

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

Procedure No. TEB-CCER-STP-0615

Revision: 0.0 Date: 7 April 2014

STANDARD TESTING PROCEDURE (STP) TO CONDUCT MAN TEST 4 FOR CLOSED-CIRCUIT ESCAPE RESPIRATORS (CCERs) TO BE USED IN UNDERGROUND COAL MINES

1. <u>PURPOSE</u>

This test establishes the procedures for ensuring that the level of protection provided by the Man Test 4 requirements 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 84.304(a) (5) 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. <u>GENERAL</u>

This STP describes the Man Test 4 for Closed-Circuit Escape Respirator test in sufficient detail that a person knowledgeable in the appropriate technical field can assemble the appropriate equipment, conduct the test, and determine whether or not the product passes the test.

3. <u>EQUIPMENT/MATERIALS</u>

- 3.1. The list of necessary test equipment and materials follows:
 - 3.1.1. One B-D Yale (2317 100YL) 100cc (Becton, Dickson and Co.) syringe "Luer-Lok", Becton Dickson & Company, Rutherford, NJ, or equivalent
 - 3.1.2. Doric Series 400A Digital Trendicator, Doric Scientific Division, Emerson Electric Company, 3883 Ruffin Road, San Diego, CA 92123 or equivalent
 - 3.1.3. Gould Stratham Transducer Readout, Model SC1012, Gould, Inc., 2230 Stratham Blvd., Oxnard, CA 93030 or equivalent
 - 3.1.4. Temperature Compensated Strain Sensitive Resistance wire-type transducer (Stratham Instruments) Pressure range +0.5 psig or equivalent
 - 3.1.5. Electric timer, calibrated to 100ths of a minute (Precision Scientific Co.) or equivalent
 - 3.1.6. Digital timer/stopwatch calibrated to 100ths (0.01) of a minute to or equivalent

Approvals: First Level	Second Level	Third Level	Fourth Level

- 3.1.7. Applied Electrochemistry CO₂ Analyzer Model CD-3A or equivalent
- 3.1.8. Applied Electrochemistry Oxygen Analyzer Model S-3A/I or equivalent

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- 3.1.9. Certified calibration gas with O2 at 80.0 % and CO2 at 8.0% and N2 at 12%.
- 3.1.10. Fifty-pound sack or equivalent
- 3.1.11. Forty-five pound pipe weight or equivalent
- 3.1.12. Forty-five pound weight pulling machine (U.S. BOM) or equivalent
- 3.1.13. Knee pads or equivalent
- 3.1.14. Model 18-49B Horizontal Treadmill, 0-6 MPH, Quinton Instruments or equivalent
- 3.1.15. Model 24-90 Ladderwalk 0-130 feet/minute, Quinton Instruments, or equivalent
- 3.1.16. An automated external defibrillator (AED) at the test scene

4. TESTING REQUIREMENTS AND CONDITIONS

- 4.1. Two test subjects meeting 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. 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 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 HSRB 12-NPPTL-04, "Protocol for tests with human subjects of closed-circuit breathing apparatus in certification, quality assurance, and development" for the proper consent form and complete details on the use of human test subjects in closed-circuit escape respirator certification testing.

5. <u>PROCEDURE</u>

Note: Reference Section 3 for equipment, model numbers and manufacturers. For calibration purposes use those described in the manufacturer's operation and maintenance manuals.

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- 5.1. Use the test operating procedure as follows:
 - 5.1.1. The man tests are conducted in duplicate in accordance with the specific duration test schedule corresponding to the service time approval requested by the manufacturer.
 - 5.1.2. During the sampling periods the following parameters are monitored:

Closed Circuit

- a) breathing resistance
- b) gauge pressure
- c) subject pulse rate
- d) subject respiration rate
- e) oxygen in inhalation tube
- f) carbon dioxide in inhalation tube
- g) temperature (mask and ambient)
- 5.1.3. Prior to tests the oxygen and carbon dioxide analyzers must be calibrated with the proper calibration gas (see 3.1.10).
- 5.1.4. All tests require the services of a physician, the presence of two persons currently certified in CPR/AED use and an automated external defibrillator (AED) located adjacent to the test area.
- 5.1.5. Test subjects are used for evaluation of a CCER for use in coal mines. Refer to HSRB 12-NPPTL-04 "Protocol for tests with human subjects of closed-circuit breathing apparatus in certification, quality assurance, and development".

