DETERMINATION OF PERFORMANCE OF AS-RECEIVED AND ENVIRONMENTALLY TREATED CLOSED-CIRCUIT ESCAPE RESPIRATORS (CCER)

1. PURPOSE

This procedure establishes the test for ensuring that Closed-Circuit Escape Respirators (CCER) submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet the certification standards as set forth in Section 84.305 (a) (1) and (2), of Subpart O−Closed Circuit Escape Respirators updated requirements to 42 CFR Part 84.

2. GENERAL

This Standard Testing Procedure (STP) describes the CCER performance test, equipment, instruments, materials, and minimum performance criteria in sufficient detail such that a person knowledgeable in the appropriate technical field can select the equipment with the necessary resolution, conduct the test, and determine whether or not the respirator passes the test.

3. EQUIPMENT / MATERIALS

3.1. The ABMS instrument and equipment schematic (Figure 1 in the Attachments), includes using a LabVIEW digital display, control, and data recording software.

3.2. The following instruments performing stressor measurements should be capable of breath-by-breath responses and have the following measurement ranges:

3.2.1. Carbon dioxide (CO_2) gas analyzer capable of detecting CO_2 from 0.00 to 15.00 volume %, accurate to within ±0.02% CO_2, with a response time of approximately 100 milliseconds and possessing a digital display readout (resolution) ±0.01% (such as AEI Technologies Carbon Dioxide analyzer Model CD-3A or equivalent)

3.2.2. Oxygen (O_2) gas analyzer capable of detecting O_2 from 0.00 to 100.00 volume %, accurate to within ± 0.01% O_2, with a response time of approximately 100 milliseconds and possessing digital display readout (resolution) ±0.01% (such as AEI Technologies Oxygen analyzer Model S3-A/I or equivalent gas analyzer)

3.2.3. Thermocouple modified to induce evaporative cooling from its tip (thermocouple wire junction point) and capable of measuring a breathing circuit wet bulb temperature ranging from 0 to 100 $^{\circ}$C (such as an Omega P/N 5SRTC-TT-T-36-36 Type 'T', 0.005-inch outer diameter thermocouple with appropriate junction point covering)

3.2.4. Pressure transducer capable of measuring breathing circuit breathing resistance from -562.5 to +562.5 mm water (such as a Validyne Model P55D-1-N-2-28-S-4-A or equivalent pressure transducer).

3.3. Support/control instruments and equipment include the following:

3.3.1. Thermocouple capable of breath-by-breath response and measuring a breathing circuit dry bulb temperature ranging from 0 to 100ºC (such as an Omega P/N 5SRTC-TT-T-36-36 Type 'T', 0.005-inch outer diameter thermocouple, or equivalent)

3.3.2. Gas sample system electronic moisture removal device, electronic gas chiller capable of lowering the automated breathing and metabolic simulator (ABMS) gas sample system dew point to 3.5 ˚C, (such as the DEEC Instadryer or equivalent)

3.3.3. CO_2 Mass Flow Controller (MFC) capable of measuring 0-5 LPM (such as the Brooks SLA5850S CO_2, or equivalent)

3.3.4. N_2 MFC capable of measuring 0-1.7 LPM (such as a Brooks SLA5850S or equivalent)

3.3.4.1. Activated when N_2 flow rates decrease below 1.6 LPM; deactivated when N_2 flow rates increase above 1.7 LPM

3.3.5. N_2 MFC capable of measuring 0-20 LPM (such as a Brooks SLA5850S or equivalent)

3.3.5.1. Activated when N_2 flow rates increase above 1.7 LOM; deactivated when N_2 flow rates decrease below 1.6 LPM

3.3.6. Weigh scale with a 0 to 35,000 mg range with 1 mg scale resolution (such as the Ohaus Ranger R71MHD35 weigh scale or equivalent)

3.3.7. Gas spirometer (such as the Collins P-1700-120 Liter scale gas spirometer or equivalent)

3.3.8. Timer (accurate to 0.01 percent)

3.3.9. Physitemp Thermalert Model TH-8 temperature indicator, or equivalent, with calibrated 'T' type thermocouple

3.3.10. Electronic barometric pressure transducer (such as the Vaisala PTU300 electronic barometric pressure transmitter or equivalent)

3.4. Materials required include the following:

3.4.1. Nitrogen (N_2) Cylinder – at minimum, High Purity grade containing $\geq$99.99% N_2

3.4.2. Carbon dioxide cylinder – at minimum, Coleman/Instrument grade containing $\geq$99.99% CO_2

3.4.3. Calibration gas traceable to recognized international standards containing 80.0% oxygen, 12.0% nitrogen, and 8.0% carbon dioxide

3.4.4. Phenolphthalein

3.4.5. Deionized water for the ABMS recirculating water system

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Prior to beginning any test, confirm that all measuring equipment and instruments employed have been calibrated in accordance with the testing laboratory's calibration procedure and schedule. All measuring equipment and instruments utilized must have been calibrated using a method traceable to recognized international standards when available.

