



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
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Procedure No. STP-00001-PSDB-0011		Revision: 2.0	Date: 3 April 2012
Level 1	Level 2	Level 3	Level 4

STANDARD TEST PROCEDURE (STP) FOR WEARABILITY OF CLOSED-CIRCUIT ESCAPE RESPIRATORS

1. PURPOSE

- 1.1. This procedure describes the standard test for ensuring that Closed-Circuit Escape Respirators (CCER) submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet the minimum certification standards set forth in Sections 84.306, Wearability, and 84.303(d) of Subpart O—Closed Circuit Escape Respirators updated requirements to 42 CFR, Part 84, Volume 60, Number 110, June 8, 1995 as published in Federal Register / Vol. 77, No. 46 / Thursday, March 8, 2012 / Rules and Regulations pp. 14168-14197.

2. GENERAL

- 2.1. This STP describes the Wearability Test of Closed-Circuit Escape Respirators in sufficient detail such that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the procedure, and determine whether or not the product passes the test.

3. EQUIPMENT AND MATERIALS

- 3.1. Test subjects must meet requirements of the NIOSH Human Subject Review Board (HSRB) approved Protocol. Refer to “Protocol for tests with human subjects of closed-circuit breathing apparatus in certification, quality assurance, and development” HSRB 12-NPPTL-04 for the proper consent form and complete details on the use of human test subjects in respirator certification testing.
- 3.2. The measurement instruments used must be capable of breath-by-breath response and have the following measurement ranges:
 - 3.1.1. Carbon dioxide (CO₂) analyzer: 0 to 10%
 - 3.1.2. Oxygen (O₂) analyzer: 0 to 100%

3.1.3. Pressure transducer: -400 to +400 mm H₂O

3.1.4. Ventilation (exhalation volume) 0-100 L/min

3.2. Additional equipment includes the following:

3.2.1. Calibration gas cylinder – 80% O₂; 8% CO₂; 12% N₂

3.2.2. Multi-channel (≥ 4) strip chart recorder or equivalent.

3.2.3. Calcium sulfate desiccant Drierite[®] or equivalent

3.2.4. 7.5 inch length of tube for extension (1/16 interior diameter)

3.3. The equipment necessary to perform the wearability test is as follows:

3.3.1. Doric Series 400A Digital Trendicator, Doric Scientific Division, Emerson Electric Company, 3883 Ruffin Road, San Diego, CA 92123 or equivalent.

3.3.2. Validyne Digital Readout - Model CD23 or equivalent.

3.3.3. Temperature compensated pressure transducer (Validyne Engineering Model No. DP45) or equivalent.

3.3.4. Electric timer, calibrated to 100ths of a minute (Precision Scientific Co.) or equivalent.

3.3.5. Timer, Digital stopwatch, calibrated to hundredths of a minute (Cronus Precision Products, Inc.) to hand carry. or equivalent.

3.3.6. Applied Electrochemistry CO₂ Analyzer - Model CD-3A or equivalent.

3.3.7. Applied Electrochemistry Oxygen Analyzer - Model S-3A or equivalent.

3.3.8. Fifty-pound sack or equivalent.

3.3.9. Oxygen - U.S.P or equivalent.

3.3.10. Twenty pound weight or equivalent.

3.3.11. Carbon dioxide - calibration gas, 4-5%, 1-2%, 3-4% Matheson Scientific Company, E. Rutherford, NJ or equivalent.

3.3.12. Carbon dioxide calibration curve or equivalent.

3.3.13. Knee pads or equivalent.

3.3.14. Matheson Gas Products Model # 8320 carbon dioxide regulator, East Rutherford, NJ or equivalent.

- 3.3.15. Dwyer Slant Manometer 0-3", F. W. Dwyer Manufacturing Co., Michigan City, Indiana or equivalent.
- 3.3.16. Model 18-49B Horizontal Treadmill, 0-6 MPH, Quinton Instruments, 3051 44th Avenue, West Seattle, Washington 98199 or equivalent.
- 3.3.17. National Draeger Endless Ladder, 0-130 feet/minute S/N181-2486 or equivalent.
- 3.3.18. A crash cart with current dated drugs and equipment at the test scene.
- 3.3.19. A hospital type gurney (or a bed for test subject to lay on) or equivalent.
- 3.3.20. A 4' by 8' pad for test subject to crawl on or equivalent.

4. PROCEDURE REQUIREMENTS AND CONDITIONS

- 4.1. All measuring equipment and instruments to be used must have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST) in accordance with the manufacturer's calibration procedure and schedule.
- 4.2. Normal laboratory safety practices must be observed. These include safety precautions given in the current *NIOSH-Pittsburgh Health and Safety Manual*, Job Hazard Analysis (JHA), work instruction documents and test equipment manufacturer recommended practices.
- 4.3. Any laboratory using this procedure to supply certification test data to NPPTL will be subject to the provisions of the NPPTL Supplier Qualification 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 NPPTL.
- 4.4. Refer to "Protocol for tests with human subjects of closed-circuit breathing apparatus in certification, quality assurance, and development" HSRB 12-NPPTL-04 for the consent form and complete details on the use of human test subjects in respirator certification testing.
- 4.5. Prior to performing the wearability tests, all tests with a breathing and metabolic simulator (BMS) required for certification must have been completed and all BMS tests must have been passed.
- 4.6. From the BMS test results determine the following using the Standard Procedure for the Assessment of Stressors during CCER Capacity, Performance and Wearability Tests with Human Subjects:

