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 AND PERFORMANCE TESTS OF A CLOSED-CIRCUIT ESCAPE RESPIRATOR (CCER) USING AUTOMATED BREATHING AND METABOLIC SIMULATOR (ABMS) STANDARD TEST PROCEDURE (STP)

1. PURPOSE

This test establishes the procedure for ensuring that the capacity and performance provided by Closed-Circuit Escape Respirator submitted for Approval, Extension of Approval, or examined during Certified Product Audits meet the certification requirements set forth in the *Closed-Circuit Concept Paper,* dated : xxx and *42 CFR Part 84, Subpart G, Section 84.63(a)(c)(d)*; Volume 60, Number 110, June 8, 1995.

2. GENERAL

This STP describes the testing in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test and determine whether the product passes the test.

3. EQUIPMENT AND MATERIAL

3.1. The list of necessary test equipment and materials follows:

3.1.1 Automated Breathing and Metabolic Simulator (ABMS), manufactured by Ocenco, Inc. and modified to specific details determined by NIOSH.

3.1.2 Cold Temperature Chamber manufactured by XXX, temperature range limits xx ^{o}C to –xx ^{o}C.

3.1.3 Oxygen / carbon dioxide calibration gas, primary standard 90% O_2, 8% CO_2 with balance N_2.

3.1.4 Nitrogen gas, zero grade ≥99.85%

3.1.5 Carbon dioxide gas cylinder ≥99.8%

Approvals:			
First Level	Second Level	Third Level	Fourth Level

3.2. Test fixture for mounting facepieces or mouth bit.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1 The respirator system must first complete the NIOSH Standard Test Procedure entitled *Determination Of Durability Test For Environmental, Transportation, And Rough-Handling Conditions On Closed-Circuit Escape Respirators (CCER) Standard Test Procedure (STP).*

4.2 Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with the manufacturer's calibration procedure and schedule. At a minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months using a method traceable to the National Institute of Standards and Technology (NIST).

4.3 Any laboratory using this procedure to supply certification test data to NIOSH will be subject to the provisions of the NIOSH 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 the Institute.

4.4 Precision and accuracy (P&A) must be determined for each instrument in accordance with laboratory procedures and NIOSH/NPPTL guidance. Sound practice requires, under *NIOSH Manual of Analytical Methods*, demonstrating a tolerance range of expected data performance of a plus or minus 25% of a 95% confidence interval of the stated standard requirement. NIOSH/NPPTL P&A tolerance can be higher but not lower.

4.5 Compressed gas cylinders must meet all applicable Department of Transportation requirements for cylinder approval as well as retesting / requalification.

4.6 Normal laboratory safety practices must be observed. This includes safety precautions described in the current NIOSH Pittsburgh Health and Safety Program.

4.6.1. Workbenches must be maintained free of clutter and non-essential test equipment.

4.6.2 When handling any broken glass laboratory equipment, lab technicians and personnel must wear special gloves, which may protect against lacerations or punctures.

4.7 **Please refer to Material Safety Data Sheets and the NIOSH Health and Safety Manual for the proper protection and care in handling, storing, and disposing of the chemicals and gases used in this procedure.**

5. PROCEDURE

5.1 Make sure metabolic valves are at zero positions with white marks aligned.

5.2 Ensure that water reservoir in rear has sufficient water (near the top of the beaker).

5.3 Turn on front panel switch (#2) for the gas analyzers and pressure transducers. When O2 analyzer T.C. temperature reads 6.790 mV, continue.

5.4 Turn on computer and monitor.

5.5 Open Main Calibration program.

5.6 Turn on two other front panel switches (#1-Water pump and heaters; #3-Lung and metabolic valve movement, solenoid valve, and vacuum pump).

5.7 Ensure that sample gas flow meters in rear both read 4 .

5.8 Ensure that chart recorder power is on.

5.9 When water reservoir temperature reads 43 C, turn on compressed-air for the Nafion sample-gas counter-flow to read 11 on ball-float flow meter. Ensure that Drierite is still good.