4.2. Tests will be conducted at the following ambient conditions.

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

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

4.3. Prior to beginning the Performance Test Procedure, the CCER will be inspected using the manufacturer's and NIOSH inspection criteria. The manufacturer's inspection will be specific to their respirator unit and are defined in the User Instructions (UI). NIOSH inspections will include:

4.3.1. Applying a -300mm H_2O vacuum to assess the integrity of the breathing tube and associated parts.

4.3.2. Using a phenolphthalein swab to detect alkaline chemicals present in the CCER unit user interface.

4.4. Performance Test Requirements and Conditions

4.4.1. Performance tests will continuously monitor the stressors listed in Table 1. The stressors will be measured at the interface between the CCER and the ABMS "mouth" by instruments capable of breath-by-breath measurement. Stressor measurements will be evaluated as one-minute averages. The operating (overall) averages of each stressor will be calculated upon the completion of each test as the average of the one-minute measurements of the stressor recorded during the test.

4.4.2. Performance testing of a CCER will conclude when the stored breathing gas supply has been fully expended or any one-minute average stressor measurement is outside the acceptable excursion range.

4.4.3. The performance test is performed on at least five units submitted for approval (refer to Table 3), as follows:

4.4.3.1. Three units will be tested in the condition in which they are received from the applicant.

4.4.3.2. Two units will be tested after being subjected to the environmental treatments according to standard procedure for environmental treatments of CCERs.

4.4.4. Each unit will be tested by application of a repeating cycle of work rates, according to the sequence and requirements in Table 2.

4.4.5. The performance test will begin with two exhalations into the unit at the specified ventilation rate to determine the design's susceptibility to hypoxia.

4.4.6. Performance testing of CCERs with less than 50 liters of oxygen capacity will require the submission of additional test units to fully apply the work-rate test sequence and requirements specified in Table 3. The testing of each individual unit will complete the cycle specified in Table 3 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 cycle where the previous unit ended (overlap to previous cycle point may be no more than 2 minutes).

5. PROCEDURE

5.1. Initial Startup

5.1.1. Verify all equipment is on and all test system operating parameters are in the appropriate range for valid testing.

5.1.2. Calibrate the O_2 and CO_2 exhaust flows analyzers.

5.1.3. Perform ABMS gas analyzer calibration for O_2 and CO_2.

5.1.3.1. Confirm the response times for each gas analyzer are within acceptable ranges as established by the manufacturer.

5.1.4. Verify correct waveforms for the specific performance test work rate cycle.

5.1.4.1. For the peak work rate portion of the performance test work rate cycles , set the VO_2 to 3.00 L/min; see Figure 2.

5.1.4.2. For the high work rate portion of the performance test work rate cycle, set the VO_2 to 2.00 L/min; see Figure 3.

5.1.4.3. For the low work rate portion of the performance test work rate cycle, set the VO_2 to 0.50 L/min; see Figure 4.

5.1.5. Mount the CCER unit on the ABMS trachea and perform a leak check for the ABMS. Ensure all orifices are properly sealed and that the system is leak tight.

5.1.6. Select the Performance Test protocol just prior to beginning the simulation operation.

5.2. Perform the performance test by selecting the appropriate test protocol to set the corresponding VO_2, VCO_2, ventilation rate, and respiratory frequency operating conditions just prior to beginning the simulation.

5.2.1. The manufacturer's recommended start-up procedure for the CCER being tested must be simulated on the ABMS as closely as possible, as described in the manufacturer's UI.

5.2.2. Monitor the values in Table 1 throughout the test.

5.2.3. Determine the completion time as the time elapsed from test start to when the gas supply is fully expended. Expended gas supply is usually indicated when either the breathing bag is empty, or (if present) the O_2 cylinder is empty, and (as a result) peak inhalation pressure begins to spike below -300 mmH_2O. The test is also stopped if the peak breathing resistance exceeds +200 mmH_2O.

