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ASSESSMENT OF STRESSORS DURING CLOSED-CIRCUIT ESCAPE RESPIRATORS (CCERs) TESTS WITH HUMAN SUBJECT: CAPACITY, PERFORMANCE AND WEARABILITY

1. PURPOSE

This procedure describes the methods for assessing stressors during CCER tests with human subjects to ensure 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 Sections 84.303, 84.304 (a) (4), 84.305 (a) (3), and 84.306 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 standard test procedure (STP) describes the protocol for assessing stressors monitored during human capacity, human performance, and wearability tests in sufficient detail such that a person knowledgeable in the appropriate technical field can conduct the assessment of stressors associated with human subject testing of closed circuit escape respirators (CCER).

3. EQUIPMENT

3.1 Specific equipment requirements are found in the standard test procedures for wearability, human-subject performance and human-subject capacity.

3.1.1 TEB-CCER-STP-0610 for wearability of closed-circuit escape respirators

3.1.2 TEB-CCER-STP-0613 for performance test of closed-circuit escape respirators (CCER) with human subjects on treadmill

3.1.3 TEB-CCER-STP-0612 for capacity test of closed-circuit escape respirators (CCER) with human subjects on treadmill

4. PROCEDURE REQUIREMENTS AND CONDITIONS

4.1. During human subject tests the stressors in Table 1 are monitored on a breath-by-breath basis and continuously recorded using LabView software and/or a strip chart recorder. (See Appendices).

4.2. Prior to performing CCER tests with human subjects, perform the calculations specified in the standard test procedure for capacity and performance using current Breathing and

Metabolic Simulator (BMS) test data upon the same make and model CCER. All tests utilizing the breathing and metabolic simulator (BMS) required for certification shall have been successfully completed with passing results before performing tests involving human subjects.

5. PROCEDURES

5.1. During the tests with human subjects, the %CO2, %O2, Inhalation/Exhalation Pressure, and wet bulb temperature is continuously recorded on a multi-channel recorder and/or LabView data collection system. Beginning with the first minute and over each minute during the test:

5.1.1 The minute average for each stressor is estimated during the test.

5.1.2 The cumulative average for each stressor is estimated during the test.

5.2. Calculation of average inhaled gas concentrations from end-of-inhalation gas concentrations:

5.2.1. From the continuous chart recording or LabView display, identify the maximum end-of-inhalation % CO_2 concentration and record in the data sheet under "Maximum Inhaled CO_2 %"

5.2.2. Estimate the minute average of the inhaled % CO_2 peaks for the one-minute interval and record on the data sheet under "Minute Average CO_2 %".

5.2.3. From the continuous chart recording or LabView display, identify the minimum end of inhalation oxygen concentration and record in the data sheet under "Minimum Inhaled O_2%".

5.2.4. Estimate the minute average of the inhaled % O2 peaks for the one minute interval and record on the data sheet under "Minute Average O_2 %".

5.2.5. Complete mathematical calculations to determine the running range average for % CO2 and % O2. Use the following equation:

$$\text{Range average} = \frac{[\text{current overall average} \times \text{current elapsed time}] + \text{new minute average}}{[\text{current elapsed time} + 1 \text{ minute}]}$$

5.3. Calculation of average inhalation and exhalation breathing pressure

5.3.1. From the continuous chart recording or LabView display, identify the minimum inhalation pressure for the one-minute interval, and record in the data sheet under "Minute Minimum Inhaled Pressure".

5.3.2. From the continuous chart recording or LabView display, identify the maximum exhalation pressure for the one-minute interval, and record in the data sheet under "Minute Maximum Exhaled Pressure".

5.3.3. Calculate the range excursion for the minute in question using the following equation.

$\Delta P = \left|$ maximum exhaled pressure - minimum inhaled pressure $\right|$

5.4. Calculation of average inhalation wet-bulb temperature

5.4.1. From the continuous chart recording or LabView display, identify peak that represents the maximum inhalation wet-bulb temperature for the one-minute interval.

5.4.2. Estimate the minute average for the maxima in the proper one-minute interval graphically, and record in the data sheet under "Minute Inhaled Wet Bulb Temperature" at the proper minute.

5.4.3. Calculate the Running Range Average Wet Bulb Temperature and record on the data sheet. Use the following formula:

$$\text{Range average} = \frac{[\text{current overall average} \times \text{current elapsed time}] + \text{new minute average}}{[\text{current elapsed time} + 1 \text{ minute}]}$$

6. PASS/FAIL CRITERIA

6.1. Refer to the standard test procedure for the specific test being performed and Table 1.

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

7. RECORDS AND TEST SHEETS:

Data Sheet for Average Inhaled Carbon Dioxide and Average Inhaled Oxygen

Time	Maximum Inhaled CO_2%	Minute Average CO_2 %	Running Range Average CO_2 %	Minimum Inhaled O_2%	Minute Average O_2 %	Running Range Average O2 %
Minute	Limit= ≤4%	Limit = 4%	Limit ≤ 1.5% at test end	Limit= ≥15%	Limit = 15%	Limit = >19.5% at test end
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Add rows as needed						
Test end						

Data Sheet for Peak Breathing Pressures

Time	Minute Minimum Inhaled Pressure	Minute Maximum Exhaled Pressure	Running Range Excursion
Minute	Limit ≥ -300 mm H_2O	Limit ≤ 200 mm H_2O	Limit $\lvert \Delta Pressure \rvert$ ≤ 200 mm H_2O
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
Add rows as needed			
Test end			

Data Sheet for Wet-Bulb Temperature

Time	Minute Inhaled Wet Bulb Temperature	Running Range Average Wet Bulb Temperature
Minute	Limit ≤ 50°C	Limit ≤ 43°C at test end
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
Add rows as needed		
Test end		

8. ATTACHMENTS

None

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.
4.0	21 May 213	TEB Changes