5.10 Turn on DEEC Insta-Dryer. When internal temperature is 3.5^{o}C, continue

5.11 Adjust oxygen and CO_2 analyzers to read dry room air: 20.93% oxygen and 0.04% CO_2.

5.12 Open calibration gas cylinder a crack. Open N_2 and CO_2 cylinders at least five turns.

5.13 Connect sample gas line input to calibration gas line ‘T’ connection output.

5.14 When oxygen and CO_2 readings are stable, turn chart recorder speed dial from Chart Stop to mm/min and press Chart Speed button below to 50; adjust CO_2 and oxygen pens to read ambient conditions. Press All-Gases button to perform automatic analyzer AD calibration and calculation of response and transport times for each gas. Ensure that chart recorder CO_2 and oxygen pens and analyzer panel

meters read 8% CO_2 and 90% oxygen during sample-gas flow. Turn speed dial back to Chart Stop and press Chart Speed button 5. After calibration is completed, when prompted, assent to printing results.

5.15 Press Save Calibration button. Do not assent to printing results again.

5.16 Exit Main Calibration program.

5.17 Open Main Runtime program.

5.18 Enter the barometric pressure of the day after reading it on the barometer and subtracting 3 mm Hg from the reading to account for temperature being ambient instead of $0^{o}C$.

5.19 Select protocol file by pressing top Go button.

5.20 Blow out any condensed water from mouth port adapter sample taps.

5.21 Connect sample-gas line and pressure line to proper-size mouth port adapter; ensure that DB and WB probes are in the middle of the air stream.

5.22 Start test (one-minute warm-up period) by pressing lower Go button.

5.23 Attach apparatus mouthpiece to mouth port adapter.

5.24 For chemical-oxygen apparatus, pull chlorate candle pin 30s before the ports switch. For compressed-oxygen apparatus, turn on oxygen cylinder about 10s before the ports switch.

5.25 Turn chart recorder speed dial from Chart Stop to mm/min. Chart Speed button below should be set to 5.

5.26 During this step of the procedure, when the oxygen concentration is stable (less than 1 % change over a minute), perform the following steps to check the Exhaust Flow.

5.26.1 Connect spirometer to vacuum pump exhaust port.

5.26.2 Collect gas for temperature measurement.

5.26.3 Turn on digital thermometer with needle probe.

5.26.4 Open spirometer exhaust port and hold needle probe in middle of interior of exhaust port while pressing down spirometer bell to force out collected exhaust air. Note stable temperature and write it in log-book.

5.26.5 Determine water vapor pressure of exhaust gas using the just-measured temperature and the water-vapor-pressure chart.

5.26.6 Calculate a conversion factor (CF) from ATPS to STPD using the formula below and the ambient barometric pressure (BP), the vapor pressure (VP) and temperature (T) of the exhaust gas:

$$CF = \frac{BP-VP}{760} \cdot \frac{273}{T}$$

5.26.7 When oxygen level is stable, close off spirometer exhaust port to begin collecting exhaust gas in spirometer. When spirometer ruler meets an agreeable number, start stop-watch. Write the spirometer ruler start-number in the log book.

5.26.8 Check the computer screen for the time-average oxygen fraction at the mouth (listed in last column of two-breath data readings on the screen). Divide this number into the target VO_2. This is the target exhaust flow.

5.26.9 After at least a minute of gas collection and at least a 2-cm movement of the ruler, stop stop-watch at another agreeable ruler number.

5.26.10 Write the final reading of the spirometer ruler in the log-book.

5.26.11 Check the computer screen for the time-average oxygen fraction at the mouth again. If it has changed by more than 0.01, calculate the average of the two.

5.26.12 Subtract the original ruler number from the final ruler number. Multiply this number by the factor 1.355 L/cm (spirometer calibration factor) to get the volume of exhaust gas collected over the stop-watch-recorded time period. This volume is at ambient spirometer conditions, saturated.

5.26.13 Convert the stop-watch reading to a decimal reading by dividing the number of seconds by 60.

5.26.14 Determine the exhaust flow rate by dividing the volume collected by the period of time it took to do so. This flow rate is at ambient conditions in the spirometer, saturated. To convert it to STPD (standard temperature and pressure, dry), multiply it by the CF calculated in step 5.26.6.