5.2.4. The Peak, High, and Low work rates will be cycled through as the corresponding VO_2, VCO_2, ventilation rate, and respiratory frequency levels are varied as per the settings and time sequences in Table 3.

5.2.4.1. Start-up for a performance test must include two complete exhalations prior to beginning the simulation operation. If the manufacturer requires that an exhaled breath be imparted prior to start-up, this exhaled breath will be considered as one of the two complete exhalations required for performance testing.

5.2.5. For CCER undergoing performance approval testing that contain less than 50 Liters of capacity, the simulation operation shall be paused immediately prior to the capacity being depleted and the breathing bag collapsing. After replacing the expended CCER with a new CCER, simulation operation must restart immediately thereafter. At least one full work rate cycle (peak, high, and low) must be completed for testing of CCERs with less than 50 Liters capacity.

5.3. Data analysis

5.3.1. Determine the completion time as the time elapsed from test start to when the breathing gas supply is fully expended. Expended breathing gas supply is usually indicated when either the breathing bag is empty, or (if present) the O_2 cylinder is empty, and (as a result) peak inhalation pressure begins to spike below -300 mm H_2O.

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

6. PASS/FAIL CRITERIA

6.1. The apparatus fails this test and approval if:

6.1.1. Any average stressor measurement (as the overall average stressor from test start to when the breathing gas supply is fully expended) is outside the acceptable operating average range shown in Table 1 (middle column).

6.1.2. If from the test start up to when the breathing gas supply is fully expended any one-minute average stressor measurement is outside the acceptable excursion range shown in Table 1 (last column).

Table 1: 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 Resistances	$\Delta P \leq 200$ mm H_2O	$-300 \leq \Delta P \leq 200$ mm H_2O
Wet-bulb temperature	<43˚C	≤50˚C

6.1.3 The apparatus fails approval if the achieved capacity is below the minimum capacity as indicated in Table 2.

Table 2: 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	VO_2 (L/min)	VCO_2 (L/min)	Ve (L/min)	RF (breaths/min)
1. Peak	5 min.	3.00	3.20	65.0	25
2. High	15 min.	2.00	1.80	44.0	20
3. Low	10 min.	0.50	0.40	20.0	12

VO_2 = volume of oxygen consumed/min; VCO_2 = volume of carbon dioxide produced/min
Ve = ventilation rate; RF = respiratory frequency

7. RECORDS / TEST SHEETS

7.1. Data shall be recorded and stored as an attached data sheet to include the following information in the TEST DATA SHEET (INCLUDING PRE-TEST CHECK DATA) FOR DETERMINATION OF CCER PERFORMANCE, STP 0603.

TEST DATA SHEET (INCLUDING PRE-TEST CHECK DATA) FOR DETERMINATION OF CCER PERFORMANCE, STP 0603

Date	Barometric Pressure (mm Hg)	S/N #	Manufacturer Date	Expiration Date	Phenolphthalein (Pass or Fail)	Oxygen Flow Rate (LPM)	CCER Leak Flow Rate (mL/min)
Case Integrity	Case Seal	Secure Tape or Latch	Oxygen Indicator (psig)	Oxygen Starter	Temperature Indicator	Moisture Indicator	Waveform/Protocol
Oxygen Response (ms)	Carbon Dioxide Response (ms)	Oxygen Criteria Time (ms)	Carbon Dioxide Criteria Time (ms)	ABMS Leak Rate (mL/min)	ABMS Leak Rate with CCER (mL/min)	Technician Initials	Comments

Table 3: Example Test Summary Data for all CCER Units Submitted for NIOSH Approval

Device ID	**Test**	**Test date**	**Completion time**	**Calculated Capacity**	**Indicate Minimum Capacity**	**Comments**
	As-received					
	As-received					
	As-received					
	Environmental treatments					
	Environmental treatments					

8. ATTACHMENTS

8.1. Figure 1: Schematic of the ABMS
8.2. Figure 2: Graph for the Peak Work-Rate Test
8.3. Figure 3: Graph for the High Work-Rate Test
8.4. Figure 4: Graph for the Low Work-Rate Test

