National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
P.O. Box 18070
Pittsburgh, PA 15236

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DETERMINATION OF CAPACITY 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 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

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. 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% CO_2, and 0-100% O_2;

3.1.2. Pressure transducer with a readout range of -400 to +400 mm H_2O and resolution of 1millimeter H_2O

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 capacity test is as follows:

3.2.1. Doric Series 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 timer, digital stopwatch calibrated to100ths (0.01) of a minute or equivalent

3.2.6. Applied Electrochemistry CO_2 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 H_2O, or equivalent

3.2.9. Model 18-49B Horizontal Treadmill, 0-6 MPH, 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 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.

4.7. 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 performing the capacity 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 the VO_2 to be used in the test as shown in Table 1.

4.9. Conduct all procedures at the following ambient conditions:

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

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

4.10. Prior to performing the 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)

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

4.10.3. 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.

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)**
Cap 1	$20 \leq L \leq 59$	2.50
Cap 2	$60 \leq L \leq 79$	2.00
Cap 3	$L \geq 80$	1.35

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

4.11. The capacity test with human subject is conducted on one unit submitted for approval in the 'as received' condition.

4.12. 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 multichannel strip chart recorder, digital data display, or equivalent.

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

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

4.12.1.2. 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

4.12.2. 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.

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 certified 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. Use consent form and procedures included in HSRB 12-NPPTL-04 for the capacity test.

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 capacity 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 value(s) 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 any one-minute average measurement meets or exceeds an excursion limit listed in Table 2, the test is stopped.

5.6. In addition, 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, or by manufacturer instructions for indication of the end of breathing gas supply.

5.8. After test is stopped:

5.8.1. Stop chart recorder paper drive.

5.8.2. Let gas sample pump operate until water droplets 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

None

8. ATTACHMENTS

None

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.
		Former document number - STP-00001-PSDB-0024
0.0	7 April 2014	New document number to reflect numbering in the approval library, normalization of format. No changes to procedure from historical document.