)(c)(d)

Test:
Determination of Practical Performance Level for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER)Standard Testing Procedure (STP)

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

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

Test Subject No.	Test Subject Identification	Assigned Hood Size	Practical Performance (Pass/Fail) Trial 1	Practical Performance (Pass/Fail) Trial 2	Reason for Practical Performance Failure
44					
45					
46					
47					
48					
49					
50					
51					
52					
53					
54					
55					
56					
57					
58					
59					
60					
61					
62					
63					
64					
65					

APPENDIX A
Practical Performance Level Observation Data Sheet (Page 5 of 8)

Task No.:

STP No.: 0456

Manufacturer:

Reference No.: 42 CFR 84.63 (a)(c)(d)

Test:
Determination of Practical Performance Level for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER)Standard Testing Procedure (STP)

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

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

Test Subject No.	Test Subject Identification	Assigned Hood Size	Practical Performance (Pass/Fail) Trial 1	Practical Performance (Pass/Fail) Trial 2	Reason for Practical Performance Failure
66					
67					
68					
69					
70					
71					
72					
73					
74					
75					
76					
77					
78					

Total # of 'Pass' PPT trials from Trail 1 column here →		Box 1P
Total # of 'Fail' PPT trials from Trail 1 column here →		Box 1F
Total # of 'Pass' PPT trials from Trail 2 column here →		Box 2P
Total # of 'Fail' PPT trials from Trail 2 column here →		Box 2F

APPENDIX A
Practical Performance Level Observation Data Sheet (Page 6 of 8)

Task No.:

STP No.: 0456

Manufacturer:

Reference No.: 42 CFR 84.63 (a)(c)(d)

Test:

Determination of Practical Performance Level for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER)Standard Testing Procedure (STP)

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

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

Calculation of % 'Pass' Practical Performance Trials

Note: The Calculation of % 'Pass' Practical Performance Trials is to be computed following the completion of trials to fulfill the test requirements of Human Subject Breathing Gas and Laboratory Respirator Protection Level.

Total # of 'Pass' PPT trials from Trail 1 column here →		Box 1P
Total # of 'Fail' PPT trials from Trail 1 column here →		Box 1F
Total # of 'Pass' PPT trials from Trail 2 column here →		Box 2P
Total # of 'Fail' PPT trials from Trail 2 column here →		Box 2F
Add the number of trials in Box 1P and Box 2P here →		Box A
Add the number of trials in Box 1F and Box 2F here →		Box B
Add the numbers in Box A and Box B here →		Box C

Box A = Total # of 'Pass' PPT trials for Trials 1 and 2

Box B = Total # of 'Fail' PPT Trials for Trials 1 and 2

Box C = Total # of 'Pass' and 'Fail' PPT trials for Trials 1 and 2

% 'Pass' Practical Performance Trials = (Box A ÷ Box C) X 100%.→

Overall Pass Percentage:	**Overall Result:**
≥ 95%	% 'Pass' Practical Performance Trials

APPENDIX A
Practical Performance Level Observation Data Sheet (Page 7 of 8)

Task No.:

Manufacturer:

Test:

Determination of Practical Performance Level for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER)Standard Testing Procedure (STP)

STP No.: 0456

Reference No.: 42 CFR 84.63 (a)(c)(d)

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

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

Was all equipment verified to be in calibration throughout all testing? Yes No
Were all part numbers verified against the hardware? Yes No

Comments:

Signature:

Laboratory Technician Date

Concurrence:

Laboratory Supervisor

APPENDIX A
Practical Performance Level Observation Data Sheet (Page 8 of 8)

Task No.:	**STP No.:**	0456
Manufacturer:	**Reference No.:**	42 CFR 84.63 (a)(c)(d)
Test: Determination of Practical Performance Level for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER)Standard Testing Procedure (STP)		Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Self-Contained Escape Respirator

Requirement: Practical Performance Test (PPT)