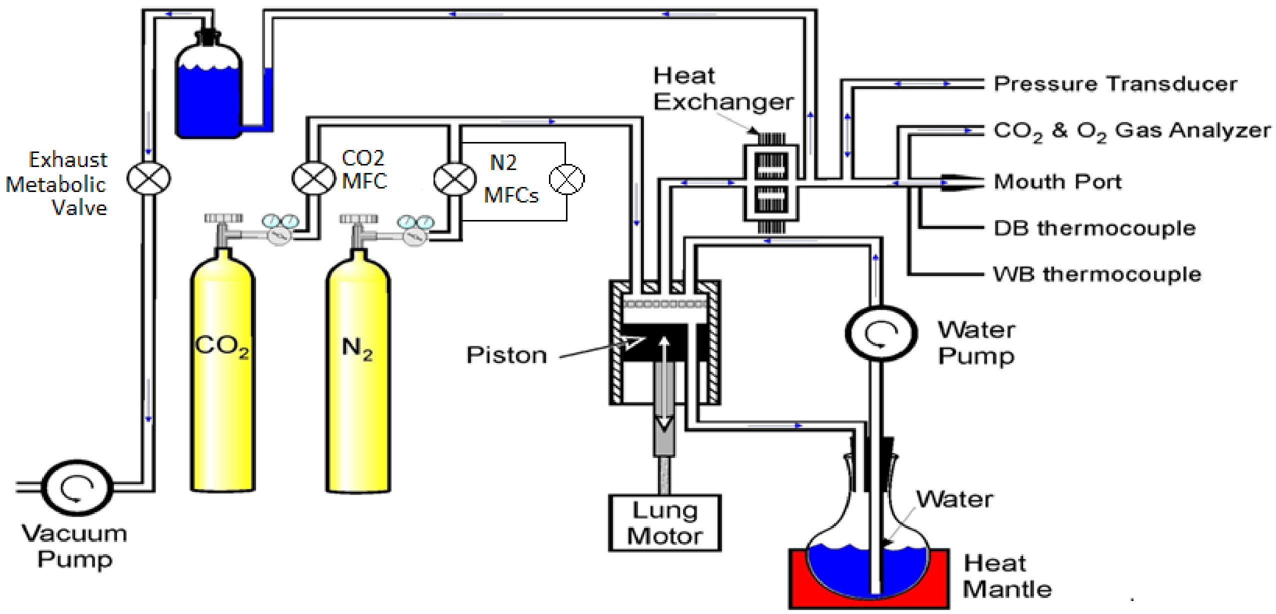

Figure 1: Schematic of the ABMS

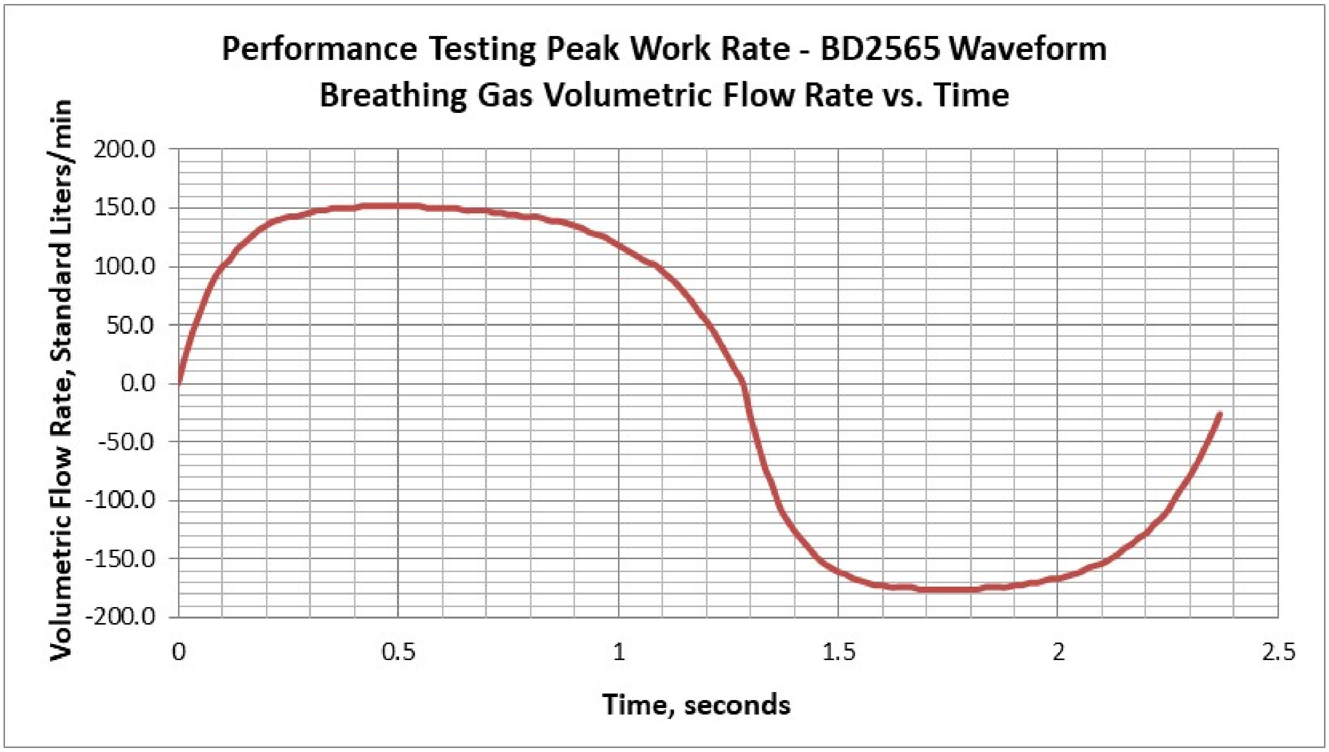

Figure 2: Example graph for Peak Work Rate, showing breathing gas volumetric