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National Personal Protective Technology Laboratory
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Procedure No. TEB-CCER-STP-0613

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DETERMINATION OF PERFORMANCE OF CLOSED-CIRCUIT ESCAPE RESPIRATORS (CCER) WITH HUMAN SUBJECTS ON TREADMILL

1. PURPOSE

This procedure describes the standard test with human subjects for ensuring that the level of protection provided by the performance on 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 Section 84.303 and 84.305, 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 procedure for Human Subject Performance Test of CCERs 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. Gas analyzer with resolution of 0.1% gas concentration, and range of 0-10% CO₂, and 0-100% O₂;

3.1.2. Pressure transducer with resolution of 1 millimeter H₂O, range from -400 to +400 mm H₂O

3.1.3. Wet and dry-bulb thermometers with resolution of 0.1°C, range 0-100°C

3.2. The equipment necessary to perform the performance test is as follows:

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

3.2.2. Temperature Compensated pressure (Validyne Engineering Model No. DP45) with digital readout or equivalent.

Approvals: First Level	Second Level	Third Level	Fourth Level

- 3.2.3. Multi-channel (≥ 4) strip chart recorder, digital data display, or equivalent
- 3.2.4. Bench top electric timer, calibrated to 100ths (0.01) of a minute or equivalent
- 3.2.5. Handheld digital timer/stopwatch calibrated to 100ths (0.01) of a minute or equivalent
- 3.2.6. Applied Electrochemistry CO₂ Analyzer - Model CD-3A or equivalent
- 3.2.7. Applied Electrochemistry Oxygen Analyzer - Model S-3A/I or equivalent
- 3.2.8. Manometer -400 to 400 mm H₂O, or equivalent
- 3.2.9. Model 18-49B Horizontal Treadmill, 0-6 MPH, Quinton Instruments, 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. 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. 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.
- 4.5. 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 performance test with human subjects, all tests with a breathing and metabolic simulator (BMS) required for certification must have been completed and all BMS tests must have been passed.

- 4.7. 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. Prior to conducting the performance test with human subjects on a treadmill use Standard Operating Procedure for Human-Subject Oxygen Demand (VO_2) Determination (TEB-CCER-SOP-0616) with the specific subject to establish treadmill speed and inclination needed for each VO_2 required for each work rate in Table 1 (below).
- 4.9. Conduct all procedures at the following ambient conditions:
 - 4.9.1. Ambient temperatures of $23^\circ\text{C} \pm 3^\circ\text{C}$; and
 - 4.9.2. Atmospheric pressures of $735 \text{ mm Hg} \pm 15 \text{ mm Hg}$.
- 4.10. Prior to conducting the performance 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:
 - 4.10.1.1. As contained in one or more of the following required topics:
 - 4.10.1.1.1. Procedures for donning and use (§ 84.302 (h) (1) (iii))
 - 4.10.1.1.2. Procedures for inspecting the operating condition of the CCER (§ 84.302 (h) (1) (iv))
 - 4.10.1.1.3. 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))
 - 4.10.1.2. Training may involve use of a training unit(s).
 - 4.11. One CCER unit, as-received from the manufacturer, is subjected to the performance test with the human subject on a treadmill.
 - 4.12. The stressors listed in Table 2 are measured at the interface between the CCER and the subject's mouth by instruments capable of breath-by-breath measurement and continuously recorded on a strip chart recorder, digital data display, or equivalent.
 - 4.12.1. Testing of CCERs with less than 50 liters of capacity, as determined by the capacity testing under § 84.304, requires additional CCER units to fully apply the

work-rate test sequence and requirements specified in Table 1. The testing of the initial individual unit continues until the breathing supply of the initial test unit is exhausted. This initial test unit will then be replaced by a second unit, which will continue the test cycle, commencing at the point in the work rate in the cycle where the previous unit ended (overlap to previous cycle point may be no more than 2 minutes). Up to three units may be used to complete the performance test cycle.