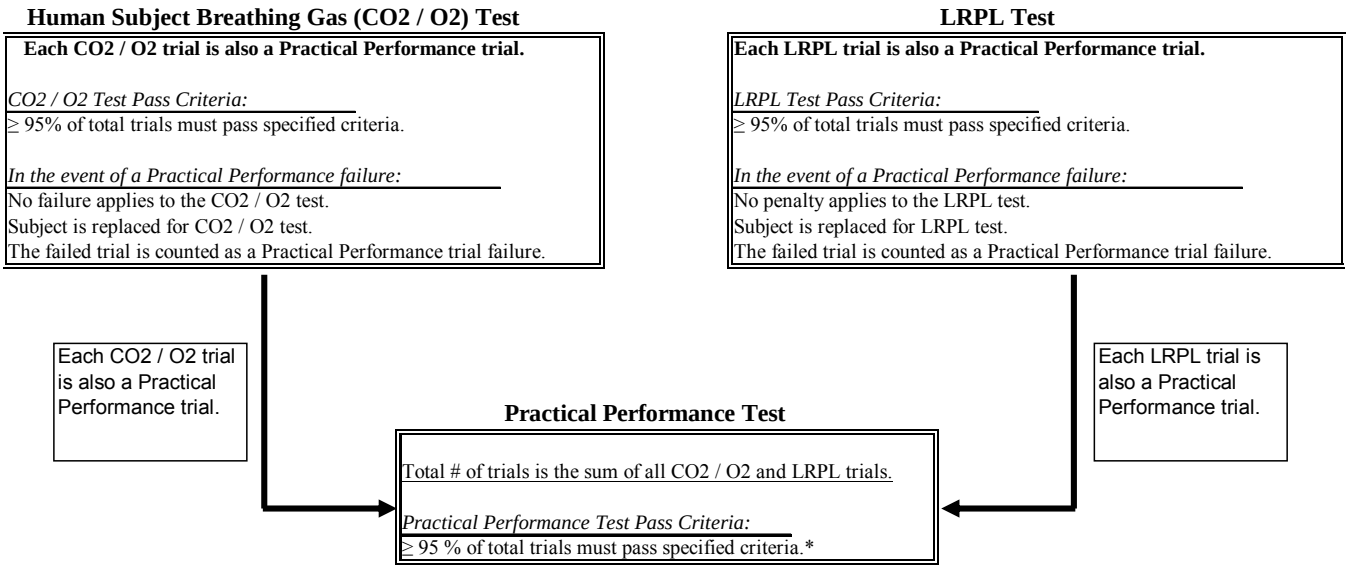
Each Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER) seeking a Chemical, Biological, Radiological and Nuclear (CBRN) protection rating will be self donned, worn, and self doffed by a voluntary human test subject in accordance with the applicant's User Instructions in a controlled laboratory environment, under specified laboratory conditions and shall be qualitatively evaluated on human interface issues associated with the use of the escape respirator.

The Practical Performance of the Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER) shall be evaluated as part of the test procedures of Human Subject Breathing Gas, and Laboratory Respirator Protection Level. The Practical Performance of the respirator shall evaluate human interface issues associated with the use of the escape respirator. Test subjects shall be trained on proper use of the escape respirator in accordance with the applicant's instruction requirements identified in the current Statement of Standard specific to the APER and SCER. Factors that will be evaluated on a Practical Performance pass / fail basis (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 self don and doff the respirator. Additionally, the inability of any test subject participating in the test procedures of Human Subject Breathing Gas, or 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 Human Subject Breathing Gas, and 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, Human Subject Breathing Gas, and 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.

If the human test subject cannot doff the escape respirator efficiently or exhibits emergency concerns requiring immediate removal of the APER, laboratory personnel are authorized to remove the APER from the human test subjects head without causing bodily harm. Each wearer is not subjected to any undue discomfort or encumbrance because of the donning or doffing of the respirator during certification testing period.

APPENDIX B
Relationship of Practical Performance Level Test to the Laboratory Respirator Protection Level Test and Human Subject Breathing Gas Test (Page 1 of 1)



* If the ≥ 95 % requirement is not met for Practical Performance, the Human Subject Breathing Gas test and / or the LRPL test may be run a second time to increase the total amount of trials for evaluating Practical Performance with the following considerations:

1) Each test (the Human Subject Breathing Gas test and / or the LRPL test) may only be rerun only one time.
2) If tests are rerun, the total number of trials used to evaluate Practical Performance will be the total number of trials from all Human Subject Breathing Gas tests and LRPL tests. Total trials will include both the number of trials from the original tests plus the rerun tests.
3) If the Human Subject Breathing Gas test and / or the LRPL test are rerun, the number of trials used to evaluate those individual tests will be the sum of trials from the original test plus the rerun test.

Revision History

Revision	Date	Reason for Revision
0	18 February 2004	Historic document
1.1	22 December 2005	Update header and format Update references to other STPs No changes to method