flow rate (y-axis) vs. time (x-axis).

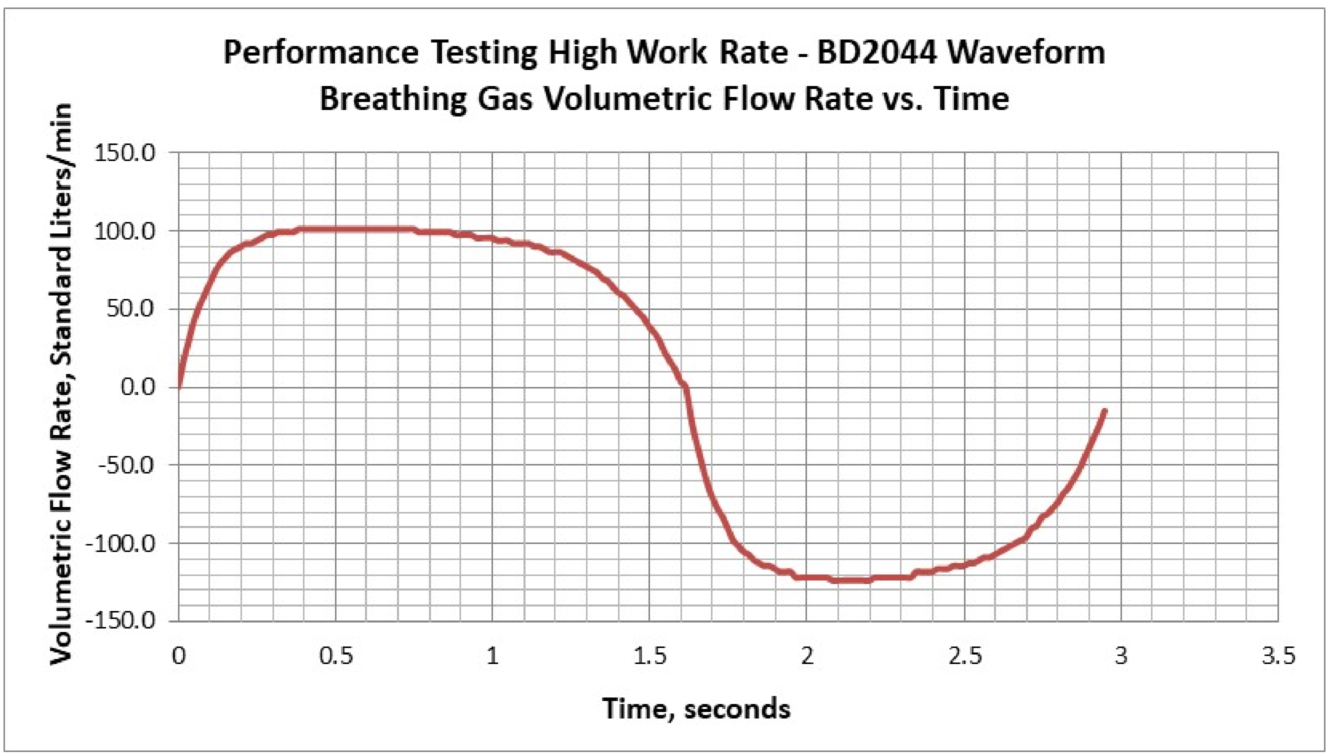

Figure 3: Example graph for High Work Rate, showing breathing gas volumetric flow rate (y-axis) vs. time (x-axis).