5.2. Data Analysis

- 5.2.1. All sample values must be within the regulations requirements. Other factors are also evaluated during the tests, such as; strap length, position and adjustments; comfort; weight; profile; total performance. Expert test subjects give test feedback and opinions for the SCBA evaluated and are geared towards:
 - 5.2.1.1 General comments
 - 5.2.1.2. Specific comments per intended application.

Note: This test will be done on a minimum of two respirators, or more if additional testing is required (42 CFR, Part 84, Sections 84.12, 84.30, and 84.60.)

6. PASS/FAIL CRITERIA

6.1. The criterion for passing this test is set forth in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d), and Subpart H, Section 84.70, 84.79(a), 84.97, 84.99, 84.100, 84.103, Volume 60, Number 110, June 8, 1995.

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- 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.
 - 84.79 Breathing gas; minimum requirements
 - (a)-1 Breathing gas used to supply apparatus shall be respirable and contain no less than 19.5 (dry atmosphere) volume percent of oxygen.
 - 84.97 Test for carbon dioxide in inspired gas; closed-circuit apparatus; maximum allowable limits.
 - (c) During the testing required by paragraphs (a) and (b) of this section, the concentration of carbon dioxide in inspired gas at the mouth will be continuously recorded, and the maximum average concentration during the inhalation portion of the breathing cycle shall not exceed the following limits:

Where the service time is	Maximum allowable average concentration of carbon dioxide in inspired air percent by volume		
Not more than 30 minutes	2.5		
1 hour	2.0		
2 hour	1.5		
3 hour	1.0		
4 hour	1.0		

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- 84.99 Man tests; testing conditions; general requirements.
- (a) The man tests described in Table 4 represent the workload performed in the mining, mineral, or allied industries by a person wearing the apparatus tested.
- (b) The apparatus tested will be worn by personnel trained in the use of selfcontained breathing apparatus, and the wearer will, before participating in these tests, pass a physical examination conducted by a qualified physician.
- (c) All man tests will be conducted by the Institute.
- (d) The apparatus will be examined before each man test to ensure that it is in proper working order.
- (e) Breathing resistance will be measured within the facepiece or mouthpiece and the wearer's pulse and respiration rate will be recorded during each 2-minute sample period prescribed in tests 1, 2, 3, and 4.
- (f) Man tests 4 will be conducted in duplicate.
- (g) If man tests are not completed through no fault of the apparatus, the test will be repeated.
- 84.100 Man test 4; requirements.

Man test 4, set forth in Table 4 respectively, prescribe the duration and sequence of specific activities. These tests will be conducted to:

- (a) Familiarize the wearer with the apparatus during use;
- (b) Provide for a gradual increase in activity;
- (c) Evaluate the apparatus under different types of work and physical orientation; and
- (d) Provide information on the operating and breathing characteristics of the apparatus during actual use.

- 84.103 Man tests; performance requirements.
- (a) The apparatus shall satisfy the respiratory requirements of the wearer for the classified capacity (Cap 3 for one hour test duration).
- (b) Fogging of the eyepiece shall not obscure the wearer's vision, and the wearer shall not experience undue discomfort because of fit or other characteristics of the apparatus.
- (c) When the ambient temperature during testing is 24 degrees \pm 6 degrees C. (75 degrees \pm 10 degrees F.), the maximum temperature of inspired air recorded during man tests shall not exceed the following, after correction for deviation from 24 degrees C. (75 degrees F.):

Where service life of apparatus is	Where percent relative humidity of inspired air is	Maximum permissible temperature of inspired air shall not exceed		
1/4 hour or less	0-100	135 57		
1/2 hour to 3/4 hour	0-50	125	52	
	50-100	110 ¹	43 ¹	
1 to 2 hours	0-50	115	46	
	50-100	105 ¹	41 ¹	
3 hours	0-50	110	43	
	50-100	100¹	38 ¹	
4 hours	0-50	105	41	
	50-100	95 ¹	35 ¹	

¹Where percent relative humidity is 50-100 and apparatus is designed for escape only, these maximum permissible temperatures will be increased by 5°C (10°F).