- 4.6.1. The differences between average inhaled and end-of-inhalation gas concentrations using the Determination of the difference between average inhaled and end-of-inhalation gas concentrations from BMS test results of CCER.
- 4.6.2. The values required for the Method of determining if operating average for average inhaled CO₂ and average inhaled O₂ exceeds acceptable range throughout test
- 4.7. Tests are conducted at the following ambient conditions:
- 4.7.1. Ambient temperatures of 23°C ± 3°C; and
- 4.7.2. Atmospheric pressures of 735 mm Hg ± 15 mm Hg.
- 4.8. The wearability test is conducted on a total of three of the units submitted for approval each with a different human subject.
- 4.8.1. Three human subjects (two (2) males and one (1) female), one subject per unit, will conduct the tests. The three subjects will range in height and weight as follows: one subject of height ≥ 174 cm and weight ≥ 90 kg; one subject of either 163 cm ≤ height < 174 cm, regardless of weight, or 72 kg ≤ weight < 90 kg, regardless of height; and one subject of height < 163 cm and weight < 72 kg.
- 4.9. Prior to performing the wearability test, each subject will receive training in how to don, operate and doff the CCER.
- 4.9.1. The training will cover procedures indicated and/or recommended in the CCER instructions, as contained in one or more of the following required topics:
- 4.9.1.1. Procedures for donning and use (§ 84.302 (h) (1) (iii)).
- 4.9.1.2. Procedures for inspecting the operating condition of the CCER (§84.302 (h) (1) (iv))
- 4.9.1.3. Any procedure by which the user should inspect the CCER and determine when the CCER should be removed from use (§ 84.302 (h) (2) (iii))
- 4.9.2. Training may involve use of a training unit(s).

5. PROCEDURES

- 5.2. Prior to test, attach gas and pressure sample lines and wet-bulb thermometer to breathing tube of CCER device.
- 5.3. Calibrate the gas analyzers using a primary standard calibration gas with O₂ at 80.0 % and CO₂ at 8.0%.
- 5.4. Use consent form and procedures included in HSRB 12-NPPTL-04 for wearability test.

- 5.5. Instruct subject on procedure for donning CCER, and each activity to be performed.
- 5.6. The subject dons the CCER device and performs any prescribed user checks.
- 5.7. After correct donning the CCER device any appropriate checks of stressor instrumentation are made, the subject performs the wearability test requirements in Table 1.
- 5.8. The stressors listed in Table 2 are continuously monitored and recorded throughout the wearability test. Using the Standard Procedure for the Assessment of Stressors during CCER Capacity Performance and Wearability Tests with Human Subjects:
 - 5.8.1. Each stressor measurement are evaluated as one-minute average
 - 5.8.2. The resulting one-minute average value(s) are compared to the excursion(s) listed in Table 2.
 - 5.8.3. The interim operating average of each stressor is compared to the operating average listed in Table 2.
 - 5.8.4. If the one-minute average measurement of any stressor listed in Table 2 occurs outside the acceptable excursion range specified in Table 2 the test is stopped.
 - 5.8.5. If the interim operating average of any stressor listed in Table 2 occurs outside the acceptable operating average range specified in Table 2 the test is stopped.
- 5.9. In addition to the stressors, NIOSH will also continuously monitor CCER use by each test subject during the activities specified in Table 1 and evaluate the ability of the CCER to provide an adequate and uninterrupted breathing supply without harming or hindering a user.
- 5.10. When the activities specified in Table 1 are completed the subject performs any prescribed user checks and doffs the CCER device.

Table 1: Wearability Test Requirements

Activity	Minimum Duration
Sitting	1 min.
Stooped walking	1 min.
Crawling	1 min.
Lying on left side	1 min.
Lying on right side	1 min.
Lying on back	1 min.
Bending over to touch toes	1 min.
Turning head from side to side (at least 10 times)	1 min.
Nodding head up and down (at least 10 times)	1 min.
Climbing steps or a ladder mill (1 step/sec)	1 min.
Carrying 50-lb bag on treadmill at 5 kph	1 min.
Lifting 20-lb weight from floor to an upright position (at least 10 times)	1 min.
Running on treadmill (10 kilometers/hour)	1 min.

Table 2: Monitored Stressors and their Acceptable Ranges

Stressor	Acceptable Range Operating Average	Acceptable Range Excursion
Average inhaled CO ₂	<1.5%	≤4%
Average inhaled O ₂	>19.5%	≥15%
Peak Breathing Pressures	$\Delta P \leq 200 \text{ mm H}_2\text{O}$	$-300 \leq \Delta P \leq 200 \text{ mm H}_2\text{O}$
Wet-bulb temperature	<43°C	≤50°C

6. PASS/FAIL CRITERIA

6.1. The test is a failure if:

6.1.1. A one-minute average measurement of any stressor listed in Table 2 occurs outside the acceptable excursion range specified in Table 2.

6.1.2. The interim operating average of any stressor listed in Table 2 occurs outside the acceptable operating average range specified in Table 2.

6.1.3. A human subject cannot complete the test for any reason related to the CCER, as determined by NIOSH.

6.2. NIOSH will not approve a CCER if the use of any unit during these activities indicates any potential for the CCER to harm or hinder the user or to fail to provide an adequate and uninterrupted breathing supply to the user during reasonably anticipated conditions and activities of an escape.

7. RECORDS AND TEST SHEETS

7.1. Recordings of results from each activity.

8. APPENDICES

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9. REVISION HISTORY

Revision	Date	Reason for Revision
0.0	15 September 2011	Initial Record
1.0	15 September 2011	Review with TEB
1.0	23 January 2013	Administrative changes – Document number changed
2.0	3 April 2012	Administrative changes were made to include information from the release of the proposed rule