National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
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Level 1	Level 2	Level 3	Level 4

Standard Test Procedure (STP) for Capacity Test of Closed-Circuit Escape Respirators (CCER) with Human Subjects on Treadmill

1. PURPOSE

1.1 This procedure describes the standard test with human subjects for ensuring that the level of protection provided by the capacity 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 84.304, 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 both the procedure for Human Subject Capacity 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 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 All sensors with breath-by-breath response capability:

3.2.1 Gas analyzer with resolution of 0.1% gas concentration, and range of 0-10% CO_2, and 0-100% O_2;

3.2.2 Pressure transducer with resolution of 1millimeter H_2O, range from -700 to +700 mm H_2O.

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

3.3 The equipment necessary to perform the following measurements is as follows:

3.3.1 One B-D Yale (2317/100 yh) 100 cc Hypodermic Syringe "Luer-Lok," Becton Dickson & Company, Rutherford, NJ. or equivalent

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

3.3.3 Gould Stratham Transducer Readout, Model SC1012, Gould, Inc., 2230 Stratham Blvd., Oxnard, CA 93030 or equivalent.

3.3.4 Temperature Compensated Strain Sensitive Resistance wire type transducer (Stratham Instruments) Pressure range + 0.5 psig or equivalent.

3.3.5 Multi-channel (≥4) strip chart recorder.

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

3.3.7 Timer/stopwatch to hand carry or equivalent.

3.3.8 Beckman LB-2 (digital readout) with positive/negative mode and positive and negative peak detectors, heated sample inlet and other accessories desired, Beckman LB-2 Medical Gas Analyzers available from Beckman Instruments, Inc., Electronic Instruments Division, 3900 River Road, Schiller Park, Illinois 60176 or equivalent.

3.3.9 Beckman Medical Gas Analyzer – OM-11 (oxygen) or equivalent.

3.3.10 Oxygen – USP or equivalent.

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

3.3.12 Carbon dioxide calibration curve or equivalent.

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

3.3.14 Dwyer Slant Manometer, F. W. Dwyer Manufacturing co., Michigan City, Indiana (Fisher Scientific Company) or equivalent.

3.3.15 Model 18-49B Horizontal Treadmill, 0-6 MPH, Quinton Instruments, 3051 44*Avenue, West Seattle, Washington 98199 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 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.

4.3 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 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 capacity test with human subjects on a treadmill as described in this procedure, 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 CO_2 and Average inhaled O_2 exceeds acceptable range throughout test

4.7 Prior to performing the capacity test with human subjects on a treadmill use Standard Operating Procedure for Human-Subject Oxygen Demand (VO_2) Determination with the specific subject to establish treadmill speed and inclination needed for the VO_2 to be used in the test as shown in Table 1.

4.8 Conduct all procedures 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 Prior to performing the 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:

4.9.1.1 As contained in one or more of the following required topics:

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

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

4.9.1.1.3 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)

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

4.9.3 Each unit will be tested at a constant work rate which depends on the capacity specified by the manufacturer, according to the requirements in Table 1.

4.10 The capacity test with human subject is conducted on one unit submitted for approval as received.

4.11 Throughout Capacity test the stressors 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.

4.11.1 Using the Standard Procedure for the Assessment of Stressors during CCER Capacity and Performance Tests with Human Subjects, perform the following:

4.11.1.1 Determine each stressor measurement as one-minute average and evaluate against the acceptable range excursion in Table 2.

4.11.1.2 For each stressor estimate the interim operating (overall) averages and evaluate against the acceptable range overall in Table 2.

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	$\Delta P \leq 200$ mm H_2O	$-300 \leq \Delta P \leq 200$ mm H_2O
Wet-bulb temperature	<43˚C	≤50˚C

4.11.2 At the end of the test calculate the operating (overall) average of each stressor as the average of the one-minute measurements of the stressor recorded during the test.

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

Capacity Rating	**Capacity (L)**	$\dot{V}O_2$ **(L/min)**	$\dot{V}CO_2$ **(L/min)**	$\dot{V}e$ **(L/min)**	**RF (Breaths/min)**
Cap 1	$20 \leq L \leq 59$	2.50	2.50	55	22
Cap 2	$60 \leq L \leq 79$	2.00	1.80	44	20
Cap 3	$L \geq 80$	1.35	1.15	30	18

$\dot{V}O_2$=volume of oxygen consumed/min; $\dot{V}CO_2$=volume of carbon dioxide produced/min

$\dot{V}e$ = ventilation rate; RF = respiratory frequency

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 H_2O 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 a primary standard calibration gas with O_2 at 80.0 % and CO_2 at 8.0% and N_2 at 12%.

5.2.2 Ensure that instruments 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 calculated 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 Human subjects performing tests read and sign consent form.

5.4 Begin capacity test:

5.4.1 Set treadmill speed and inclination to the values required to achieve the work rate appropriate for the CCER Capacity rating 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 walking on treadmill belt.

5.4.2.3 Remind subject that they can stop the test at any time.

5.5 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:

5.5.1 Values for each stressor are averaged over each minute of test.

5.5.2 The resulting one-minute average is compared to the excursion(s) listed in Table 2.

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

5.5.4 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.

5.5.5 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.

5.6 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.

5.7 The subject stops the test and doffs the CCER when apparatus oxygen supply is depleted or if the subject cannot continue for subjective reasons.

5.7.1 The depletion of apparatus oxygen supply which is usually indicated by the one minute average of peak breathing pressure, ΔP, falling below -300 mm H_2O.

5.8 After test is stopped:

5.8.1 Stop chart recorder paper drive.

5.8.2 Let gas sample pump operate until water droplet are no longer present in lines preceding gas dryer.

5.8.3 Determine the completion time as the time elapsed from test start to when the oxygen supply is expended.

5.8.4 Calculate the overall average for each of the stressor measurements using the one-minute average values from the test start to when the oxygen supply is fully expended.

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 gas 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

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8. APPENDICES

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9. 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	10 April 2012	Administrative changes were made to include information from the release of the proposed rule.