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Tables to Subpart H of Part 84

Table 4-Duration and Sequence of Specific Activities for Test 4, in Minutes [42 CFR part 84, subpart H]

Activity	Service time-									
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2 hours	3 hours	4 hours
Sampling and readings				2	2	2	2	(2)	(3)	(⁴)
Walks at 4.8 km. (3 miles) per hour				1	2	2	2			
Climbs vertical treadmill 1 (or equivalent)	1	1	1	1	1	1	1			
Walks at 4.8 km. (3 miles) per hour		1	1	1	2	2	2			
Pulls 20 kg. (45 pound) weight to 5 feet		30 times in 2 minutes	30 times in 2 minutes	30 times in 2 minutes	60 times in 5 minutes	60 times in 5 minutes	60 times in 5 minutes			
Walks at 4.8 km. (3 miles) per hour			1	1	1	2	3			
Carries 23 kg. (50 pound) weight over overcast				1 time in 1 minute	1 time in 1 minute	2 times in 3 minutes	4 times in 8 minutes			
Sampling and readings			2		2	2	2			
Walks at 4.8 km. (3 miles) per hour				1	3	3	4			
Runs at 9.7 km. (6 miles) per hour		1	1	1	1	1	1			
Carries 23 kg. (50 pound) weight over overcast			1 time in 1 minute	1 time in 1 minute	2 times in 3 minutes	4 times in 6 minutes	6 times in 9 minutes			
Pulls 20 kg (45 pound) weight to 5 feet	15 times in 1 minute			15 times in 1 minute	60 times in 5 minutes	30 times in 2 minutes	36 times in 3 minutes			
Sampling and readings				2	2	2	2			
Walks at 4.8 km. (3 miles) per hour	1		1			2	6			
Pulls 20 kg. (45 pound) weight to 5 feet						60 times in 5 minutes	60 times in 5 minutes			
Carries 20 kg. (45 pound) weight and walks at 4.8 km. (3 miles) per hour						3	3			
Sampling and readings						2	2			

¹Treadmill shall be inclined 15° from vertical and operated at a speed of 30 cm. (1 foot) per second.

²Perform test No. 1 for 30-minute apparatus; then perform test No. 4 for 1-hour apparatus; then perform test No. 1 for 30-minute apparatus.

³Perform test No. 1 for 1-hour apparatus; then perform test No. 4 for 1-hour apparatus; then perform test No. 1 for 1-hour apparatus.

⁴Perform test No. 1 for 1-hour apparatus; then perform test No. 4 for 1-hour apparatus; then perform test No. 1 for 1-hour apparatus twice (i.e., two one-hour tests).

7. <u>RECORDS\TEST SHEETS</u>

7.1. All test data will be recorded on the MAN TESTS, SELF-CONTAINED BREATHING APPARATUS test data sheet.

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- 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 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 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 Team Leader, or his designee, following the standard operating procedures outlined in Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-0005-00.

MAN TESTS, SELF-CONTAINED BREATHING APPARATUS #4 - 4 HOUR

PROJECT NO:	DATE :
Subject:	_ Age :
Subject weight: Initial Final	
RESPIRATOR TYPE: 4 hour	
Unit weight: Initial Final	
Observers:	
Sampling Sch	<u>edule</u>
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	
0-2	
20-22	
40-42	
58-62	
83-85	
102-104	
118-122	
140-142	
160-162	
178-182	
200-202	
220-222	
238-240	
Alarm min. at psig.	