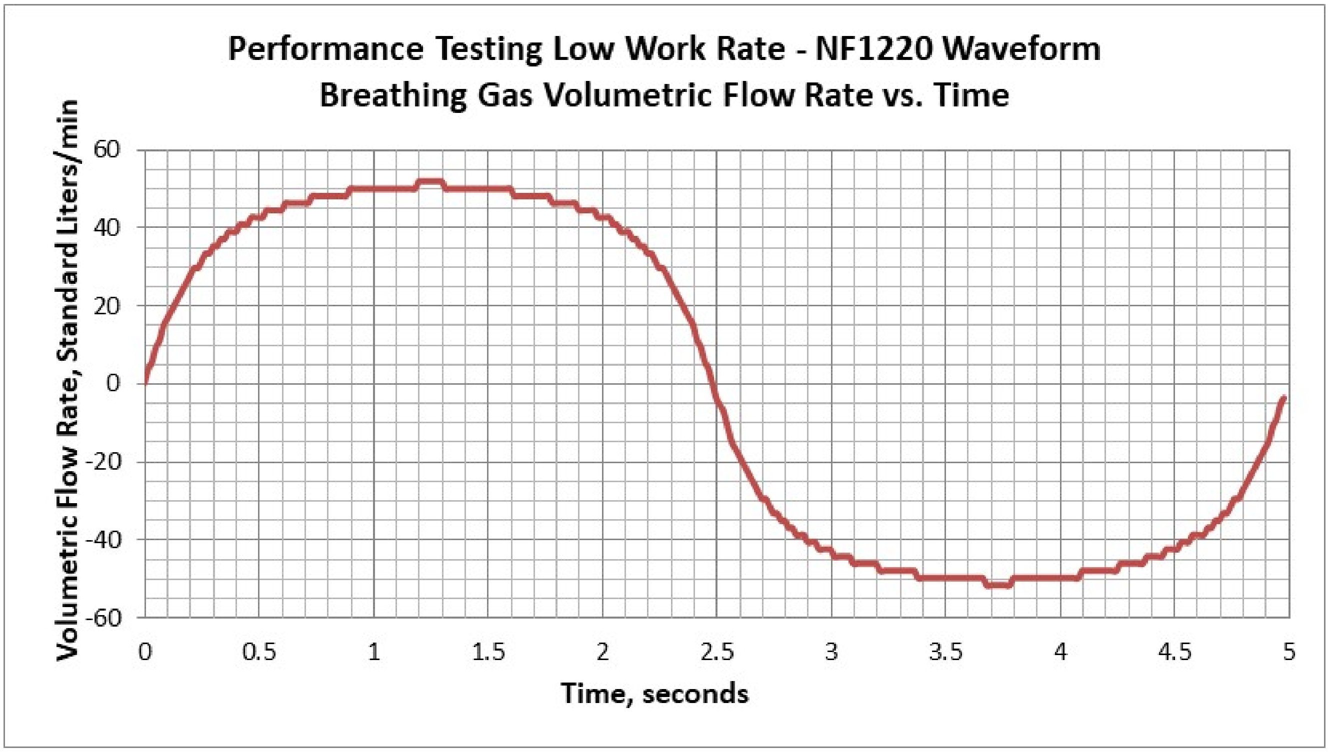

Figure 4: Example graph for Low Work Rate, showing breathing gas volumetric flow rate (y-axis) vs. time (x-axis).

Revision History

Revision	Date	Reason for Revision
0	14 October 2009	Initial Record
1.0	02 August 2011	Final Review
1.0	22 November 2011	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-0007
0.0	25 March 2014	New document number to reflect numbering in the approval library, normalization of format. The only change made in the procedure is in section 4.6.6. The restart of subsequent units was changed from commencing the next work rate from where the previous unit ended, to the point at which the previous unit ended with no more than a 2 minute overlap. No other changes to procedure from historical document.
1.0	05 January 2022	Changes were made to the equipment, materials, and the procedure. Examples waveforms were added as Figures.