Table 1: Performance Test Requirements for a cycle (All volumes are given at standard temperature (0°C) and pressure (760 mm Hg), dry)

Work-Rate Test Sequence	Duration per cycle	$\dot{V} O_2$ (L/min)
1. Peak	5 min.	3.00
2. High	15 min.	2.00
3. Low	10 min.	0.50

$\dot{V} O_2$ = volume of oxygen consumed/min

Table 2: Monitored Stressors and their Acceptable Ranges

Stressor	Acceptable Range Overall Test Average	Acceptable Range Excursion for one-minute average
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 ≤ $\Delta P \leq 200 \text{ mm H}_2\text{O}$
Wet-bulb temperature	<43°C	≤50°C

5. PROCEDURE

5.1. Prepare CCER unit for test:

- 5.1.1. The CCER will be opened and visually inspected using manufacturer's and NIOSH inspection criteria. This inspection will include:
 - 5.1.1.1. Applying a -300mm H₂O vacuum to assess the integrity of the breathing tube and associated parts.
 - 5.1.1.2. A phenolphthalein swab to detect alkaline chemicals present in the CCER user interface
- 5.1.2. Mount instrument sampling lines and thermocouples into apparatus mouthpiece (or proximally in breathing tube).

5.2. Prepare instruments for test:

- 5.2.1. Calibrate the gas analyzers using certified calibration gas with O₂ at 80.0 % and CO₂ at 8.0% and N₂ at 12%.
- 5.2.2. Ensure that instrument values displayed on chart recorder correlate with instrument readings.
- 5.2.3. Note the excursion limits for the stressors on the chart recorder scale.
 - 5.2.3.1. Apply the differences determined in 4.6.1 for oxygen and carbon dioxide.

5.3. Human subjects

- 5.3.1. Perform all instruction required in protocol.
- 5.3.2. Use consent form and procedures included in HSRB 12-NPPTL-04 for the performance test.

5.4. Begin performance test:

- 5.4.1. Set treadmill speed and inclination to the previously determined values to achieve the initial cycle work rate (1. Peak) given in Table 1.
- 5.4.2. Subject dons CCER.
 - 5.4.2.1. Chart recorder paper drive is started.
 - 5.4.2.2. Subject begins Test Sequence 1. Peak on treadmill.
 - 5.4.2.3. Remind subject that they can stop the test at any time.
- 5.5. Continue test by application of the cycle of work rates, according to the sequence and requirements in Table 1 until the oxygen supply is exhausted.
- 5.6. The stressors listed in Table 2 are continuously monitored and recorded throughout the performance test, using the Standard Procedure for the Assessment of Stressors during CCER Capacity Performance and Wearability Tests with Human Subjects:
 - 5.6.1. Values for each stressor are averaged over each minute of test.
 - 5.6.2. The resulting one-minute average value(s) is compared to the excursion(s) listed in Table 2.
 - 5.6.3. The interim operating average of each stressor is compared to the operating average listed in Table 2.
 - 5.6.4. If any one-minute average measurement exceeds an excursion limit listed in Table 2, the test is stopped.

- 5.7. 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.
- 5.8. The subject stops the test and doffs the CCER when apparatus oxygen supply is depleted or if the subject cannot continue for subjective reasons.
 - 5.8.1. The depletion of apparatus oxygen supply which is usually indicated by the one minute average of peak breathing pressure, ΔP , falling below -300 mm H₂O, or by manufacturer instructions for indication of the end of breathing gas supply.
- 5.9. After test is stopped:
 - 5.9.1. Stop chart recorder paper drive.
 - 5.9.2. Let gas sample pump operate until water droplets are no longer present in lines preceding gas dryer.
 - 5.9.3. Determine the completion time as the time elapsed from test start to when the oxygen supply is expended.
 - 5.9.4. Calculate the overall average for each of the stressor measurements using the one-minute average values from the test start to completion time.

6. PASS/FAIL CRITERIA

- 6.1. The apparatus fails this test and certification if:
 - 6.1.1. If from the test start up to when the oxygen supply is fully expended any one-minute average stressor measurement is outside the acceptable excursion range shown in Table 2 (last column).
 - 6.1.2. Any average stressor measurement (as the overall average from test start to when the gas supply is fully expended) is outside the acceptable operating average range shown in Table 2 (middle column).

7. RECORDS AND TEST SHEETS

None

8. ATTACHMENTS

None

Revision History

Revision	Date	Reason for Revision
0.0		Initial record
1.0	18 August 2011	Review
2.0	20 August 2012	Administrative changes – changed document number
3.0	09 April 2012	Administrative changes were made to include information from the release of the proposed rule.
		Former document number - STP-00001-PSDB-0015
0.0	7 April 2014	New document number to reflect numbering in the approval library, normalization of format. List of equipment required (section 3) has been updated to reflect those currently employed. Current HSRB requirements are highlighted in section 4. Accessibility enhancements affected. No changes to procedure from historical document.