Work Schedule

<u>Exercise</u>
sample
walk - 3mph
vertical
walk - 3mph
rope pull - 60x5min
walk - 3mph
overcast - 4x8min
sample
walk - 3mph
run - 6mph
overcast - 6x9min
rope pull - 36x3min
sample
walk - 3mph
rope pull - 60x6min
carry 45lb weight & walk 3mph

Work Schedule (cont)

Time/Mi	<u>n.</u>	Exerc	rise
118-122		sampl	le
122-140		walk	- 3mph
140-142		sampl	le
142-160		walk	- 3mph
160-162		sampl	le
162-178		walk	- 3mph
178-182		sampl	le
182-200		walk	- 3mph
200-202		samp	le
202-220		walk	- 3mph
220-222		samp	le
222-238		walk	- 3mph
238-240		sampl	le
Comments:			
Test Engineer:		PASS	FAIL

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8. <u>ATTACHMENTS</u>

TEST SUBJECTS CHECK LIST

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	Subject veek Notice	MSHA Personnel 2-week Notice
1	Arrange Test Dates	1 Arrange Test Dates
	2Confirm with Letter	
(A)	Confirm M.D. Avai	lability
	1 on planned test dates	
	2 call Manufacturer (test dates)	
	3Test Prep. Sheet and Man Test Sheet	
(B)	Subject Arrival	
	1Orientation (Protocol Activity Sheets)	
	2 Subject Reads Protocol	
	3 Subject Signs NIOSH IRB protocol Con	sent Form
	4 Orientation on Exercise Equipment	
	5 Explain Respirator Operation and Donni	ng
(C)	Conduct	Tests
(D)	Meet and	Review Comments
(E)	Pay Partic	cipants
(F)	Write Let	ter of Appreciation

OUTLINE (TEST SUBJECT SAFEGUARDS)

- I. Presubmission Manufacturer performs tests, as required by Part 84, on their apparatus to demonstrate conformance to regulations.
- II. Apparatus Testing
 - (A) Laboratory tests performed
 - 1. Must meet all applicable performance requirements
 - 2. Must be of safe design
 - (B) Modifications must be made by manufacturer and apparatus retested for performance
- III. Pre-subject preparation
 - (A.) All testing personnel have current CPR (including AED) training and certificates
 - (B.) Notices of subject tests are sent to appropriate NIOSH personnel including:
 - 1. Staff involved in testing
 - 2. Physician
 - 3. Front desk guard
 - 4. Administrative Officer
- IV. Pre-test preparation
 - (A.) Physician and Team Leader have pagers for immediate notification of:
 - 1. Emergency
 - 2. Problems
 - (B.) Test subject receives a physical examination by Physician
 - 1. Must meet all physical requirements
 - 2. Must be referred by Physician as satisfactory
 - (C.) Test subject orientation
 - 2. If new, tries out work exercise equipment
 - 3. Is given information regarding test apparatus
 - 4. Reads and signs HSRB document to safeguard subject
 - 5. Reads protocol (test)
 - 6. Given opportunity to ask questions
 - 7. Is told that he is permitted to stop test anytime for any reason he feels justified
 - 8. Asked if he is prepared to begin test

V. Testing

A. Two personnel present during tests

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B. Crash cart present with current drugs and calibrated defibrillator