5.26.15 This is the actual exhaust flow rate. To determine how close this is to the desired rate, divide this number into the target exhaust flow rate. Note the actual exhaust flow rate and the difference between the actual

flow rate and the desired flow rate in the data file. See appendix 8.2
Example: Exhaust flow = .976 target = -55 ml/min.

5.27 Stop test when oxygen supply is expended and inhalation pressure reaches -200 mm H_2O (piston takes about 6 breaths to stop after STOP button is pressed).

5.28 Remove sample-gas line and pressure line.

5.29 Drain mouth port adapter of condensed water.

5.30 Open ballast valve on vacuum pump.

5.31 Write test number and date on chart recording.

5.32 Turn off front panel switches #1 and #3 only after all water droplets have disappeared from Nafion tubing.

5.33 Turn off DEEC Insta-Dryer

5.34 Turn off compressed air for Nafion gas dryer counter-flow.

5.35 After about an hour of drying out, close vacuum pump ballast valve and pull plug for vacuum pump. Then relieve residual pressure in exhaust line by pulling out and re-inserting quick-disconnect line to exhaust metabolic valve.

6. PASS OR FAIL CRITERIA

6.1 The criteria for passing this test are set forth in the *Closed-Circuit Concept Paper,* dated : xxx and *42 CFR Part 84, Subpart G, Section 84.63(a)(c)(d*); Volume 60, Number 110, June 8, 1995.

6.2 This test establishes the standard procedure for ensuring that:

84.63 Test requirements; general.

(a) Each respirator and respirator component shall, when tested by the applicant and by the Institute, meet the applicable requirements set forth in subparts H through L of this part.

(c) In addition to the minimum requirements set forth in subparts H through L of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

6.3 Three units will be tested in as-received condition using an automated breathing and metabolic simulator (ABMS).

6.4 Two units will be tested using an ABMS after being subjected to environmental treatments specified in TEB-STP-xxxx.

6.5 Two units will be tested using an ABMS at the lower temperature limit recommended by the manufacturer, after the unit has been stored for a minimum of 24 hours at this limit.

6.6 Capacity and performance tests will continuously monitor the stressors listed in Table 1 while tested using an ABMS.

6.6.1 The stressors and their respective acceptable ranges will be measured at the interface between the CCER and the mouth with instruments capable of breath-by-breath measurement. Stressor measurements will be recorded and evaluated as one-minute averages. Operating averages will be the average of these values over the operating life of the apparatus.

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_20	$-300 \leq \Delta P \leq 200$ mm H_20
Wet-bulb temperature[1]	<43 ^oC	≤50 ^oC

Table 1: Monitored Stressors and their Acceptable Ranges

[1] Wet-bulb temperature is a measurement of the temperature of a wet surface. It represents the temperature of the inhaled breathing gas in the CCER user's trachea.

6.6.2 Capacity and performance tests will conclude when the stored gas supply has been fully expended.

6.6.3 The Institute will determine a CCER to have failed a capacity, performance or wearability test if any of the following occurs during the test

6.6.3.1 A minute-average measurement of any stressor listed in Table 1 occurs outside the acceptable excursion range specified in Table 1; or

6.6.3.2 An average stressor values over the operating life exceed the operating average values specified in Table 1; or

6.6.4 Unless otherwise stated, tests required under this subpart will be conducted at the following ambient conditions

6.6.4.1 Ambient temperatures of 23ºC ± 3 ºC; and

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

7. RECORD AND TEST SHEETS

7.1. All test data will be recorded on the ABMS data sheet.

7.2. All videotapes and photographs of the actual test being performed, or of the tested equipment shall be maintained in the task file as part of the permanent record.

7.3. All equipment failing any portion of this test will be handled as follows:

7.3.1. If the failure occurs on a new certification application, or extension of approval application, send a test report to the TEB Team Leader and prepare the hardware for return to the manufacturer.

7.3.2. If the failure occurs on hardware examined under an off-the-shelf audit, the hardware will be examined by a technician and the TEB Team Leader for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the Branch Chief, or the Branch Chief's designee, following the standard operating procedures outlined in *Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-0005-00*.

8. APPENDIXES

8.1. ABMS Set-Up.

8.2. Data Sheet.

9. RECORD OF CHANGE

Appendix 8.1: ABMS Set-Up.

Appendix 8.2: Test Data Sheet