DETERMINATION OF WEARABILITY OF CLOSED-CIRCUIT ESCAPE RESPIRATORS

1. PURPOSE

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

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. The measurement instruments used must be capable of breath-by-breath response and have the following measurement ranges:

3.1.1. Carbon dioxide (CO_2) analyzer: 0 to 10%

3.1.2. Oxygen (O_2) analyzer: 0 to 100%

3.1.3. Pressure transducer: -400 to +400 mm H_2O with digital readout

3.1.4 Wet/dry bulb thermocouples capable of reading 0-100° Celsius

3.2. Additional equipment includes the following:

3.2.1. Calibration gas cylinder – 80% O_2; 8% CO_2; 12% N_2

3.2.2. Multi-channel (≥4) strip chart recorder, digital data display, or equivalent

3.2.3. Calcium sulfate desiccant Drierite® or equivalent

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

3.3.1. Doric Series 400A Standard Resolution Digital Temperature indicator or equivalent

3.3.2. Temperature compensated pressure transducer (Validyne Engineering Model No. DP45) with digital readout, or equivalent.

3.3.3. Bench top electric timer, calibrated to l00ths (0.01) of a minute or equivalent

3.3.4. Handheld timer, Digital stopwatch, calibrated to100ths (0.01) of a minute or equivalent

3.3.5. Applied Electrochemistry CO_2 Analyzer - Model CD-3A or equivalent

3.3.6. Applied Electrochemistry Oxygen Analyzer - Model S-3A/I or equivalent

3.3.7. Fifty-pound sack or equivalent

3.3.8. Twenty-pound weight or equivalent

3.3.9. Knee pads or equivalent

3.3.10. Manometer -400 to 400 mm H_2O, or equivalent

3.3.11. Model 18-49B Horizontal Treadmill, 0-6 MPH, Quinton Instruments, or equivalent

3.3.12. National Draeger Endless Ladder, 0-130 feet/minute S/N181-2486, steps with handrail, or equivalent

3.3.13. An automated external defibrillator (AED) located adjacent to the test area

3.3.14. A hospital type gurney (or a bed for test subject to lay on) or equivalent

3.3.15. A 4' by 8' pad for test subject to crawl on or equivalent

4. PROCEDURE REQUIREMENTS AND CONDITIONS

4.1. 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.

4.2. 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.

4.3. 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.

4.4. 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.

4.5. 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.

4.6. 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 passed certification criteria.

4.7. 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:

4.7.1. The differences between average inhaled and end-of-inhalation gas concentrations (ΔCO_2 and ΔO_2) using the Calculation of average inhaled gas concentrations from end-of-inhalation gas concentrations.

4.7.2. The values required for the Calculation of average inhaled gas concentrations from end-of-inhalation gas concentrations shall not exceed acceptable range throughout test.

4.8. Tests are conducted at the following ambient conditions:

4.8.1. Ambient temperatures of 23ºC ± 3ºC; and

4.8.2. Atmospheric pressures of 735 mm Hg ± 15 mm Hg.

4.9. The wearability test is conducted on a total of three of the units submitted for approval each with a different human subject.

4.9.1. Three human subjects (two males and one 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.

4.10. Prior to performing the wearability test, each subject will receive training in how to don, operate and doff the CCER.

4.10.1. The training will cover procedures indicated and/or recommended in the CCER instructions, as contained in one or more of the following required topics:

4.10.1.1. Procedures for donning and use (§ 84.302 (h) (1) (iii))

4.10.1.2. Procedures for inspecting the operating condition of the CCER (§84.302 (h) (1) (iv))

4.10.1.3. 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))

4.10.2. Training may involve use of a training unit(s).

5. PROCEDURES

5.1. Prior to test, attach gas and pressure sample lines and wet-bulb thermometer to breathing tube of CCER device.

5.2. Calibrate the gas analyzers using certified calibration gas with O_2 at 80.0 % and CO_2 at 8.0%.

5.3. Use consent form and procedures included in HSRB 12-NPPTL-04 for wearability test.

5.4. Instruct subject on procedure for donning CCER, and each activity to be performed.

5.5. The subject dons the CCER device and performs any prescribed user checks.

5.6. After correct donning of the CCER device, any appropriate checks of stressor instrumentation are made. The subject performs the wearability test requirements in Table 1. CCERs with lower volumes of oxygen may require more than one unit to complete the wearability test sequence. Each subsequent portion of the testing shall begin where the last sample unit ended.

5.7. The stressors listed in Table 2 are continuously monitored and recorded throughout the wearability test. Refer to the Standard Procedure for the Assessment of Stressors during CCER Capacity Performance and Wearability Tests with Human Subjects for guidance.

5.7.1. Each stressor measurement is evaluated as a one-minute average

5.7.2. The resulting one-minute average value(s) are compared to the excursion(s) listed in Table 2.

5.7.3. The interim operating average of each stressor is compared to the operating average listed in Table 2.

5.7.4. If any one-minute average measurement meets or exceeds an excursion limit listed in Table 2, the test is stopped.

5.7.5. 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.

5.8. 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.

5.9. 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	$\Delta P \leq 200$ mm H_2O	$-300 \leq \Delta P \leq 200$ mm H_2O
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 falls outside of the acceptable excursion range specified in Table 2.

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

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. ATTACHMENTS

None

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
		Former document number - STP-00001-PSDB-0011
0.0	7 April 2014	New document number to reflect numbering in the approval library, normalization of format. Numbering changes in section 3 have been applied to reflect the proper sequence. No changes to procedure from historical document.