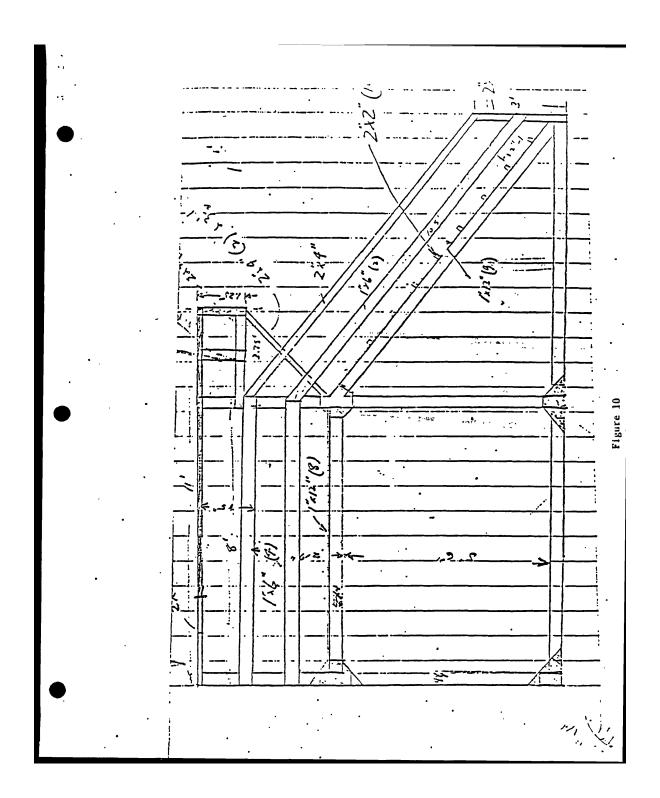
C. Subject monitored for oxygen concentration. CO_2 levels, resistance, temperatures, respirations, pulse rate (test stopped if regulations levels are exceeded), and blood oxygen saturation (pulse oximetry).

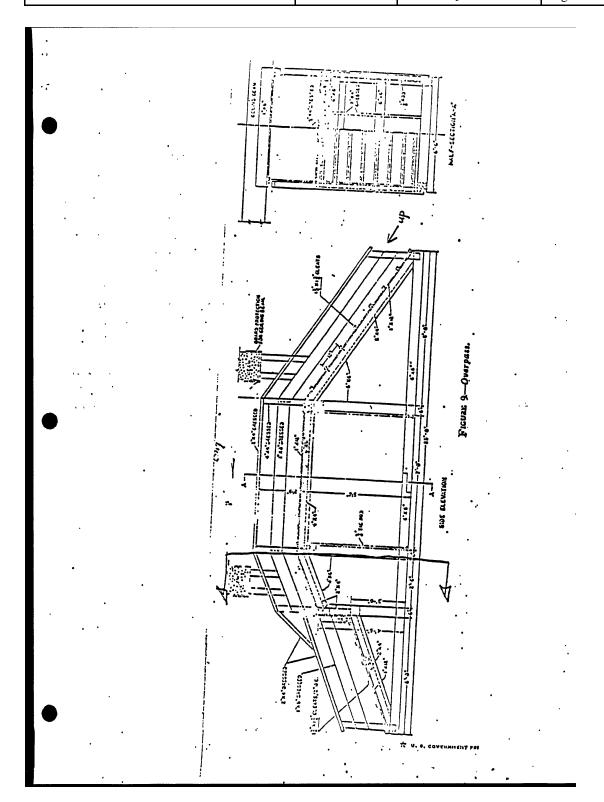
BEFORE-EACH-MAN-TEST CHECK LIST

1.	Suction	Mach	ine

- 2. Batteries and Bulbs in Laryngoscope
- 3. Batteries and Bulbs in Flashlight
- 4. Dates on Medication
- 5. Check O₂ Cylinder
- 6. Unlock Crash Cart

Date Checked	<u>Signature</u>	Task Number	<u>Unit</u>	Man Test No.





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Revision History

Revision	Date	Reason for Revision
00	07 October 2009	Initial Record
1.0	16 November 2011	Administrative change – Document number changed
2.0	20 February 2012	Man Test 4 for CAP-3 Closed-circuit Escape Respirators (CCER) Standard Testing Procedure (STP)
3.0	28 March 2012	Administrative changes were made to include information from the release of the proposed rule.
		Former document number - STP-00001-PSDB-0004
0.0	7 April 2014	New document number to reflect numbering in the approval library, normalization of format. Various figures are moved into the attachments section from the body of the document for the sake of clarity. No changes to procedure from historical document.